

**International Perspectives on the
Prescription of Heroin to Dependent Users:
A collection of papers from the United Kingdom,
Switzerland, the Netherlands and Australia**

Edited by Gabriele Bammer

**Feasibility Research into the Controlled Availability
of Opioids Stage 2
Working Paper Number 14**

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Prescription Heroin as Treatment for Dependence - Current UK Situation (Philip M Fleming) © Philip M Fleming

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The Prescription of Heroin to Heroin Addicts: A Proposal for the Netherlands

(Ferdinand Sturmans) © Ferdinand Sturmans

Heroin Prescription - A Comparison of the English, Swiss, Dutch and Australian Situations (Gabriele Bammer) © NCEPH

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Foreword

There is considerable international interest in the prescription of pharmaceutical heroin to people who are dependent on illegal heroin. In the United Kingdom such prescription has always been possible, but the evidence about its effectiveness is highly contested. Like much other medical practice, the effects of heroin prescription have not been carefully evaluated. Evaluation has therefore become a central issue in recent considerations of heroin prescription. Trials started in Switzerland in 1994 and have been approved to begin in the Netherlands, probably in 1997. Considerable research into the feasibility of conducting a trial has been carried out in Australia, but as yet political approval for it to proceed is lacking.

The core for this collection of papers comes from presentations at the 7th International Conference on the Reduction of Drug Related Harm held in Hobart, Australia, in March 1996. Philip Fleming presented an overview of current prescribing practice in the United Kingdom and the influences which have shaped it. To that I have added an earlier paper written by the late Bing Spear. That paper was originally written in early 1994 to assist the British Embassy in Washington DC respond to queries about the "British system". Bing had anticipated that it would be published in the United States of America, but when that did not eventuate, I offered to include it in a feasibility study working paper.

There is keen interest in the current Swiss trials and descriptions of results from clinics in Bern and Zurich were presented at the Hobart conference by Robert Haemmig and Urs Vontobel, respectively. In June Dieter Ladewig from Basel visited Australia and presented information from the Basel clinic as well as preliminary results from the Swiss trials as a whole. That seminar presentation is also included here.

The series concludes with papers by Ferdinand Sturmans and myself. The first presents some of the considerations which have shaped thinking in the Netherlands and the second is a comparison of the English, Swiss, Dutch and Australian situations.

Unlike the previous working papers which shaped the final decision about whether or not a trial of heroin prescription should be conducted in Australia, this one was prepared after that decision had been made. Detailed consideration of the benefits and risks of a trial of heroin prescription led to the conclusion that a carefully designed and rigorously evaluated trial was essential to inform policy decisions about the future of this treatment option. While there are certainly risks in conducting a trial, many can be minimised, and they are outweighed by the benefits (Bammer, 1995).

The future of the Australian trial rests with politicians and other policy makers. The ACT government accepted one of the twelve feasibility study recommendations and immediately after release of the Stage 2 report in June 1995 established a Task Force to ascertain ACT and Australian community responses and to consider the implications of the report and community comment especially with regard to trial effectiveness and possible adverse consequences. That Task Force reported in January 1996 and recommended that the first pilot proceed, that the protocol for moving to the second pilot and full-scale trial be adopted and that a steering committee to monitor the pilot be established (Heroin Pilot Task Force, 1996).

In July 1996, the trial proposal was discussed by the Ministerial Council on Drug Strategy. The Council consists of the Ministers responsible for health and law enforcement from each state and territory and the federal government. The Council refused to endorse a trial but referred it to a sub-committee of the National Drug Strategy Committee (a committee of the relevant health and law enforcement officials from each jurisdiction) for further consideration. The proposal will be considered again at the 1997 meeting of the Ministerial Council on Drug Strategy.

Feasibility Research Director

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Bammer, G. 1995 *Report and Recommendations of Stage 2 Feasibility Research into the Controlled Availability of Opioids*. Canberra: National Centre for Epidemiology and Population Health, The Australian National University and the Australian Institute of Criminology.

Heroin Pilot Task Force, 1996 *The Report of the Heroin Pilot Task Force*. Canberra: Department of Health and Community Care.

PRESCRIPTION HEROIN AS TREATMENT FOR DEPENDENCE - CURRENT UK SITUATION

Philip M Fleming

Introduction

The current situation in the UK, with respect to heroin prescribing as a treatment for opiate addicts, needs to be understood in the context of the history of opiate prescribing in Britain. I shall briefly outline this concentrating on the changes over the past thirty-five years. I shall describe the present situation as well as the available data allows and then end with some general comments. For anybody interested in studying the history and development of drug policy in relation to heroin addiction in the UK, I would strongly recommend the book edited by John Strang and Michael Gossop (Strang & Gossop 1994).

History of Opiate Prescribing in Britain

The report of the Rolleston Committee (the Departmental Committee on Morphine and Heroin Addiction) in 1926 has become the defining moment for the start of the 'British System', indeed the term was coined by E W Adams who had served as Secretary to the Committee and helped draft its report. A committee of doctors was set up by the Ministry of Health under the chairmanship of Sir Henry Rolleston, then President of the Royal College of Physicians to provide advice on 'the circumstances in which the supply of morphine and heroin to persons suffering from addiction to these drugs may be regarded as medically advisable'. This approach was in marked contrast to that in the US where the Harrison Act of 1916 had stopped the prescription of pharmaceutical opiates to addicts.

In essence this report established the right of the medical practitioner in the UK to prescribe regular supplies of an opiate drug to an addict in the following circumstances:

- 1) where patients were under treatment by the gradual withdrawal method with a view to cure;
- 2) where it has been demonstrated after a prolonged attempt to cure that the use of the drug could not be safely discontinued entirely on account of the severity of the withdrawal symptoms produced; and
- 3) where it has been similarly demonstrated that the patient, while capable of leading a useful and normal life when a certain minimum dose was regularly administered, became incapable of this when the drug was entirely discontinued.

Over the next thirty years the number of opiate addicts in the UK was between 400-600, half of whom were therapeutic addicts. The bulk of the remainder were physicians and other professionals who had become addicted because of their privileged access to pharmaceutical supplies of opiates. There were less than 100 heroin addicts and almost all were middle aged or older.

Heroin Prescribing and the Creation of the Drug Clinics

In 1958 an Interdepartmental Committee on Drug Addiction was set up under the chairmanship of a distinguished neurologist Sir Russell (later Lord) Brain. This reported in 1961 and in essence suggested no changes stating that there was no evidence that the right of doctors to provide drugs of addiction in the treatment of opiate dependent patients had led to any increase in the number of addicts.

In the early 1960's the number of young heroin addicts was increasing, and this increase was being fuelled by the activities of a small number of London doctors; GPs and private practitioners who were prescribing large amounts of heroin as treatment to young drug users much of which was leaking onto a growing black market. Concern about this led to the reconvening of the Brain Committee in 1964 and the publication of its influential second report the following year (Interdepartmental Committee on Drug Addiction, 1965). The recommendations led to a number of far reaching changes of which I will briefly mention the most relevant to this discussion.

- 1) Limits were put on the rights of doctors to prescribe heroin or cocaine. Only those doctors holding a special licence could prescribe either of these drugs to addicts. This has subsequently been extended to include dipipanone.

Currently, under the Misuse of Drugs [Notification of and Supply to Addicts] Regulations 1973, only doctors who hold a special licence issued by the Home Office are permitted to prescribe heroin, dipipanone or cocaine to addicts for the purpose of treating their addiction. In practice these licences are given to doctors working in specialist treatment centres.

- 2) A system of compulsory notification was set up. The aim of this was in part to keep track of the spread of addiction and the analogy of the notification of infectious diseases was used. It was also to provide an up-to-date central list for doctors who could check if a new addict was already known to any doctor, and importantly whether or not he or she was already receiving a prescription of addictive drugs. The current legislation requires any doctor to notify the Chief Medical Officer at the Home Office in writing, if he/she attends a person who they consider (or have reasonable grounds to suspect) is addicted to certain controlled drugs. These include, amongst others: heroin, morphine, dipipanone, cocaine, and methadone.
- 3) Setting up of specialist outpatient treatment clinics. By more controlled prescribing of pure drugs it was hoped to undercut the black market and thereby lead to its shrinkage and also to reduce the necessity for addicts to be involved in acquisitive crime. Connell writing at the time the clinics were first set up (Connell 1969), outlined their rationale and included the following statements:

"1) The prescribing of heroin to addicts must be under some tighter control than before.

- 1) Heroin provided free at special treatment centres will obviate the need for the addict to commit crimes to obtain money for the drug.
- 2) The pure, British-made heroin which the addict will receive is less likely to cause complications and death than the impure material which circulates in a criminally organised system.
- 3) The addict is a sick person and properly comes within the ambit of medical practice. His dependence on the drug and his craving is so strong that he is unable to behave rationally.
- 4) Punitive detention of the addict under a penal system has not been shown to be successful in curing addiction in other countries and should not be adopted hastily."

Changing Prescribing Policies in the Clinics

The Clinics' policy was to provide controlled prescriptions of drugs and for the most part addicts were prescribed heroin and in some cases injectable methadone. It was hoped that, through contact with clinic staff, addicts would develop the motivation to come off their drugs which could then be slowly reduced. Edwards noted (Edwards 1969):

"There are believed to be some patients who cannot - or cannot for the time being - function without the drug, but who on a regular maintenance dose can lead a normal and useful life as a 'stabilized addict'; such patients will be maintained on heroin rather than have their drug withdrawn."

Gradually injectable and oral methadone began to be prescribed instead of heroin in the early 1970's; the rationale here was that addicts would not need to inject so frequently. Mitcheson reports (Mitcheson 1994) that during the latter part of the 1970's the amount of heroin prescribed in the London clinics (the location of the largest treatment centres in the UK) fell dramatically. The prescription of injectable methadone peaked in

the mid 1970's, and both were replaced by oral methadone. This change in practice had been brought about by a number of factors (Fleming 1995). It was becoming clear that younger users were not necessarily becoming more stable on prescriptions of heroin. In 1976 the first results of a random controlled study in London (Hartnoll et al 1980) of prescribing heroin against oral methadone were becoming available. These results were interpreted by many (though not the authors) as indicating that oral methadone was the treatment of choice. A second factor was that clinics were gradually becoming silted up with long-term patients, and staff were beginning to get demoralised. Towards the end of the 1970's with an influx of new addicts the system became overloaded; this together with an increasing disenchantment with long term prescribing led to the introduction of time limited prescribing programmes.

With the emergence of AIDS, harm reduction has increasingly become the priority of drug services in the UK. There has been a considerable expansion of services for drug users during the last ten years and an influx of a new generation of drugs workers unencumbered by the attitudes of a previous generation. During recent years the influential Advisory Council on the Misuse of Drugs has published three reports on AIDS and Drug Misuse, the most recent of which has acknowledged the value, both in public health and in individual terms, of methadone maintenance programmes (ACMD 1993). The value of substitute prescribing as a harm reduction measure is now widely acknowledged by drugs workers. This climate has, I believe, encouraged doctors to reconsider different types of substitute prescribing. There is evidence of an increasing amount of amphetamine prescribing for dependent amphetamine users and an increase in the prescription of injectable methadone for opiate users.

Heroin Prescribing from 1980 to Date

The available evidence suggests that over the past fifteen years there has been a small amount of heroin prescribing in the UK, probably between 1 and 2% of those receiving a prescription for the treatment of opiate dependence. The figures we have, which are of those drug users notified to the Home Office, are as follows (Home Office 1995):

1977	1978	1979	1980	1981	1982	1983	1984	1985	1986	1987	1988
232	211	189	162	208	214	189	182	312	179	186	194

after this the figures have been presented differently:

1989	1990	1991	1992	1993	1994	
10	26	17	25	30	22	New Addicts
59	90	106	92	144	133	Re-notified addicts
69	116	123	117	174	155	Total

By comparison in 1994 there were 15504 addicts being treated by methadone in all its forms. It has to be said that these figures are acknowledged to be incomplete as doctors have been shown not to be always compliant with the requirement to notify the Home Office.

In a recent survey (Sheridan et al 1996) of a one-in-four sample of community pharmacists in England and Wales it was found that heroin was prescribed to 64 cases (1.6% of the prescriptions for addicts). If the findings from the sample are extrapolated to the total population, and the non-response rate (25.2%) is taken into account, approximately 340 addicts were receiving heroin prescriptions.

The Home Office report that there were 109 heroin prescribing licences in force in 1995. However, these licences are valid for three years and not all those doctors who have them use them continuously.

Current Clinical Practice

Unfortunately very little has been written about current clinical practice in the UK as far as heroin prescribing is concerned. Battersby and colleagues (Battersby et al 1992) at the Maudsley Hospital described their experience of 40 opiate-dependent individuals who were prescribed injectable drugs, five of whom received heroin only. The group as a whole showed limited gains when reviewed. Strang et al in reviewing the prescribing of heroin and other injectable drugs conclude that in the absence of properly conducted studies no reliable conclusions can be drawn about such prescribing (Strang et al 1994).

In a recent study of the attitudes and practice of addiction specialists (Sell et al 1996) respondents were asked "do you believe that prescribing heroin can be clinically justified?" There were 105 respondents and they answered as follows: often -6; sometimes -45; rarely -35; never justified -13; not answered -4. The authors concluded that "there is a solid body of professional opinion in England and Wales which regards prescribing of heroin as a legitimate option in the range of treatments offered to drug misusers".

One of the most outspoken advocates of heroin prescribing in the UK has been Dr John Marks (Marks 1985, 1991). It is interesting to look at his situation as a possible pointer to the future of heroin prescribing in Britain. For many years Dr Marks had run drug clinics in North Cheshire and for a period he had also run the Liverpool drug clinic. He has strongly put the case for harm reduction in the treatment of drug addicts and many of his arguments are similar to those of Connell (see above). His clinical practice for the most part has been unexceptional; however, it has been in his practice of heroin maintenance for some addicts that he has gained notoriety. One interesting treatment has been his use of heroin 'reefers' to wean injectable heroin users away from injecting (Marks 1990). Unfortunately, this treatment has never been properly evaluated. In 1995 the Health Authority moved the contract for providing drug services in North Cheshire from Dr Marks to another clinic. One reason for this has been cited as the cost of heroin prescribing and the lack of evidence of its effectiveness (Ashton 1995). In spite of this setback, Dr Marks continues to provide a service for other health authorities who refer and pay for treatment for their difficult cases. He currently has some fifty patients who are receiving prescriptions of heroin (Marks - personal communication).

In an attempt to get a broader view of current heroin prescribing practice, I have contacted a number of colleagues around the UK to ask them about what they do. This is in no sense a scientific study and is intended to give an impression of what is happening in the clinic. The doctors concerned were in total prescribing heroin for about 240 addicts which represents over three quarters of all those receiving heroin in the UK.

Some were prescribing only for those who had received prescriptions of heroin for many years. These were the aging 1960's addicts all of whom were over age 40 and three of whom were in their 60's. These doctors had not started any new addicts on heroin for many years. Many of the addicts had associated health problems and most had difficulties in injecting having run out of veins to inject into; dosages varied from 10 mg to 300 mg daily.

A few of the doctors had tried prescribing 'reefers', cigarettes impregnated with heroin. Two commented that the cigarette burns too hot to allow the heroin to be easily inhaled and that a considerable amount literally goes up in smoke and not into the user's lungs. This is likely to be because the reefers are made by injecting diamorphine hydrochloride which has a higher melting point and is thus less volatile than the heroin base that is usually smoked.

For those doctors who would consider prescribing heroin to a user this would only be considered where other treatment had failed. Thus users would be long term injectors with a long history of dependent opiate use, and usually in their thirties or older. They would have been tried at least once on an oral methadone programme with adequate doses and have failed to stop persistent injecting of heroin. They would need to show some evidence of compliance with treatment, for example regular attendance for outpatient appointments. Once on heroin, programmes varied as to how closely the addicts were monitored. If there was evidence that the addict's behaviour or health was deteriorating then usually the heroin prescription would be withdrawn.

As far as dosage is concerned this varied. Most addicts received 200 mg or less of heroin a day in ampoule form. A few received higher doses, the highest recorded being 1g daily. Many addicts also received a dose of methadone orally, which was given to minimise withdrawal symptoms between injections, especially at night.

What about outcome? Only one of the prescribers was undertaking a formal trial of heroin treatment. Others only had their clinical impressions to guide them, and these varied. Some addicts who had been seeking a heroin prescription for many years seeing it the answer to their difficulties found that this was not the case and this seemed to provide the motivation for them to make some changes in their lives. For others there were no dramatic improvements. Several of the prescribers would prefer to offer injectable methadone if they were going to consider an injectable at all, on the basis that its longer duration of action had a more stabilising effect.

Conclusion

Heroin prescribing continues in the UK at a level of probably not more than 2% of all prescriptions of opiates to addicts. The official view of such prescribing has been cautious. For example, in the AIDS and Drug Misuse Update report of the Advisory Council on the Misuse of Drugs (ACMD 1993) comments that injectable prescribing 'should remain a minority activity for exceptional circumstances'. The evidence is that there has not been a significant increase in heroin prescribing in recent years although in general there is more substitute prescribing, mostly of methadone in oral form but also of amphetamines and to a certain extent of injectable methadone.

Recent changes in the organisation of the NHS will probably ensure that heroin prescribing does remain a minority activity. Health services in the UK are purchased by local Health Authorities which are increasingly looking at both the cost and the effectiveness of services. Some Health Authorities have stated that they do not want to purchase a heroin prescribing service; others have limited the numbers of such patients they are willing to pay for.

The issues of effectiveness and of outcomes have been underlined by Health Authorities in the UK, but as far as heroin prescribing is concerned these are issues that confront us all. We need to have adequate outcome studies on such prescribing and good trials of its effectiveness. Connell writing in 1970 on the impact of the then new approaches to drug dependence in Britain made the following comment which is as pertinent today as it was 26 years ago (Connell 1970):

"Finally, the importance of research cannot be over-emphasised. Only broadly based research into the efficacy of methods of handling addicts, together with comprehensive follow-up studies, will answer the question as to the optimum methods of treating addicts, or perhaps more important which addicts are suitable for which form of treatment. It will be tempting to by-pass the research areas in terms of following scientifically unsupported belief systems which appear to 'get things done' and promise to solve the problem."

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HEROIN AND THE "BRITISH SYSTEM"

H B Spear

One of the enduring legends of my native county of Cornwall is that of the giant, Jan Tregeagle, who, for his sins, was doomed to bale out a moorland lake, Dozmary Pool, with a limpet shell with a hole in it. After over 30 years close involvement with narcotic control in the United Kingdom, countless hours of which have been spent trying to explain to overseas visitors the basic philosophy and practice of that control, and the British approach to the treatment of addiction, I can sympathise with Jan's undoubted frustration. Many of these seekers after truth have come from the United States but as the misuse of drugs now affects more and more countries, so there is an increasing international interest in how the British have responded to the problem. Yet despite all our efforts to explain our approach, there is today even more confusion, misunderstanding and misinformation about drug misuse in the United Kingdom than there was almost 50 years ago when the late Professor Alfred Lindesmith, of Indiana University, first incurred the displeasure of the Federal Bureau of Narcotics by daring to suggest that prohibition was not the only response to the problem of heroin addiction. Why this confusion persists is only partly due to differences between countries in matters of culture and tradition, language, social conditions and social organisation; equally important is the practice, not unknown in my country, of adapting facts to fit preconceived academic theories or entrenched political prejudices. What then are these facts and the major distortions which have for so long bedevilled rational discussion of how the British treat their drug addicts?

The term "British system", (so often equated with the "British Heroin Maintenance Programme"), is an American invention and although we have been, and still are, willing to use it for the purpose of discussion, no one directly concerned with United Kingdom drug control, has ever accepted the term as an accurate reflection of our approach. "System" and "Programme" suggest coordination, order and an element of (state) planning and direction, all totally alien to the fundamental ethos of the British approach, which is to allow doctors to practice medicine with minimal bureaucratic interference. Our drug controls, like those of the United States, have their foundation in the same international agreements, which, from the Hague Convention of 1912 have been aimed at restricting the production and availability of certain drugs to "legitimate medical and scientific needs". So why should the way in which we, in the United Kingdom, have implemented the Hague principles stimulate such intense and persistent curiosity?

From the outset it was recognised, and readily accepted, that our post-Hague domestic controls must interfere as little as possible with the normal conduct of medical practice but equally importantly, should preserve the tradition of clinical freedom which our doctors have long enjoyed. As the British Medical Association commented in 1955, "for generations the doctor in Britain has taken for granted that he can prescribe for his patients any drug of which, in his professional judgement, they stand in need ... this tradition of complete clinical freedom is part of the air the doctor breathes...". Similarly, over the years the General Medical Council, the profession's regulatory body, has repeatedly made clear that it is not for the Council to approve or disapprove a particular line of treatment, however unorthodox that may be. The Council's "Guide to Professional Conduct" explains that the Council is primarily concerned with errors in diagnosis and treatment, and with the kind of matters which give rise to action in the criminal courts for contraventions of the law, and in the civil courts for negligence. But in the latter context, it is only when the doctor's conduct has involved such a disregard of professional duties as to raise a question of serious professional misconduct, that the Council may become involved.

With this tradition of clinical freedom the background, the Dangerous Drugs Regulations of 1921 authorised "any duly qualified medical practitioner ... *so far as is necessary for the practice of his profession or employment in such capacity to be in possession of and supply the drugs*". These regulations did not specify which drugs doctors could or could not use, or the circumstances or dosages in which they could use them. This is the bedrock principle of the "British system", although the precise wording of current legislation is slightly different and there has been an *administrative* change, discussed later, in respect of the use of some drugs in the treatment of addiction. How does this statutory language translate into practice?

As most students of the "British system" probably identify the prescribing of heroin as its unique feature, it may be useful to look at the operation of our controls in relation to this drug. But first, as we are the world's only major user of pharmaceutically manufactured heroin, the British attitude to this drug needs to be addressed. Almost from its discovery, heroin has been used in the United Kingdom for the relief of the pain of terminal illness and as a cough suppressant, although it is now much less used for the latter purpose. In this sense, therefore, it has always been a "legal" drug in this country and the references by so many

commentators on the "British system" to the "legalisation" of heroin in the United Kingdom are incorrect. However, opinion among British doctors about its indispensability, and whether there are effective substitutes, is by no means unanimous. In the words of the British Medical Association, "in the last analysis it comes down to the judgement of the individual doctor by the bedside of his patient" but there is a cardinal belief that even if only a few doctors are convinced of the therapeutic benefits of a particular drug, that drug should be available for their use. This belief has manifested itself in consistent opposition to the U.S. inspired international attempts over the years to prohibit all legitimate manufacture and use of heroin. In 1955 when the British Government finally succumbed to international pressure and decided to introduce a ban, the profession reacted so strongly that the Government were relieved to discover, at the 11th hour, that their statutory powers extended only to the control of the manufacture of narcotic drugs, and not to their total prohibition. (The use of heroin in the treatment of addiction raises other important issues, which are discussed later.)

Those in the United States who might be tempted to dismiss this as a typically British selfish, unrealistic, even irresponsible attitude would do well to examine the "evidence" which persuaded the U.S. House of Representatives in 1924 to pass the Bill presented by Representative Stephen G. Porter, proposing the prohibition of the importation of crude opium for the purpose of manufacturing heroin. Reading the transcript of those Hearings it is difficult to avoid the conclusion it is heroin and heroin alone which is the "villain of the piece" and that personal, social or any other factors play no part in the addiction process. Two examples of the weakness of Porter's case against heroin will suffice. When asked if heroin produced insanity, he confirmed that it "undoubtedly" did, an opinion for which neither he nor Surgeon-General Dr Rupert Blue, who had agreed with his answer, offered any supportive statistical evidence. Far more serious, however, was his success in misleading the Ways and Means Committee into believing that the manufacture of heroin was so complicated that there were only about eight establishments in the country properly equipped for its manufacture. The reality is, of course, quite the reverse as the eminent authority, Dr Charles E. Terry, had already pointed out in the New York Herald in March 1924, "anybody can make it, as a matter of fact, with a crude chemical laboratory ... and it would be necessary first to eliminate morphine to eliminate heroin". Whether the Committee would have come to some other conclusion had the true facts been put before them, no one can say but it seems unlikely as the campaign against heroin was clearly political. Yet on the basis of such false, flimsy "evidence", and the spurious thesis that the banning of pharmaceutical heroin would in some way assist in reducing the traffic in entirely illicitly manufactured heroin, the United States has successfully pressured almost the entire world into denying their terminally ill a drug which might in some circumstances provide relief from their suffering.

Fortunately, terminally ill patients in the United Kingdom are not, and never have been, under such disadvantage and can expect to be prescribed heroin, or any other narcotic pain relieving drug, if need be, in whatever dosage their doctors consider appropriate. If doctors decide to use heroin they do not require any special authority, nor do they have to use a special prescription form or keep special records, simply because the drug is heroin. Similarly, dispensing pharmacies are not required to have a special authority to hold a stock of heroin, or to take security precautions beyond those required for the other controlled analgesics. As for the authorities, their interest in such a case is limited to confirming that the illness is terminal or that the patient has some other painful condition for which the prescribing of heroin would be medically justified. This seemingly casual attitude to heroin does not mean that it is the drug of choice in every, or even the majority of terminal cases. Many doctors believe in and use alternative approaches, but in recent years with the growth in the hospice movement, there has been a significant increase (to around 250 kgs per year) in the quantity of heroin being used in the United Kingdom for pain relief.

However, it is the British use of heroin in the treatment of addiction which arouses the most interest and controversy. For any clear understanding of this the starting point again has to be the Hague Convention of 1912, which unfortunately offered no guidance on how "legitimate medical need" was to be interpreted. The implementation of the Hague requirements into United Kingdom domestic legislation immediately raised the question of whether the prescribing of morphine or heroin to someone who was addicted was a proper function of medical practice. For an answer the Government turned to the medical profession and in 1926, after pondering the matter for over a year, the Departmental Committee on Morphine and Heroin Addiction (usually known as the Rolleston Committee, after the name of its Chairman, Sir Humphrey Rolleston, then President of the Royal College of Physicians) concluded that there were circumstances in which it would be acceptable practice for a doctor to prescribe or supply drugs to an addict. Briefly, these were when the doctor was attempting to cure the addict by the gradual withdrawal of drugs, or when it could be clearly shown that the prospects for a permanent cure in the foreseeable future were minimal, in which case it might be necessary for the supply of drugs to continue for an indefinite period. It is this latter conclusion which has given rise to the erroneous concept of a highly successful "British Heroin Maintenance Programme", which

for many years prevented the development of a heroin addiction problem comparable to that existing in the United States.

The deliberations and recommendations of the Rolleston Committee have been discussed in detail by numerous overseas commentators, almost all of whom have failed to appreciate, or comment on, the fact that the Rolleston Committee was not established to provide a solution to what was then a non-existent "drug problem". The Committee were asked to give an answer to the essentially medical question of what was the legitimate medical practice in relation to the treatment of narcotic addiction. Discussion of the effect this post-Rolleston "British system" has had on the misuse of drugs in the United Kingdom, a pre-occupation of most of these commentators, is therefore totally irrelevant. Furthermore, what is also not often appreciated is that the Rolleston Committee's recommendations were never accorded statutory status, which meant that despite the Committee's view, doctors remained free to treat addicts as they alone considered appropriate. This might involve the long-term prescribing of heroin but if it did, it was on the basis of the individual doctor's clinical judgement and not part of a Government directed or controlled "maintenance programme". All the Rolleston Committee had done was to confirm that the supply of drugs to an addict, in the course of treatment, was as proper an exercise of a doctor's authority under the Regulations, as the supply of drugs to a terminally ill patient.

This remained the position until 1964 when the Government was again forced to seek the assistance of the medical profession. The reason was a considerable increase in the number of young heroin addicts, whose main source of supply was the liberal prescribing of a few doctors, which, for reasons beyond the scope of this short article, could not be dealt with under existing legislation. On this occasion the "solution" was provided by another medical committee, the Interdepartmental Committee on Drug Addiction, chaired by a former President of the Royal College of Physicians, Lord Brain. In 1965 Lord Brain and his colleagues proposed that a number of treatment centres for addicts should be established, mainly in London where the problem was most serious, and that only those doctors working at the centres should be permitted to prescribe heroin and cocaine to addicts. This first ever limitation on doctors' hitherto unfettered clinical freedom in respect of narcotics was accepted by the medical profession and from 16th April 1968 it became unlawful for any doctor, unless specially licensed by the Home Secretary, to prescribe heroin or cocaine to an addict. (In 1985 this restriction was extended to dipipanone, a synthetic opioid which addicts had discovered was a more than acceptable substitute for heroin.) However, this administrative change did not affect the doctors' right to use heroin in the treatment of the terminally ill or to use any other drug, such as methadone or morphine in the treatment of addicts. These special licences are issued at the discretion of the Home Secretary on the advice of the Chief Medical Officer and while at present the policy is to restrict them to doctors working at treatment centres, it is open to any doctor to apply for a licence and, if refused, to challenge that refusal in the courts.

These important changes have been both widely misunderstood and misrepresented. The 16th April 1968 has been seen by many as marking the demise of the "British system", the end of what has also been described, quite incorrectly, as the "experiment with the legalisation of heroin". A particularly good illustration of the mythology which has grown up around these changes has been provided by Professor James Q. Wilson, Collins Professor of Management and Public Policy at U.C.L.A., who, in an attempt to bolster his argument against the legalisation of drugs, has demonstrated his remoteness from the true facts in the following piece of creative writing. In *The New Republic* on 10th July 1989, Wilson wrote:-

Great Britain once allowed physicians to prescribe opiates for addicts. The system worked reasonably well so long as the addicts were middle-class people who had become hooked as a consequence of receiving painkillers in hospitals. But when thrill-seeking youth discovered heroin, the number of addicts increased 40-fold, and so Britain ended the prescription system. It was replaced at first with a system of controlled dispensation from government clinics, and then with a system of substituting methadone for heroin coupled with the stringent enforcement of the laws against the latter. Moreover, as British experience showed, there is no such thing as "controlled distribution". Inevitably there will be massive leaks of government-supplied drugs into the black market.

Leaving aside Wilson's cavalier approach to statistics — by 1990, in another article, the 40-fold increase had been reduced to 30-fold during an unspecified 15 year period — let us see how this piece stands as an accurate academic analysis of the British situation.

Firstly, Britain has not ended the "prescription system" nor was it ever limited to private physicians. Individuals addicted to heroin may attend any doctor of their own choice, whether the doctor practices within

the National Health Service or in the private sector. The addict is under no compulsion to attend one of the special National Health Service treatment centres which were established in 1968 to deal with heroin and cocaine addiction. How doctors respond to approaches by addicts is entirely a matter for them. They may decline to accept the addict as a patient, they may offer counselling or they may feel that a regular prescription of narcotics would be justified. If they do, the only limitations are that to prescribe heroin, cocaine or dipipanone, they would need to be licensed, and that their prescribing should be "responsible". Although in 1984 the Department of Health issued "Guidelines of Good Clinical Practice in the Treatment of Drug Misuse" (a revised version appeared in 1992), doctors treating addicts are under no legal obligation to follow this advice and they cannot be compelled by any medical authority, however eminent, or even a Minister of the Crown, to follow a particular line of treatment. There is, however, one statutory requirement on *any* doctor who comes into professional contact with a person considered or suspected to be addicted; in such circumstances certain details about that individual must be notified to the Chief Medical Officer at the Home Office. This requirement applies irrespective of whether or not the doctor intends to accept the addict as a patient or to prescribe narcotics. The purpose of "notification", which was proposed by the Interdepartmental Committee, is partly epidemiological and partly to provide a central reference point from which doctors can obtain information, in confidence, about addicts previously unknown to them. Notification, which is frequently wrongly interpreted as "registration" implying that addicts are entitled to a regular supply of drugs, does not confer any official or special status upon the addicts. Their treatment remains entirely a matter for the doctors concerned.

Secondly, the implication that "the substitution of methadone for heroin" was a deliberate act of Government policy is grossly misleading. There has indeed been a significant move away from even the short-term prescribing of heroin to heroin addicts but this has resulted from changes in medical thinking and practice, not from any Government direction. It was the clear intention of the Interdepartmental Committee (and was provided for by the licensing arrangements), that after 16th April 1968 heroin should still be supplied to addicts when thought necessary. However, almost from the outset the views of a small number of influential consultant psychiatrists began to dominate treatment practice and methadone soon became the drug most frequently prescribed for new heroin addicts. It was a change based on largely irrelevant United States experiences of the use of methadone, and ethical considerations, rather than on any long-term scientific evaluation. But any doctor holding a licence is perfectly free to defy this conventional orthodoxy and prescribe heroin when considered appropriate. Doctors who follow such an independent line could, of course, have their licences revoked but the Home Secretary, if challenged, would have to explain the reasons for this action. To date no licences have been revoked solely on the grounds that the doctor was not following the 1984 Guidelines and there are still a very small number of doctors in the United Kingdom who believe that the prescribing of heroin is a viable treatment option.

Wilson's third misrepresentation of "British experience" after 1968 is that the concept of the "controlled distribution" of drugs to addicts is untenable because "inevitably, there will be massive leaks of government supplied drugs into the black market". But if this prediction is to be taken seriously, why did "massive" leaks not occur during the period of what he refers to as a quasi-experiment with "controlled dispensation from government clinics"? It is difficult to reconcile Wilson's defeatist scenario with what actually happened. Independent observers were generally agreed that the problem had been contained, offering, as Professor Griffith Edwards, an internationally renowned authority was to comment in 1979, the comforting appearance of "an epidemic seemingly brought under control". And how can it be "controlled distribution" when doctors can still treat addicts as they alone think fit, and which may or may not involve the supply of narcotics?

Despite the efforts of Wilson and many others over the years to deride British experience and practice, the principles of the treatment of addiction set out by Sir Humphrey Rolleston and his colleagues in 1926 remain intact 70 years later. But the extent and nature of the "drug problem" has changed dramatically, as has medical thinking, with the result that there is now little long-term prescribing of narcotics especially of heroin to addicts. However, this does not mean that the Rolleston principles have failed or been abandoned. If there was to be a further shift in medical opinion to a return to more general heroin prescribing, this would be perfectly permissible within the existing legal framework. The essence of the "British system" is that it allows the individual doctor total clinical freedom to decide how to treat an addict patient.

H B (Bing) Spear joined the Home Office Drugs Branch in 1952 and was appointed Chief Inspector in 1977. He retired in 1986. He witnessed the major changes in drug misuse that occurred in Britain in the mid-1960s and the subsequent developments in policy. His work brought him into close contact with all those

involved - misusers, clinicians, pharmacists, police, social workers, researchers and policy makers. Many researchers and clinicians overseas well as in Britain have benefitted from his readiness to share his wide experience and knowledge of the British drug scene. He published several papers on the subject in academic books and journals and, at the time of his death in 1995, was finalising a book on the development of British drug policy since 1916. He was awarded the Imperial Service Order in 1985 and in 1989 was given an award for Achievement in the Field of Drugs Control and Enforcement by the Drug Policy Foundation, Washington DC.

KODA-1 IN BERN: MEDICAL ASPECTS

Robert B Haemmig

The KODA-1 project started as a three-pronged project in June 1994: it had 50 places in each of heroin, morphine or intravenous (iv) methadone substitution. The project offered the participants the opportunity to choose between these three substances. At first we thought we would be able to work out medical indication guidelines to allocate the patients to one or other of the groups, but this proved to be impossible. We told applicants that the heroin prescription would probably stop at the end of 1996, and that it would be possible according to the laws on narcotics to continue morphine prescription beyond this point. We advertised iv methadone as a more comfortable option because iv methadone has only to be taken once a day and thus gives more freedom and independence from the drug dispensary.

After a change in the decree covering the trials in Spring 1995, we were able to raise the number of heroin places to 108; the morphine places were reduced to 25 and iv methadone places to 15. In fact heroin is prescribed to 108 patients, morphine to six and iv methadone to one.

KODA-1 February 1996

	available places	occupied places
heroin	108	108
morphine	25	6
iv methadone	15	1

When we had only 50 heroin places, we had 13 patients in morphine prescription for a short time, but when given the opportunity to switch to heroin all but two decided to take heroin. This situation was stable until the heroin places were filled; only then were people interested in morphine prescription again. The conclusion is that heroin is the best accepted drug of the three and morphine is only second best.

Psychiatric Aspects

The patients in the project are not an homogeneous group apart from a long history of drug use and many unsuccessful treatment attempts. Data have not yet been evaluated, so at the moment only clinical impressions can be presented. The evaluation will be finalised in 1997.

There are only a small number of patients with a double-diagnosis of psychosis and dependence but they are generally doing especially well under treatment with heroin. They show good stabilisation, and psychotic states are easily manageable with only small doses of neuroleptics. Some of the depressed patients with chronic antidepressant resistant symptoms are improving, but in other cases no change in the depression is discernible. We deplore the suicide of one of our patients who had a history of many previous serious suicide attempts.

Somatic Aspects

Generally the patients seem to be in better health than at the time of entry into the project. Most of them are gaining weight, in some cases very obviously. Severe chronic underlying health problems are, of course, hardly affected in their progression. One of our patients, for instance, died of a long-existing liver cirrhosis, and there is one patient who will probably not survive to the end of the trials because of AIDS.

We have data on the serologic states of pre-existing viral infections. At the end of 1995 we had test results for 114 patients, 87 men and 27 women. Thus we have a sex distribution of 76.3% men and 23.7% women. Of the men 23.0% tested positive for HIV and of the women only 7.4%; so overall 19.3% tested positive for HIV. This sex difference may be explained by the fact that women in the project are younger (Mann-Whitney U-Test, $p=0.001$) and have a shorter history of drug use (Mann-Whitney U-Test, $p=0.02$).

	HIV negative	HIV positive	Total
Male	67	20	87
	77.0%	23.0%	76.3%

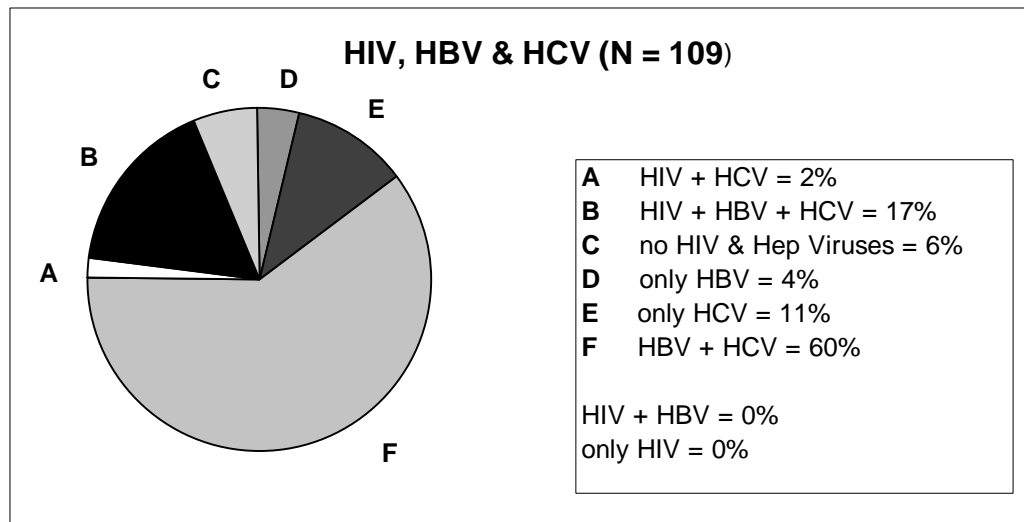
Female	25 92.6%	2 7.4%	27 23.7%
Total	92 80.7%	22 19.3%	114 100.0%

Overall the prevalence of HIV is quite low, which was not expected. However it should be considered that in Switzerland HIV/AIDS prevention efforts with needle exchange started in 1985, so that many of the patients had already been able to benefit from the measures.

The situation with Hepatitis B and C is much worse: 82% have markers of an infection with Hepatitis B and 92% with Hepatitis C. There is almost no sex difference.

	Hepatitis B (Hbc-Ak)	Hepatitis C (Core, NS3, NS4 Yeast & E coli)
Male	71 81%	82 92%
Female	24 86%	26 90%
Total	95 82%	108 92%

Combinations of virus infections are also noteworthy, mainly because the combination of chronic Hepatitis C and HIV seems to have a bad prognosis. Sixty percent of our patients are infected with HBV and HCV. The second largest group of 17% are those with an additional infection with HIV. Only 6% had no infection with one of the three viruses. In our sample, none of the patients had HIV infection alone, it was always combined with HCV or HBV or both. The infection with one of the three viruses correlates with the length of time of drug use; particularly infection with HCV ($R=0.3$, $p=0.001$).



The proper diagnosis of chronic hepatitis is quite difficult and expensive. A liver biopsy seems to be mandatory for a clear diagnosis. A less expensive and invasive indicator is the measurement of the glutamic pyruvic transaminase (GPT). Forty-four percent of our population tested positive for this enzyme.

Glutamic Pyruvic Transaminase

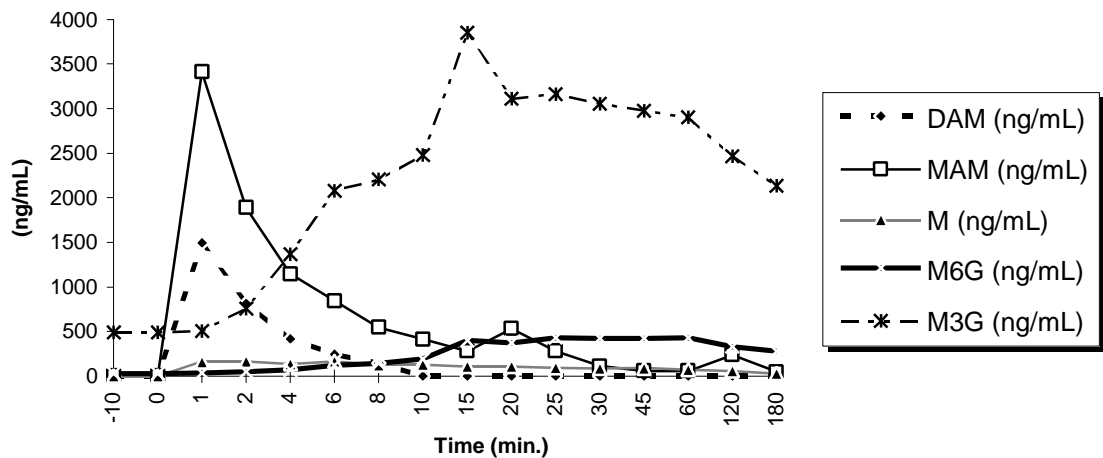
GPT	no Hep. viruses	HBV or HCV	HBV & HCV	Total
no elevated GPT	5 83.3%	11 57.9%	48 53.9%	64 56.1%
elevated GPT	1 16.7%	8 42.1%	41 46.1%	50 43.9%

Total	6 5.3%	19 16.7%	89 78.1%	114 100.0%
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Substances

There are a lot of questions concerning the substances given to the patients. Because of prohibition, there is inadequate information in the scientific literature about the use of opiates in high doses. The doses used in analgesia may be not very relevant for the situation of drug addicts. We therefore examined plasma profiles of a dose of 200 mg diamorphine (DAM; heroin). Interestingly heroin itself disappears from the plasma within ten minutes and only its metabolites are detectable. This reinforces the hypothesis that heroin acts not by itself but through its metabolites. The psychoactive metabolites are probably mono-acetyl-morphine (MAM), morphine (M) and morphine-6-glucuronide (M6G). It has to be added that the situation in the plasma may not reflect the situation of the opiate receptors in the brain.

Plasma profile after i.v. administration of 200 mg Diamorphine

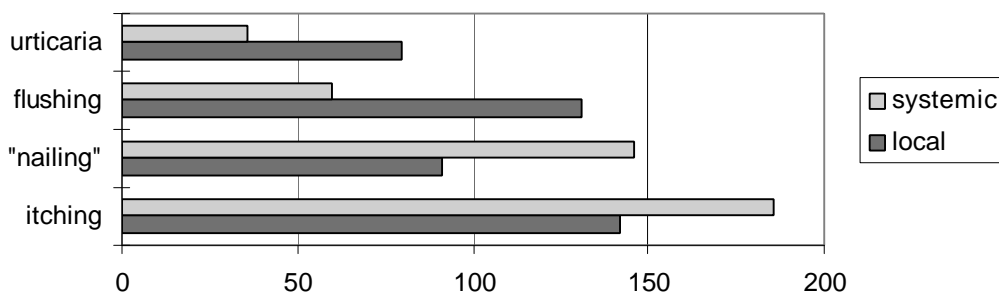


A further question on the substances concerns the side effects, mainly the histaminic reactions. Clinically drug users seem to be so accustomed to these effects that they normally do not complain about them. That is why we did a small study in 1995. Over five days we asked each patient after each application if he or she suffered from the symptoms of a histaminic reaction, that is flushing, urticaria, itching and a phenomenon the patients call 'nailing', which describes the feeling of being pricked from the inside by needles. In addition we investigated if the symptoms were local (at the site of injection) or systemic. At the time of the study 50 patients were prescribed heroin and 12 morphine. All of the patients with morphine suffered from histaminic reactions and only five (10%) of the patients with heroin had no reactions. The 50 patients with heroin injected 786 times in five days; thus the average daily injection rate was 3.14. The 12 patients on morphine injected 208 times and the average daily injection rate was 3.46.

Five day study

	average rate of injections per day	average amount per injection	average daily amount
heroin	3.14	164.3 mg	515.9 mg
morphine	3.46	135.4 mg	468.5 mg

Overall there were statistically more side-effects under morphine than under heroin (χ^2 , $p=0.00002$). But there was no difference in the frequency of local reactions and the highly significant difference between the substances was only due to more systemic reactions under morphine. The systemic reactions consisted of generalised and localised reactions: body parts involved were the head, the back, the buttocks and the soles of the feet. Despite the fact that according to the scientific literature, women are more susceptible to histaminic reactions, we could not find any gender difference. We also could not find a relationship with dose. The most frequent symptom was itching, both local and systemic.

histaminic reactions (5 day study)

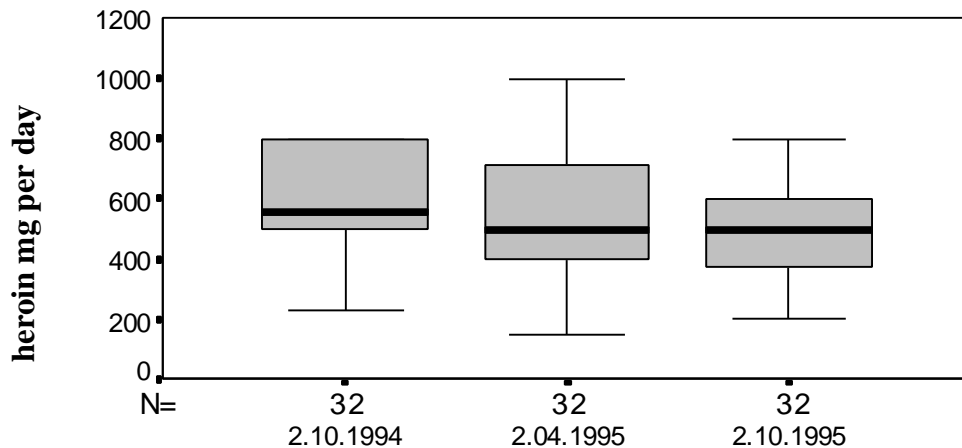
The scientific literature maintains that 10 mg of morphine equals 5 mg of heroin. This value was found some decades ago and has been used in every study in the last year of analgesic effects of these substances. Perhaps this equivalence is correct for low-dose opiates up to 40 mg per day, but we use a different value. In our five day study the average daily amount of heroin was 515.9 mg and the daily amount of morphine was astonishingly even lower, at 468.5 mg. In our project we studied the doses for a longer period, too. The average dose of heroin over a month was 522 mg per day and that of morphine was 541 mg per day.

Doses over 1 month

	morphine	heroin
average	541 mg	522 mg
lowest	450 mg	499 mg
highest	599 mg	541 mg

There were some strange fluctuations from day to day for which we have no explanations. The fluctuations are even stranger if we look at the amount of substance per injection. If we look at the dosage over a year there is not much change at all.

Heroin use on 3 days over one year



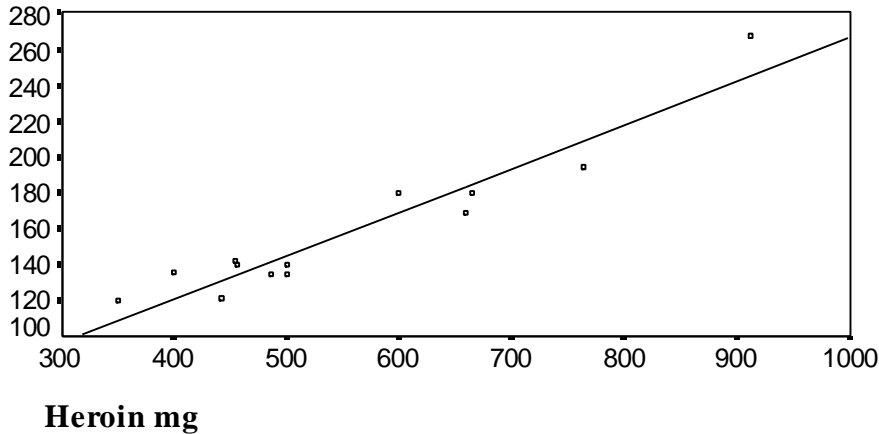
Because there is no control group, a valid equipotency cannot be calculated from the above figures. So we were lucky to be given the opportunity to switch patients from morphine to heroin in Spring 1995 and those patients could function as their own controls. All patients were on stable daily morphine doses when the switch took place; within two days every one of the ten patients found the appropriate heroin dose. This allowed us to calculate an equipotency factor for high-dose heroin and morphine.

Calculation factors

heroin dose multiplied by	0.7	=morphine dose
heroin dose multiplied by	0.28	=oral methadone dose

The equipotency factor is 0.7, so to calculate an appropriate morphine dose from a known heroin dose, we multiply the heroin dose by 0.7. That means that 2 mg of heroin roughly equals 3 mg of morphine. In January 1996 we were able to conduct a similar natural experiment for heroin and oral methadone. Some of our patients participated in a skiing camp and because heroin is allowed only on the premises of our clinic they had to switch to oral methadone. The factor was 0.28 and there was a linear correlation even on very high doses such as 1g heroin per day.

Methadone mg

Equipotency: i.v. heroin / oral methadone

It was important for us to know an exact equipotency because we planned to do a randomised double blind study with crossover between heroin and morphine. If we had used the common 1:2 correlation, people would have been underdosed when they were switched from morphine to heroin; and even worse, people who were switched from heroin to morphine would have been overdosed. A further complication was that morphine solution has a slight brownish colour, so morphine solution can be distinguished from heroin by eye. Alteration of the solution did not solve the problem. Finally we used syringes of brown plastic so that we could guarantee a double blind condition.

Thirty patients were involved in this study and the data collection is finished, but the data have not been analysed yet. However in some cases the change from heroin to morphine led to severe histaminic reactions with drop in blood pressure, strong headaches and itching and 'nailing', so that for these patients the double blind situations had to be uncovered. A preliminary glimpse at the data showed that heroin is better tolerated and that patients are more satisfied with heroin. We hope that we will be able to present the results at the next conference!

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PSYCHO-SOCIAL ASSISTANCE IN ONE OF THE SWISS HEROIN TRIALS

Urs Vontobel

I am trained as a psychiatric nurse and had worked for years in an abstinence-oriented therapeutic institution, before I changed to the heroin-program of the Social Welfare Department of Zurich. I had realised that not everybody is capable or ready to go through the hardship of therapy. I had seen people fail and later die in some hidden corner of the city because their lives had been miserable since early childhood. I stopped clinging to the opinion that therapy is the only way for everybody. The heroin trials seemed to be an adequate attempt to support those who had several failed bids to change their situation and who were still alive. At the beginning of our program in January 1994, I was prepared to face the possibility that the trials would prove to be a failure. Today I am deeply convinced that what we are doing in Zurich and other cities of Switzerland is a most valuable element in the network of harm reduction for drug addicts.

Before I introduce you to the non-medical aspects of our work, I would like to give you a brief overview of our organisation. The two outpatient clinics "Lifeline" and "Crossline" are the most recent of a number of medical and social low threshold programs and projects that have been brought into effect in the city of Zurich in the last decade. We have not entered into competition with other facilities and institutions. On the contrary, the prescription of opiates is not only an addition to other harm reduction programs, as well as to therapy, but it is also an alternative to prison. Today we are collaborating with all the other programs and we are recognised as valuable partners by all of them. At the moment we are looking after close to one hundred patients who are all Zurich locals. In each clinic there are, apart from the doctors, seven professionals, each with different training and each with a background in drug-related work. All of them act as case managers or in the role of "parent" to the patients, as well as supervisors during the injection hours. Therefore, for all practical purposes we are in contact with the addicts on a daily basis and that distinguishes us from other service providers.

To give you an idea of our approach to psycho-social assistance, let me share some important observations which we have made over the last two years:

Dispensing Of Heroin Is A Means To An End: It Affords Us The Opportunity To Achieve What We See As One Of Our Primary Objectives, Which Is The Provision Of Psycho-Social Assistance To The User

If we agree that addiction is just a symptom of a major psychological or social deficiency, then we are not surprised that simply dispensing heroin does not solve any personal problems.

As a matter of fact, the addict loses the daily occupation of procurement and that is more than just a relief. In our experience, that after a short period of euphoria, patients suddenly have time to realise who they are and what kind of situation they are in. For most of them this is very depressing.

They are most likely unemployed, to be in financial straits and probably look back on long criminal records. It is very tempting to try to “cure“ the pain of hopeless perspectives with additional excessive consumption of drugs. At that point the importance of psycho-social assistance as a major factor in our treatment is seen clearly for the first time. This is the stage when psycho-social aspects predominate over medical aspects.

We must recognise that heroin is the means to get and keep in contact with the addicts, but psychological and social support is our main duty after a certain time.

Psycho-Social Assistance Is “Guidance To Self-Help”

Before being admitted to the program, the patient’s personal situation is carefully analysed. Housing, occupation, education, finances, social contacts, criminal record and drug-related history are evaluated, together with the person’s motivation to make a change of any kind. This leads to a priority list that will be the basis for our work. Quite often people are almost “over-assisted”. They are already linked with several offices that support them in different respects. But the contacts are low intensity and impersonal, for example, collection of unemployment benefits at a social welfare desk, a meeting with the probation officer every half year or a casual contact with the responsible person in a housing program. We actively take over a coordinating role since we are in contact daily and therefore can build up a dependable and long-term cooperation. In other words, we take over case management.

In the beginning we were working particularly at the basic problems, classic social work. Over one-third of the patients were homeless, so we introduced them to Zurich city housing programs. Disastrous financial problems needed to be faced and dealt with. New ways of spending time usefully needed to be talked about and initiated.

Generally a lot of questions had to be asked: Who is entitled to collect unemployment benefits and has not as yet? Is everybody’s health-insurance paid up? (In Switzerland there is no free health benefit scheme like Medicare.) What is required to ensure that a patient is sentenced to a therapeutic measure instead of prison? Who qualifies for a pension? How do you get a new identity card? For all these questions the patients need our support, but they have to take action themselves and bear responsibility once again.

Recreational activities are being initiated in order to help patients rediscover their resources and forgotten feelings, as well as to provide inspiration and ideas.

From the beginning, patients had *periodic talks* with the case managers acting as “parents” covering all aspects of hygiene, HIV-prevention and how to structure the day. At the same time unrealistic patient aims have to be tackled and realistic perspectives developed. In some cases new relationships are the focus of discussion, in others impending death. Family problems emerge in almost every case. Feelings of guilt, shame and grief must be addressed. Then our work gets an almost therapeutic touch.

In *group sessions* the goal is to rebuild basics like talking and listening and other social skills. Christmas, New Year and birthdays are always times to remember and therefore usually times that need special attention. Since these sessions are compulsory, all different kinds of resistance have to be faced.

The variety of problems are as large as the number of patients, and they have been neglected and pushed aside for years and years. They need practical and psychological attention. There is a thin line between frustration and contentment, there is always the temptation of drugs to offer quick relief again. Motivating towards a new orientation in life, reviving the patient’s own initiative, and encouraging autonomous efforts are part of our work again and again.

There has to be an almost *behavioural setting!* We had to learn to set limits in order to be able to do our work properly. Our original approach which was to put psycho-social assistance on a completely voluntary basis turned out to be a delusion. Those patients who were totally “disintegrated” especially avoided contact as much as they could and we learned to be more demanding. This change of approach has increased the compliance of the patients. It seemed as if they wanted us to take over responsibility at the beginning of treatment.

Psycho-social assistance is a process, a step-by-step support that takes time. It is therefore essential to rely on staff with a long-term commitment to ensure continuity, especially since our patients have seen numerous social workers come and go in their drug careers. Ability to build up an atmosphere of mutual trust determines the quality of cooperation, and ultimately whether the patients are capable of translating the issues discussed into action.

An Important Element Of Success Is Improvement Of The Patient's Psycho-Social Situation

When people talk about "success", it means something different to each one of them, especially when it comes to discussions about heroin prescription. To some, mainly politicians, only full rehabilitation as drug-free members of society is a good enough achievement for all patients. The results of the trails fall short of this expectation. The individual changes in situations of the addicts which have been brought about by the programs differ very much, and thus, we must weigh with different measures.

All of our patients look back on a long-term addiction career. Their average age is over thirty years and they have undergone treatment of various kinds. The majority have several mental and health deficits. They have fallen through the social and professional nets and their chances for complete rehabilitation are, in most cases, very slim.

Our support is aimed at daily relief: humane living conditions, eliminating the need for crime and prostitution, improving their financial situation, more creative use of time, and last but not least, regular social contacts outside the drug scene. All prepare the foundation for stabilisation of mental health. Most of the patients have achieved one or more improvements in their daily life, and that is success. In support of this I would like to give you two very brief case histories of people who joined our program at the beginning of 1994:

Michael:

Two years ago when Michael joined the program he was in a devastated state of health. Numerous pneumonias, meningitis and other AIDS-related infections had weakened him to an extent that any more time in the open drug scene would have soon killed him. He worked on the lowest level of the drug business; he supplied clean spoons and syringes in exchange for used filters, from which he extracted the drugs he injected. Every day and in every weather he had to go out and get supplies for his addiction.

Since he joined the program he is taking medication regularly for the first time in his medical history and he is still alive. He has stopped consuming cocaine. In between injections at our premises, he is at home resting, reading books and working on his old computer. He has come to terms with his family again, which was one of his major concerns. He qualified for a pension and now no longer has financial problems.

Lately, the subject of our talks has been moving him to a nursing home for AIDS-patients, since he is weakening steadily and death is impending. He has repeatedly told us that our project has given him the opportunity of dying in a humane way.

Allan:

A couple of months before Allan was admitted to our program, he had lost his job because he had been absent from work too often. He had been busy finding supply for his addiction. Consequently he could not afford his apartment and had become homeless.

So he had been wheeling and dealing in the open drug scene and it was only a matter of time before he would have added another prison sentence to his criminal record. Once he had joined the program he considered himself a complete failure and showed strong symptoms of depression that led to a short stay in a psychiatric clinic. In order to stabilise his situation he was guided into finding a room to live in and to enrolling for unemployment benefits. Subsequently his mental state improved remarkably and he began thinking about his future. After about one year in the program, with a number of relapses during which he

consumed cocaine heavily, he suddenly came up with the prospect of a drug-free life. Then our work consisted mainly of introducing him to what therapy means and where he could be helped. Today he is in a rehabilitation program and writes us letters regularly.

To Reach A Larger Population Of Drug Addicts We Would Need More Flexible Settings For Prescription Of Heroin

In the Swiss heroin trials the same conditions apply for everybody, and this means that there are hurdles that are too high for some and too low for others. Many addicts could not go through the procedure for admission because they are simply not capable of meeting an appointment, others do not want to be subjected to this level of control. A setting has to be established that is appropriate to heavily marginalised people and is totally unacceptable to those whose social skills are intact. Addicts who have managed to keep a job and a place to live are not able to come to the clinics three times a day, and those who start working again have to change their consumption patterns drastically.

That is why the future lies in a more flexible approach to prescribing heroin, to make sure we can reach patients in different settings and circumstances. It must be possible to adjust the modalities individually. I have a "step program" in mind that is implemented with controls tight enough to prevent misuse. We could adapt the assistance accordingly, for example, in the group-sessions where we could concentrate on subjects of common interest much more.

In my opinion, the opportunities that the prescription of heroin offers to all the persons involved – doctors, social workers and addicts – outweigh the concerns of its opponents. The past has shown how difficult it is to assist people with severe long-term addiction problems. Prescription is feasible without being irresponsible, it is a relief to the persons concerned and to their families, and it provides an opportunity to make a change without the demand for abstinence. It is a humane way of dealing with people who cannot cope with their lives without the comfort of drugs.

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HEROIN SUBSTITUTION TRIALS IN SWITZERLAND - CONTEXT, PRELIMINARY DATA AND FINDINGS FROM AN EVALUATION PERSPECTIVE

Dieter Ladewig and Peter Kury

Basel is one of a number of Swiss cities participating in trials of heroin, morphine and intravenous methadone prescription for people dependent on heroin. Before discussing this trial, some background information about methadone maintenance treatment in Basel is presented. Basel has a population of 198,000, of whom 2,000-3,000 are estimated to be drug dependent. In October 1995 1,195 patients were receiving methadone maintenance treatment. Basel has 603 methadone places per 100,000 inhabitants compared to the Swiss average of 156 methadone places per 100,000 inhabitants. There are three centres in Basel where dependent drug users can be admitted to treatment.

Table 1 presents the number of methadone patients in each type of treatment program. At the time when these data were collected, there were 958 methadone patients, of whom 494 received prescriptions from private physicians (n = 235) or private pharmacies (n = 82). There was also a private treatment program which runs a clinic catering for 276 patients.

Table 1. Number of patients in methadone maintenance treatment in different programs in Basel

Type of program	Number of patients
University psychiatric hospital	162
Psychiatric outpatient department	26
Private physicians and pharmacies	494
Private treatment program	276
Total	958

Detailed information was available for 847 patients receiving opioid substitution treatments in October 1995 (Table 2).

Table 2. Proportion of patients receiving different types of maintenance treatment

Maintenance drug	n	%
Methadone	824	97.3
Buprenorphine	4	0.5
Hydrocodon	19	2.2

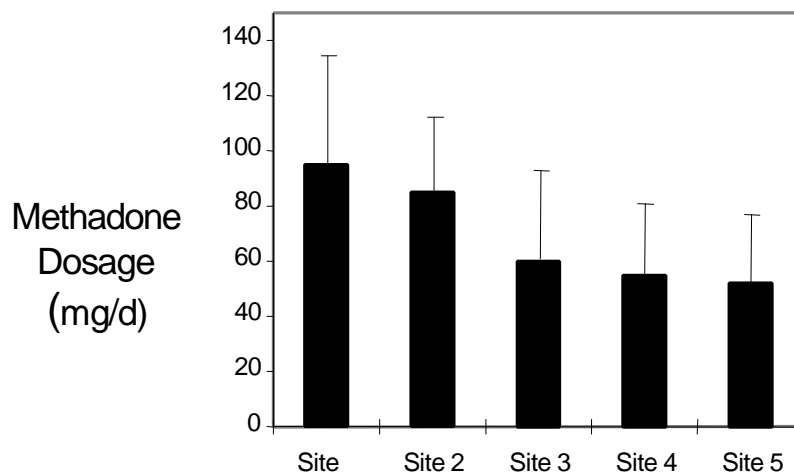
Two hundred and three patients (24%) were also receiving some additional form of medication and 61% (522) were still using illicit drugs. The methadone doses prescribed are shown in Table 3. The average dose was 66 mg per day.

Table 3. Range of methadone doses prescribed

Methadone dose (mg)	n	%
less than 60	401	48.3
60-79	174	21.0
more than 80	255	30.7

Figure 1 shows the average doses prescribed at the different programs.

Figure 1. Average doses of methadone prescribed in Basel



Site 1 = University Psychiatric Hospital
 Site 2 = Psychiatric Outpatient Department
 Site 3 = Private Physicians
 Site 4 = Private Pharmacies
 Site 5 = Private Program

Table 4 presents some of the characteristics of the 847 people receiving opioid substitution treatment. Two-thirds were men and the average age was 30 years. Two thirds were receiving welfare payments or a disability pension.

Table 4. Sex, age and employment status of dependent heroin users receiving opioid substitution treatment

Characteristics	n	%
Male	551	66
Female	291	34
<i>Age</i>		
17-19	13	1.5
20-24	162	19.2
25-29	235	27.7
30-39	351	41.5
40-49	82	9.7
50-59	3	0.4
<i>Employment status</i>		
Employed full-time	279	33
Public assistance (welfare)	278	33
Pension for medical/psychiatric disability	279	33

Somatic and psychological status were also assessed (Table 5), as were infections with HIV and hepatitis (Table 6).

Table 5. Physical and psychological health of patients receiving opioid substitution treatment

Health	n	%
<i>Somatic status</i>		
good	488	50
average	236	24
bad	116	13
<i>Psychological status</i>		
good	322	33
average	365	38
bad	168	17

Table 6. HIV and hepatitis infection status of patients receiving opioid substitution treatment (n=847)

Infection status	n	%
HIV-positive	114	12.0
Hepatitis B	267	31.5
Hepatitis C	243	28.7
Hepatitis B&C	156	18.4

In 1992 the Swiss government authorised a three-year, multi-centre scientific research program, the "medical prescription of diversified narcotics program". The first projects were set up in January 1994 and there are now 17 projects in 16 different cities. The narcotics prescribed are intravenous (iv) heroin, morphine and methadone. By May 1996 there were 800 treatment places with heroin prescription and 100 each for morphine and iv methadone. Of these 750, 27 and 38, respectively, were filled.

In Basel 106 trial participants receive heroin prescriptions, 10 receive morphine and 14 iv methadone. There are 96 men and 34 women, the average age is 31 years and the average length of opiate dependence is 11 years. The retention rate is high compared with oral methadone programs. Despite high doses, symptoms of sedation or intoxication are rare. Most participants have been successfully stabilised and this has led to a greater demand for counselling and increased interest in abstinence. To date 10 people have left the program and become drug free.

The Basel trial started in November 1994 as a randomised controlled trial, with participants being randomly allocated to treatment with intravenous heroin, morphine or methadone. Table 7 presents information about stabilisation on these drugs during the randomisation period.

Table 7. Stabilisation of participants randomly allocated to intravenous heroin, morphine and methadone

Group	n at 1/12/94	n at 31/12/94	Number of dropouts	Latency to first stable dose (days)	First stable dose (mg/d)	Dose at 1/12/94	Dose at 31/12/94	Differ- ence over time
Heroin	27	21	1	5.3±2.7	351±102	481±172	605±259	p<0.001
Morphine	21	18	7	3.2±3.0	217±91	273±178	207±192	NS
Methadone	35	26	5	1.9±3.9	91±43	85±61	118±91	NS
Difference between drugs				p<0.02				

Of the participants who were randomly allocated more dropped out of morphine and methadone treatment than heroin treatment. There was a significant difference between the drug treatments in the time taken to reach a stable dose, with those receiving heroin treatment taking the longest. For morphine and methadone, there was no significant change in dose over time after participants had first been stabilised, whereas the dose of heroin needed for stabilisation continued to increase. After about six months of further treatment this increase stopped at a dose of about 500 mg. These changes are the subject of an ongoing research project.

The preliminary results of the Swiss trials (Uchtenhagen et al., 1996) have shown that:

- the trials reach a strongly marginalised group of long-term heroin addicted people who have failed or not improved in other treatments;
- the trials were only partially successful in reaching dependent heroin users who had not been in treatment for a long time;
- there was a satisfactory retention rate; retention was lowest among participants who continued to consume cocaine, continued to work as prostitutes or who showed signs of severe psychiatric morbidity;
- after the first six months there was improvement in the participants' psychosocial situation, measured by accommodation and employment, illegal activities, contacts with the drug scene, continued consumption of narcotics and health.

In particular, the preliminary data show that, after six months there was:

- stabilisation of accommodation, with a reduction of homelessness from 15% to 3%
- improvement in employment from 18% to 46%
- reduction of illegal activities from 53% to 13%
- reduction of contacts with the drug scene, the percentage with no contact increased from 13% to 44%
- some reductions in daily drug consumption
 - daily cocaine use dropped from 31% to 9%
 - daily cannabis use dropped from 34% to 32%
 - daily benzodiazepine use dropped from 20% to 13%

- involvement in prostitution dropped from 13% to 6%
- significant improvement in health, especially reduction of syndromes related to infections
- significant reduction in psychopathology, especially depressive and paranoid-anxious states.

Figures 2 and 3 present more detailed information about changes in drug consumption and depression.

Figure 2. Changes in daily drug consumption for trial participants

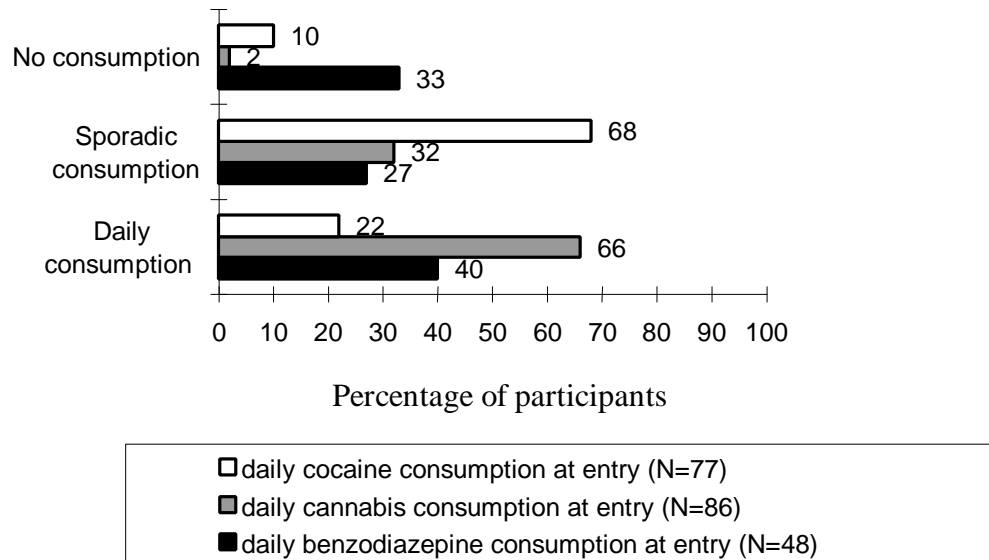
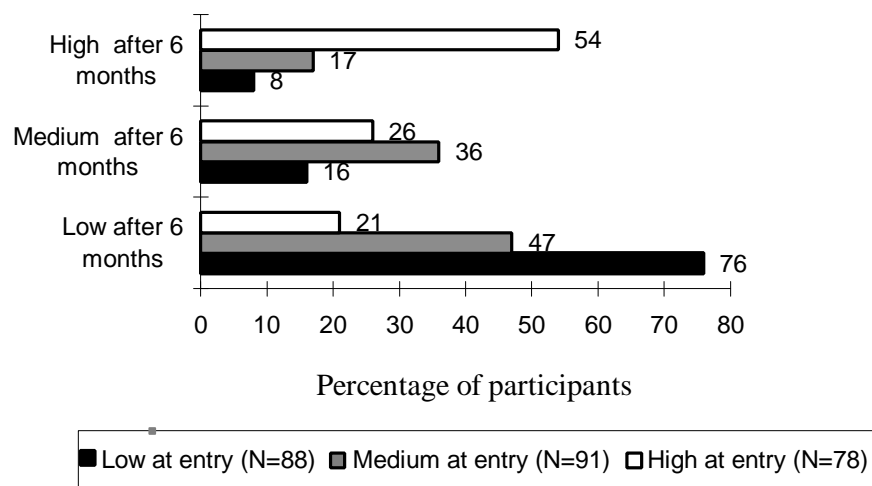


Figure 2 shows that of the 77 people who consumed cocaine on a daily basis at the start of the trials, 22% were still consuming cocaine daily after 6 months, 68% were consuming occasionally and 10% no longer used cocaine. There were smaller reductions in cannabis and benzodiazepine use, with 66% of those using cannabis daily before the trial and 40% of those using benzodiazepines daily before the trial continuing to use daily after six months.

Figure 3. Changes in depression for trial participants



Fifty-four percent of those whose depression score was high before the trial continued to have a high depression score after six months, whereas for 26% the score had become medium and for 21% it was low. Of those who had a low depression score at entry, most (76%) continued to have a low score after six months, although depression scores increased for 24%; 16% moved to medium depression and 8% scored high on depression.

Other detailed results are available in an interim report (Uchtenhagen et al., 1996).

Overall the results of the Swiss trials are very positive. The Swiss trials will conclude at the end of 1996. These first results suggest that chronic intravenous drug users who have been unsuccessful in other

treatments can be treated with intravenous heroin, morphine or methadone with positive effects. Of these three options, heroin seems to be by far the best accepted.

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Uchtenhagen, A.; Gutzwiller, F.; Dobler-Mikola, A.; Blättler, R. 1996 *Program for a Medical Prescription of Narcotics. Interim Report of the Research Representatives*. Zürich: Institut für Suchtforschung in Verbindung mit der Universität Zürich und Institut für Sozial- und Präventivmedizin der Universität Zürich.

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THE PRESCRIPTION OF HEROIN TO HEROIN ADDICTS: A PROPOSAL FOR THE NETHERLANDS

Ferdinand Sturmans

The Netherlands has been discussing the provision of heroin for more than fifteen years now. If we take a look at some other countries, where drugs are considered to be the people's worst enemy, we should be thankful that we have a climate in which it is possible to discuss this issue.

As one of the results of the heroin supply debate in the Netherlands in the early eighties, it was decided within the framework of the morphine provision programme to provide a number of carefully selected extremely problematic drug users with combined methadone and morphine for at least two years on a trial basis in the period 1983-1987 (Derks, 1990 a-c). In order to ensure the manageability of the provision of drugs, only Dutch people registered and living in Amsterdam and well known to the Amsterdam drug care organisations were permitted to participate. The basis of the provision programme was the individual well-being of the users. Reduction of crime and nuisance were explicitly not included in the objectives of this experiment. Due to the small scale of the trial - only 37 extremely problematic drug users were included - and the broadly defined objectives, the results of the trial were not spectacular. The reports refer to a change in the addiction careers which runs parallel with the treatment targets. Since there was no control group, it is not possible to convincingly establish the effect of the provision programme on a comparative basis. However, the doubts frequently expressed before and during the project regarding the feasibility and results of this provision programme proved to be unfounded. The provision of opiates is not a solution to the drug problem, but it clearly does not necessarily have to lead to an unmanageable situation.

Currently drugs are being provided in a number of Swiss cities within the framework of a three year scientific trial, aimed at studying whether prescribing drugs can help to reduce the use of illegal drugs by so-called "severely addicted users". The objective of the project is principally of a medical nature (Uchtenhagen, 1994).

Progress reports have been published (Uchtenhagen et al., 1995) and we can conclude from these reports that the provision of various drugs is feasible, that target groups are successfully reached by the provision programmes, that there are few problems regarding the manageability of the programmes and that heroin is more acceptable to users than morphine and methadone. Due to the fact that there are no data yet about the envisaged control group, no clear-cut answers can be expected from Switzerland concerning the question as to whether the provision of heroin, morphine or intravenous methadone produces better results than the provision of oral methadone. The reason is that the groups to whom the drugs are being supplied are not being compared in a scientifically valid way with

comparable groups in the normal methadone programmes. So there still seems to be room for the Australian and Dutch initiatives to start a heroin provision trial.

In Canberra, Australia in 1991 a group of drug experts realised that although opiates are being provided in different parts of the world, no proper evaluation of these programmes has been made and that there are questions concerning the supply of drugs which need to be answered before drug policy in Australia can be reviewed. A provision trial could provide an answer to these questions. The proposed trial will in essence be a traditional randomised controlled trial with a control group which receives only methadone (Bammer, 1995). The status of this Australian recommendation is comparable with the recommendation of the Health Council of the Netherlands made in 1995.

The Health Council of the Netherlands (1995) concluded that there is a need in the Netherlands for supplementary forms of treatment for those addicts for whom treatment has not yielded any or sufficient improvements.

Those eligible for the experiment are severely addicted heroin users who do not respond or who respond inadequately to the pharmacological interventions which are currently available. The goal is to determine whether these addicts can be stabilised, whether their bio-psycho-social well-being can be enhanced, whether additional use of substances can be reduced, whether they can possibly be encouraged to bring their addiction to an end.

Apart from such a scientific medical experiment, palliative treatment with heroin or opiates equivalent to heroin should be facilitated for seriously ill patients with a long lasting permanent addiction to heroin and short life expectancy.

On the basis of the recommendation from the report of a committee of the Health Council of the Netherlands the four major cities elaborated the following proposal.

It is generally accepted that the allocation of participants into an experimental group and a control group should take place after the participants have declared that they are willing to take part in the trial. This is valid reasoning as long as the study can remain double blind or at least single blind as far as the participants are concerned. This is the traditional randomised controlled trial: first informed consent and after that randomisation of the consenting participants into two groups, an experimental one and a control group. There are circumstances however in which it is desirable to carry out the randomisation before asking participants for informed consent. If, for example, heroin addicts are asked to participate in a study into the effects of the controlled provision of heroin and agree to participate, it is possible that the addicts who are by chance not allocated to the heroin provision group will drop out of the trial in order to make another attempt to get heroin prescribed, particularly if they know that they are in

principle eligible. You are then faced with selective drop-out as a result of which the experimental and the control group are no longer comparable. It looks like the Swiss experiment suffers from this problem.

In order to prevent this risk of selective drop out from the control group as far as possible, a researcher can first allocate the eligible addicts at random to the two treatment groups and only then ask the patients if they wish to participate in the treatment programme to which they have been allocated and provide them with the necessary information. This method was developed by Zelen (1979, 1990). Since the provision of methadone is a standard intervention for which heroin addicts are automatically eligible, and which they already receive when they are in a methadone programme, it will only be necessary to ask the permission of the addicts allocated to the heroin provision programme. In this way the behaviour of the methadone patients in the control group will not be affected. A Zelen design — first randomisation and then informed consent — therefore seems to be a good solution for trials with controlled provision.

This Zelen design is also under consideration for yet another trial to evaluate among drug addicts the policy of involuntary treatment in a justice setting, to minimise drug nuisance, aggressive behaviour and drug related crime. The experimental group would consist of convicted drug addicts to whom a choice will be offered between two ways of detention: imprisonment or treatment in a justice setting. We expect most, if not all, of them will choose the treatment in a justice setting. The control group will consist of convicted drug addicts to whom that choice will not be offered. This group is imprisoned. To obtain informed consent of all participants as in a traditional randomised trial seems counterproductive. After all they are convicted to imprisonment. In the Zelen design randomisation of the potential participants into an experimental and a control group is the first step. Informed consent is only asked for in the experimental group.

The number of drug addicts to be considered for participation in the trial is estimated at about 200: this is the 10% of all drug addicts in Rotterdam responsible for about 80% of all drug related crime, drug nuisance and aggressive behaviour. An unknown fraction of this 10% will actually be convicted.

To collect data about the period during and after imprisonment an active follow up policy has to be developed using routine administrative and social welfare systems to evaluate the social outcome of the new policy compared with the traditional one. It is essential that the follow up procedures are the same for both the experimental group and the control group.

Summarising: the population of drug addicts can be divided into three subgroups.

The first subgroup is those who are doing rather well on methadone substitution therapy. For the moment no trial is envisaged for this subgroup.

The second subgroup of addicts is using methadone substitution therapy but also substantial amounts of illegal heroin and they have only incidental police contacts. For this subgroup the heroin provision trial according to the Zelen design is envisaged.

The third subgroup consists of those 10% who are responsible for 80% of the drug-related crime. They are not regularly using methadone substitution therapy, they do however use illegal heroin and have frequent police contacts. For them the trial with the involuntary treatment in a justice setting is envisaged according to the Zelen design.

These two trials are linked to each other that one of the positive results of the medical trial could be that compared to the control group less participants from the experimental group will be the subject of consideration for inclusion in the justice trial.

With these two trials we hope to provide some factual evidence for the discussion about new ways of treatment of drug addicts to minimise drug nuisance, aggressive behaviour and drug related crime.

Application of the Zelen design to a heroin provision experiment

If it is plausible that the selected users would prefer to receive heroin rather than methadone, the Zelen design can be applied as follows.

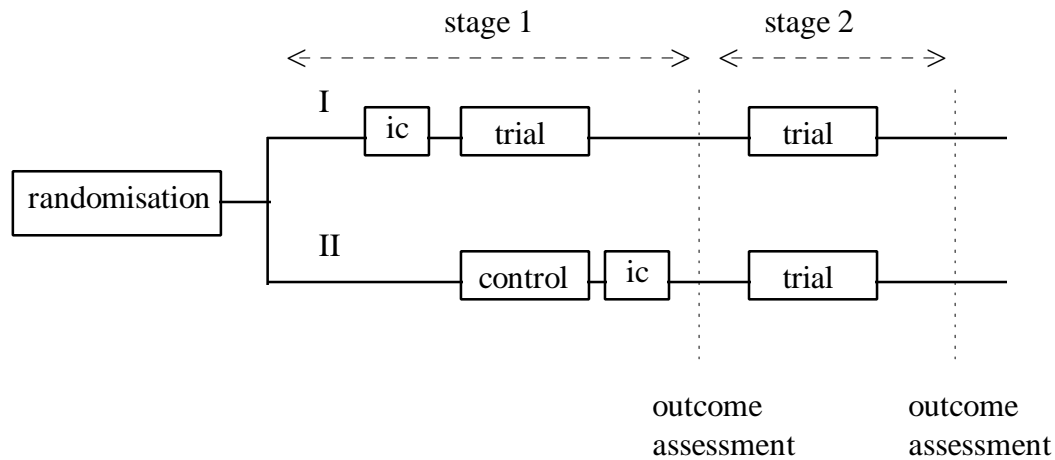
The Zelen design can only be used under the following conditions:

- a. the comparison is between a trial treatment and standard treatment, and
- b. an individual baseline assessment is not necessary.

In a study into the effects of heroin provision, the control group will be offered the standard methadone treatment. This complies with the first condition for the use of the Zelen design. An individual baseline assessment is also usually carried out in the methadone programmes, although not all information considered relevant will be collected in this way. Before an addict is registered for a methadone programme, a medical and social selection takes place in which information is also collected about the addict's health and psychosocial well-being. This largely complies with the second condition for the use of the Zelen design.

Additional contact is necessary with the participants to measure outcomes related to physical health and psychosocial functioning. In the case of the traditional design, this causes no problem after informed consent. If the Zelen design is used, the participants in the control group need to be motivated to take part in such additional assessments.

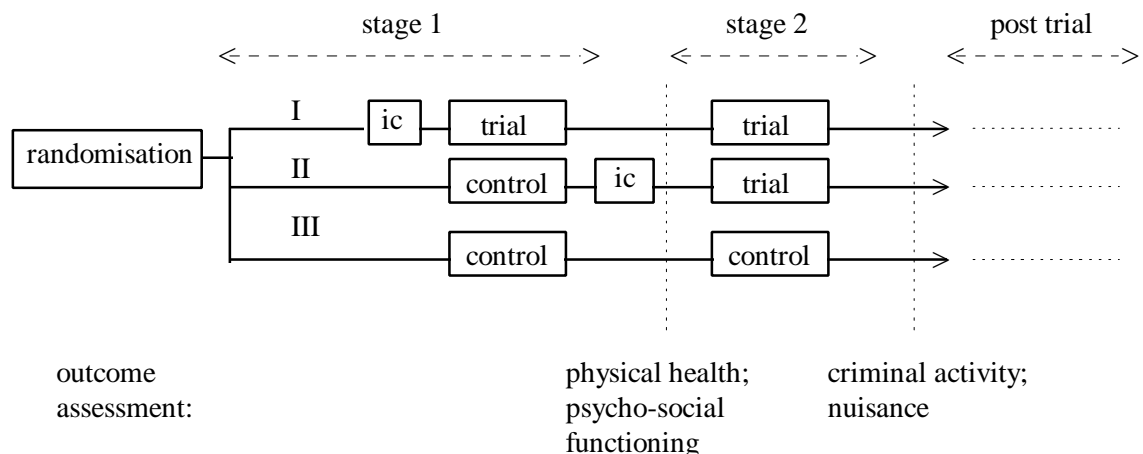
The following variant of the Zelen design provides a solution to this.



Following the randomisation and the informed consent (ic) procedure, group I receives the experimental treatment. Group II acts as a control group and receives the standard treatment. This design consists of two stages. After the first stage the outcomes relating to physical health and psychosocial functioning can be assessed. In order to facilitate assessments at an individual level in Group II, at the end of the first stage, this group is also asked to give their permission to undergo the trial treatment in the second stage. It is assumed that almost all trial participants will agree to this. In the case of this group, the baseline assessment for the second phase also serves as the final assessment for the first stage. During stage II, the trial treatment of group I will be continued. At the end of the second stage, follow-up assessments will be carried out for groups I and II with regard to physical health and psychosocial well-being.

This design in two stages has an important advantage in that the statistical analysis of the data from the first stage can be carried out during the second stage. This means that the results of the health effects are known before the end of the trial. These results can be incorporated into the decision-making process concerning what will happen after the trial. Should the controlled provision of heroin then form part of the standard treatment package, it would not be very beneficial for a number of reasons to reduce the provision of heroin while awaiting the decision in this respect.

Another advantage is that the second stage can be used to obtain a picture of the change in criminal activity and nuisance caused by heroin users. This can most probably be done on the basis of anonymous information provided by care organisations, the court and police, so that a personal approach for a final assessment can be omitted. Since only a small percentage of crime is registered and known to the courts, in order to show a minimal difference, a larger number of trial participants will be necessary than in the case of the effects on health and psychosocial functioning. In order to achieve this, at the start of the study randomisation can take place into three groups rather than two. The third group can function as a control group to assess the criminal activity effects. This leads to the following variant of the Zelen design.



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- This paper was presented at the 7th International Conference on the Reduction of Drug Related Harm, Hobart, Australia, 3-7 March 1996.

HEROIN PRESCRIPTION - A COMPARISON OF THE ENGLISH, SWISS, DUTCH AND AUSTRALIAN SITUATIONS

Gabriele Bammer

The prescription of heroin to dependent users in four countries is compared. The prescription of heroin is taking place in two of those countries — the United Kingdom and Switzerland — and is proposed for two others — the Netherlands and Australia. Unlike other western countries, the prescription of heroin was never made illegal in the United Kingdom. The ability to prescribe to dependent users was restricted to doctors with special licences in the 1960s, but has, nevertheless, been part of on-going medical practice. Trials of heroin prescription were introduced in Switzerland in 1994 and their status will be reviewed at the end of 1996. The Dutch are planning to begin trials in 1996¹. If the trials are successful, they could be followed by "a broader social experiment" (Health Council of the Netherlands, 1995, p. 78) The Australian proposal, for which I directed the feasibility study, differs from the others in that it is still unknown whether there will ever be the political will to implement it. The proposal is for two sequential pilot studies, each lasting six months, which, if they meet pre-determined criteria for success, will be followed by a two-year trial.

In the United Kingdom heroin is treated like any other pharmaceutical in that patients receive a doctor's prescription which they take to a pharmacy where they are given heroin to take-away to inject. In contrast, Swiss practice and the Dutch and Australian proposals would only allow heroin injection to take place in a clinic under supervision, along with psycho-social counselling. In the Swiss trials and Australian proposal, trial participants can or would be able to come to the clinic to inject heroin up to three times per day (although in Basel, injection is restricted to twice a day). This is not specified in the Dutch proposal.

Heroin prescription to dependent users is no longer widely practised in the United Kingdom (Fleming, 1997). Some of those receiving prescriptions are being continued in maintenance treatment which first started in the 1960s, when heroin prescribing was more common. These days heroin prescription is regarded as a treatment of last resort when all other attempts have failed. The Swiss trials have targeted "hard core" dependent users who have health problems and "several symptoms of social failure and who have either not been reached by the traditional therapeutic methods, or have been unsuccessfully integrated in them" (Uchtenhagen et al., 1996a, pp 47). The Dutch proposal focuses on "severely addicted heroin users who do not respond or who respond inadequately to the pharmacological interventions which are currently available" (Health Council of the Netherlands, 1995, p. 76). The Australian proposal would aim to determine who benefited most from heroin treatment and thus would target three groups - those who had dropped out of methadone treatment, those on methadone treatment who would prefer heroin and those who had never been in treatment (Bammer, 1995). While the first group is comparable to those targeted in the United Kingdom, Switzerland and the Netherlands, prescription to the other two groups would provide considerable new information. These conditions are summarised in Table 1.

In the United Kingdom, there are currently around 50 doctors who prescribe heroin to about 300 dependent heroin users (Fleming, 1997; personal communication from the Home Office and heroin prescribers).

In Switzerland, heroin prescribing was originally trialled in six of seven pilot centres (Uchtenhagen et al., 1996a). One of the other pilot centres trialled intravenous methadone prescription only. The success of those pilots has meant that there are now trials in at least 14 centres (Uchtenhagen, 1995). The original proposal was to make heroin prescription available to 250 participants with another 250 receiving injectable morphine and 200 being prescribed injectable methadone. Problems with the last two drugs led to a revision in the protocol, with 800 places being made available for injectable heroin and 200 for either injectable morphine or methadone (Uchtenhagen et al., 1996a). Heroin is available alone or in combination with methadone.

This would also be the case in the Dutch trials which would involve more than one centre, although a large number of participating centres is considered unmanageable (Health Council of the Netherlands, 1995). The locations could include areas other than big cities. It is anticipated that around 100 participants would be needed in each group for a trial to be able to demonstrate statistically significant differences when heroin (alone or in combination with methadone) was compared to the oral methadone control treatment. The "broader social experiment" which would follow a successful trial would be likely to have 2,000 to 3,000 participants (Health Council of the Netherlands, 1995, p.78).

¹ Since this paper was originally presented, the Dutch proposal has changed and the trials are now planned for 1997. The detailed trial design is still being prepared.

In the Australian proposal the pilot studies would take place in one city, with the full-scale trial involving three cities. The first pilot would have 40 participants, each receiving a choice of injectable heroin alone, injectable heroin plus oral methadone, or oral methadone alone. The choice of treatment would be up to individual participants who could move freely between options, within the limits of medical safety. The second pilot would have 250 participants - half receiving the same choice of options and half receiving only oral methadone. If drop-outs were limited, the numbers would be sufficient to detect statistically significant differences in outcomes. The full-scale trial would have 1,000 participants, with 500 receiving a choice of treatments (injectable heroin alone, injectable heroin plus oral methadone, or oral methadone alone) and half receiving oral methadone only (Bammer, 1995).

In the United Kingdom, a heroin prescription costs around 5.25 pounds, but is free for those on low incomes (personal communication from heroin prescribers). Most patients receive a prescription which must be filled every day, although some receive prescriptions for up to one week at a time. Swiss trial participants pay 15 Swiss francs per day, which is generally affordable even for those receiving welfare payments (personal communication from several people involved in the

Swiss trials). Under the Australian proposal, participants would not pay for heroin during the trial phase, although if heroin was subsequently instituted as a standard treatment option, it would be charged for using similar guidelines to charges for methadone treatment (Bammer, 1995). It is not clear if payment would be required in the Dutch proposal. These conditions are summarised in Table 2.

In the United Kingdom, general practitioners can prescribe both oral and injectable methadone. Licensed medical practitioners can prescribe injectable heroin and some also prescribe smokable heroin. A method of injecting heroin into tobacco cigarettes has been developed (Marks & Palombella, 1990; Clitherow, personal communication). Licensed practitioners can also prescribe cocaine and dipipanone. Prescription of other opioids and stimulants is not restricted to licensed practitioners, but can be carried out by any medical practitioner (Fleming, 1997).

Oral methadone is also widely prescribed in Switzerland. As already indicated the trials were centred on injectable heroin, morphine and methadone. Smokable heroin was not found to be successful (Uchtenhagen et al., 1996a). The heroin was added to herbal (woodruff) cigarettes and the absorption into the body was found to be very low (about 10%). The acceptance of the herbal cigarettes was also not particularly high. The Swiss also trialed cocaine cigarettes, but the results were inconclusive (Uchtenhagen et al., 1996a). Ways of improving the delivery of heroin are currently under investigation, including the use of oral slow-release and inhalant preparations (Uchtenhagen et al., 1996a).

Oral methadone is also commonly prescribed in the Netherlands and Australia and the trials in those two countries would provide injectable heroin. If a reliable method of application could be found, smokable heroin would also be included in these trials. The Dutch would also consider trialing heroin in aerosol, sublingual and/or suppository forms (Health Council of the Netherlands, 1995). These results are summarised in Table 3.

There has been relatively little interest in evaluation of heroin prescribing in the United Kingdom. A randomised controlled trial in the 1970s compared the new treatment oral methadone (n=52) with the then standard treatment, injectable heroin (n= 44; Hartnoll et al., 1980). The most striking finding was a high drop-out rate from oral methadone treatment and a lack of difference between the groups in health, employment and consumption of non-opioid drugs. The group prescribed heroin continued to supplement their maintenance prescription (the licit prescription ranged from 30-120 mg daily, which is very low compared to the doses used in the current Swiss trials - see Haemmig, 1997 and Ladewig & Kury, 1997) and to be involved with the drug subculture and criminal activity. Those prescribed methadone (10-120 mg daily) were more likely to either become abstinent or be even more involved than the heroin group with illegal heroin use, the drug subculture and criminal activity. Despite the lack of clear-cut advantages in prescribing methadone, there was a change away from heroin prescribing (see Fleming, 1997; Mitcheson, 1994 and Spear, 1997 for possible reasons). The experience in the United Kingdom is also unique in that there has been long-term

follow-up by Stimson and colleagues of 128 people drawn from 372 who were receiving heroin prescriptions from 13 of 15 London-based clinics in 1969. This study has led to two books and multiple papers which are difficult to summarise briefly. A follow-up in 1977 found that 40 of the sample were abstinent and a 1979 follow-up found that 19 had died and that 17 had received heroin prescriptions continuously since 1969. Those whose lives were most 'chaotic' were least likely to be continuously maintained on heroin (Stimson and Oppenheimer, 1982).

Evaluation is and would be central to the Swiss, Dutch and Australian trials. A number of evaluation strategies are being used in the Swiss trials (Uchtenhagen et al., 1996a). Individualised prescription to injectable heroin, morphine or methadone has been most common, with some trials emphasising contextual differences and one focused on women involved in sex work. There have also been double-blind comparisons between injectable morphine and heroin. A randomised controlled trial was conducted for a short period in Basel (Ladewig & Kury, 1997). The Swiss are undertaking extensive work on the pharmacology of the drugs under consideration, including the development of tolerance, the range of therapeutic doses, side effects, withdrawal symptoms and bioavailability (Uchtenhagen et al., 1996b). The trials also examine questions of compliance with and retention in the prescribed treatment and preferences for different forms of treatment and there is to be a cost-benefit analysis (Uchtenhagen et al., 1996b). The overall results from the trials will be compared to standard oral methadone programs for ability to be implemented, effectiveness in achieving outcomes and cost-benefit (Uchtenhagen et al., 1996b).

Randomised controlled trials are prominent in both the Dutch and Australian proposals (Health Council of the Netherlands, 1995; Bammer, 1995). Sturmans (1997) outlines how a Zelen design could be used. The trials in the Netherlands would have improvement of relationships with treatment services as an intermediate goal (Health Council of the Netherlands, 1995). The Dutch also mention improvement in palliative care for "severely addicted patients who are seriously ill and whose life expectancy is limited" (Health Council of the Netherlands, 1995, p. 76). In addition, only the Dutch trials mention encouraging the achievement of an end to dependence as an outcome measure (Health Council of the Netherlands, 1995).

The Australian proposal would include a randomised controlled trial for the first year, followed by free choice for the second. In addition to a randomised controlled trial, the Australian trial also aims to measure changes in attraction into and retention in treatment of dependent heroin users, the social effects of conducting a trial and the cost-effectiveness of heroin prescription. The full-scale trial would only proceed if the pilot studies showed that participants could be stabilised on heroin and that participants could move safely between heroin and methadone (Bammer, 1995). The package of social indicators included in the Australian proposal consists of crime levels and patterns and public perceptions of crime; illicit drug markets, including the leakage of trial drugs onto the illicit market; drug use patterns, particularly among young people; heroin users moving to the trial city(ies); offensive public behaviour by illicit drug users, including the discarding of injecting equipment in public places; effects on public health and safety, including numbers of overdoses and drug-related motor vehicle crashes; and effects on other treatment services, law enforcement and the ambulance service (Bammer, 1995).

There is considerable agreement between the different trials in the central outcome measures, although there are differences in emphases and in the way they are described. All examine changes in physical and mental health and in social functioning. The Dutch refer to this as stabilization of bio-psycho-social wellbeing (Health Council of the Netherlands, 1995). Continued illicit drug use is also a central outcome measure in all trials. Changes in other criminal behaviour are also outcome measures, but the trials differ in whether or not these are central aims.

The evaluations are summarised in Table 4.

It can be seen that each country has a different approach to heroin prescription. Taking all the trials and different experiences together will allow much to be learnt about the place of this new treatment as a standard maintenance option for dependent heroin users.

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FEASIBILITY RESEARCH INTO THE CONTROLLED AVAILAI

The Feasibility Research into the Controlled Availability of Opioids arose from a request to the National Centre for Epidemiology and Public Health at the Australian National University from the Select Committee on HIV, Illegal Drugs and Prostitution established by the Australian Capital Territory Government.

A first stage of research, conducted in 1991 in collaboration with the Australian Institute of Criminology (AIC), found that a trial of heroin maintenance for dependent users was feasible in principle. It was recommended that a second stage of feasibility investigations to examine logistic issues be conducted.

The report of the Stage 2 research, released in June 1995, found that a trial was logistically feasible and recommended that two pilot trials be conducted. If the desired outcomes were achieved, these would be followed by a full-scale trial.

The recommendations are currently under consideration by politicians and other policy makers.

The background work which led to the Stage 1 recommendations and most of the work underlying Stage 2 is now published. Further work yet published will be disseminated during 1997. These include:

- examination of historical and current international evidence about the efficacy of treatment of dependent users with short-acting opioids;
- a study of ACT methadone clients and dependent users who have never been in treatment or who have dropped out of treatment to assess the need for and the benefits of about expanding maintenance treatment to include heroin prescription and behaviours relevant to trial outcomes;
- results of surveys of the ACT and Australian populations concerning opinions of drug use, drug users, treatment, attitudes and behaviours;
- analysis of the effects of heroin on driving skills;
- a detailed proposal for the service provision component of a heroin trial; and
- a detailed proposal for evaluation of a heroin trial.

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Full citation for working papers should include the following publication details - Canberra: National Centre for Epidemiology and Population Health, The Australian National University and the Australian Institute of Criminology

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Newsletters

- # Newsletters reporting project results are also published from time to time.

These publications are available free from:

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Most reports, working papers and newsletters are available on the NCEPH Web site at the follo

<http://www-nceph.anu.edu.au/Pub/opioids/opioids.htm>

Table 1. Current status, clinical practice and target groups of heroin prescription in the United Kingdom, Switzerland, the Netherlands and Australia

	United Kingdom	Switzerland	Netherlands
Status	on-going	1994-1996	start 1996/7; if trial successful follow by broader social experiment
Clinical Practice	doctor prescribes; pharmacy dispenses; unsupervised injection	supervised injection at clinic; up to 3x/d (except Basel 2x/d)	supervised injection at clinic; frequency not specified
Target Group	<ul style="list-style-type: none"> • last resort • historical 	hard core dependent users, several symptoms of medical and social failure, not helped by current treatments	severely addicted who do not respond to current treatments

Table 2. Numbers of prescribers and/or prescribing centres, clients and cost for heroin prescription in the United Kingdom, Switzerland, the Netherlands and Australia

	United Kingdom	Switzerland	Netherlands
# Prescribers / centres	about 50 prescribers	pilots in 6 centres, trials in 14	multicentre (unspecified)
# Participants	about 300 clients	originally planned 250 people on heroin, increased to 800. 250 places on injectable morphine and 200 on injectable methadone were reduced to 200 places on either	about 100 participants; 2-3,000 in broader social experiment
Payment	£ 5.25 but free if can't afford	15 SF per day	not specified

Table 3. Types and routes of psychoactive drugs prescribed for drug dependence in the United Kingdom, Switzerland, the Netherlands and Australia

United Kingdom	Switzerland	Netherlands
Methadone - Oral - Injectable	Methadone - Oral - Injectable	Methadone - Oral
Heroin - Injectable - Smokable	Heroin - Injectable (- Smokable) - Slow-release? - Inhalant?	Heroin - Injectable - Smokable? - Aerosol? - Sublingual? - Suppository?
Other opioids	Morphine - Injectable	
Cocaine	Cocaine (- Smokable)	
Other stimulants		

Table 4. Evaluation of heroin prescription in the United Kingdom, Switzerland, the Netherlands and Australia

United Kingdom	Switzerland	Netherlands
<p>1970s RCT comparing injectable heroin with oral methadone</p> <p>Outcomes - health, employment, illicit drug use, criminal activity, involvement with drug subculture</p>	<p>Major component: Individualised prescription</p> <p>Minor component: RCT comparing injectable methadone, morphine and heroin (all can also have oral methadone)</p> <p>Outcomes - physical and mental health, social functioning (including criminal behaviour and risky injecting and sexual behaviours), illicit drug use</p>	<p>RCT comparing heroin (with or without methadone) and oral methadone; Zelen design?</p> <p>Outcomes - stabilisation ie regulation of physical, mental and social wellbeing</p> <p>Minor outcome measures: course of addiction, overdoses, additional use of illegal drugs; contact with drug subculture, individual crime</p>
<p>Long-term follow-up by Stimson and colleagues</p>	<p>Double-blind comparison of heroin with morphine</p>	
	<p>Pharmacology, including development of tolerance, the range of therapeutic doses, side effects, withdrawal symptoms and bioavailability</p>	
