DRUG-SUBSTITUTION TREATMENT IN GERMANY: A CRITICAL OVERVIEW OF ITS HISTORY, LEGISLATION AND CURRENT PRACTICE

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Within a global context, Germany was relatively late in its acceptance of substitution treatment, having first introduced methadone maintenance treatment (MMT) in the late 1980s. Since the early 1990s, Germany has taken a number of legal steps which favor harm reduction, assistance and treatment, rather than the law enforcement approach that was dominant before. As a result of this new commitment, Germany now also allows the use of non-methadone substitutes, such as buprenorphine, LAAM, dihydrocodeine (DHC) and codeine. A heroin maintenance trial has been scheduled to begin in early 2002. Despite the fact that the overall number of participants in drug-substitution treatment has risen over the past decade from about 1,000 in the early 1990s to more than 55,000 in 2001 and that MMT has been comprehensively evaluated in Germany with favorable outcomes, there remains a lack of availability of and accessibility to substitution treatment, due to rigid entry and treatment criteria imposed by the social health insurers (SHI).

INTRODUCTION

Despite good evidence that "opioid replacement therapies" (Ward, Mattick, & Hall, 1998) or "drug-substitution treatment" (European Agency for the Evaluation of Medicinal Products [EMCDDA], 2000) using methadone, buprenorphine, LAAM

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JOURNAL OF DRUG ISSUES 0022-0426/02/02 503-522

(levacetylmethadol), dihydrocodeine or codeine reduces addicts' risks of non-HIV related mortality, their risk of HIV and hepatitis infection and leads to reductions in criminal activity, it remains a controversial treatment for heroin addiction and addicts in many countries are still denied effective access to maintenance treatment and Germany is no exception. Due to a predominant abstinence-orientation in German drug policy and in addiction treatment philosophies throughout the 1970s and 1980s, drug-substitution treatment has only recently been accepted. In the following material, historical aspects of substitution treatment, the German legislative framework and the current state of the art will be discussed.

HISTORICAL ASPECTS

After heroin found its way onto the German illegal drug market around 1970, there was a rapid increase in the number of heroin users and addicts, from none to around 30,000 - 40,000 within only a few years. Against the backdrop of experiences reported for methadone treatment in the USA and Sweden, a first experimental methadone program was carried out in Hannover from 1973 to 1975. Measured against the original criteria of success identified by Dole and Nyswander (Dole & Nyswander, 1966), there was a success rate of "almost 100 percent" (Krach et al., 1978, p. 292). However, the judgement of the authors of the Hannover final report was that the trial had been a failurebecause "following cessation of methadone treatment, virtually all subjects relapsed to opiate use and the dramatic improvement in social function was reversed" (Newman, 1988, p. 27).

In contrast to MMT as introduced by Dole and Nyswander, the Hannover project had been conceptualized as a maintenance-to-abstinence program and, corresponding with the abstinence paradigm dominating addiction treatment and policies at that time, the program staff interpreted the alleged failure of the trial as evidence of the superiority in effectiveness of therapeutic communities (TCs) over MMT. Unfortunately, the vast majority of German drug experts (and others who considered themselves to be experts) medical associations, the Federal Medical Board (Bundesärztekammer) and public health insurers, adopted this judgement without further investigation. Subsequently, for over a decade, the Hannover methadone trial results were misrepresented as providing clear evidence that methadone programs are not adequate alternatives to TCs (Gerlach & Schneider, 1994).

Throughout the 1970s and the 1980s the drug policies of German governments continued to be dominated by a rigid adherence to the abstinence paradigm and repression, a 'war on drugs' mentality, and policies that would foster harm reduction were blockaded (Michels, 1993; Kalke, 1997a). The therapeutic ideal of achieving permanent abstinence for all opiate users was considered the only valid premise for providing practical survival support and the only valid criterion for successful

addiction treatment. Thus, drug-free therapy and TCs were proclaimed as the 'Royal Road to Recovery' (Gerlach & Schneider, 1991).

Until the early 1990s, methadone could only be administered in Germany to drug users after highly specific selection criteria had been met (e.g. emergency cases such as life-threatening conditions associated with withdrawal or conditions involving severe pain). In general medical practice, however, German doctors were prevented from using methadone to treat heroin addicts, since MMT was considered to be a form of medical malpractice. Nevertheless, there were a few general practitioners (GPs) who ignored the legal regulations and prescribed methadone to opiate addict patients, although most of these doctors were persecuted and prosecuted on the basis of 'evidence' presented by medical 'experts'. "For some doctors the result was shattered lives and permanently destroyed careers. For others, civil and criminal proceedings dragged on for years, robbing them of their time, energy, and their financial resources" (Newman, 1995, p. 28).

These court procedures, strongly suggestive of medieval witch trials, mark one of the darkest chapters in the history of addiction treatment in Germany. As a result of these prosecutions some GPs began prescribing codeine or DHC to addict patients, as these substances were not restricted by law (Grimm, 1992; Ulmer, 1997). Other doctors soon followed this example and, for many years, until February 1998, codeine or DHC could be legally prescribed to very large numbers of addicts, due to a loophole in the narcotics regulations.

It was the emergence of AIDS in the mid-1980s, rising addict criminality, increasing mortality rates among drug users, and the narrow range and unattractiveness of abstinence-oriented services that finally generated demands for alternative, harm-reduction-oriented concepts to be integrated into drug policy and addiction treatment (Gerlach & Schneider, 1991).

Several early pilot programs showed MMT to be effective (e.g. Degkwitz, Chorzelski, & Krausz, 1993; Gastpar, 1995; Verthein, Kalke, & Raschke, 1995), and the German Social Health Insurers (SHI) (Gesetzliche Krankenversicherung – GKV) approved this treatment modality, introducing methadone treatment guidelines called 'NUB-Richtlinien' (Richtlinien über neue Untersuchungs- und Behandlungsmethoden). The 'NUB-Richtlinien' were drawn up by the Federal Association of Physicians and Social Health Insurance Organizations (Bundesausschuß der Ärzte und Krankenkassen). These guidelines, now called BUB-Richtlinien (Richtlinien über die Bewertung ärztlicher Untersuchungs- und Behandlungsmethoden), focus on the reimbursement of costs for treatment and medication by social health insurers (SHI).

In Germany, treatment and prescription (medication) costs are generally covered by public health insurance schemes (SHI) that are legally mandatory for nearly 90

percent of the population (in special cases, e.g. homelessness, doctors' fees are paid by social welfare services). Patients also have the freedom to choose their own general practitioner (GP) or hospital (Whitney, 1993; Weil & Brenner, 1997). However, regarding opiate addiction treatment, this highly-praised German health care system has failed, as the public health insurers are not under any legal obligation to meet drug-substitution treatment and prescription costs. Even at the present time, they do not accept opiate addiction by itself as a sufficient indication for treatment with substitute substances. The German Narcotics Act was revised in 1992, finally clarifying the status of drug-substitution treatment as legal.

INVESTIGATIONS OF DRUG-SUBSTITUTION TREATMENT

Methadone treatment has been comprehensively evaluated in Germany (Verthein, Kalke, & Raschke, 1998). Because the various studies used different methodological approaches, evaluation periods and sample sizes and populations, the research results are only partially comparable. However, following Gerlach (2000), several important common aspects regarding the overall results of German studies and investigations can be presented:

- The average age of methadone patients is above 30 years. The duration of heroin use before starting MMT lies between 10 to 12 years on average.
- More than two thirds of the patients had received treatment in inpatient, drug-free TCs (usually several attempts at treatment) prior to MMT, but few stayed in that treatment as long as was expected. One third of those who left regular therapy immediately relapsed into heroin use.
- MMT shows considerably higher retention rates than TCs (Some 65% of clients leave TCs within the first four months of treatment). In North Rhine-Westphalia, for example, the MMT retention rates were 87% after one year, 66% after three years, 53% after five years and 48% after seven years (Ministerium für Gesundheit, Arbeit und Soziales, 1998). An evaluation of MMT in Hamburg showed retention rates of 84% after three years, 77% after four years, and 71% after five years (Raschke, Verthein, Kalke, 1996).
- Even during the initial phase of treatment, there is a remarkable improvement in the general health status of methadone patients. The health status of patients infected with HIV or hepatitis also stabilizes in the course of treatment. HIV seroconversion rates are well below 1% during MMT.
- The risk of mortality is drastically reduced. The survival rate of methadone patients is three to five times higher than that of untreated heroin users.
- There is also a reduction in the use of illegal drugs. Final cessation of the illegal use of opioids is dependent on the duration of participation in treatment.

After one year in MMT, positive heroin urinalysis ceases for 80-90% of methadone patients. With an increasing length of time in treatment there is also a decline in, or termination of, the collateral use of other psychotropic substances.

- About 10% of treatment participants eventually become totally abstinent (methadone included) (Finkbeiner & Gastpar, 1997). At present, there are no follow-up studies available on the stability of abstinence. However, experiences to date demonstrate that imposing time limits on methadone treatment (detoxification or maintenance-to-abstinence) often results in relapse into illegal opiate use and physical as well as psychological instability.

In 1996, a survey on the attitudes and beliefs of German methadone prescribers and their knowledge of the effects of methadone was carried out in the region of Westfalen-Lippe. Of the 247 SHI approved doctors included in the study, some 50% supported, and 25% strongly supported, abstinence-oriented policies. The strength of support doctors gave abstinence-oriented policies probably reflects the recent domination of German addiction treatment services by the abstinence paradigm. Their attitudes and relative lack of knowledge of the basic pharmacology of methadone are probably also due to the country's short experience with MMT. These doctors' attitudes are likely to adversely affect the quality of care given heroin addicts as well. While the survey respondents were probably representative of methadone prescribers in the Westfalen-Lippe region, their attitudes may be different than those of other German methadone prescribers (Gerlach & Caplehorn, 1999). Thus, the findings are not generalizable. However, even five years after the study had been conducted there remains a strong abstinence-orientation in drug-substitution treatment (Gerlach, 2001).

In 1998, for the first time in Germany cases of iatrogenic methadone deaths occurring in the initial phase of MMT were reported. Servais and Erkens investigated six cases of methadone-related death in which the initial dose of methadone was too high, leading to overdoses. Two patients who died on the first day of treatment had been prescribed 100 mg of racemic methadone. Another patient who was given 75 mg on the first and second days in treatment died on the second day. Three deaths occurred with levomethadone: two patients who were prescribed initial doses of 35-40 mg died on the first day. In the third case, the doses were increased over three days (30 mg the first day, 35 mg the second, and 50 mg on the third day). The doctors responsible for the latter cases began these treatments with initial doses that are recommended for racemic methadone, probably not knowing that the levomethadone type is twice as strong. In another three deaths, methadone had been prescribed to non-opioid-tolerant patients (Servais & Erkens, 2000). Cases of

iatrogenic methadone toxicity during early treatment must not be underestimated, since similar fatalities have been reported in Australia (Caplehorn, 1998).

According to one Hamburg study of drug deaths where methadone was detected in the blood of about 20% of all 1995 drug-related fatalities (Heinemann, Ribbat, Püschel, Iwersen-Bergmann, & Schmoldt, 1998). In 1998, some 25% of all death cases registered in Berlin and Stuttgart occurred with the administration of psychotropic substances (e.g. cocaine, benzodiazepines, alcohol), in combination with methadone. The latest available data suggest that, on average, methadone is detected in about 20% of all drug fatalities registered in Germany (Die Drogenbeauftragte der Bundesregierung, 2001). It is important to note that the majority of those who died of speedball (mixtures of cocaine and heroin) overdoses were not enrolled in MMT at the time. Diversion of methadone to the black market is also an increasing phenomenon. Thus far, the Federal Bureau of Criminal Investigation (Bundeskriminalamt) has not reported the discovery of any illegal methadone production sites, however. Apparently the substance enters the black market when MMT patients sell their take-home doses. This leads to the conclusion that the black market is constantly fed by GPs who are lax in their prescribing practices. The fact that there is a considerable demand for methadone on the black market, however, clearly shows that there is still a significant shortage of treatment slots in many cities and rural areas (Faltin, 2001). The availability of and accessibility to drug-substitution treatment are dependent on the drug users' place of residence, since there are huge regional variations in the provision of such facilities.

As noted earlier, there have been several drugs other than methadone used in the treatment of addiction. One of these involves the drug codeine/DHC. To date, there is one important follow-up study showing that MMT and codeine/DHC treatment are similarly effective in treatment progress and outcomes (Krausz, Verthein, Degkwitz, Haasen, & Raschke, 1998). Due to the very brief experience with buprenorphine (Subutex®) – the substance was first approved for substitution treatment in 2000 – results of follow-up studies cannot yet be presented. Several case reports have been published, suggesting that switching drug users or methadone patients to buprenorphine has proven especially useful with pregnant women and low-dose methadone patients (Hönekopp, 2000). Buprenorphine also appears to be effective when used in detoxification treatment (Berger, Türbsch, & Wambach, 2000).

Worldwide, there is a remarkable paucity of qualitative research on the subjective views of patients participating in substitution treatment progress (exceptions include Gerlach & Schneider, 1994 [Germany], and Christie & Hil, 2000 [Australia]). The attitudes and views of treatment participants deserve to be studied carefully, however,

because one may assume that the more treatment philosophies, policies and settings are oriented towards patients' needs, the more successful those efforts will be.

DRUG-SUBSTITUTION TREATMENT LEGISLATION

The modern German Narcotics Act was passed in 1971 and modified in 1982. Several amendments have been enacted. This act has priority over all other regulations regarding narcotics. As regards substitution treatment with methadone, it was only in 1992 that the amendment of the Regulation on the Prescription of Narcotics (BtMVV – Betäubungsmittelverschreibungs-Verordnung) was introduced, a directive that clarified the legal position of methadone prescribers. According to the latest modification of the BtMVV (effective as of July 1, 2001), doctors are entitled to prescribe the following maximum quantities of substitute substances to a patient within a period of 30 days: methadone 3,000 mg; levomethadone 1,500 mg; codeine and DHC 40,000 mg; buprenorphine (Subutex®) 720 mg; LAAM 2,000 mg. These substances have been approved for substitution treatment by the Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte). Doctors prescribing these substances have to keep to the "generally accepted state of the art of medical science." The Federal Medical Board is the authoritative body charged with defining the state of the art. The principle regulations regarding substitution treatment, as documented in section five of the BtMVV, are summarized below:

In accordance with section 13 (1) of the Narcotics Act, substitute drugs may be prescribed for the following regulation purposes (treatment goals):

1. treatment of opiate addiction with the goal of step-by-step recovery to abstinence inclusive of improvement and stabilization of the general health status;
2. treatment of patients addicted to opiates who have to undergo medical treatment for severe medical illnesses; and
3. to reduce the risks of opiate addiction during pregnancy and after birth.

Doctors are authorized to prescribe substitute substances if and as long as:

1. the patient is eligible for substitution treatment;
2. substitution treatment is embedded in a comprehensive treatment concept incorporating necessary accompanying psychiatric, psychotherapeutic or psychosocial care;
3. they register their patients at the Federal Narcotics Control Board (Bundesopiumstelle) (effective July 1, 2002); and

4. there is no evidence that the patient
   a. receives substitution substances on prescription from another doctor;
   b. does not participate in necessary accompanying treatment and care;
   c. uses substances that endanger the purpose of substitution treatment;
   d. does not use the substitute as directed by law;
5. the patient sees his/her doctor regularly (usually once a week); and
6. they have qualified for addiction treatment according to the guidelines of the appropriate state or regional medical boards (to be effective of July 1, 2002).

Doctors are obliged to document all relevant patient and treatment data. Upon request, they have to turn their files over to the relevant state authorities (local health authorities, public prosecutors' offices). Prescriptions must be written on special prescription pads, and they must be marked with the letter "S". When maximum quantities are exceeded, the prescription must also be marked with the letter "A". The law regulating narcotics is a criminal law. For violations of the Regulation on the Prescription of Narcotics, a doctor may face a fine of up to 50,000 DM ($23,000) or a prison sentence of up to five years.

These substitute drugs must not be prescribed for parenteral (intravenous) use. The substitute may be dispensed and/or taken under supervision in GP's offices, hospitals, pharmacies or other facilities approved by the relevant state authorities.

Take-home medication of up to seven daily doses is allowed when the determination of the appropriate maintenance dose has been resolved and when there is no noxious and/or intravenous concomitant use of other substances. In case of international (overseas) travel, a doctor may prescribe 30 take-home doses ("carries" or "take-aways") per patient per year in exceptional circumstances, for example, when continued treatment cannot be arranged in the country of destination. Information on import regulations and possible continuation of treatment can be obtained from the *International Coordination and Information Service for Patients in Drug-Substitution Treatment Seeking to Travel Abroad*, located at INDRO in Muenster, Germany. This is the only agency providing such assistance worldwide (travel information is available on the internet via www.indro-online.de/travel.htm).

Regarding SHI-funded substitution treatment, additional guidelines have been drawn up by the Federal Association of Physicians and Social Health Insurance Organizations (Kassenärztliche Bundesvereinigung), which regulate the conditions for reimbursement of treatment costs (BUB-Richtlinien). These guidelines may be ignored with patients who have no public health insurance.

Compared with the Regulations on the Prescription of Narcotics (BtMVV), the core of the BUB guidelines allows for discrimination on the basis of particular indications. The SHI have not approved heroin addiction per se as justification for

maintenance treatment with substitute drugs. According to §§ 3 and 3 a of the BUB guidelines, SHI-funded drug substitution treatment is possible if one of the following criteria is met:

1. Indications for unlimited periods of drug substitution treatment:

- opiate addiction in case of malignant tumor;
- opiate addiction in case of HIV infection; and
- opiate addiction in case of chronic hepatitis (B and C).

2. Indications for limiting drug-substitution treatment limited to a period of 12 months:

- opiate addiction in case of chronic recidivist abscesses;
- opiate addiction in case of repeated (bronchial) pneumonia;
- opiate addiction in case of tuberculosis when treatment of the disease is necessary;
- opiate addiction in other cases of severe illness (concomitant and subsequent illnesses of drug use, including psychiatric diseases); and
- opiate addiction during pregnancy and up to 6 months after birth.

3. Indications for limiting drug-substitution treatment to a period of 6 months:

- to facilitate opiate addicts'ability to participate in inpatient settings (TCs); and
- temporary substitution treatment ('bridging') in case of opiate addiction when there is proof of the fact that the patient will be accepted for participation in an inpatient detoxification unit and subsequently in a TC

4. Substitution treatment, provisionally limited to a period of 12 months, can also be permitted if

- a patient is not suitable for participation in TCs for medical reasons; and
- there is a chance that treatment will result in a stabilized and improved health status and abstinence can be achieved by step-by-step dose reductions.

Doctors have to seek permission from a "substitution commission" (BUB- or KV-Kommission), located at their relevant regional Association of SHI-Approved Physicians (Kassenärztliche Vereinigung - KV), in order to treat a patient with

methadone or other substitutes. This requires a time-consuming application procedure, however, and this hurdle keeps many doctors from treating drug users. The KV commission scrutinizes each individual application and decides whether SHI-funded substitution treatment may be approved. Each KV region has a commission of three doctors nominated by the KV (two of these have to be experienced in drug-substitution treatment), and three SHI representatives. In the worst case, a BUB commission consists of two experienced GPs and four administrative unit servants. The commissions meet on a regular basis to review these applications (every 3 to 4 weeks). It takes at least four weeks (sometimes even eight) for the commission to deal with an individual application. Costs for treatment and medication will not be covered by SHI until the application has been approved.

Doctors who administer substitute drugs are required to test their patients' urine and to monitor poly-drug use. There are no rules regulating the frequency with which they must take urine samples, however. In practice, during the first weeks of treatment doctors usually give their patients' urine tests at least once a week. According to the BUB guidelines, continued collateral use of addictive substances (no substances listed!) must result in the termination of treatment.

All doctors seeking to provide drug-substitution treatment must first be authorized to do so by the regional KVs. When applying for this consideration, they must provide evidence of their being qualified in pharmacology and drug addiction by having participated in special medical qualification programs. Training in these programs covers topics such as opioid dependence and the role of substitute drugs, understanding and caring for the substitution patient, assessment and management, and clinical practice dosing procedures (Poehlke, Flenker, Schlüter, & Busch, 2000).

Depending on the number of substitution treatment providers in a given locale, doctors may be authorized to treat up to 20 patients or more funded by SHI, although there is no such limitation articulated in the Regulations on the Prescription of Narcotics (BtMVV). Thus, doctors approved to treat 20 SHI patients may care for another 20 patients who are funded by social welfare or paying for their treatment themselves.

Doctors treating substitution patients according to the BUB guidelines (SHI-accredited GPs) also have to meet the regulations of the BtMVV and the Narcotics Act. Beginning in July 2002, all substitution patients will have to be registered at the Federal Narcotics Control Board ("Bundesopiumstelle"). It is important to note that the regulations and guidelines listed above drastically limit the doctors' freedom to provide medical treatment. There are no similar regulations for any other diseases or treatment modalities. Though doctors prescribing substitute substances have special medical qualifications in addiction treatment, the commission, which consists

largely of civil servants, is assigned the responsibility of approving or disapproving applications for SHI-funded treatment.

While SHI-funded patients and most of the patients supported by social welfare funds have to be suffering from illnesses other than drug addiction itself in order to be accepted for substitution treatment, patients paying for the treatment out of their own pockets only need to be diagnosed as being addicted to heroin. There are no regulations regarding the minimum age of potential patients. In general practice situations, drug users will be accepted for treatment when there is a documented history of compulsive drug use of two years (according to SHI), and when they are at least 18 years of age. Despite the fact that the BUB guidelines are effective nationwide, there are variations between the federal states with regard to the organization and delivery of substitution treatment and accompanying psychosocial care.

As documented above, legislation on drug substitution treatment remains oriented towards abstinence rather than maintenance, although research findings and experience gathered from medical practice indicate that limiting the duration of participation in treatment does not prove successful for a majority of patients (Gerlach, 2001). Achieving a status of lifelong abstinence from opioids, including all substitute substances, appears to be an unrealistic goal for any treatment participant (Hser, Hoffman, Grella, & Anglin, 2001).

CURRENT SITUATION OF DRUG SUBSTITUTION TREATMENT

Despite the severe restrictions on substitution treatment, the number of patients receiving methadone maintenance funded by SHI increased dramatically from about 1,000 in April 1992 to between 32,000 and 33,000 in 2000. The total number of methadone patients, including all those without SHI support, increased from about 1,000 in 1991 to an estimated 40,000 to 45,000 in 2001. In addition, there are about 5,000 codeine/DHC patients and another 5,000 patients who receive buprenorphine (Subutex®). More than 10,000 methadone patients receive treatment without public health insurance. Methadone patients without SHI support either pay for their medication directly or receive funds from the social welfare system with which to do so. Since doctors need not report their patients to the local health authorities, the total number of patients in substitution treatment can only be estimated. It must be emphasized that there currently is no reliable documentation system. As noted above, beginning on July 1st, 2002 all patients in drug-substitution treatment will have to be registered with the National Narcotics Control Board (Bundesopiumstelle). The government estimates that 30 to 50 percent of all heroin users are currently in addiction treatment. Some 10,000 addicts participate in drug-free in- or outpatient

treatment settings, and another 50,000 to 55,000 receive drug-substitution treatment (Die Drogenbeauftragte der Bundesregierung, 2001).

It is estimated that about 90% of substitution patients receive their medication from doctors in independent medical practice (GPs). In a survey carried out by Gerlach and Caplehorn in spring 1996 in the Westfalen-Lippe region of Germany, 70% of all SHI-approved methadone prescribers (598 physicians) in the area were general practitioners, 20% were specialists in internal medicine and 6% were psychiatrists (Gerlach & Caplehorn, 1999). On average, each SHI-approved doctor treats 22 patients (Caspers-Merk, 2001). Nationwide, more than 2,600 physicians (mostly primary care physicians) have been authorized to provide MMT under public health schemes (SHI) (Rheinberger & Sander, 2000), and 60 to 70 percent of them do in fact prescribe methadone. In major cities and some rural areas there are also specialized outpatient (ambulatory) centers for substitution treatment, most of which have caseloads of more than 100 patients.

There are some 50,000 to 60,000 prisoners in Germany, 30 to 50% of whom were intravenous drug users (IVDUs) at the time of their imprisonment. Despite rigid controls, about 50% of all imprisoned IVDUs continue to use drugs in the institutional setting. It is estimated that the active drug using population in prisons exceeds 10,000. Of course, these are only rough estimates since there are no accurate (generalizable) data available. Also, there is no information available on the number of substitution patients who are being treated in penal institutions. Only six out of sixteen federal states in Germany provide substitution treatment in prisons (Hamburg, Bremen, Berlin, Hesse, Lower Saxony, and North Rhine-Westphalia). Entry criteria vary between the states and substitution treatment is not available in each of the individualized states' prisons (Keppler, 2000; Stöver, 2001).

Methadone is the substance most frequently prescribed in substitution treatment. As described earlier, there are an estimated total of 40,000 to 45,000 methadone patients in Germany at the present time. In contrast to other countries, there are now two forms of methadone available in Germany, the racemic mixture (d,l-methadone) (this has only been available since February 1, 1994), and levomethadone (l-methadone, L-Polamidon®). In addition to its use in maintenance treatment, methadone is also used during detoxification in qualified units where the doses are gradually reduced over a period of one to three weeks.

Despite the fact that a follow-up study on codeine treatment clearly demonstrated that the patients' progress was comparable to that achieved by MMT (Krausz et al., 1998), since February 1998, codeine or DHC can only be used in specific medical cases, such as those in which users cannot tolerate methadone. While the earliest experiences gathered in Frankfurt showed that quite a number of former codeine patients relapsed into heroin use or bought codeine on the black market (Weber,

1998), a study of the consequences of the changed law concluded that switching codeine patients to methadone had been successful with 73 percent of their sample. Twenty percent of the codeine patients could not be changed over to methadone (Degkwitz, Chorzelski, & Krausz, 2000). Due to the change of law the number of codeine/DHC patients decreased markedly from 25,000 to 30,000 patients in early 1998 to 5,000 patients in 2001.

LAAM or levacetylmethadol (Orlaam®) had first been used within the setting of a controlled, randomized multi-center study in 1998 (Finkbeiner, Hagen, & Wolstein, 2000), and was approved for drug-substitution treatment in 1999. On April 19, 2001, the European Agency for the Evaluation of Medicinal Products (EMEA) recommended the suspension of marketing authorization for Orlaam® (LAAM) because of dangerous side effects (life-threatening cardiac disorders) observed with 10 patients (European Agency for the Evaluation of Medicinal Products, [EMEA], 2001). For this reason, LAAM is no longer used in Germany.

Buprenorphine (Subutex®) was approved for substitution treatment by the Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte) in early 2000. It is estimated that the current number of buprenorphine patients is around 5,000.

Both the BtMVV and the BUB guidelines demand mandatory participation of patients in psychosocial care, although there is no empirical evidence of a general necessity for psychosocial support for *all* patients (Ullmann, 1996). However, these regulations do not provide any instructions regarding the frequency, mode and scope of psychosocial care provisions and, to date, there are no nationwide standards of how to organize and structure these supportive services. Psychosocial care is a collective term that encompasses a number of different activities. These may include, for example, legal advice, managing financial problems (e.g., debts, rents), recreational activities, crisis intervention, (psychotherapeutic) group sessions, assistance with finding living accommodations and jobs, and qualifying for school and vocational training. Psychosocial care is not funded by the SHI. There are great variations in psychosocial provision between different states and communities, as well as differences in quality and funding.

With regard to employment, the labor market is not easy for patients participating in drug-substitution treatment due to a high general unemployment rate (9.2% in July 2001 = nearly 3.8 million jobless people), and negative attitudes and beliefs towards the patients on the part of employees. Also, the socio-demographic and biographical characteristics of patients participating in substitution treatment (e.g., minor school and vocational qualifications, criminal records) reduce their chances of employment. Though there are educational and vocational projects in several

major cities, accompanying support regarding education and employment is still not generally available.

Since 1998, substitute substances may be legally dispensed via pharmacies. The dispensation of these substances in pharmacies is backed by the umbrella organization of the German Associations of Pharmacists, the Bundesvereinigung Deutscher Apothekerverbände (ABDA). In Hamburg, however, local pharmacies have, from the beginning, been involved in the dispensation of methadone. This treatment was introduced in 1988 in the form of state-specific regulations. According to a study conducted in 1996, 80% of all Hamburg methadone patients received their medication in pharmacies during that year. Pharmacy dispensing is patient-friendly and saves patients long or time-consuming travels and/or waiting periods in doctors' offices (Kalke, 1997b). So far, the Hamburg investigation into the dispensation of methadone in pharmacies is the only such study that has been conducted in Germany.

FINAL REMARKS

Following nearly twenty years of commitment to drug-free therapy, MMT was launched in Germany in the early 1990s, mainly in response to the HIV/AIDS epidemic and its links to injecting drug use. There has been an extremely rapid expansion in the provision of drug-substitution treatment over the last decade and methadone continues to be the most widespread opiate substitute. However, despite the fact that all German studies on the effectiveness of maintenance treatment observed favorable outcomes, legislation on drug substitution treatment remains oriented towards abstinence rather than maintenance, and the public health insurers (SHI) do not accept opiate addiction alone as a sufficient indication for treatment with substitutes. Moreover, the duration of participation in SHI-funded treatment remains quite limited (although a prolongation of participation in treatment is possible). As a result, drug-substitution treatment is still not available for many of those who need it, and many heroin users who have been excluded from adequate treatment have to supply themselves with black market methadone and run the risk of death by methadone overdosing or dangerous drug mixtures.

The current German government has taken a number of steps which favour harm reduction, assistance and treatment rather than law enforcement, including the legalization of medically supervised injecting rooms and the introduction of heroin-prescription trials (See Michels and Stoever in this issue). While these legal steps have been seen as absolutely essential in view of the rising numbers of drug-related fatalities (1997: 1,501; 1998: 1,674; 1999: 1,812; 2000: 2,023), the government must not neglect to put pressure on the Federal Association of Physicians

and Social Health Insurance Organizations to relax the admission criteria for SHI-funded drug-substitution treatment as documented in the BUB guidelines. The application procedures need to be simplified and streamlined: It is difficult to fathom why there are civilian 'substitution commissions' when doctors prescribing these substances have a special medical qualification in drug addiction treatment. The Drug Commissioner of the Federal Government (Drogenbeauftragte der Bundesregierung) has announced talks with the Federal Association of Physicians and Social Health Insurance Organizations regarding the BUB guidelines (Caspers-Merk, 2001). At the same time, the Federal Medical Board is about to draw up substitution treatment guidelines in accordance with the Regulation on the Prescription of Narcotics (BtMVV). It remains to be seen whether these activities will result in further improvements in the quality and availability of drug-substitution treatment in Germany.

REFERENCES

Berger, H., Türbsch, L., & Wambach, L.
2000 Buprenorphin in der Detoxifikation: Erste Erfahrungen im psychiatrischen Alltag. *Suchtmedizin in Forschung und Praxis, 2(2),* 112-113.

Caplehorn, J.R.M.
1998 Deaths in the first two weeks of maintenance treatment in NSW in 1994: Identifying cases of iatrogenic methadone toxicity. *Drug and Alcohol Review, 17(1),* 9-18.

Caspers-Merk, M.
2001 Rede der Drogenbeauftragten Frau Caspers-Merk im Bundesministerium für Gesundheit anläßlich der Fachtagung "Mehr als abhängig? Substitution zwischen Leben und Sterben" in Berlin am 18. Mai 2001.

Christie, G., & Hil, R.
2000 *Service users' and providers' perceptions of a methadone maintenance program : A Queensland qualitative pilot study*. Brisbane: Queensland University of Technology

Degkwitz, P., Chorzelski, G. & Krausz, M.
1993 Five years of methadone prescription in Germany. In M. Reisinger (Ed.), *Proceedings of a Seminar on AIDS and Drug Addiction in the Twelve European Communities Member States. Aids and drug addiction in the European community* (pp. 81-89). Brussels: European Monitoring Centre for Drugs and Drug Addiction (EMCDDA).

Degwitz, P., Farnbacher, G., Kalke, J., Schmidt, V., & Verthein, U.
2000 Die Umstellung der Substitution von Codein auf Methadon – Kurzfassung einer Studie über die Auswirkungen neuer betäubungsmittelrechtlicher Vorschriften. In Zerdick, J. (Ed.), *Suchtmedizin – aktuell* (pp. 171-206). Berlin: Verlag für Wissenschaft und Bildung.

Die Drogenbeauftragte der Bundesregierung
2001 *Sucht- und Drogenbericht 2000*. Berlin.

Dole, V.P., & Nyswander, M.E.
1966 Rehabilitation of Heroin Addicts After Blockade with Methadone. *New York State Journal of Medicine*, 55*(15),* 2011-2017.

European Agency for the Evaluation of Medicinal Products (EMEA)
2001 *EMEA public statement on the recommendation to suspend the marketing authorisation for ORLAAM (Levacetylmethadol) in the European Union*. London, April 19.

European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) (Ed.)
2000 *Reviewing current practice in drug-substitution treatment in the European Union.* Lisbon: EMCDDA.

Faltin, T.
2001 Suchtpraxen müssen dutzende Abhängige wegschicken. In *Stuttgarter Nachrichten*, August 4.

Finkbeiner, T. & Gastpar, M.
1997 Der aktuelle Stand der Substitutionsbehandlung Drogenabhängiger. *Nervenheilkunde, 16,* 215-221.

Finkbeiner, T., Hagen, S., & Wolstein, J.
2000 Differenzierte Substitutionstherapie mit LAAM. In Zerdick, J. (Ed.) *Suchtmedizin – aktuell* (165-169). Berlin: Verlag für Wissenschaft und Bildung.

Friedman, J., & Alicea, M.
2001 *Surviving heroin*. Gainesville: University Press of Florida.

Gastpar, M.
1995 Methadone substitution: Results of a trial in the German state of North Rhine-Westphalia. In C. Stefanis & H. Hippius in collaboration with D. Naber (Eds.) *Research in addiction*. *Volume 2* (pp. 105-115).

Gerlach, R.
2000 Germany. In European Monitoring Centre for Drugs and Drug Addiction (Ed.) *Reviewing current practice in drug-substitution treatment in the European Union* (pp. 69-97). Lisbon: EMCDDA.

Gerlach, R.
2001 "Elend" Methadon-Substitution (?). In Schneider, W. (Ed.) *Illegalisierte Drogen* (pp. 59-92). Berlin: Verlag für Wissenschaft und Bildung.

Gerlach, R., & Caplehorn, J.R.M.
1999 Attitudes and beliefs of doctors prescribing methadone to addicts in the Westfalen-Lippe region of Germany. *Drug and Alcohol Review*, 18, 163-170.

Gerlach, R., & Schneider, W.
1991 Abstinence and acceptance? The problematic relationship between the German abstinence paradigm, low-threshold oriented drug work, and methadone. *Drug and Alcohol Review, 10,* 417-421.

Gerlach, R., & Schneider, W.
1994 *Methadon- und Codeinsubstitution*. Berlin: Verlag für Wissenschaft und Bildung.

Grimm, G.
1992 *Drogen gegen Drogen*. Kiel: Veris.

Heinemann, A., Ribbat, J., Püschel, K., Iwersen-Bergmann, S., & Schmoldt, A.
1998 Rauschgifttodesfälle mit Methadonbeteiligung (Hamburg 1990-96). *Rechtsmedizin, 8,* 55-60.

Hönekopp, I.
2000 Buprenorphin-Substitution in der Schwangerschaft: Geringeres Risiko neonataler Abstinenzsyndrome. *Suchtmedizin in Forschung und Praxis, 2(3),*166-167.

Hser, Y., Hoffman, V., Grella, C.E., & Anglin, M.D.
2001 A 33-Year Follow-up of Narcotics Addicts. *Archives of General Psychiatry*, *58,* 503-508.

Kalke, J.
1997a Methadonpolitik in der Bundesrepublik Deutschland - Rückblick und Perspektiven. In akzept e.V. (Ed.) *DrogenVisionen* (pp. 289-300). Berlin: Verlag für Wissenschaft und Bildung.

Kalke, J.
1997b Die Vergabe von Methadon durch Apotheken - der Hamburger Weg. *Gesundheitswesen, 59(3),*181-185.

Keppler, K.H.
2000 Methadonsubstitution im Gefängnis. In Jäger, H. (Ed.) *AIDS* (pp. 530-534). Landsberg: Verlag Moderne Industrie.

Krach, C., Lotze, J., Peschke, H., Peter, U., Rabe, M.-L., & Schönhöfer, P.
1978 Ambulantes Therapieprogramm mit Methadon. Aus dem Jugend- und Drogenberatungszentrum Hannover - 2 Jahre danach. *Niedersächsisches Ärzteblatt, 51(9),* 289-292.

Krausz, M., Verthein, U., Degkwitz, P., Haasen, C., & Raschke, P.
1998 Maintenance treatment of opiate addicts in Germany with medications containing codeine – results of a follow-up study. *Addiction, 93(8),*1161-1167.

Michels, I.-I.
1993 Critical analysis of the drug treatment policy in Germany. In M. Reisinger (Ed.), *Proceedings of a Seminar on Aids and Drug Addiction in the Twelve European Communities Member States*. *AIDS and drug addiction in the European community* (pp. 90-102). Brussels: European Monitoring Centre for Drugs and Drug Addiction (EMCDDA).

Ministerium für Arbeit, Gesundheit und Soziales des Landes Nordrhein-Westfalen (Ed.)
1998 *Medikamentengestützte Rehabilitation i.v. Opiatabhängiger – Katamnese*. Düsseldorf: MAGS

Newman, R.G.
1988 Is there a role for methadone in Germany? *AIDS & Public Policy Journal*, *3(2),* 23-29.

Newman, R.G.
1995 Another wall that crumbled – methadone maintenance treatment in Germany. *American Journal of Drug & Alcohol Abuse*, *21(1),* 27-35.

Poehlke, T., Flenker, I., Schlüter, H.-J., & Busch, H.
2000 *Suchtmedizinische Versorgung, 2. Drogen*. Berlin: Springer.

Raschke, P., Verthein, U., & Kalke, J.
1996 *Substitution in Hamburg - Methadonbehandlung Opiatabhängiger von 1990 bis 1995.* Hamburg.

Reuter, B., & Küfner, H.
2002 Ergebnisse der Methadonsubstitution in Deutschland – eine qualitative und quantitative Zusammenfassung. *Suchtmedizin in Forschung und Praxis*, *4(1),* 31-45

Rheinberger, P., & Sander, G.
2000 Methadon-Substitution. Steigende Akzeptanz. *Deutsches Ärzteblatt*, *97(36),* 1733-1734.

Servais, D., & Erkens, M.
2000 Methadon-assoziierte Todesfälle im Raum Aachen. *Rechtsmedizin*, *10(2),* 65-70.

Stoever, H.
2001 *An overview study: Assistance to drug users in European Union prisons*. Lisbon: European Monitoring Centre for Drugs and Drug Addiction.
Ullmann, R.
1996 Vorstellung der DGDS-Leitlinien bei den Suchttherapietagen am 29.05.1996 in Hamburg.
Ulmer, A.
1997 *Die Dihydrocodein-Substitution.* Stuttgart/New York: Thieme.
Verthein, U., Kalke, J., & Raschke, P.
1998 Substitution treatment with methadone in Germany: Politics, programmes and results. *International Journal of Drug Policy*, *9,* 71-78.
Verthein, U., Raschke, P., Kalke, J.
1995 Methadone therapy in Hamburg. *European Addiction Research, 1,* 99-105.
Ward, J., Mattick, R.P., & Hall, W.
1998 *Methadone maintenance treatment and other opioid replacement therapies.* Amsterdam: Harwood Academic Publishers.
Weber, U.
1998 *Maintenance with codeine in Germany*. Paper presented at the conference "Expanded Pharmacotherapies for the Treatment of Opiate Dependence," New York Academy of Medicine, New York City, September 25.
Weil, T.P., & Brenner, G.
1997 Physicians and other ambulatory care services in Germany. *Journal of Ambulatory Care Management, 20,* 77-91.
Whitney, C.R.
1993 Medical care in Germany: With choices and for all. (January 24). *The New York Times.*