

Wayne Hall

**Assessing the Population Level Impact
of the Swiss Model
of Heroin Prescription**

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1 INTRODUCTION

The "scientific studies of medically prescribed narcotics" in Switzerland (for brevity the Swiss trials) were set up to investigate the feasibility and effectiveness of prescribing injectable opioid drugs (including heroin, morphine and methadone) to severely opioid dependent and destitute patients under medical supervision. The aim of prescribing injectable opioids was to improve the health and psychosocial well-being of the dependent drug users who either had not responded to, or had not been reached by, existing forms of treatment (Rihs-Middel, 1997; Uchtenhagen, Dobler-Mikola and Gutzwiller, 1997).

The results of the Swiss trials demonstrated the feasibility and safety of medical prescription of heroin to heroin dependent persons as a treatment of last resort, with patients self-administering heroin under medical supervision, and receiving good medical care and social and welfare support. The trials also provided reasonable evidence that heroin dependent persons benefit from this type of heroin prescription. Their illicit heroin and cocaine use was substantially reduced, their health, psychological well being and social functioning greatly improved, and their involvement in acquisitive property crime and the drug scene substantially declined (Uchtenhagen, Gutzwiller and Dobler-Mikola, 1998).

1.1 THE POPULATION IMPACT OF HEROIN PRESCRIPTION

As with any research program, the Swiss trials did not answer all the questions raised by medical prescription of heroin. Sceptics who only accept evidence of benefit from randomised controlled trials have not been satisfied that the trials have demonstrated the efficacy of heroin prescription (e.g. Aeschbach, 1998). In the absence of a comparison condition the relative contributions of heroin and social and medical care cannot be disentangled (Farrell and Hall, 1997; Uchtenhagen et al, 1998).

Although there are important questions that remain to be answered about the impact of heroin prescription on those who receive, it I want to address a different question: Does heroin prescription have an impact at the population level on the adverse health and social consequences of dependent heroin use?

There are two inter-related reasons for asking this question. First, demonstration of a population level impact, whether on public health or public order, would make it easier to justify public funding for a relatively expensive treatment for heroin dependence. Moreover, because many of the opioid dependent patients who are most likely to benefit from this intervention cannot pay the costs of their own treatment, it is necessary to publicly fund it. In most democracies this may mean that we need to demonstrate that the provision of this treatment has a public benefit.

A second reason is that some proponents of heroin prescribing have claimed that it will have a population level impact (e.g. Marks, 1987). Given this claim, this is a standard against which heroin prescription will be evaluated. It is accordingly worth considering the chances are of its having such an impact and of being able to demonstrate that it has.

1.1.1 WHAT IS A POPULATION LEVEL IMPACT?

The population level impact of any intervention for heroin dependence may be defined as a change for the better, which is detectable at a population level, in the prevalence, incidence or severity of the adverse health and social consequences of illicit heroin use or dependence. These consequences include adverse health consequences of heroin use, such as, transmission of blood-borne viruses (BBV) via sharing needles and other injection equipment, heroin overdose deaths, and morbidity caused by non-fatal heroin overdoses. More speculatively, it may also include the prevalence of heroin dependence in the community, if, as some proponents of heroin prescription have argued, untreated dependent heroin users recruit new heroin users through drug dealing (e.g, Marks, 1987).

The population level impact of dependent heroin use also includes drug and property crime engaged in by dependent heroin users (Hall, 1996). A reduction in the criminal activity in which some heroin dependent individuals engage is an important social goal of heroin treatment and drug policy. Economic evaluations of drug treatment (Gerstein and Harwood, 1990) and heroin prescription (Uchtenhagen et al, 1998) indicate that the major economic benefits of drug treatment are the result of a reduction in crime among treatment participants. This in turn reduces the costs of policing, processing offenders in the criminal justice system, and imprisonment. These savings are probably one of the major reasons why MMT is public funded in Australia (Hall, 1996). It is also likely to be a strong motive for public funding of heroin prescription.

1.2 NECESSARY CONDITIONS FOR DEMONSTRATING A POPULATION LEVEL IMPACT

A number of conditions must be met for the Swiss model of heroin prescription to be demonstrated to have a detectable population level impact. These are:

that it is a safe and effective intervention;

that it can be scaled up to make a detectable impact at the population level on the adverse consequences of illicit heroin use;

that it will attract enough of the patient population into treatment to have a detectable population level impact;

that the public is prepared to publicly fund it for patients who cannot afford to pay the full costs of treatment, and communities will allow heroin prescription programs to operate within them;

that it is possible for research to detect changes for the better at the population level in the public health and order outcomes of interest ;

and that any population changes for the better can be plausibly attributed to the effects to the heroin prescription rather than to other causes.

1.3 THE SWISS MODEL OF HEROIN PRESCRIPTION

The Swiss model of medical prescription of heroin has a number of key features. First, heroin prescription is restricted to heroin dependent persons who have failed at existing forms of treatment, including MMT. Second, patients receive heroin on site, self-administer it under supervision, and are not allowed take-away doses. Third, they also receive regular medical care and social support. Fourth, they make a small but symbolically important financial contribution to the costs of their treatment. This model differs markedly from the “British system” which allows all doses to be taken away and consumed when the patient chooses (Strang and Gossop, 1994). I will assume (unless otherwise specified) in the rest of this paper that it is the population level impact of the Swiss model that is being discussed.

2 EVIDENCE OF SAFETY

The Swiss trials provided good evidence of the safety of the Swiss model of medical prescription of heroin. There were no overdose fatalities among participants while they remained enrolled in the program. Indeed, there were no such adverse events in over 3000 patient years of observation during the Swiss trials. Nor was there any evidence of diversion of heroin from trial sites or of overdoses or other adverse events among persons using diverted heroin (Uchtenhagen et al, 1998). An important question that will be discussed below is: will patient safety be maintained if heroin prescription is scaled up to produce a population level impact on dependent heroin use?

3 EVIDENCE OF EFFICACY

There are clinical reports that heroin prescription reduces illicit opioid use, crime and heroin overdose and other adverse health consequences of heroin dependence (e.g. Marks, 1987; Marks, 1997). There are some recent small cohort studies (e.g. Metrabian et al, 1998) which support these reports but there are only two published randomised controlled clinical trials of the effectiveness of heroin prescription (Hartnoll et al, 1980; Perneger et al, 1998).

Hartnoll et al’s study compared oral MMT with injectable heroin maintenance (HMT) on the British model (that is, with take away doses). Their findings suggested, within the limits of the small sample size, that HMT and MMT were of approximately equally effective although they varied in their pattern of outcomes. HMT retained more patients in treatment while MMT was more successful in reducing illicit opioid use. However, in this study patients were given small doses of heroin (60 mg per day) and sub-optimal doses of oral methadone.

More recently, Perneger et al (1998) reported a RCT of heroin prescription using the Swiss model. As in the larger Swiss trials, treatment was restricted to persons who had failed at existing treatment, heroin was self-administered on-site and accompanied by comprehensive health and social services. The projected sample size of the trial was 40 patients per study

arm but there were difficulties recruiting this number of patients. Perneger et al randomly assigned heroin addicts to either immediate entry to heroin prescription (N = 24) or delayed entry after six months (N = 27). While on the waiting list, controls received their choice of an existing form of treatment for heroin dependence. Most of them chose MMT.

The study showed that it was feasible to stabilise and safely maintain heroin addicts on injectable heroin for six months. In the process, heroin prescription produced substantial changes for the better in the health and social well being of participants. The small sample size meant that the study had limited ability to detect differences in some outcomes between the heroin prescription and control treatments. Failures to find statistically significant differences were necessarily equivocal. But this makes the statistically significant differences that were obtained in favour of heroin prescription all the more impressive. These included a marked reduction in the proportion of daily illicit heroin users, and reductions in daily cocaine use, and the prevalence of self-reported drug overdoses (Perneger et al, 1998).

The results were not wholly supportive of heroin prescription. As noted above, the program did not attract the number of persons anticipated, and only a third of the controls wished to be transferred to heroin prescription at the end of the six-month waiting list period. Moreover, a substantial proportion of those in the delayed entry group who received MMT were also substantially improved, even if their average improvement was less than that of the heroin prescription group. The treatment outcomes were also all self-reported. Although there is good evidence for the validity of self reported drug use and crime (Darke, 1998), the reliance upon self-report provided grounds for scepticism among critics of heroin prescription (e.g. Aeschbach, 1998).

As already mentioned, the main Swiss heroin trials also demonstrated that it is feasible to maintain opioid dependent persons on injectable heroin for up to 2 years. Injectable heroin was attractive to the trial participants; it retained two thirds of participants in treatment at 18 months. The prescription of injectable heroin benefited the trial participants. The initial evaluation reports depended upon self-reported drug use, health status, social functioning, and criminal activities collected by interviewers who were not involved in treatment. The credibility of these results was increased by their subsequently corroboration by independent indicators of outcome such as: physician assessments of health status, low rates of infection with BBV and premature mortality, and substantial reductions in police records of arrests and convictions among trial participants (Uchtenhagen et al, 1998).

3.1 UNRESOLVED QUESTIONS ABOUT EFFICACY

Given the evidence of benefit to trial participants, and the absence of a comparison group, the more difficult question to answer is: how much of the improvement in trial participants can be attributed to the effects of heroin prescription as against the intensive psychosocial intervention that accompanied it, and the enthusiasm of the project staff and the trial participants that accompanies the introduction of a new therapeutic intervention for a chronic condition.

In the Swiss trials an attempt was made to address the issue of causal attribution by a quasi-experimental comparisons with earlier cohorts of patients entering oral MMT and

residential treatment programs (Uchtenhagen et al, 1998). There are also plans to compare outcomes in patients entering MMT at the same time and places as new entrants to phase 2 of the Swiss trials. The validity of these comparisons may be impaired by the much lower rates of participation among entrants to MMT than heroin prescription. The difference in rates of participation may mean that participants in the heroin trials and MMT are not equivalent on baseline characteristics and the differences may be too large to be adequately controlled by statistical adjustment after the fact (Uchtenhagen et al, 1998).

The opportunity to conduct further randomised controlled trials of heroin prescription in Switzerland has probably passed now that it has become a part of the Swiss treatment system. The results of the Swiss trials have, however, created an interest in doing controlled trials in other countries. Investigators involved in these trials may be able to benefit from the Swiss experience by implementing controlled clinical trials that enable more confident inferences to be made about the efficacy of heroin prescription, and the relative contributions to outcome of providing heroin and good social and medical care.

4 CAN HEROIN PRESCRIPTION BE SCALED UP?

If heroin prescription is to have an impact for the better at the population level it needs to be scaled up to reach a substantial proportion of the heroin addict population. What proportion of the population does heroin prescription need to reach on order to have a potential population level impact? A precise answer is difficult but it is conceivable that as few as 5-10% of the population of dependent heroin users may be sufficient if these patients comprised the most heavy heroin consumers and the most criminally involved users. Better estimates could be derived from data on rates of heroin use, overdose and criminal involvement among Swiss heroin users who seek to enter heroin prescription trials.

Two methods of scaling up can be distinguished although they are not mutually exclusive. One way is to increase the capacity of existing clinics; the other is to increase the number of clinics that prescribe heroin. In practice, some combination of these two strategies will need to be used. There are risks in each. The possibility of economies of scale if existing capacity is increased probably makes this an attractive option. But if existing clinics have already met demand in their area then new clinics will need to be established in other sites where there is a population in need.

The major challenges raised in scaling up and routinely delivering heroin prescribing are ensuring quality of treatment delivery so that the safety and efficacy observed in the Swiss trials are maintained. Experience with MMT in the USA (Goldstein, 1994) and Australia shows that there is low public tolerance of imperfections in the delivery of MMT. Any evidence of diversion, the occurrence of opioid overdose deaths, and social nuisance around MMT clinics puts public support for MMT at risk. If these adverse effects occur during the scaling up of heroin prescribing, then public and political support for it may be put at risk. This could make it difficult to open new clinics and may create pressure to close existing clinics.

The safety of scaled up provision is a salient issue in Australia where MMT places have expanded at 10% pa for more than a decade. Much of this expansion occurred in the “private” medical sector with minimum oversight. The quality of provision in some of the larger states has declined with methadone overdose deaths occurring during induction into MMT because of poor patient assessment and observation, and methadone overdose deaths have occurred as a result of the use of diverted methadone (Drummer et al, 1992; Caplehorn and Drummer, 1999). These outcomes have raised public concern about the safety of MMT; similar occurrences during the scaling up and routine operation of heroin prescription may weaken public support for heroin prescription.

5 WILL HEROIN PRESCRIPTION BE ATTRACTIVE TO PATIENTS?

In the Australian debate about trialing heroin prescription, it has often been assumed that heroin prescription under the Swiss model will be attractive to most dependent heroin users. But the Swiss experience suggests that this may be optimistic. There was a slower than expected rate of recruitment in the Swiss trials and some sites did not fill their allocated places. Perneger et al's study, for example, was unable to recruit all the patients that they had intended to, and only a minority of patients on the waiting list accepted the subsequent offer of heroin prescription (Perneger et al, 1998).

The proportion of heroin dependent patients who are attracted into heroin prescription on the Swiss model may be smaller than necessary to have a population level impact. We should not be surprised if this occurs, as avoidance of MMT has been reported among dependent heroin users in the USA (e.g. Hunt et al, 1986). This may arise with heroin prescription because some users do not see themselves as “addicted”, and hence not as in need of treatment; it may be the result of reluctance to accept the restrictive conditions that are part of the Swiss model; or it may reflect the stigmatisation of trial participants within the heroin using population and the broader community. These questions need to be explored by ethnographic and observational studies of the heroin using population who are candidates for heroin prescription.

The attractiveness of heroin prescription may also depend upon the price and availability of heroin in the black-market and whether heroin use is steady, rising or falling. When the population of older dependent heroin users is declining and heroin is expensive and difficult to get, heroin prescription may be attractive to many dependent users, enough to have a population level impact. But its attractiveness to dependent users may change when heroin is cheap, pure and readily available. If there is also an increase in recruitment to heroin use among younger people, more newly dependent heroin users may seek treatment. They may want to become abstinent and reject all forms of maintenance treatment. The families of new users may also be especially likely to demand abstinence, and to want it NOW.

Ultimately, patients will vote with their feet on heroin prescription. That is, they will, or will not, fill sufficient of the treatment places prescription to have a reasonable chance of producing a population level impact. If heroin prescription proves less attractive than hoped, then we may need to consider changing the way it is delivered so that it is more attractive to

potential patients. This could, for example, mean relaxing conditions for entry to include patients who have not tried existing treatments, allowing some take-away heroin doses, and reducing therapeutic demands made upon patients. The risk is that these changes may reduce the public acceptability of heroin prescription, impair its safety, or reduce its impact per participant, and hence its population level impact.

6 WILL HEROIN PRESCRIPTION RETAIN PUBLIC SUPPORT?

The Swiss political process provides strong prima facie evidence of public support for heroin prescription. This includes the positive outcomes of Federal, Cantonal and City votes and referenda that allowed the trials to proceed, and the failure of a citizen-initiated referendum proposal that proposed to stop the heroin trials (Uchtenhagen et al, 1998). The parliamentary vote to fund a continuation of heroin prescription by the Swiss Federal parliament also indicates strong public support for heroin prescription.

But public support may also depend upon what is happening with heroin use in the population. There may, for example, be more public compassion towards dependent heroin users when their numbers are declining and those who are seeking treatment are seriously ill. But renewed recruitment to heroin use among young adults may bring, as it has in Australia, increased demands for abstinence as a goal of treatment, an increased intolerance towards all forms of maintenance treatment, and the advocacy of a more punitive approach to heroin use and illicit drug use more generally. Rising heroin use may also mean that the existing treatment system is overwhelmed by renewed demand that makes it harder to fund alternative treatments like heroin prescription. Increased property crime and social disorder surrounding drug markets may also reduce tolerance and compassion towards addicts. In this setting it is easy for its opponents to present heroin prescription as perversely rewarding "bad behaviour".

The sense of "crisis" that is created by media attention to a new wave of heroin recruitment, and dissatisfaction with existing treatment options, may also create a market niche for treatment "innovators". In Australia these have included medical practitioners from outside the addictions field, such as, gynaecologists, anaesthetists, and neurologists who present their ignorance of the addictions field as a virtue: they are not "captives" of the conservative thoughtways of the addictions field; nor are they part of the "methadone industry". Some have presented a simple biological view of addiction which see the addict as the host of disordered opioid receptors in need of rapidly-induced "blockade". This "scientific" rationale has enabled some medical entrepreneurs to promise what many patients and their parents want: a quick and simple (if expensive) "cure" for addiction.

When these claims have been uncritically repeated in the media, and supported by parent groups, charismatic doctors, and testimonials from photogenic patients, advocates of heroin prescription have found it difficult to get a sympathetic hearing. All these phenomena, have been exemplified in Australia in the past two years where in the absence of any evidence of efficacy (Gossop and Strang, 1997; Herman and Czechowicz, 1996), there has been a therapeutic enthusiasm for naltrexone accelerated-withdrawal and naltrexone maintenance

(Hall et al, 1997). Advocates of this approach (who unsurprisingly have included opponents of the Australian heroin trial) have argued that heroin prescription is unnecessary because we have a “cure” for heroin addiction.

I conjecture that heroin prescription is more likely to be accepted by the public if it is seen as therapeutic approach of last resort rather than as a state-sponsored form of heroin supply. This has been the experience in Australia with MMT. Public acceptance of and support for MMT has recently declined in some states. This has probably been in part because therapeutic demands have been relaxed with the public health aim of attracting more dependent users into treatment. Continued expansion of the program has also seen slippage in quality of delivery, the consequences of which have been seized upon by those who are opposed to MMT on moral grounds. The same issues can be anticipated in the scaling up of heroin prescription.

Social survey research on public attitudes towards heroin prescription would provide interesting information on trends in, and possibly advanced warning of weakening, of support for heroin prescribing. In combination with the content analyses of popular media, this research would provide interesting material for social and historical analyses of the reasons for changes in public support for heroin prescription. More generally, a social history of the Swiss trials cries out to be written while documentation is still around and the memories of the key participants are still fresh.

7 ASSESSING CHANGES FOR THE BETTER: MEASUREMENT

How do we measure the public health impact of heroin prescription? We can easily measure the number of individuals who are attracted into heroin prescription and how many are retained and for how long. It is also relatively straightforward to measure the impact of heroin prescription on participants' heroin use, health status and involvement in crime. All this was done in the Swiss trials.

It is much more difficult to measure the impact of treatment at the population level on these adverse effects of heroin use. We have at best imperfect estimates of the adverse population level consequences of heroin use.

In the case of BBVs, we have to use data on rates of BBV infection attributed to injecting drug use among persons who seek testing or are tested on entry to prisons. In the case of opioid overdose deaths, we have to rely upon the results of forensic examinations of suspicious deaths and the vagaries of coding of causes of death. In the case of the prevalence of heroin dependence we have at best imprecise guesstimates of the number of heroin users in the community, usually with such wide bounds around them that it is difficult to decide when prevalence has changed (Hall, 1995).

A major constraint upon our ability to detect changes for the better in time series data on the adverse consequences of heroin use is limited statistical power. Statistical power depends critically upon the size of the expected population level impact. It will be difficult to detect

an incremental reduction in the prevalence of BBV infection or opioid overdose deaths due to heroin prescription when there is an extensive public MMT. It will be easier to detect the impact of a sharp, substantial and sustained increase in the availability of drug substitution treatment when none previously existed. This seems to have occurred in Washington and Chicago in the early 1970s where the most evident impact was on crime rates (Jonnes, 1997). Something similar may have occurred with opioid overdose deaths in France following the introduction and massive expansion of buprenorphine. It is plausible that something similar has occurred in Germany with the introduction of MMT and other measures in the past five years.

It will be obviously easier to detect an impact for the better at the population level in the latter situation than the former. But it is of course the former situation that Switzerland faces and the same is true in other parts of Europe that are currently conducting (eg. The Netherlands) or contemplating trials of heroin prescription (e.g. Britain and Germany). If this is true, it may be that the countries that are most likely to implement heroin prescription on a large enough scale to produce a population level impact may be the places in which any such impact is least likely to be detected.

8 ASSESSING CHANGES FOR THE BETTER: CAUSAL ATTRIBUTION

Assuming that we are able to detect changes for the better at the population level, the more difficult task is to plausibly attribute these changes to heroin prescribing. The only strategy for doing so is quasi-experimentation (Cook and Campbell, 1979). This involves generating plausible alternative explanations of the changes that have been observed, using the categories of explanation suggested by Cook and Campbell (1979). We then attempt to exclude these rival hypotheses, as best we can, by using other data. As a result, we arrive by a process of exclusion at heroin prescription as the most plausible explanation of the changes observed. I will briefly illustrate this strategy.

The first alternative hypothesis to be considered is that the change is an artefact of changes in instrumentation. All the measures of adverse outcomes of heroin use are sensitive to the effects of increased scrutiny or to changes in definitions. For example, some outcomes, such as, an opioid overdose death are poorly defined and changes in the way they are defined, or in the way that the cause of death is coded, may affect their rates. The definition of a drug-related property crime is also contentious and susceptible to changes in method of recording and method of classification.

History and maturation are other plausible hypotheses. Given the cyclical nature of illicit drug use, would any changes for the better have happened in the absence of heroin prescription as a result of a decline in the prevalence of heroin use and the ageing and maturation of existing heroin users? The absence of similar trends in population level outcomes in other settings within the same country that did not have heroin prescription would reduce the plausibility of this hypothesis. In a small country like Switzerland this is a less promising option than in the USA; trends in neighbouring countries may be the next best option. But even this may not be a possibility if heroin use is rising or falling in most

similar countries, as seems to have happened in the heroin epidemics of the late 1980s in most of Europe. Moreover, even if heroin use was declining in countries which did not have heroin prescription, we would be uncertain whether heroin prescribing had accelerated the decline in heroin use and its adverse consequences.

More confident answers about the impacts of heroin prescribing may only come when we have been able to assess its impact over two or more cycles of heroin use, in a number of different settings. Our confidence in any conclusion that heroin prescribing has an impact will be increased by the replication of similar effects in a number of different cultural settings.

Cycles in illicit drug use do not exhaust the list of plausible alternative explanations of any changes for the better in the adverse consequences of heroin use. There are also social and demographic changes that may influence the prevalence of heroin use and the severity of its consequences for public health and public order. For example, some have argued that crime may decline because of changes in policing practices. This is a topical issue in the USA with debate about the merits of the competing explanations of declining rates of violent crime in New York and other large cities, namely, “zero tolerance” policing as against an improved labour market, a decline in crack cocaine use, and a decline in the size of susceptible population of young males.

9 CONCLUSIONS

Assessing the population level impact of heroin prescribing may be critical to securing political support and public funding for heroin prescription programs as a treatment of last resort to dependent heroin users. But any such population impact will be difficult to assess. The major issues are: demonstrating the safety and effectiveness of heroin prescribing in routine practice when it is scaled up to have a population level impact; the attractiveness of heroin prescribing to the potential patient population; continued public support for an expanded heroin prescription program; technical issues in detecting change for the better at a population level in the adverse consequences of heroin use against a background of other interventions; and the most difficult requirement, that of being able to confidently attribute any population level changes that occur to heroin prescribing.

It may be that the countries that are most likely to implement heroin prescribing on a scale sufficient to detect a population level impact are the least likely to be able to detect any population level benefit. If this is the case, then the justification for heroin prescribing will have to depend upon the demonstration of its benefits to patients who participate in these programs, and the case for public funding of heroin prescription for those who are unable to afford it will need to be based upon community values of compassion and human solidarity rather than on a utilitarian calculation of benefits to society as a whole.

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