

Heroin-assisted treatment in Switzerland: a case study in policy change

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ABSTRACT

Background Switzerland introduced a pragmatic national drug policy when the former conservative abstinence-orientated politics proved unable to cope with an escalating number of users and related negative consequences for public health and public order. The high visibility of 'needle parks' and the size of the acquired immune deficiency disorder (AIDS) epidemic called for a new approach and for national leadership. **Aims** To describe the intentions, the process and the results of setting up the new treatment approach of prescribing heroin to treatment resistant heroin addicts, as an example of drug policy change. **Materials and Methods** A systematic collection of relevant documents is analysed and used as evidence for describing the process of policy change. **Results** Measures to reduce the negative consequences of continued use and to prevent the spread of AIDS were started mainly by private initiatives and soon taken up officially in the 'four-pillar' drug policy (including harm reduction, prevention, treatment and law enforcement). Medical prescription of heroin to chronic, treatment-resistant heroin addicts was one of the innovations, based on extensive scientific and political preparation. Detailed documentation and evaluation, ample communication of results, adaptations made on the basis of results and extensive public debate helped to consolidate the new policy and heroin-assisted treatment, in spite of its limitations as an observational cohort study. All necessary steps were taken to proceed from a scientific experiment to a routine procedure. **Discussion** Comparable policy changes have been observed in a few other countries, such as The Netherlands and Germany, based on the Swiss experience, with equally positive results of heroin-assisted treatment. These experiments were designed as randomised controlled trials, comparing intravenous heroin against oral methadone, thereby demonstrating the specific value of pharmaceutical diamorphine for maintenance treatment in opiate dependence. The positive impact of policy change and the positive outcomes of heroin-assisted treatment were acknowledged increasingly nationally and internationally, but made it difficult to continue the process of adapting policy to new challenges, due to the low visibility of present drug problems and to changing political priorities. **Conclusion** A major change in drug policy was effectively realised under typical conditions of a federalist country with a longstanding tradition of democratic consensus building. Facilitating factors were the size and visibility of the heroin problem, the rise of the Aids epidemic, and a pragmatic attitude of tolerating private initiatives opening the way to official policy change.

Keywords Drug policy, drug treatment, harm reduction, heroin, heroin prescribing, opiate substitution treatment.

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THE SITUATION BEFORE 1990

Situated in the middle of Europe, Switzerland saw its own version of youth unrest in 1968, which had started violently in Germany and France as a student revolt. Young people of all social strata defied or left their parents' homes and educational institutions, gathered in the streets, occupied empty buildings, blocked schools or

began to involve teachers in political discussion. Dominant values of law and order, of caring for career and social acceptability were questioned and young people demanded more freedom for alternative thinking and activities. One of the main vehicles to express protest was via the use of drugs such as cannabis, lysergic acid diethylamide (LSD) and amphetamines [1].

Traditional responses such as psychiatric hospitalization or youth court interventions were unable to cope with the challenge and, as a result, new services were called for. In 1970, the first drop-in centre for young people and a medical emergency service for drug-induced crisis situations were started in Zurich. In the following years, the characteristics of drug users changed considerably. During and after the 1968 revolts, students, artists and journalists experimented with cannabis and hallucinogenic drugs, influenced by the concept of 'widening experience'; many of them had to face 'bad trips' and had to learn how to use without problems. Hard drugs, especially heroin, followed and were taken up by young people in distress, coming from broken homes and/or having major educational and social deficits. Private shelters for runaway and homeless people were opened, as well as the first Therapeutic Communities. With the advent of heroin, doctors started to prescribe methadone, and the first methadone clinics were set up [2].

National narcotic legislation was revised in 1975, introducing sanctions for the use of illicit substances and the need for licensing doctors engaged in methadone-assisted treatment. The role of the Federal government was restricted to funding continued education for professionals in drug prevention and treatment, while individual cantons remained responsible for health and social interventions [3].

New waves of violent unrest in 1980 culminated in the demand for an 'autonomous youth centre' [4]. Such a self-governed centre was set up in Zurich and grew into a place for drug use and trafficking; when it was closed by the district administrator, the drug scene moved to a neighbouring area [5].

Dissatisfaction with this mainly prohibitionist policy was growing. In 1991, a national drug conference (the first of its kind in Switzerland) reviewed the situation and new policy options [6].

WHAT TRIGGERED THE POLICY CHANGE?

Open drug scenes ('needle park')

In a growing number of Swiss cities, open drug scenes were the most visible challenge during the 1980s. In contrast to the early 1970s, when students experimented with hallucinogens, in the 1980s vulnerable young people from problematic backgrounds, many with psychiatric comorbidity, took increasingly to injecting heroin mainly as a means to anaesthetize their painful emotions. They also tried to find contact and company among peers with similar backgrounds and flocked into the cities from rural regions, neighbouring cantons and countries [7].

After years of chasing these gatherings around the cities, police strategy changed to allow them to stay in

an area where nuisance for the neighbourhood was minimal: in public parks, open for police observation and accessible to emergency services to help with frequent overdose incidents. The drug market was rampant, offering mainly heroin, controlled by dozens of trafficking gangs fighting each other with growing violence. All sorts of marginal people felt attracted to the scene and thousands of injectors came each day. The situation was typified by misery and dirt, and television teams from all over the globe visited the dark heart of proper and efficient Switzerland [8].

The human immune deficiency virus/acquired immune deficiency syndrome (HIV/AIDS) epidemic

The HIV epidemic hit Switzerland relatively early and hard. From 1985 to 1995 incidence and prevalence figures were the highest in Europe [9]. While the gay community learned how to protect themselves, virus transmission by contaminated syringes and needles increased rapidly and sexual transmission from injectors to non-injecting partners was perceived as a threat to the population [6,10]. Reaching out to as many injectors as possible with HIV prevention and with treatment programmes became a public health priority.

Responses to the challenge: a sea of troubles

What could be done? There was no consensus, no guidelines and little concerted action [6]. Low-threshold services, public and non-governmental, started activities (contact centres, needle exchange programmes, safe injection rooms, shelters) which provoked political controversy and legal threats to those engaged in these initiatives. Treatment services were expanded, with Therapeutic Communities as well as office-based and state-run methadone maintenance. These services were in conflict more often than they worked together in an organized system. Authorities on different political levels—communal, cantonal and federal—had no joint strategy and were paralysed by divergent views on what to do. When the cantonal drug commission in Zurich published its reports on the situation and the measures to be taken [11,12], it took years until obstacles were overcome to implement these measures. However, in 1986 the previous ban on providing users with sterile needles and syringes was replaced by needle exchange programmes, following a massive intervention of the Cantonal Medical Association and of the Public Prosecutor. The city administration of Zurich began to subsidize private services. A large part of the services were provided by non-governmental organizations [13]. A multitude of parties formed a complex political network (32 organizations in the case of Zurich), and their parallel or

conflicting activities, especially of cantonal and city authorities, were poorly coordinated [5].

All in all, the situation grew out of hand, became intolerable and damaged the image of a well-organized society. First steps towards harm reduction measures were taken, but the activities of the diverse players in response to the situation lacked shared guidance and collaboration.

STEPS TO A FEDERAL DRUG POLICY: THE MAIN PLAYERS

Party coalitions and advocacy networks

Switzerland is governed on all levels by coalitions of the main political parties, not by a ruling party controlled by opposition. Initiatives for political change must be agreed upon by such coalitions, otherwise they have no chance in parliament. Consequently, one of the important steps to reform was a shared national drug policy platform of three major parties (radicals, social democrats and Christian democrats). Such a platform was devised in 1989/1990 and finally issued in 1994, after a gradual effort to harmonize the various standpoints. The parties wanted to overcome the polarized positions with a well-balanced policy, including measures to care for active drug users and to reduce the consequences of drug consumption.

A harm reduction advocacy network emerged, where health professionals, social workers, law enforcement agents, judges, lawyers, journalists, politicians and others contributed to shaping an alternative to the prohibitionist policy model. This alternative recognized the inappropriateness of enforced abstinence and of waiting for the addicts' readiness to engage in abstinence; caring for active users and minimizing the health and social risks of continued use were the new aims through low-threshold services and HIV prevention [14]. In Zurich, a private organization (Association for Risk Reduction in Use of Drugs: ARUD) was established in 1991 by Dr André Seidenberg, which then set up the first low-threshold methadone clinic and heroin clinic [15].

The initiative of city administrations

Although the cities were burdened primarily with the drug problem, Federal and cantonal governments had the legal power to change the situation [6]. The Swiss City Association (*Städteverband*) took the initiative to make the need for change urgent. Dr Emilie Lieberherr, member of the Zurich City Council, was a member of the 'Frankfurt resolution of European cities on drug policy', asking for a harm reduction policy and signed in 1990 by 19 cities and regions across the continent [16]. In 1989 she presented a strategy paper for a new drug policy, including heroin prescribing, and in the following year the City

Council formulated the 'four-pillar strategy', including harm reduction, in addition to the traditional elements of prevention, treatment and law enforcement. She invited all rural mayors to visit 'needle park' as an 'eye-opener'. Backed up by almost daily media reports on the latest news from the drug front [17], these initiatives succeeded in rapidly mobilizing the Federal government. Support also came from an analysis covering the differing cantonal situations [18].

The Federal government drug policy proposal

In 1991, a national drug policy was formulated and submitted to parliament for the first time; it contained the new element of harm reduction. In all four pillars, innovative approaches were invited, plus efforts to document and evaluate such approaches, as a basis for a continued evidence-based policy. The Federal Office of Public Health was to take the leadership in implementing the policy [19,20]. Parliament agreed. Prescribing heroin was one of the proposed innovations within the treatment pillar, not only as a harm reduction measure. Its target was the growing number of chronic addicts not profiting adequately from available treatments and with severe health and social problems (the rate of non-responders to methadone maintenance treatment varied between 16% and 24%, the rate of premature dropouts between 23% and 35% [12]).

PREPARING THE HEROIN TRIAL: THE ROLE OF SCIENCE

Initiative of a national expert commission

The subgroup on drugs of the Federal Narcotic Commission published reports and recommendations for a future Swiss drug policy in 1983 and 1989 [21,22]. They proposed measures to reduce the risk of drug consumption by decriminalizing use, utilizing therapeutic alternatives to imprisonment for drug addicts and by expanding opportunities for low-threshold interventions including opiate substitution treatment. The idea of heroin prescribing, first mentioned in parliamentary interventions in 1979 and in 1985, was rejected in favour of methadone maintenance treatment, which was expanded [23].

Review of former experience and launch of a scientific project

In 1989, a member of the subgroup on drugs, Dr Annie Mino, was mandated to review all previous scientific experience with heroin and morphine prescribing. The review examined the aims, outcomes and fates of narcotic clinics in the United States and Sweden, the Dutch morphine trials and the United Kingdom experience with injectable narcotics, and came to the conclusion that a

new scientific experiment should be recommended [24]. Based on the recommendation, the author of this paper was invited to present a detailed protocol for the prescription project. After extensive discussions in the subgroup as well as in the Narcotic Commission, this proposal was submitted to the Federal government through the Federal Office of Public Health [23,25].

Mission to Widnes/Liverpool

During the late 1980s, psychiatrist Dr John Marks in Widnes, near Liverpool, reactivated the 'British system' of heroin prescribing in the United Kingdom, using smokeable heroin as a safer alternative to injection, although needle distribution was also practised [26]. Delegations from Switzerland and other countries visited his clinic, including a delegation from the Zurich government, which reported positive acceptance by local police and a comparatively low HIV infection rate in the region.

This scientific preparation resulted in support for a Swiss project, especially because the increasing number of methadone patients had led to an important number of 'methadone-resistant' patients who continued to inject heroin in spite of adequate methadone dosages and care. At the same time, the HIV epidemic made it a priority to reach out to as many injectors as possible. On this basis, the proposal for prescribing heroin as the preferred substance of addicts gained interest and support, after years of scepticism and rejection.

POLITICAL CONDITIONS FOR THE TRIAL

Merging political and scientific interests

The scientific standards for designing and evaluating the project were important considerations. These included: a randomized controlled design; a carefully detailed research protocol; instruction of data collectors on how to implement the protocol; an independent group of researchers in charge of evaluation and reporting, and an external scientific board to review and follow-up the scientific process [23].

Politically, pressure came mainly from cities, and they were interested in gaining relief from the problems associated with large numbers of addicts out of treatment. This meant attracting the 'hard-core' chronic addicts known to be associated with social nuisance and crime involvement into the project and to include a sufficient number to make a difference. Entry criteria had to take these interests into consideration, and the threshold should not be discouragingly high. A limited randomized study was clearly not acceptable.

Avoiding undesired side effects

Undesired side effects had to be anticipated and, where possible, prevented. The following were considered:

- 'drug tourism': addicts coming to the planned clinics from many places;
- overdose death from prescribed heroin;
- diversion of prescribed heroin into the illegal drugs market;
- multiple prescriptions to individuals; and
- accidents to patients under the influence of prescribed heroin.

The preventive measures were: previous residency at the site of the clinic, controlled daily intake of injectables, central registry of all enrolled patients and deposition of drivers' licences during enrolment [27].

In view of other, non-anticipated undesired events, a special safety group was established with experts from various scientific fields, to whom all unexpected observations had to be reported for independent evaluation and recommendations [23].

Respecting legislation and regional attitudes

The Federal Office of Public Health ordered two expert reports from the Federal Office of Justice on the legal feasibility and conditions for heroin prescribing. They concluded that the trial was compatible with national legislation as well as with international United Nations conventions. Opinions and attitudes regarding drug policy issues were not unanimous throughout the country. The German-speaking cantons were most affected by the urban drug scenes, while the French- and Italian-speaking cantons were less prone to change their traditional conservative attitudes, with the exception of the internationally flavoured Geneva. Therefore, all but one of the heroin clinics were set up in German-speaking cities. In general, implementation of the national drug policy and related measures went different ways, as documented in a series of 15 case studies in cities and cantons [17].

IMPEDIMENTS FOR IMPLEMENTATION

Opposition and concerns

As expected, opposition to the project came from many sides: right-wing political parties with an abstinence-only orientation, parts of the judiciary, parts of the clergy, some parent organizations and some professionals working in the drug-free treatment arena. They formed an informal abstinence-only advocacy network [14]. Opposition was stronger in the non-German-speaking parts of the country, but overall in a clear minority compared to partisans of policy change and of heroin-assisted treatment.

The five main arguments against heroin-assisted treatment were the following:

- 1 Prescribing heroin will lead to never-ending dose increases with high risks.
- 2 Addicts will remain forever in heroin-assisted treatment, dependence will be prolonged and recovery not possible.
- 3 The image of heroin will become positive when prescribed as medication, and young people will be more inclined to experiment with it.
- 4 Other treatment approaches will no longer be acceptable to addicts, will be neglected or will disappear.
- 5 Prescribed heroin will be diverted into the illegal drug market.

None of the concerns were substantiated by outcome results [28].

Original design and changes to be made

The original design of the study was a classical RCT: three arms with a total of 700 patients (intravenous methadone, intravenous morphine, intravenous heroin), with identical entry criteria and identical assessment and care programmes. This was decided with regard to the British practice with intravenous (i.v.) methadone [29] and the Amsterdam i.v. morphine study [30].

In the early months of the study, serious side effects of i.v. methadone and of i.v. morphine were recorded and made public, whereupon recruitment into the respective arms became difficult. The design was changed, the heroin arm was increased to 500 slots and the methadone and morphine arms reduced to 100 slots each [23]. The decision was taken to keep the RCT design for sub-studies in Basel, Bern and Geneva, while the main study was now conceived as an observational, non-controlled, prospective cohort study with i.v. heroin only. The Basel study compared i.v. heroin with i.v. methadone and i.v. morphine [31], the Bern study was a double-blind randomized study with i.v. heroin versus i.v. morphine [32], and in Geneva a waiting-list control group was used comparing i.v. heroin versus any other treatment while waiting for 6 months [33].

International comments

The International Narcotic Control Board (INCB) was sceptical about the potential effects of the Swiss study; similar developments in less well-controlled and organized countries were of particular concern [34]. However, the importation of the required amounts of heroin (and later of morphine for producing heroin) was agreed.

The first reactions came from neighbouring countries and from the United States. Negative reactions were

directed against heroin prescribing, but also against harm reduction as an essential element of drug policy and sometimes against substitution treatment. At the same time, there was great international interest in the Swiss study [35–37], and political and/or professional delegations from many countries visited the clinics and discussed policy and technical issues. Heroin prescription studies were prepared in a growing number of countries (e.g. the Netherlands, Belgium, France, Germany, United Kingdom, Spain and Canada) and have been conducted so far in the Netherlands, in Germany, Spain and Canada [38]. A number of local, national and international (1998 in New York, 1999 in Bern, 2006 in Cologne) conferences on heroin-assisted treatment were organized.

Finally, the World Health Organization (WHO) expert committee on drug dependence was asked by the United Nations Commission on Narcotic Drugs (UNCND) to give an opinion on the growing advocacy of the non-medical use of heroin and its controlled supply to heroin addicts. The WHO expert committee wrote that advocacy of non-medical use was not backed by any evidence, but made no recommendation with regard to medically controlled heroin prescribing to addicts, considering the available evidence not to be sufficient [39].

THE PROCESS OF CONSOLIDATING CHANGE

The fates of the four-pillar drug policy and of heroin-assisted treatment were linked, but not identical. While the initial criticism of the new drug policy was replaced by growing acceptance (rapidly on a national level, more incremental on an international level), the acceptance of heroin-assisted treatment was slower, and is still limited internationally.

Communication and debate

National drug policy conferences in 1991 and 1995 helped to involve all the main political and professional actors in an intensive debate; the conference reports opened the debate to the media and the public with widespread acceptance of the pragmatic policy approach [40,41]. Drug policy reviews were published [42,43]. Two national referenda on an initiative to return to an abstinence-only policy ('youth without drugs') in 1997 and on an initiative to legalize drugs ('for a reasonable drug policy with youth protection') in 1998 resulted in a more than a two-thirds majority in favour of the four-pillar policy, rejecting both initiatives [44,45].

Harm reduction measures were implemented mainly in collaboration with city administrations and private non-profit organizations. The Federal role focused on facilitating this process financially through a national

agency providing counselling of institutions and through mandating research. Evaluation was continuous and extensive on needle exchange programmes, low-threshold contact centres, safe injection rooms, sheltered living and day programmes for marginal people, especially drug users [43,46].

Heroin-assisted treatment, on the other hand, was conceived as a scientific experiment. Any political decision on its continuation depended on the results. Public availability of trustworthy information, on process and outcome data, was paramount. Multi-lateral controls had to guarantee credibility of information through collaboration between the Federal Office of Public Health, the national expert committee supervising the process, the external scientific monitoring and data evaluation group, the independent safety advisory group and last, but not least, the staff at the heroin clinics and the cantonal authorities involved.

A vast range of process and outcome data on heroin-assisted treatment was collected, analysed and published during the scientific study (interim and final reports) and after its termination [28]. Work is still continuing. Additional findings from national and international studies were collected and published by the Federal Office of Public Health [47–49]. These provided the evidence base for professional and public debates, especially before the referenda on drug policy and on heroin-assisted treatment. In 1999, the latter resulted in a majority of 54% in favour [23].

Scientific findings and review

The substance-related, patient-related and service-related results were published in detail, summarizing a range of substudies [28]. All findings documented feasibility of the programme implementation, positive changes in patients, safety of medication and absence of major negative events. Self-report data were backed up by police data on delinquent behaviour and partly by urine analysis data on illicit drug use. The main limitation of the overall study was the absence of a control group; the changes in health and social status and addictive behaviour were measures in a pre–post comparison. Only substudies were designed as randomized controlled trials (RCTs).

On request from the Federal Office of Public Health, the WHO mandated an international expert group to review the design, implementation and findings of the main study. The final report of the expert group confirmed the findings but recommended further studies following the randomized controlled design, because the Swiss cohort study could not determine to what degree the use of heroin contributed to the findings, and how much was due to the comprehensive assessment and treatment programme [50].

Continued research covered the positive long-term effects for the patients in heroin-assisted treatment [51,52], feasibility and acceptability of oral heroin [53], implementation of a monitoring system [54] and the effects on drug-related delinquency in Swiss cities [55,56], among other issues. Publications in peer-reviewed journals increased the acceptability of findings.

In addition, some of the initial concerns about negative consequences of heroin prescribing could be alleviated by the following findings.

- Individual heroin dosages did not increase steadily, but were stabilized within the first 2–3 months after entering treatment ([28], figures 2 and 3).
- Addicts did not remain forever in heroin-assisted treatment; fewer than half the patients remained for 3 years or longer ([51], figure 2).
- The image of heroin did not become positive when prescribed as medication, and the incidence of new heroin users has declined every year since 1991 [57].
- Other treatment approaches did not disappear, but increased substantially during the 1990s [38].
- According to police information, prescribed heroin was not diverted into the illegal drug market ([28], chapter 4.3.2).

From scientific experiment to routine treatment

Additional steps were needed in order to move from experimental to routine treatment, including:

- the registration of injectable heroin as a medication for maintenance treatment in opioid dependence in 2001;
- the inclusion of heroin-assisted treatment on the list of provisions to be paid by health insurance in 2002; and
- a provisional legal basis for heroin-assisted treatment in 1997 [58], and finally a definite basis through revision of narcotic law in 2008 [59].

Further steps involved the transformation of some of the heroin clinics into polyvalent clinics for substance abuse treatment, the publication of a handbook on heroin-assisted treatment [60], the introduction of quality assurance measures, continued data collection in a monitoring system and continued education of staff in the heroin clinics.

Today, heroin-assisted treatment is integrated fully into the treatment system, with 23 authorized clinics (two in penitentiaries). By the end of 2007, 1283 patients were enrolled (89% of available slots); this amounts to 8% of all substitution treatments for opioid dependence nationally [61].

The drawback of success

Swiss drug policy is considered to be a success story. The main elements of documented success are:

- reduction of overdose death since 1991 by c. 50% [62];
- reduction of incidence of starting heroin use since 1991 by c. 80% [57];
- reduction of HIV infections since 1991 by c. 65% [63];
- reduction of drug-related delinquency in cities [55,56]; and
- reduction in nuisance from open drug scenes.

This resulted in an almost complete disappearance of public visibility of drug problems and to a downgrading of priority in opinion polls. Other problems, such as the influx of asylum seekers and most recently the economic crisis, are perceived to be more important issues. The political will to continue funding interventions might become a problem in a period of economic recession.

Also, the momentum of continued drug policy adaptation to new challenges almost came to a standstill. The national referendum on 30 November 2008 showed this clearly. The revision of narcotic law which consolidated the four-pillar policy legally (against right-wing opposition) was a final consequence of the success story. However, two initiatives to replace the huge illicit cannabis market with a regulated market with tolerated production sites and outlets were rejected by Parliament [64] and in a national referendum [65]).

LESSONS LEARNED, CHALLENGES AHEAD

Changing a traditionally repressive drug policy to one which combined all types of activities, including supervised injection rooms and heroin prescribing, was possible in an exceptional historical situation. Lessons can be drawn only with caution, and they are mainly lessons for the future of Swiss drug policy, while the international reader may consider them to be observations. These are as follows.

- Drastic policy changes were facilitated when ongoing policy completely failed to cope with an increasing and highly visible problem.
- In a federal democracy such as Switzerland, with its system of referenda, such drastic changes are accomplished more easily in a process of political and professional debate with active participation of all actors, including the media.
- Initial change in this case was facilitated because civil disobedience was tolerated as a way of experimenting with new approaches.
- Good documentation and evaluation of policy changes were a condition for continued public support, which gave research and research findings an especially important role.

It may have helped that the Swiss have a rather pragmatic attitude in many areas; they distrust ideological and authoritarian positions and are used to finding out for themselves what is best. The present and future challenges in the field of drug policy are numerous, especially when considering how to cope with these problems in a consistent policy framework. So far, practitioners and policy makers have expressed their willingness to continue the process at national level and first steps have been taken to cope with the pending issues by consensus-building in a typically Swiss manner.

Declaration of interest

None.

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