



Reviewing current practice in drug-substitution treatment in the European Union

Planning group

Michael Farrell
Annette Verster
Marina Davoli
Margareta Nilson
Petra Paula Merino

Editorial group

Michael Farrell
Samantha Howes
Annette Verster
Marina Davoli
Ulrik Solberg
Gloria Greenwood
Kathy Robertson

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Coordinated by Kathy Robertson and Ulrik Solberg, EMCDDA.

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Foreword

In this edition of its *Insights* series, the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) focuses on one of the most widely discussed drug-related topics in Europe today: substitution treatment. The EMCDDA has devoted much energy in recent years to obtaining greater knowledge on this issue and to disseminating its findings to a wide audience as part of an overall goal to interpret new issues in the drugs field.

The publication builds on the results of a study undertaken on behalf of the EMCDDA by the Osservatorio Epidemiologico Regione Lazio (OERL), Rome, and the National Addiction Centre (NAC), London, in 1998 and 1999.

The main aim of the publication is to offer an overview of the latest patterns and trends in substitution treatment at European level and to present national country profiles on related practices in the European Union Member States. It also strives to illustrate the highly complex nature of the issue, to underscore its nuances and aid comprehension.

At a time when substitution treatment constitutes a topic of considerable political and public interest, I trust that the pages that follow will provide an essential contribution to the work practised and planned in this field of European drug policy.

Georges Estievenart

Executive Director
EMCDDA

Acknowledgements

This publication is the result of an EMCDDA-commissioned study undertaken by the Osservatorio Epidemiologico Regione Lazio (OERL), Rome, and the National Addiction Centre (NAC), London.

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Introduction

Substitution treatment has grown steadily in Europe since its introduction in the 1960s and is now more widespread and accepted than ever before. Nevertheless, up-to-date information in the European Union (EU) Member States regarding this issue, and the evaluation thereof, has been scarce. It was therefore a high priority for the EMCDDA to shed light on this topic and to publish the results.

The decision to carry out a study on substitution treatment was taken when the debate on this issue moved into the spotlight in the mid-1990s. The main reasons for this attention were: the launch of a heroin trial in Switzerland in 1994; the start of levo-alpha-acetyl-methadol (LAAM) treatments in Portugal the same year; the beginning of buprenorphine treatment in France in 1996; and, last but not least, the rapid extension at that time of already existing methadone programmes throughout Europe, especially in Spain and Italy ⁽¹⁾. These initiatives led to an increased focus on substitution treatment itself and to the trajectories it was to follow in the future.

Findings in the field of substitution treatment, and on the evaluation of substitution-treatment programmes, are of high priority to the EMCDDA in the context of its mission to provide ‘objective, reliable and comparable information’ on drugs in the EU and to

⁽¹⁾ Definitions of these and other substitution substances are provided in the section ‘Types of opiate substitution’ on page 24.

promote a ‘culture’ of evaluation to better guide policy-makers on what constitutes effective action. Although the Member States report a growing number of substitution-treatment programmes, and although evaluation of such measures is also growing, this evaluation has yet to become routine. What can be said so far is that substitution treatment, at the individual level, leads to increased physical, psychological and social well-being and reduces criminality. However, there is still remarkably little information available on the quality of treatment on offer and its influence on outcome.

Over the past five years (1995–2000), there has been considerable investment in the development of drug-information systems in all European countries. The establishment by the EMCDDA of the Reitox network of national focal points ⁽²⁾ has made the acquisition of information on individual countries a great deal easier. However, the nature of the data remains complex, with continued difficulty in ascertaining reliable estimates, such as the size of the chronic opiate-dependent population in all countries. In addition, there is considerable variation in how different countries document and monitor data. As regards treatment activity, some countries carefully document each treatment episode, while others leave data collection to more locally or regionally based sources, rendering national estimates more difficult to interpret.

Despite these limitations, a substantial amount of information exists on the different levels of substitution treatment provision. However, although this permits cross-national comparison, it does not adequately allow for regional variations in treatment provision within countries. There are also substantial differences in the organisation of health and social services in different countries, and even the terms used in one country to describe professional roles may not translate very accurately to other countries or settings.

⁽²⁾ Reitox, the European information network on drugs and drug addiction, consists of one national focal point in each EU Member State, one from the European Commission and one observer focal point from Norway. The network is coordinated by the EMCDDA.

The study, which forms the basis of this book, had three main goals:

- to provide an overview of recent trends in the field of substitution treatment in the EU, including the substances used, the range and extent of services and the consumption of substitution substances;
- to present the main characteristics of such treatment in each of the EU Member States, including the role of substitution treatment in the national drug strategy, the monitoring of substitution treatment and the evaluation of substitution-treatment programmes; and
- to disseminate the information obtained (the data and insights) to politicians, decision-makers, professionals and others engaged in the field.

All 15 EU Member States were included in the study. Each country was invited to provide an overview of its treatment system, with a specific focus on drug substitution, using key national informants. These informants subsequently prepared a country report, which was used as background information in the preparation of this published overview.

All key informants were invited to a two-day seminar in Rome (15 and 16 March 1999), where issues of comparability and differences across national programmes were discussed.

The Rome meeting explored key issues in the delivery of methadone and other substitution treatment across the EU. The informants examined the factors influencing the following issues:

- levels of treatment provision;
- accessibility of treatment to users;
- quality of treatment delivery;
- diversification of drug substitution;
- use of primary-care services; and
- delivery of drug substitution within prison settings.

The study represented another step forward in investigating substitution treatment in the European Union. It is the hope of the EMCDDA that an ongoing analysis of the subject will be a move in the right direction towards encouraging an evaluation culture in the field of drug treatment.

Margareta Nilson

**Head of the Demand Reduction Department
EMCDDA**

Substitution treatment in the European Union: an overview and recent trends

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HISTORICAL BACKGROUND

Substitution treatment made its first appearance in the European Union in the late 1960s, when drugs such as opium, morphine and heroin found their way onto the European illegal drug markets. Despite the overall predominance of drug-free therapy at that time, some Member States began launching substitution treatment. However, this only became a major option in the 1980s, mainly in response to the HIV/AIDS epidemic.

Today, all EU Member States run drug-substitution-treatment programmes in some shape or form, although the extent and nature of the treatment vary considerably between countries. Over the last five years (1995–2000), many Member States have reported an expansion in this treatment and the trend is still rising. Between 1993 and 1999, the number of persons in treatment roughly tripled, and, in 2000, it is estimated that over 300 000 drug users in the EU are receiving substitution care from general practitioners (GPs), treatment centres, methadone clinics, mobile ‘methadone buses’ and pharmacies.

The first substitution-treatment programmes launched were methadone programmes, and methadone continues to be the most widespread substitution substance. Despite the dominance of methadone, however, its status has been challenged over the last few years and many Member States now provide alternatives to it.

Table 1 shows when treatment substances began to be prescribed in the EU Member States and offers an insight into the diversity of the substances used in the EU today. Besides methadone, other opiate-addiction substitution substances now include buprenorphine, levo-alpha-acetyl-methadol (LAAM), dihydrocodeine, slow-release morphine and heroin.

Triggered by the Swiss experiment with prescribing heroin to the most deprived drug users (1994–97), the substitution-treatment debate spread to all EU Member States. This led to governmental policy proposals in some Member States, although, to date, only

**TABLE 1: LAUNCH OF SUBSTITUTION AND HEROIN TREATMENTS
IN THE 15 EU MEMBER STATES**

COUNTRY	METHADONE-SUBSTITUTION TREATMENT FIRST AVAILABLE	INTRODUCTION OF OTHER FORMS OF SUBSTITUTION TREATMENT ⁽¹⁾
Belgium	1997	No other substitution treatment given
Denmark	1970	LAAM and buprenorphine (1998) ⁽²⁾ ⁽³⁾
Germany	1992	Buprenorphine (2000) ⁽²⁾ ⁽³⁾ and heroin ⁽³⁾ ⁽⁴⁾
Greece	1993	No other substitution treatment given
Spain	1983	LAAM (1997)
France	1995	Buprenorphine (1996) ⁽²⁾
Ireland	1992	No other substitution treatment given
Italy	1975	Buprenorphine (1999) ⁽²⁾ ⁽³⁾
Luxembourg	1989	Mephenon® (1989) ⁽²⁾ and buprenorphine (2000) ⁽²⁾
Netherlands	1968	Heroin (1997) ⁽¹⁾
Austria	1987	Buprenorphine (1997) and slow-release morphine (1998) ⁽²⁾ ⁽³⁾
Portugal	1977	LAAM (1994) ⁽²⁾
Finland	1974	Buprenorphine (1998) ⁽²⁾ ⁽³⁾
Sweden	1967	No other substitution treatment given
United Kingdom	1968	Buprenorphine (1999) ⁽²⁾

⁽¹⁾ Only ongoing projects have been included. The year refers to when a political decision was taken.

⁽²⁾ Where buprenorphine is mentioned, it is in the form of Subutex® (and not Temgesic®) as this only contains small amounts of buprenorphine.

⁽³⁾ As a trial only.

⁽⁴⁾ Heroin treatment scientific trial (foreseen for 2001).

⁽⁵⁾ Mephenon is methadone in pill form.

Source: Table 2, EMCDDA (2000).

Germany and the Netherlands have actually launched, or are launching, heroin-prescription trials.

The LAAM trial in Portugal spread to Denmark and Spain, while the French experiments with buprenorphine, initiated in 1996, led to small-scale use in Denmark, Germany and Austria and to the granting of a licence for its use in the United Kingdom.

Dihydrocodeine was used for a number of years in Germany, although, since 1998, its use has been significantly reduced by law and it is only used in specific medical cases. Finally, the use of slow-release morphine was initiated in Austria in 1998.

Substitution treatments are almost exclusively targeted at opiate addiction. However, substitution treatments targeted at other addictions do exist, a fact highlighted by the country reports in the second section of this publication.

A report by Farrell (1995) charted the evolution, organisation and diversified nature of methadone treatment in the European Union. Since that report, the use of methadone and other types of substitution treatment has rapidly expanded, particularly in those countries with low baseline levels of provision.

It is now estimated that approximately 300 000 people receive substitution treatment in Europe today, 110 000 in the United States and 20 000 in Australia. While many countries in the world are involved in different forms of drug substitution, the bulk of this treatment to date is still carried out in these three areas. These overall estimates would suggest that approximately half a million people are involved in drug-substitution treatment globally.

DEVELOPMENT OF OPIATE-RELATED PROBLEMS IN THE EUROPEAN UNION

There are striking similarities across Europe in the timescale of the development of illicit drug problems. It is clear that problems occurred on a very limited scale until the late 1960s in all countries. Then came a dramatic change in the 1970s and 1980s with the epidemic growth of heroin addiction.

Greece, Spain, Portugal and Finland appear to have developed heroin problems at a later date, probably on account of political and geographical factors. However, some north European countries, such as Sweden, have experienced higher levels of amphetamine abuse and dependence and comparatively low levels of heroin dependence.

Number of problem opiate users

Estimates of the size of the opiate-dependent population in different countries need to be interpreted with particular caution (EMCDDA, 1998). Few countries have effective monitoring systems and prevalence data are generally educated estimates. The sources of data vary, with some figures derived from national surveys, others from capture–recapture studies ⁽³⁾ and most from the extrapolation of treatment and criminal justice indicator data.

Given these data limitations, it is not possible to provide clear estimates; thus, for the purposes of this report, the data have been collapsed into comparable groups (Table 2). The data are population adjusted to represent those aged 15–64. The figures collated originate from country informants and from the EMCDDA's *Annual report on the state of the drugs problem in the European Union* (EMCDDA, 2000). Estimates range from 200 to over 600 opiate-dependent subjects per 100 000 population aged 15–64. The overall impression is that, despite some variation, each country now has a sizeable and comparable long-term opiate-dependent population.

Route of administration

There are considerable variations in the proportions of addicts who smoke and inject drugs across the EU. Again, accurate information is unavailable in most countries. However, in Greece, Italy and Luxembourg, injecting rates are high, with reports of 70–80 % of addicts entering drug-treatment programmes being opiate injectors. Conversely, in the Netherlands, it is estimated that only 14 % of users entering treatment for opiate addiction actually inject (EMCDDA, 1998).

⁽³⁾ 'Capture–recapture' is one of the major methods used in epidemiology to estimate hidden populations. Also known as 'mark–recapture', it involves 'capturing' a random sample of individuals who are 'marked' and returned to their habitat. A second sample is then 'recaptured' and the marked persons from the first sample are observed.

**TABLE 2: ESTIMATED NUMBERS OF PROBLEM OPIATE USERS
PER 100 000 POPULATION
AGED 15–64 IN THE 15 EU MEMBER STATES**

	COUNTRY (ORDERED ACCORDING TO PREVALENCE)	NUMBER OF PROBLEM OPIATE USERS PER 100 000 POPULATION AGED 15–64
Lowest	Germany	200–400 per 100 000 population (0.2–0.4 %)
	Finland	
	Sweden	
	Austria (¹)	
	Netherlands	
	Greece	
	Belgium	
	Denmark	
	Ireland	
	France	
Highest	Portugal (¹)	400–600 per 100 000 population (0.4–0.6 %)
	Spain	
	United Kingdom	
	Italy	
	Luxembourg	Over 600 per 100 000 population (over 0.6 %)

(¹) These figures are not research based but estimates provided by country informants and have been added to this table for the purpose of this *Insights* publication.

NB: Given the difficulties in measuring the size of the problem opiate population, many calculations are based on educated estimates.

Source: Figure 8, EMCDDA (2000).

HIV and AIDS

In many countries, maintenance substitution treatment developed, often reluctantly, in response to the HIV risk associated with injecting opiates and other drugs. As a result, the latter half of the 1990s saw the containment of new AIDS cases among injecting drug users (IDUs) in most countries. In Germany, for example, only 12 % of the AIDS cases reported in 1997 were among IDUs (Robert Koch Institut, 1998). However, some countries still have a relatively high incidence of AIDS amongst drug injectors. For example, in Portugal, 45 % of reported AIDS cases recorded in 1997 were IDUs (CNLCS, 1998). The EMCDDA's annual reports provide prevalence estimates for HIV and AIDS among injecting drug users (EMCDDA, 1999; see also Table 3).

**TABLE 3: PREVALENCE OF HIV INFECTION
AMONG INJECTING DRUG USERS
IN THE 15 EU MEMBER STATES**

COUNTRY	PREVALENCE OF HIV INFECTION AMONG INJECTING DRUG USERS IN THE EU MEMBER STATES (%)
Belgium (French Community)	1.6
(Flemish Community)	2.2
Denmark	(0–3.4)
Germany	3.8
Greece	0.5–3.2
Spain	32
France	15.5–17.3
Ireland	3.5
Italy	16.2
Luxembourg	3.0
Netherlands	(1–26)
Austria	0–(2)
Portugal	14–(48)
Finland	(3)
Sweden	2.6
United Kingdom (England and Wales)	1

NB: Comparability is limited because figures are from different sources and reflect different methods.

Figures for Germany and Italy relate to opiate users in treatment and underestimate prevalence among injectors.

Information based on local data is given between brackets.

Source: Complementary statistical tables to the EMCDDA Annual report 2000 (see <http://www.emcdda.org>).

The growth in the provision of methadone services has been mirrored by a reduction in the incidence of AIDS cases related to injecting drug use in most EU countries. The link between these trends is complex, but, overall, there are now reasonable data to support the case that, at an individual level, methadone treatment, along with other harm-reduction measures, is an effective component of HIV prevention. In parallel, substantial medical advances have been made in delaying the onset of AIDS.

Hepatitis

While HIV appears to have been contained, the introduction of tests for hepatitis C has indicated that there are high rates of the hepatitis C virus (HCV) among injectors in all countries. In Germany, for example, a study by Batz (1997) suggested that around 50 % of IDUs have become infected with hepatitis B and 70–80 % with hepatitis C. In Portugal, recent surveys estimate that 85 % of those who inject drugs are infected with the hepatitis C virus (Godinho et al., 1996). Similarly, at a drug-addiction outpatient department in Austria, hepatitis C antibodies were found in 80 % of a random sample of drug users attending the clinic (Gombas et al., 1998).

Most estimates of the prevalence of hepatitis are based on clinical samples and need to be interpreted with a degree of caution until larger community samples have been completed. However, the high rates of hepatitis C in most countries present a significant public health challenge similar to that of HIV in the 1980s.

It is likely that strategies for prevention will be similar to those for HIV, and will include methadone treatment and programmes aimed at lowering the frequency of sharing and injecting among IDUs and at reducing the progression to injecting drug use from other forms of drug use.

Drug-related crime

The rise in drug use in Europe over recent decades has led to a series of related problems, one of the most significant being the increasing involvement of drug users in criminal activities. Two prime issues have come to the fore:

- the increasing number of drug users in Europe, and the consequently increasing visibility of drug-related problems, has highlighted the issue of drug use and public nuisance; and
- the rise in drug-related crime has led to an increased need for finding responses to reduce crime.

Providing drug users with a substitution substance, most often in the form of methadone, is a way of attempting to reduce and prevent drug-related crime and of dealing with the problem of public nuisance. Research in recent years confirms that methadone-substitution treatment reduces crime committed by addicts (Leuw, 1995; Gossop et al., 1998).

Drug- and methadone-related deaths

There are several major problems in assessing methadone-related deaths:

- the criteria used to classify cause of death differ across countries;
- it is difficult to establish what contribution substitution substances make to deaths which involve other central nervous system (CNS) depressants (such as alcohol and benzodiazepines); and
- some countries have more vigilant monitoring and investigation of drug-related deaths than others, which may create the impression that they have a higher drug-related death rate.

However, it is clear that countries such as the United Kingdom (Neeleman and Farrell, 1997) and Germany (Heinemann, 1998) have identified a significant problem associated with methadone-related deaths. Most studies have found that methadone- and opiate-related deaths are more common among those not in treatment (Stenbacka et al., 1998). Similarly, in France, there has been a considerable number of casualties implicating the use of buprenorphine (Tracqui et al., 1998). In Austria, Seidler et al. (1996) conducted a survey of opiate-related overdoses amongst hospital admissions in Vienna. Figures for individual countries are presented in the second section of this report.

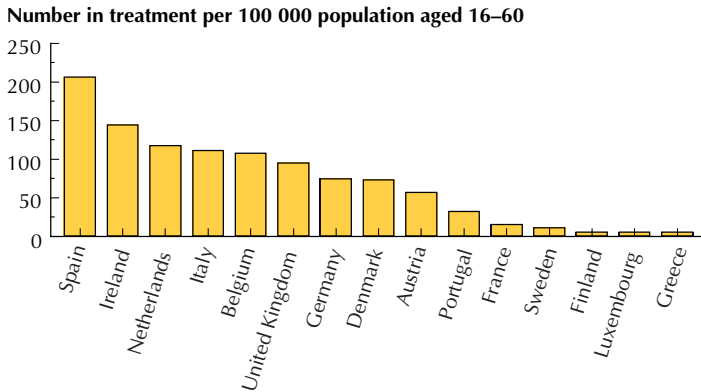
DEVELOPMENT OF METHADONE-SUBSTITUTION TREATMENT

Methadone-substitution treatment has a long and varied history across Europe, where changes in medical opinion and legislation have led to developments and changes in prescribing practices. Table 1 above provides an indication of when formal methadone-substitution treatments began in each country. It is important to note that, in countries such as Denmark, the Netherlands, Sweden and the UK, where methadone has been available since the late 1960s, the number of opiate addicts receiving methadone was relatively small in the early years.

Numbers in methadone-substitution treatment

In many countries, it is difficult to establish the exact size of the methadone-treated population, partly because of the absence of centralised data-gathering systems. The figures presented in

**FIGURE 1: ESTIMATED NUMBER OF DRUG USERS
IN METHADONE-SUBSTITUTION TREATMENT
IN THE 15 EU MEMBER STATES (1997)**



Source: EMCDDA (1998).

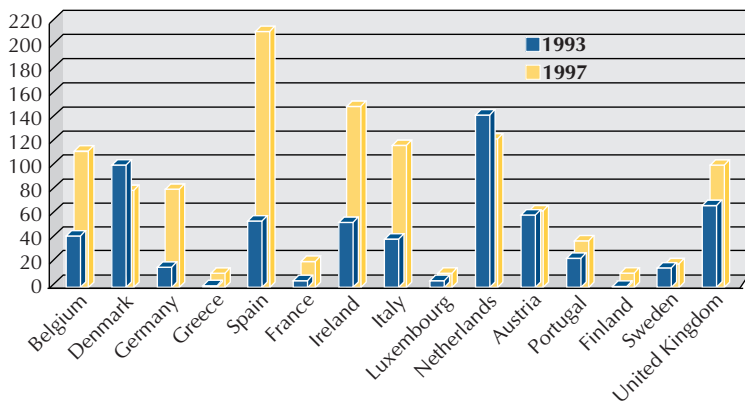
Figure 1 represent the best estimates for those receiving methadone treatment (whether for maintenance or detoxification) in 1997. The figures have been population adjusted and range from a high of 207 treated in Spain (per 100 000 population aged 16–60) to a low of 6 treated in Finland, Luxembourg and Greece (per 100 000 population aged 16–60).

It is important to note that, in most countries, there are huge regional variations in the provision, organisation and delivery of methadone treatments (e.g. Bühringer et al., 1995).

A rapid expansion in services

Over the past five years, all countries except Denmark and the Netherlands have seen a rapid expansion in the provision of substitution services. This is most evident in Germany, Spain and France, and in countries with low baseline levels of provision, such as Greece, Luxembourg and Finland. The impetus for this expansion in substitution treatments has largely been a response to

FIGURE 2: ESTIMATED NUMBER OF ADDICTS IN METHADONE-SUBSTITUTION TREATMENT PER 100 000 POPULATION AGED 16–60 (1993 AND 1997)

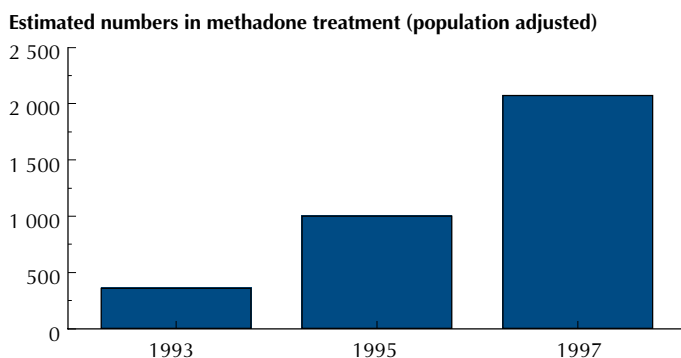


Sources: Annual reports of the International Narcotics Control Board (INCB) and the EMCDDA.

the HIV epidemic and its links to injecting drug use. In Spain and Italy, for example, it has been estimated that more than 60 % of AIDS cases are injecting drug users. Other influences include growing waiting lists for treatment and the fact that political and public opinion often favour harm-reduction approaches to opiate dependency as a way of reducing the public nuisance caused by drug users and drug-related crime.

Individual country figures illustrating the increase in the number of addicts treated with methadone are shown in Figure 2. Figure 3 indicates the cumulative increase across the 15 EU Member States.

FIGURE 3: INCREASE IN THE NUMBERS OF DRUG USERS RECEIVING METHADONE IN THE 15 EU MEMBER STATES (1993–97)



NB: All figures are population adjusted to 100 000 population aged 16–60.
Sources: EMCDDA (1998) and data from country informants.

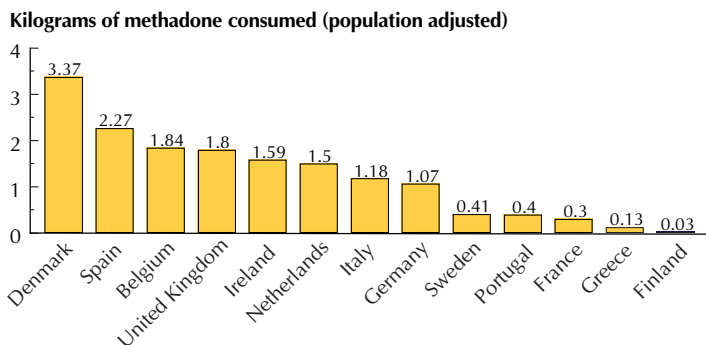
While most countries have experienced relatively few problems during this growth period, concern has been expressed in some Member States regarding the lack of training and skills of some practitioners now involved in substitute prescribing, particularly amongst non-specialist services, including general practitioners and pharmacists (IMR, 1997; Gerlach and Caplehorn, 1999;

Ministero della Sanità, 1999). There is also concern regarding controls on substitute prescribing and the risk of possible diversion of substitution substances onto the black market.

Methadone consumption

The amount (weight) of methadone consumed by all countries is recorded by the International Narcotics Control Board (INCB) ⁽⁴⁾. However, the quality of information is influenced by national approaches to data gathering. In line with overall increases in substitution treatment and possibly dosage, there has been a corresponding increase in methadone consumption. Figure 4 shows population-adjusted consumption figures for 1996. Trends in methadone consumption across the different countries are shown in Figure 5.

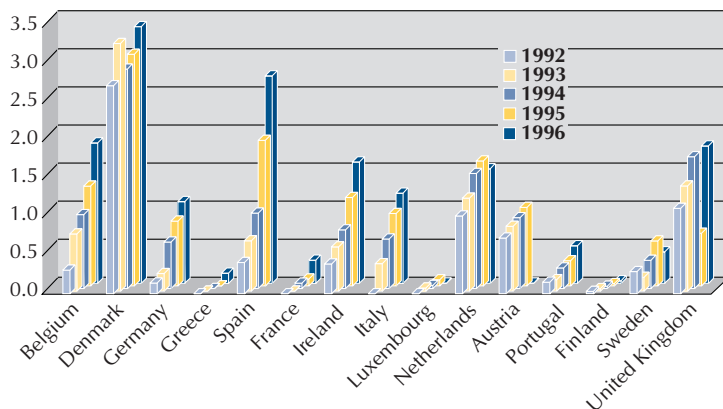
FIGURE 4: NATIONAL METHADONE CONSUMPTION (KILOGRAMS) PER 100 000 POPULATION AGED 16–60 (1996)



NB: Data unavailable for Austria and Luxembourg.
Source: International Narcotics Control Board (INCB).

⁽⁴⁾ The International Narcotics Control Board, established in 1968, is the independent and quasi-judicial control organ for the implementation of the United Nations drug conventions. The board is independent of governments and the United Nations, although it is funded by the latter (see <http://www.incb.org>).

**FIGURE 5: TRENDS IN METHADONE CONSUMPTION (1992-96)
(KILOGRAMS OF METHADONE CONSUMED
PER 100 000 POPULATION AGED 16-60)**



Sources: EMCDDA annual reports and data from country informants.

TYPES OF OPIATE SUBSTITUTION

Buprenorphine

Buprenorphine is a very long-acting agonist-antagonist opioid ⁽⁵⁾.

France has developed buprenorphine as its main agent for opiate-maintenance treatment (Auriacombe et al., 1997). Austria has developed some diversified buprenorphine treatment programmes (Diamant et al., 1998; Fischer et al., forthcoming). Buprenorphine is now being marketed in a range of European countries as an alternative form of opiate-maintenance treatment. In Finland, it is used for detoxification and, in Denmark, for both detoxification

⁽⁵⁾ Agonists are drugs that activate opiate receptors in the brain's reward system thereby creating the effect of drug consumption. Agonist-antagonists also activate opiate receptors in the brain but simultaneously limit or eliminate the effects of other drugs taken.

and maintenance therapy. The average daily dose dispensed across countries where information was available was around 8 mg daily.

Dihydrocodeine

Dihydrocodeine is a short-acting semi-synthetic ‘weak’ agonistic opioid.

Dihydrocodeine has been used in many settings, particularly where restrictions inhibit the use of methadone or where patients cannot tolerate methadone. There has been very limited evaluation of its use, but practitioners report that it is useful for detoxification and for those with low levels of opiate dependence (e.g. Krausz, 1998). Specific legislation has been enacted in Germany to restrict and control the use of dihydrocodeine following an increase in ‘grey substitution’ and codeine-related deaths.

Heroin

Heroin, pharmaceutically diamorphine hydrochloride, is a short-acting ‘strong’ agonistic opiate.

Heroin has been the subject of heated political debate in relation to substitution treatment. A large-scale outcome study has been completed in Switzerland (Uchtenhagen et al., 1997), an experimental trial is under way in the Netherlands and there are proposals for a further study to be launched in Germany in the near future. Denmark, Spain and Luxembourg have also been involved in debates about the possible use of heroin for maintenance therapy. There are low levels of heroin provision in the UK (Marsden et al., 1998).

Levo-alpha-acetyl-methadol (LAAM)

Levo-alpha-acetyl-methadol is a very long-acting synthetic agonistic opioid.

Portugal has extensively used and evaluated LAAM (Patrício et al., 1996) and, outside the EU, the United States has conducted similar experiments. It is reasonable to predict that there will be a major expansion in the use of LAAM in the near future in Europe, as a number of countries (e.g. Denmark and Spain) are beginning to run trials and introduce LAAM into services.

Methadone

Methadone, pharmaceutically methadone hydrochloride, is a long-acting synthetic agonistic opioid.

Oral forms of methadone constitute the vast bulk of substitution prescribing. It is reasonable to estimate that, apart from in France, over 90 % of opiate substitution is delivered in the form of methadone hydrochloride. There is some variation in whether it is dispensed as a concentrate or in a more dilute form. The concentrate form probably poses a greater risk for opiate-related toxicity.

Methadone tablets are used in the Netherlands, the UK and some other countries. In the UK, they have been associated with diversion and injectability, and efforts are under way to control and restrict the prescribing of this form of methadone.

Injectable medications are provided in some countries. In the UK, injectable methadone is prescribed in possibly 10 % of methadone treatment (Sheridan et al., 1996). This has not been subject to any major evaluation to date. Only one pilot study of injectable versus oral methadone has been carried out in the UK, which is yet to be reported on. Swiss studies included injectable methadone, but clients expressed a strong preference for heroin and the methadone trial had to be discontinued because of insufficient sample size.

Slow-release morphine

Slow-release morphine, sometimes referred to as prolonged-action morphine, consists of morphine sulphate, which is a long-acting agonistic opiate.

In Austria, slow-release morphine can be prescribed for maintenance therapy, although only in special clinics (Fischer et al., 1996). In France, a very cautious estimate is that around 2 000 individuals receive slow-release morphine. At the beginning of the 1990s, an experiment with morphine was carried out in Amsterdam, but the subsequent trajectory of the project is uncertain.

DEVELOPMENT OF SUBSTITUTE-PRESCRIBING SERVICES

Community resistance to the development of drug-treatment services

Establishing new centres for the provision of treatment can be particularly difficult. Drug services can be seen to attract undesirable elements into localities and to be associated with loitering, drunkenness, intoxication and burglaries. Most countries report some community resistance to treatment programmes. However, resistance from the local community has been found to be most common before programmes and centres are established and, once they become operational, the neighbourhoods seem to accept them. In some countries, active protests within the local community have impacted on the choice of sites and the opening hours of clinics. For example, in Ireland, services in Dublin were subject to major restrictions because of court action taken by local traders. This resulted in low levels of service and severely restricted opening times.

Once services were operational, problems centred on nuisance and it was often reported that groups of clients tended to congregate around the treatment premises. Measures to combat these problems included the use of mobile units, such as the methadone buses in Spain, Italy and the Netherlands, and active collaboration with the police. In addition, processes of community consultation have been developed to provide information regarding the benefits of service provision, in particular a reduction in neighbourhood crime.

The objectives of treatment

Most countries use methadone for a range of purposes, from short-term use for detoxification purposes to longer-term maintenance therapy. Today, most countries have accepted the importance of maintenance as part of a harm-reduction strategy, with particular relevance for HIV prevention and reducing drug-related crime. Greece, Finland and Sweden continue to have very high-threshold services, with limited overall access.

TABLE 4: THE BALANCE BETWEEN METHADONE MAINTENANCE AND DETOXIFICATION TREATMENT (1998)

COUNTRY	MAINTENANCE OR DETOXIFICATION
France Ireland Portugal Sweden	Primarily maintenance (75–100 % of treatment aimed at maintenance)
Denmark Germany Spain Netherlands Austria Finland United Kingdom	50–75 % of treatment aimed at maintenance
Greece Italy	Primarily detoxification (under 30 % of treatment aimed at maintenance)

NB: Data unavailable for Luxembourg and Belgium.

Source: Country informants. It is important to note that these data are not generally based on research but on informed and educated estimates.

Table 4 above shows the balance between detoxification and maintenance prescribing across 13 of the 15 EU Member States. It is important to note that the estimates provided are not generally research based but are intended to offer a qualitative overview based on informed and educated estimates made by country informants.

Detoxification

Most countries have no clear mechanism to distinguish between detoxification and other forms of substitution treatment. Some countries, such as Germany and Sweden, have high levels of provision of inpatient detoxification facilities. During the 1990s, forms of non-opiate detoxification, such as the alpha-adrenergic agonists lofexidine and clonidine ⁽⁶⁾, have been developed and are widely used in some countries. There is also interest in the use of buprenorphine, which is a partial agonist that may play a role in both detoxification and maintenance.

In addition, some countries have seen an explosion of interest in other forms of rapid opiate detoxification, some using light sedation and others general anaesthetic. These procedures sometimes include antagonisation with naltrexone ⁽⁷⁾.

Maintenance prescribing

Most countries now appear to have a significant population of heroin users on methadone-maintenance treatment and to place greater emphasis on long-term maintenance. It is also clear, however, that abstinence is the ultimate goal of treatment in most countries.

⁽⁶⁾ Alpha-adrenergic agonists such as lofexidine and clonidine are antihypertensive agents; that is, they suppress withdrawal symptoms such as restlessness, lacrimation, rhinorrhea and sweating.

⁽⁷⁾ Naltrexone is an opioid antagonist that hinders, or drastically decreases, the effect of opiates taken.

Access to methadone treatment

The demand for treatment has continued to increase faster than investment in, and expansion of, services. There has also been a rise in polydrug use, particularly involving stimulants and benzodiazepines, for which there is currently little evidence of any benefit from substitution treatment.

Access to treatment is largely dependent on treatment provision. In Sweden, for example, in 1997, only 600 maintenance places were available across the whole country, and only 650 were available in Greece. Waiting lists are also common in many countries. There are huge regional variations in the provision of treatment within countries, as services tend to be developed primarily in major cities.

Access is also dependent on the inclusion criteria of treatment programmes. In some countries, strict criteria are imposed (e.g. Sweden: four years' intravenous use, age 20 +, opiate as main drug and not incarcerated). In other countries (e.g. Denmark, Spain and Italy), addiction to opiates (as defined by the World Health Organisation's 10th edition of the International Classification of Diseases — ICD-10) is the only entry criterion.

Many countries report limited access to treatment for specific populations, most notably the young (under 18), mentally ill and homeless. On the other hand, pregnant women and those with HIV infection have priority access in most countries.

INTEGRATION OF SERVICES

Specific legislation in a number of countries has attempted to enhance links between the criminal justice and health sectors. The growing size of the addicted population in prisons has also emphasised the need for better links between criminal justice agencies and drug services. The challenge of combining alcohol and drug services also remains a key dimension of service development. In some countries with increasingly large numbers of

HIV-positive drug users, integration with general medical and HIV services has become a necessity. In other countries, concern regarding tuberculosis has resulted in good links between drug services and respiratory and tuberculosis services. In the long-term drug-dependent population, the growth of morbidity of clients with both major psychiatric and physical problems is becoming more evident and the need for a mixture of skills to address these problems is a key part of a long-term service planning strategy.

Mental health services

There is now substantial recognition of, and greater clarity concerning, patterns of overlap in psychiatric morbidity in the drug-dependent population. Two cohorts are well described in Germany and Greece, indicating high rates of psychiatric morbidity among this population (Krausz, 1998) and in the UK (Farrell et al., 1998). All countries reported co-morbidity as being problematic for treatment.

The care of drug-using clients with mental health problems depends on the links between psychiatric and drug services. In Italy, Finland and Sweden, good links have been established, with specialist dual diagnosis wards. In other countries, links between services are poor. In France, integrated care is restricted, as legislation prevents practitioners from prescribing substitution treatment and psychiatric medication simultaneously.

Primary care and general practitioners

There are major variations in the concept of primary care in the different countries and this renders it difficult to draw comparisons. Some countries, such as Ireland and the UK, use primary care as a gateway to secondary-care services, whereas in other countries, such as Germany and France, the primary-care and secondary-care interface is not so clear.

In many countries (e.g. Spain and Italy), general-practitioner (GP) involvement is low, due partly to a perception of clients being

difficult and unstable and partly to legal constraints. Denmark has initiated new controls on primary-care involvement and has restricted the capacity of primary-care practitioners to prescribe methadone. The UK has seen a push for a major expansion in shared care, involving general practitioners in the provision of drug services.

Prisons

It is estimated that 15–50 % of prisoners in European countries have a history of drug use. Prisons contain a unique concentration of severe drug problems and require particular attention to ensure provision of a broad range of treatment interventions. The past decade has seen substantial growth in both the development of approaches to divert individuals away from prison to treatment alternatives and in the development of a range of services within prisons.

Provision of methadone treatment within prisons varies considerably across countries. Spain and Austria have high levels of provision. In Spain, it is estimated that 60 % of drug users in prison receive methadone. In Austria, maintenance treatment has been offered in all prisons since 1991, and social and psychotherapeutic approaches are also offered. On the other hand, no prisons in Sweden provide methadone and, in Belgium, Germany, Greece, Ireland, Italy, the Netherlands, Portugal and the UK, provision is minimal, apart from when used for the purposes of detoxification.

Eligibility for entering a methadone programme in prison largely depends on levels of treatment provision. In all countries where a programme is available, a user receiving treatment outside the prison setting can continue treatment inside. In the UK, where provision is low, it is estimated that a third of those who are receiving methadone treatment before entering prison also receive it in prison. In Austria and Spain, however, a drug user can begin treatment on entering prison.

There have been a number of problems with providing methadone in the prison context. In the UK, inappropriate use in non-tolerant individuals has resulted in a number of deaths, with one prison medical officer losing his licence to practise as a result.

In Ireland, there have been two reported deaths amongst prisoners who were not prescribed methadone in prison. On release from prison, their tolerance had fallen and, consequently, they overdosed.

Pregnancy and childcare

Methadone maintenance is currently the recommended treatment for pregnant drug-using women, as opposed to detoxification (Fischer et al., 1998). In all countries, pregnant women are offered a fast track into drug-misuse services and, in many countries (e.g. Austria, Sweden and the UK), specialist services have been developed in order to help pregnant women. For many opiate-dependent pregnant women, problems begin after the child is born. There have been few studies of neonates, although it has been estimated that up to 60 % of neonates born to opiate-dependent women suffer from abstinence syndrome. Many countries operate foster schemes for individual children or for whole families, whereas other countries rely on the more traditional extended family structures to arrange appropriate childcare.

LEGAL CONTROLS AND SERVICE DEVELOPMENTS

Over the past decade, substitute prescribing of methadone or other opiate agonists has become available in all 15 European Union countries, albeit with considerable variation in levels of provision. All countries are signatories to the Vienna conventions ^(a) and conduct appropriate monitoring of the production, distribution and consumption of these drugs in order to minimise

^(a) 1961 Single Convention on Narcotic Drugs; 1971 Convention on Psychotropic Substances; 1998 United Nations Convention against the Illicit Traffic in Narcotic Drugs and Psychotropic Substances.

the risk of diversion onto the black market. There is considerable variation across countries as to who can prescribe substitute medication for the treatment of drug dependence (Table 5). Key aspects of these changes are briefly outlined below.

Country-by-country ⁽⁹⁾

Belgium: There is no legal framework regarding the provision of methadone in Belgium. Methadone is available through general practitioners, and criteria for entry to substitution programmes aim to be flexible. Substitution with other substances is marginal, although the introduction of buprenorphine is under discussion.

Denmark: A law was introduced in 1996 with the aim of tightening controls and improving the quality of treatment by handing over the responsibility for substitution treatment to the Danish counties. The result of this is that the general practitioners' involvement in substitution treatment has been significantly

TABLE 5: PRESCRIPTION PRACTICE IN THE 15 EU MEMBER STATES

COUNTRY	PRESCRIPTION PRACTICE
Greece Finland Sweden	Specialised centres, limited number
Denmark Spain France (methadone) Italy Netherlands Portugal	Specialised centres
Belgium Germany France (buprenorphine) Ireland Luxembourg Austria United Kingdom	General practitioners (GPs)

⁽⁹⁾ See also the country reports in the second section of this publication.

reduced and that the counties now run the units that hand out methadone. There has been an overall drop in the numbers in substitution treatment, but this has not impacted on the opiate-related mortality rate.

Germany: A rapid expansion in the number of addicts prescribed methadone has been observed in Germany. There have been several key changes in legislation and the regulations regarding substitution treatment. Legislative changes have also occurred which attempt to restrict the provision of dihydrocodeine.

Greece: A change in the law in 1993 allowed for the development of methadone services. Four specialist treatment centres with over 650 patients have been established and are run by a single central State organisation. General practitioners are not permitted to prescribe methadone.

Spain: A major expansion of services has occurred in response to high rates of HIV among injecting drug users in the country. Although methadone treatment on a larger scale only started in the mid-1990s, Spain appears to have the highest level of substitution provision in Europe. This is primarily provided in specialist centres, with very little general-practitioner involvement. There is substantial regional variation in service provision.

France: There has been no actual legal change in France, but a change in prescription regulations has meant that the numbers receiving methadone have increased from 50 to 5 000 and those receiving buprenorphine have risen from 0 to 60 000 over the past five years. Methadone is currently approved for prescription by any doctor working within specialist substance-abuse services, and buprenorphine is approved for prescription by any doctor in any facility. Over 90 % of methadone is given in specialist settings, but it is also possible for stabilised individuals to transfer to primary care.

Ireland: A law was introduced in 1998 to facilitate the rapid expansion of drug services with primary-care involvement. A system was introduced whereby each individual seeking substitution treatment requires a treatment card containing a photograph and

details of identity, which is issued by a central coordination unit and bears the name of both the patient and the general practitioner providing treatment. This has resulted in a substantial expansion of general-practitioner and community-pharmacist involvement. It has also reduced both the number of drug users with individual practitioners and overall methadone diversion. At the same time, this approach has maintained a good degree of confidentiality.

Italy: Methadone treatment has been permitted since 1980 and is offered through specialised centres. In 1993, there was considerable variation in provision, with an estimated 33 % of addicts receiving methadone in one region and 77 % in another. Approximately 50 % of methadone treatment is offered as part of a detoxification schedule. The proportion of clients receiving methadone in public treatment centres in Italy increased from 30 % in 1991 to 47 % in 1997 (Ministero della Sanità, 1999).

Luxembourg: The law was changed in 1999 in order to formalise existing practice. The majority of treatment is provided by general practitioners.

The Netherlands: The number of addicts receiving methadone and the level of methadone consumption have been more stable over the last five years than in many other EU Member States. Legislative changes were made in 1995 in order to reduce public nuisance caused by problem drug use. It is part of the national drug policy to make methadone widely available, thus methadone buses drive around the streets of many Dutch cities.

Austria: The Narcotics Maintenance Decree of 1987 permitted the prescription of narcotics in the treatment of drug dependence. All practitioners, both specialist and general, can prescribe, but the general practitioners have little training and support in this area of clinical activity. A new law in 1998 made substitution treatment (mainly with methadone) more readily available.

Portugal: Specialised services are provided through the government-funded organisation, the Serviço de Prevenção e Tratamento da Toxicoddependência (Service for the Prevention and Treatment of Drug Addiction), which provides both methadone and LAAM

treatment. There are plans to develop more low-threshold services ⁽¹⁰⁾, with the participation of non-governmental organisations (NGOs) and general practitioners.

Finland: Since 1997, Finland has run a specialist university hospital centre where 40 patients receive treatment. Initiation involves a two-week hospital admission for detoxification and methadone induction and subsequent attendance at a specialised outpatient clinic. There is no general-practitioner involvement.

Sweden: Methadone services were established in the late 1960s and have been subject to periods of major restriction in development. The services are now located in four specialist centres and there are substantial data on those receiving 'high-threshold' intensive treatment, including the somatic and psychological services provided. No general practitioners are permitted to prescribe methadone.

United Kingdom: New clinical guidelines for the treatment of drug dependence have been developed. These stipulate that patients should be administered with supervised consumption of medication in at least the first three months of treatment. There are also proposals for the development of a new licensing system, where a special licence would be required for any prescribing other than an oral methadone mixture for the purposes of drug-dependence management.

In **central and eastern Europe**, the availability of methadone-substitution services has also increased. Methadone maintenance constitutes one of the main treatment modalities in Slovenia and Lithuania, while, in Bulgaria, the Czech Republic, Estonia, the Former Yugoslav Republic of Macedonia (FYROM), Latvia and Poland, substitution programmes are generally operated on a pilot basis or as a single-treatment service. In Hungary, psychiatrists and general practitioners can prescribe methadone on an individual basis (EMCDDA, 1998).

⁽¹⁰⁾ Low-threshold services are those allowing relatively unrestricted access. High-threshold services, on the other hand, are those allowing access according to specific entry requirements and criteria.

While there is much discussion on the regulation and control of substitute prescribing across the EU Member States, it appears that the actual mechanisms of monitoring such activities are rather limited and that, once substitution programmes are established, they have considerable freedom in the day-to-day organisation of their activities. However, limited attention has been paid to maintaining high standards or developing methods to ensure that even minimum standards are achieved across the broad range of services. The link between such guidelines and the operational details around the organisation of services will be an important influence on the development and evaluation of these programmes.

PROBLEMS FOR SERVICES

Alcohol and polydrug dependence

The issues of alcohol and polydrug dependence remain a major problem for treatment services. Estimates suggest that approximately one quarter of service users have major problems with alcohol or with cocaine, amphetamines and benzodiazepines.

This type of dependence is associated with high-risk behaviour, management problems, higher rates of mortality from drug overdoses and poorer outcome overall. To date, there has been very limited research to indicate the optimal approach to the management of this group.

Diversion and methadone-related deaths

There is very little information on methadone-related deaths, as classifying the cause of death is difficult. It is known that methadone reduces mortality, but it is reasonable to assume that the more methadone is consumed, the higher the risk of death. In the UK, a study revealed that, in 1992, 45 % of opiate overdose deaths involved methadone. However, deaths from methadone

were more common amongst those not enrolled in methadone treatment (Hall et al., 1998).

Measures to prevent diversion include supervised consumption (where an addict takes his/her methadone in the presence of drug clinic staff), short dispensing intervals (e.g. daily pickup) and central registration of all methadone prescribed (as in the Netherlands). All new methadone patients across most countries are generally supervised during consumption for the first few months of treatment

The distribution of naloxone (a short-acting antagonist) amongst drug users in Italy, where it is available without a medical prescription, was a measure introduced to prevent overdosing. Other countries (e.g. Greece, Spain, the Netherlands and Austria) educate drug users on how to prevent an overdose or how to deal with it when it happens. In Greece and Italy, special ambulances are available for those who have overdosed.

MONITORING AND EVALUATION

Despite considerable evidence that programme organisation is a major influence on outcome for substitution treatment, there is a striking absence of quality control, monitoring and evaluation of individual programmes. The following two strategies need to be implemented:

- routine gathering of clinical data in a fashion that can account for the activities of the organisation and delivery of services; and
- development of a range of diverse interventions.

There is a striking dearth of activity on both fronts.

Some countries, however, have conducted evaluation projects. Current levels of provision at national level have been surveyed in Spain (Domingo-Salvany et al., 1999), where the roles of individual professionals and their treatment impact have also been studied (Observatorio Español sobre Drogas, 1998).

In Germany, a number of evaluation projects have been conducted in different regions (e.g. Auts, 1996; Raschke et al., 1996). In France, there has been some evaluation of changes in buprenorphine prescribing and also some detailed evaluation of certain individual programmes (Segal and Schuster, 1995). In the UK, a national treatment outcome study (Gossop et al., 1998) was initiated in 1996 which plans to follow a cohort of drug users entering treatment over time. In Italy, besides some local evaluation studies (D'Ippoliti et al., 1996, 1998), a national treatment outcome study began in 1998 which also plans to follow a cohort of drug users entering different types of treatment over time.

CONCLUSIONS

Over the past five years, there has been considerable convergence in the models of drug-service delivery in most European countries, with a major expansion in drug-substitution treatment, mainly methadone maintenance. At the same time, the predicted HIV epidemic among injecting drug users appears to have been momentarily contained.

A broader range of accessible substitution-treatment programmes has been developed. These low-threshold programmes are now quite widely delivered in many countries. Those countries that have expanded methadone treatment more recently (such as Greece and France) have followed a more specialised high-threshold approach. However, in France, the use of buprenorphine in a low-threshold service runs parallel to a high-threshold methadone service.

As a point of divergence, countries such as Denmark have moved to restrict the overall activity of general practitioners, in contrast to many countries (such as Ireland and the UK) where significant policy initiatives have been taken to involve general practitioners in the management of drug dependence.

Prisons remain an area where there is major variation in levels of provision. There are limited evaluation data to guide policy-makers

in determining the best course of action for the future. More evaluation of delivered prison treatment is needed.

Training for generalists and specialists and good models of co-operation are necessary if services are to be developed and maintained at a high standard. There are limited formal training programmes and equally limited mechanisms of accreditation for workers in this field, in most settings. Models of delivery range from purely specialist to predominantly primary care, and there is a need for better integration between primary-care and specialist approaches. Pharmacists are playing an increasingly active role in this form of treatment and have the potential to make a major contribution to substitution services. Regular monitoring, and improved communication among the various individuals involved in treatment provision, could significantly improve these services.

Diversion, drug-related deaths and methadone-related deaths continue to be a substantial problem in some countries, but levels of diversion are extremely hard to quantify. Countries with lower levels of supervision are more likely to report higher rates of diversion. There is a tendency for countries with very high levels of control to reduce these in order to increase levels of access and, conversely, for countries with low levels of supervision to increase controls.

Over the past five years, substantial growth has been seen in the evaluation of treatment that has been undertaken. The science and treatment evaluation culture continues to grow and has been promoted through research and training networks across the European Union. There have been large-scale national treatment evaluation projects, such as the 'National treatment outcome research study' (NTORS) in the UK, as well as many smaller-scale outcome evaluation studies. Awareness of the importance of evidence-based approaches to the planning and delivery of drug treatment is also growing. The Cochrane Collaboration (an international collaborative group aiming to promote evidenced-based practice through the organisation of systematic reviews of key areas of health interventions) is developing a register of trials and reviews of treatment interventions.

Given the extent of current services across Europe, very limited research and evaluation of the treatment process has been carried out to date. Such research would provide good data, not just to confirm the benefits of treatment but also to identify factors associated with good treatment. Factors might include:

- quality of management and organisation of services;
- quality and skill mix of staff; and
- the level of multidisciplinary and inter-agency work (to ensure good links across a range of community agencies).

A substantial consensus now exists on the benefits of methadone maintenance. Systematic reviews indicate that such treatment can improve psychological and social well-being, and reduce criminality and HIV transmission. There is a need for further research to determine the role of such treatment in reducing hepatitis C transmission.

In conclusion, the last five years have represented a period of considerable change and development in response to drugs. It is now generally recognised that treatment for drug dependence requires multiple approaches that combine drug-substitution with drug-free treatment. The challenge for the next decade is to determine the optimal methods for delivering high-quality treatment and ensuring that this is provided in all settings. Also, evidence regarding the cost-effectiveness of drug treatment strongly supports the case for further investment in this activity in all countries. Current work on developing models for evaluating cost-effectiveness needs to be strengthened.

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PREPARING THE COUNTRY REPORTS

This section consists of country reports from the 15 European Union Member States which, among others, demonstrate how substitution practice differs in Europe, both according to the substances used as well as to national legislation and policy ⁽¹⁾.

A national expert or informant was appointed in each of the countries concerned and asked to provide information according to specific guidelines. These guidelines consisted of six headings:

- Introduction;
- Strategy;
- Substitution;
- Surveillance;
- Problems;
- Evaluation.

The first of these sections offers a general introduction to substitution treatment in the country concerned and situates it in the overall political context.

The second provides an overview of the national drug strategy; that is to say the national policy in the field of drugs and other drug-related areas (e.g. health-related issues and social security).

The third section provides information on the substitution services available in each country and has a number of subheadings. These subheadings may vary per country, but in general deal with: the development of substitution services, their history and characteristics; the current situation and the number of persons currently receiving treatment; legislation on substitution treatment; substitution clients and the entry criteria for receiving treatment; the role of pharmacies; primary healthcare involvement in services; the

⁽¹⁾ The EMCDDA's *Annual report on the state of the drugs problem in the European Union — 2000* may also be consulted for a brief overview of substitution treatment in the EU Member States. This was compiled on the basis of data from national reports submitted by the 15 national focal points of the Reitox network.

various substances used in the country; and, finally, whether injectable substances can be prescribed.

The fourth section, on surveillance, provides an overview of how national monitoring is carried out in each country.

The fifth identifies current problems in the field of substitution which pertain to the particular situation in each Member State.

Finally, the sixth section focuses on the evaluation of substitution treatment and presents findings of recent relevant studies and research. These data address the implementation and organisation of substitution services, the substitution substances currently used, and other related aspects of substitution treatment.

BELGIUM

Juan Tecco and Isy Pelc, Hôpital Brugmann, Brussels

Introduction

In 1994, the Belgian Ministry of Public Health organised a methadone consensus conference. This conference was a key moment in the field of addiction in Belgium as it concluded that access to substitution treatment was desirable. Due to the absence of a legal framework in the country on this issue, the conclusions of the conference became a reference point for both the clinicians and authorities working in the area of substitution treatment. An evaluation of the conclusions of the conference was performed between October 1997 and June 1998, under the auspices of Professor Isy Pelc of the Hôpital Brugmann, Brussels. The methodology used consisted of auditioning national experts from various backgrounds in order to access various points of view. Most of this country report draws on the conclusions of that evaluation.

Strategy

In 1997, the Belgian Parliament and the Council of Ministers adapted the existing drug-enforcement law ⁽¹²⁾, by making penal justice the 'last resort' in cases of serious nuisance.

At this time, Belgium's drug policy priorities were also redefined. They included:

- prevention and reduction of drug use;
- reduction of the number of new drug users;
- protection of the community and its members against the drug phenomenon and its consequences; and
- provision of care to drug users and readiness to guarantee them a better life despite their use of drugs.

⁽¹²⁾ Ministry of Justice directive of 5 June 1997 on the policy to be applied in the prosecution of drug users.

Belgium's federal internal affairs policy is embedded in a philosophy of crime prevention. Meanwhile, in the communities and regions, a growing effort is being invested in striving for 'global' prevention, with a focus on general health and welfare.

In 2000, three types of service exist in Belgium, which are low threshold in nature and offer treatment for drug use. They are:

- inpatient centres;
- outpatient centres; and
- primary-care services.

These promote abstinence, harm reduction and methadone maintenance.

Substitution

Methadone substitution in Belgium is considered to be an efficient therapeutic strategy for:

- enhancing the general well-being of opiate-addicted patients; and
- promoting their social and psychological stability.

Today, in Belgium, the promotion of methadone substitution for treating physically, psychologically and socially addicted patients has three specific goals:

- to increase professional opportunities;
- to reduce criminal behaviour; and
- to prevent the spread of HIV and hepatitis.

Current situation

Considerable diversification and flexibility have evolved within the field of substance substitution in Belgium in recent years, specifically in the following cases.

- Methadone is now used extensively in general medical practice and is no longer confined to specialised centres.
- Flexibility exists in the traditional criteria for methadone maintenance, such as age, previous treatment and history of heroin dependence (these are simply guidelines for evaluating each individual case).
- Treatment programmes are flexible, due to a lack of data supporting successful outcome in specific programmes.
- Methadone substitution can be continued in prison. For the moment this only concerns patients who were in substitution treatment before being incarcerated. At present, treatment in prison consists of progressive withdrawal, but it is anticipated that substitution will soon be initiated in prison and used, not only for withdrawal, but also for maintenance.
- Between 1983 and 1992, substitution treatment was impossible without psychotherapeutic or psychosocial counselling. The setting for treatment was either a specialised centre or a network of clinical practitioners (the latter started in 1989). Due to the general trend towards flexibility, a change has occurred in the traditional therapeutic framework. Outpatient methadone prescription is losing some of its hitherto psychological focus while the somatic point of view, including treatment of associated somatic diseases, is gaining ground. The consequences of this change cannot yet be quantified, but it is probably partially responsible for the exponential increase in methadone treatment in the last few years.
- Opiate substitution involving substances other than methadone is rare in Belgium. It is recommended that other opiates be replaced by methadone (and eventually buprenorphine). Benzodiazepines and barbiturates are not accepted for opiate substitution.

Recommended clinical practice

In 2000, methadone treatment is started at a dose of 30 mg. This is evaluated within 48 hours in order to adapt the treatment, if necessary. It is recommended that, for the first six weeks, patients have their methadone administered by a pharmacist on a daily basis. An exception to this rule are patients who have professional

commitments which are incompatible with daily visits to the pharmacy. Substances other than methadone (and eventually buprenorphine) are avoided. Benzodiazepines and barbiturates are not considered for opiate substitution.

Accidents have occurred, particularly when an adult's treatment was accessible to a child. Patients should be informed of the potential dangers for children. General practitioners (GPs) should limit the number of patients following a substitution regime and favour medium- and long-term perspectives. Registration on a specific clinical-case register is strongly recommended.

Development of substitution services (low threshold)

The type and number of formal and informal restrictions for admission to treatment define a threshold. When the threshold is low, only minimal conditions for being accepted on a substitution programme are imposed.

A threshold always exists because the process involves admission to a programme and delivery control (the quantity of the substance delivered at a time is limited). The purpose of the low-threshold policy in Belgium is to allow less-motivated or socially marginal patients access to methadone substitution and its related harm reduction.

Pioneers of the low-threshold policy, the organisation Médecins sans frontières (Doctors without Borders), have developed a programme in Brussels offering free consultation in strategic geographic areas. Their target population includes those who are excluded from the healthcare system and the social system in general.

Another and very different initiative is the 'Maisons d'accueil socio sanitaires' (MASS) project ('Socio-sanitary shelters'). Co-financed by the Ministry of Health and the Ministry of the Interior, this project favours the integration of various professions, although the focus and role of each have to be clearly defined. The centres run by the project offer temporary accommodation to drug addicts

who are severely socially excluded, and often even excluded from specialised centres. Not all of the shelters provide methadone substitution. However, if they do not have the qualified medical personnel, they collaborate with outside resources willing to initiate or pursue methadone treatment.

Substitution clients

A system was established in the 1960s to register the transactions of pharmacies, based on distributors' sales to them. Due to a lack of resources, this covers only 68 % of the sales. If the available data are extrapolated, it is found that 111.8 kg of methadone were sold in Belgium in 1996, 106.9 kg of which were used for maintenance treatment. This can be confirmed through other sources. In 1996, only one pharmaceutical company was selling methadone in Belgium, and this company estimates its sales for that year at 114 kg. In 1994, a survey of over 500 patients in the city of Liège estimated the average methadone-maintenance dose at 40 mg/day.

There is considerable variation in maintenance prescription across the different regions of the country:

- methadone is prescribed less in the Flemish provinces than in the southern part of the country;
- methadone prescription in the region of Brussels is four times higher than the national average; and
- the region of Hainaut rates second, with a delivery twice as high as the rest of the country.

The Hainaut province borders France, and the French cities of Lille, Roubaix and Tourcoing are close by. It is estimated that 680 French patients underwent methadone maintenance in the Belgian province of Hainaut in 1994.

Period before methadone use

It appears that heroin addicts are seeking methadone treatment sooner than in the past. In 1996, a survey of 345 methadone users in the city of Charleroi revealed that:

- 18 % started methadone within the first year of beginning heroin use;
- 19 % started methadone between one and two years after;
- 26 % started methadone between two and three years after; and
- 37 % started methadone at least three years after.

Methadone in prison

Since 1995, methadone has been used in most prisons. Methadone is usually used as a progressive withdrawal treatment and not as a substitution treatment. It should be noted that around one half of prisoners have experienced problems related to the consumption of illegal drugs and that one third have experienced heroin-consumption problems.

Substances prescribed

The consensus conference in 1994 recommended methadone (or buprenorphine) for substitution treatment. When patients are taking substitution opiates other than heroin, it is recommended that they be switched to methadone. In 2000, other therapeutic strategies are being developed through pilot studies.

Injectable prescribing

Three universities are currently involved in a pilot study of medically controlled heroin delivery in the city of Liège. Injected methadone is forbidden.

Surveillance

Belgium is a heterogeneous country with three official languages, and many health-related issues are not federally, but regionally, planned. Regions have a great deal of autonomy in their political decisions, which has the advantage that surveillance activities in the country are closely tailored to local conditions. However, heterogeneity also brings structural disadvantages such as difficulties in implementing general plans and policy.

Problems

Heterogeneity results in inequalities in treatment provision across the country. Much attention has focused on variations in therapeutic strategies across market areas and the related question of whether differences in attitudes are due to socioeconomic/cultural variables or to uncertainty about making specific recommendations.

Evaluation

An interministerial commission, under the auspices of the Minister for Health, and a Belgian agency dedicated to the promotion of prevention and implementation of drug programmes, is trying to implement evaluation programmes for substitution treatment and to overcome the abovementioned obstacles.

DENMARK

Peter Ege, Municipality of Copenhagen

Introduction

Denmark has a population of just under 5.3 million, and democratic elections take place at three levels: national, regional and local. The regional level comprises 16 counties and the local level 275 municipalities. The responsibilities of regional and local government are defined by legislation passed by the Danish Parliament.

Since 1996, the county authorities have been responsible for the health services (primary care and hospitals) and for the treatment of drug users, including methadone prescription. Local authorities are responsible for general social welfare. In accordance with the law, the treatment of drug users is carried out in close cooperation with the county authorities, and responsibilities are allocated according to action programmes which have been previously agreed.

Strategy

Drug abuse is considered a complex problem, requiring coordination across job demarcation lines and sectors. The campaign against drug abuse is conducted both locally and centrally, and is based on:

- persistent and targeted preventive action;
- multi-pronged, optional, coordinated treatment; and
- effective control.

The Ministry of Health is responsible for coordinating drug policy at national level. Under the Serviceloven under den sociale lovgivning (Social Welfare Act), the Ministry of Social Affairs is responsible for treatment carried out in in- and outpatient institutions, and rehabilitation and care units. Questions relating to

medical treatment, including methadone prescription and the links between HIV and drug abuse, are the responsibility of the Ministry of Health. The Narkotikarådet (Council on Narcotics) is an interdisciplinary, advisory specialist body which monitors the development, secures the quality and improves the coordination of overall action against drug abuse within the areas of prevention, treatment and control. The council was set up under the Ministry of Social Affairs and is an advisory body to parliament and the ministries involved.

The level of local autonomy in planning, development and innovation is substantial, and so marked differences exist between counties in the organisation of treatment.

In 1997, 542 inpatients and 3 215 outpatients received treatment. In 1995, DKK 170.3 million (EUR 22.8 million) and in 1998 DKK 445.8 million (EUR 59.7 million) were spent on treatment.

Substitution

Development of substitution services

In the 1970s and early 1980s, the publicly funded addiction services were abstinence oriented, and therefore stubbornly against any form of substitution treatment. Methadone was only used for detoxification. However, as early as the late 1960s, methadone was used by general practitioners (GPs) as a substitution treatment for the growing number of addicts. The number of addicts increased sharply in the 1980s and, at the beginning of the 1990s, around 2 500 drug addicts were receiving methadone substitution from GPs, a figure that remained stable until 1996. In 1984, the Council on Narcotics, under the Ministry of Social Affairs, published a report on the treatment of drug addiction which recommended that methadone-substitution treatment be viewed as 'normal' and just as useful and legitimate as abstinence-based treatment. From that point onwards, methadone treatment gradually became integrated into publicly funded addiction care. There is still some resistance to the concept of substitution treatment, even among the personnel who provide such treatment.

Several reports by the Sundhedsstyrelsen (National Board of Health) and the Council on Narcotics discouraged (but did not prohibit) the involvement of general practitioners in substitution treatment. In reality, this was not enforced, and no action was taken against doctors who offered treatment. Attitudes varied from GP to GP. Many were (and still are) reluctant to treat drug addicts, whereas others saw it as a normal part of medical practice. Many saw it as a necessary evil which they were forced to adopt because of pressure from the patients and/or a lack of relevant substitution treatment in the public health system.

On 1 January 1996, Danish legislation rendered methadone treatment a county council remit (see 'Legislation on substitution treatment' below). The objectives of the change were to ensure that methadone prescription be coordinated with other treatment, that the circumstances of the user be scrutinised before prescribing and that alternative treatment be offered. Another objective was to limit the diversion of methadone. This change in legislation implied that only doctors employed in the county treatment system (including hospitals) could be authorised both to decide if a person were to be offered methadone treatment and to initiate the treatment. However, the treatment of stabilised persons may be delegated to a GP (15 % of all cases), but the county still has the final responsibility for the treatment and has an obligation to keep both the patient and the doctor under surveillance. The legislation represents a dramatic shift from a period of total permissiveness to one of strong regulation. As a result of this legislation, the capacity of the treatment system doubled, and sometimes even tripled, between 1996 and 1998, an expansion which was not without its problems.

Current situation

At present, 4 500 persons are in methadone-substitution treatment. Of these:

- 75 % are men;
- the mean age is 36 (interquartile range 29–42);

- 90 % are on transfer income (welfare payments, disability pensions); and
- between 10 and 30 % are homeless.

Only a small percentage belong to ethnic minorities.

It is estimated that there are currently 15 000 drug addicts in Denmark. The total treatment capacity (substitution and abstinence-based treatment) comprises 542 inpatient and 3 215 outpatient places. Staff/client ratios vary considerably, but, on average, it is about 1:20. Almost all substitution treatment is carried out at outpatient clinics.

As a rule, cooperation between the criminal justice system and the county treatment systems is good. Treatment is not disrupted by imprisonment. Collaboration between the treatment system and the health service is more problematic. In practice, drug users are often excluded from inpatient care in particular, on the grounds that their behaviour is unacceptable.

Drug problem surveys estimate the addict population (defined as individuals dependent on one or more illegal substances) to be about 15 000, of which 5 000 are living in the city of Copenhagen (7 500 in Greater Copenhagen — city and suburbs). HIV infection is estimated to affect 4 % of drug users and 80–90 % are estimated to be infected by hepatitis B and/or C. Statistics regarding drugs and crime show that 35 % (1 300) of the prison population are drug users. The number of persons charged with drug-related crime was 8 700 in 1996.

Legislation on substitution treatment

Until 1996, the right to prescribe methadone treatment lay with physicians. Some physicians tried to coordinate action concerning methadone treatment, for example by establishing cooperation with district medical officers. In addition, the municipal and county council treatment systems employed physicians who, apart from assessing the individual person's medical state, also decided on any methadone treatment. While the majority of drug users were

prescribed methadone by their GP and others received it from physicians at public treatment centres, physicians in the Copenhagen area set up special private clinics which were almost exclusively targeted at drug users (numbering about 400) receiving methadone treatment.

The new legislation on methadone treatment which came into force on 1 January 1996 (see above) aimed to ensure that methadone treatment takes place within the context of a more comprehensive approach. This included scrutinising the overall circumstances of the user before prescribing methadone and offering the methadone user supplementary treatment (including counselling, psychosocial support, rehabilitation, etc.).

No special licence is required for prescribing, but the above-mentioned legislation dictates that only doctors employed in the counties public treatment institutions are allowed to initiate the substitution treatment.

Monitoring procedures are laid down by the National Board of Health. According to their guidelines, urine tests for relevant legal and illegal substances should be carried out at least monthly.

Treatment registers have been established in every county. In 1996, a new national register of drug users in treatment was established by the National Board of Health in cooperation with the treatment centres in the counties. The register includes all persons treated for drug abuse by the county and/or municipal centres, irrespective of the form of treatment.

The degree of control and sanction varies considerably from county to county. In some treatment centres, clients are monitored very closely, with frequent urine controls. Expulsion from treatment is a real threat in cases of contaminated urine. Other centres use urine testing on a small scale, and do not use sanctions against, but simply react to, the use of illegal drugs.

Substitution clients

Opiate dependency (as defined in the World Health Organisation's 10th edition of the International Classification of Diseases — ICD-10) is the only entry criterion for substitution treatment in Denmark. Psychotherapy and social care are, as a rule, both required and available. Appropriate support (education, employment) is offered, although not systematically, and generally only to a limited extent.

Pharmacy activity

Pharmacies have dispensed prescribed methadone to addicts since the late 1960s. The greater part of methadone dispensing took place at pharmacies until 1997, when the treatment institutions gradually began to take over. However, pharmacies still play an important role in substitution treatment, although there is no specific training given.

The professional bodies have been divided in their attitude to the pharmacies' role as a service to drug addicts. All of them dispense methadone, but many of the professional bodies believe that pharmacies should play a limited role, except in cases where addicts are stable. From 1986 to 1996, pharmacies dispensed needles and syringes to addicts (paid for by the county), but most pharmacies have since stopped this activity because of nuisance problems. In fact, there has been some reluctance on the part of pharmacies to become further involved in treatment on account of these problems.

Primary-care involvement

In Denmark, all citizens have access to free medical care and are assigned to a local GP. Since the late 1960s, GPs have been involved in the treatment of drug addicts. One important reason for this was the refusal by treatment institutions to offer methadone-substitution treatment. As a result of the new legislation

in January 1996, many patients in methadone treatment were transferred from their GP to the public treatment institutions, and GPs were no longer permitted to initiate methadone treatment. However, as mentioned above, treatment of stabilised patients may be delegated to the GP and this has now occurred in about 15 % of all cases. A significant outcome of this law has been that the number of patients in methadone treatment with their GP has greatly diminished. Only one local study has been undertaken of primary-care involvement (in 1983) in Copenhagen (Winsløw and Ege, 1985; Winsløw et al., 1986).

Primary care is only offered to patients who have been delegated by the county to the GP. The county (and its treatment and social institutions) still has responsibility for the overall treatment plan, so the GP can obtain any support necessary from the local treatment centre. If a GP finds it difficult to manage a patient in substitution treatment, he can always refer the patient back to the county treatment centre. GPs currently do not receive training in substitution treatment.

The view of the Almindelige Danske Lægeforening (Danish Medical Association) is that drug users should be treated primarily in public treatment institutions, but that GPs also have an important role to play:

- as the drug user's primary contact with the health system; and
- as a provider of substitution treatment to the socially and medically stable patient.

However, many GPs refuse to engage in substitution treatment.

Substances prescribed

Methadone has almost exclusively been the substance of choice for substitution treatment in Denmark. However, from 1998, LAAM was also used in substitution treatment and buprenorphine in substitution and detoxification.

Methadone is prescribed at 50–120 mg daily. LAAM is prescribed at 50–120 mg three times weekly and buprenorphine at 1–12 mg daily. Methadone is usually dispensed as a mixture but sometimes as tablets. LAAM is also prescribed as a mixture and buprenorphine as sublinguettes (tablets placed under the tongue).

Substitution treatment is generally not provided for addictions other than heroin addiction, although, in practice, benzodiazepine substitution is given to some patients where detoxification is deemed impossible.

Surveillance

Since the mid-1970s, monitoring of the drug situation in Denmark has mainly been based on indirect sources (indicators). At present, the following indicators are used:

- clients in treatment for drug abuse;
- persons in lengthy methadone treatment (more than five months);
- drug users in prison;
- persons admitted to somatic and psychiatric hospitals with an abuse-related diagnosis;
- drug-related mortality;
- infectious diseases (HIV, hepatitis);
- the number of seizures and amount of confiscated drugs;
- the price and purity of drugs seized on the streets; and
- charges for violation of drugs legislation.

These indicators offer time-series data, making comparisons over time possible.

There is a great need to render the collection and validation of data, and the analysis of the data and indicators, more scientific. There has been some progress in this direction, especially as regards data on clients in treatment for drug abuse, and also with regard to drug-related mortality. A drug database is being developed, which, by pooling individual-related data from four

registers, should facilitate estimations of the numbers of drug users and monitor developments in the various cohorts.

Problems

Services face many problems, such as:

- lack of capacity;
- insufficient medical services;
- antagonism towards substitution treatment, even among some of the personnel who administer the treatment; and
- problems with handling the control aspect of the treatment.

Furthermore, there has often been great resistance to the establishment of new clinics (the 'not in my backyard' attitude). However, as a rule, established clinics seem to have good relationships with their neighbours. Generally, there is no problem with nuisance, such as loitering around the clinics.

The number of drug users in prison has increased since 1986, now comprising 35 % of all prisoners (approximately 3 000 in all). The policy of the Direktoratet for Kriminalforsorgen (Directorate for Prison and Probation Services) is that drug users in prison should be offered treatment coordinated with the social services and treatment institutions outside the prisons. Thus, in principle, treatment (including substitution treatment) should not be interrupted because of imprisonment.

Diversion is not perceived to be a great problem in Denmark.

Evaluation

Since the evaluation of substitution treatment in general practice (Winsløw and Ege, 1985), there has been no systematic evaluation of substitution treatment in Denmark, except for small qualitative investigations into consumer satisfaction. This can be ascribed to a general lack of interest in research and evaluation in the social

services, lack of funding, etc. However, plans to evaluate the area are under way.

It is known that, for Copenhagen, the retention rate in treatment is very high, at approximately 90 %. The mortality rate, which was less than 1 % in 1997, went up to 1.7 % in 1998 and 1.2 % in 1999. This increase is probably due to an increase in mortality from somatic diseases, primarily hepatitis C.

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GERMANY

Ralf Gerlach, Institut zur Förderung qualitativer Drogenforschung, akzeptierender Drogenarbeit und rationaler Drogenpolitik (INDRO e. V.), Münster

Introduction

Germany has a population of about 81.5 million. Several methods of estimating prevalence of drug use have been implemented in the country with varying techniques and definitions. There is a hidden population of controlled and recreational heroin users that can hardly be estimated by number, let alone be recorded statistically (Weber and Schneider, 1997). Taking all estimates as a basis for estimating the total number of opiate users, we can arrive at an approximate figure of between 100 000 and 200 000 heroin users, at least half of which are compulsive users (Hoffmann, 1998). Thus the rate per 1 000 inhabitants is between 1.2 and 2.5.

In a European context, Germany was relatively late as regards the introduction of substitution treatment, having introduced methadone treatment in 1992. Germany has taken legal steps which favour harm reduction and assistance over law enforcement. As a result, Germany now allows the use of other substitution substances, such as LAAM and buprenorphine, and treatment with heroin. However, it has to be borne in mind that Germany is a federal State and hence the use of these substitution substances is not evenly spread across the country.

Strategy

Drug addiction is considered an illness in Germany following a decision by the Bundessozialgerichtshof (German Federal Social Court) of 18 June 1968 which, within the social law, recognised it as such. This has been the basis of German drug policy ever since.

A variety of measures and activities are seen as necessary in order to reduce individual and social risks connected to drug problems. Under the coalition agreement of the German Federal Government in 1998, education, prevention and assistance for drug addicts, as well as law enforcement for criminal drug trafficking, are cited as ways of tackling drugs and addiction.

The Parlamentarischer Staatssekretär im Bundesministerium für Gesundheit (Parliamentary Secretary of State of the Federal Ministry of Health) is the Drogenbeauftragte der Bundesregierung (Drug Commissioner of the Federal Government), following a decision taken by the federal cabinet on 18 November 1998. The fact that responsibility for drug policy shifted from the Ministry of the Interior to the Ministry of Health at that time indicated that health and social aspects of addiction were to take precedence over enforcement, following the general rule 'help comes before law enforcement'. Prosecution of those involved in the production, distribution and possession of drugs, however, remains the responsibility of the Ministry of the Interior, the state ministries and customs authorities, which operate across borders.

Over recent years, preventive activities have increased, both in number and quality, and will be of considerable value in the future. Preventive measures will be targeted at specific groups. The services offered for drug addicts have been much developed over recent decades and today are both differentiated and professional. Self-help groups in the field of drugs are seen as an important element in achieving and sustaining a drug-free life and mental and social stability for substitution clients.

Policy developments in the field of substitution treatment

The federal government has identified harm reduction and practical survival support as important objectives of the new drug and addiction policy. This was motivated by the poor health status and social impoverishment of many drug addicts, especially injecting heroin addicts, in the open drug scene in some capitals. Infections such as HIV, hepatitis B and C, as well as psychiatric or somatic diseases, are special risks. Through different measures which are

described below, the plan is to reduce health risks, by addressing the risk factors associated with drug use, and to reduce pressures caused by drug supply and drug-related crime, while still observing the overall strategy of a drug policy oriented towards abstinence from drugs.

Substitution

In July 1999, the federal cabinet passed a bill for the 3. Betäubungsmitteländerungsgesetz (third amendment of the Narcotics Act). This was designed to close gaps concerning the authorisation of prescribing narcotics. On the one hand, quality standards will be formulated for the medical doctors who prescribe substitution substances. On the other, a registration system for patients in substitution will be installed.

In general, qualified substitution of opiates by methadone (and, in exceptional cases, codeine) will be continued and will also be extended to where it has previously been unavailable. One effect of medical prescription and administration of substitutes has been that the medical aspects of methadone treatment have demanded increased attention. A lack of standards has been mentioned by critics concerning psychosocial care, which is seen as insufficient in quantity and quality in many cases.

Heroin-supported treatment

In recent years, through the rapid expansion of low-threshold treatment, as well as through inpatient and substitution-based treatment and rehabilitation, a high-quality system of drug treatment has developed. In many cases, this has offered opiate addicts a chance to withdraw from the drug scene and successfully progress towards abstinence. However, it is also of concern that certain drug addicts are still not being reached.

This has also been the experience of other countries and, as a result, they have investigated other methods of intervention oriented towards motivation and substitution. Based on the results

and experiences of the Swiss and Dutch models, a clinical multi-centre study of ambulatory heroin-supported treatment of heroin addicts is scheduled to be launched in Germany in 2001. The study under consideration will include the clinical trial of heroin-based prescriptions, and, in addition, is expected to clarify whether heroin-supported treatment can help those opiate addicts for whom the existing services have failed. The main aims of such treatment would be:

- to stabilise the health and social situation of such addicts;
- to integrate them successfully into the help system;
- to keep them within the help system; and
- to motivate them to undertake further treatment.

The study will also research if and how:

- heroin-supported treatment may be incorporated into the treatment offered to opiate addicts; and
- risks for public security may be limited.

At a later stage, the study will examine the development of drug use in opiate-addicted clients, their motivation for treatment and the psychosocial consequences, as well as the consequences of heroin-supported treatment for public order and penal law. On the basis of paragraph 3.2 of the *Betäubungsmittelgesetz* (German Narcotics Act), the *Bundesinstitut für Arzneimittel und Medizinprodukte* (Federal Institute for Drugs and Medical Devices) can sanction such a scientific study. The study will need to take account of the following factors:

- national and international narcotics law;
- the *Arzneimittelgesetz* (Pharmaceutics Law), which aims to protect people in clinical trials;
- the *Arzneimittelprüflinien* (regulations for the testing of pharmaceuticals); and
- the rules of good clinical practice.

In February 1999, under the responsibility of the Ministry of Health, a coordination group was created, composed of representatives of interested municipalities and the German federal states

as well as a representative of the Bundesärztekammer (Federal Medical Association). This group has developed a framework outlining the general targets of the trial, its legal basis and so on. On the basis of this framework, a call for tender was agreed upon by all participants and published in the *Bundesanzeiger* (Federal Gazette) and on the Internet. Cologne, Essen, Frankfurt, Hamburg, Hanover, Karlsruhe and Munich are expected to participate in the trial initially, and other cities may join later. Parallel scientific research in this framework is fully funded by the Federal Ministry of Health.

Development of substitution services

Until the early 1990s, methadone could only be administered to drug users when highly specific indication criteria were met (e.g. emergency cases, such as life-threatening conditions of withdrawal or severe pain). In general medical practice, however, German doctors were not allowed to prescribe methadone to treat heroin addicts (Gerlach and Schneider, 1994).

The 1970s and 1980s were dominated by a rigid adherence to the abstinence paradigm. The therapeutic ideal of permanent abstinence for all opiate users was considered the only valid premise for providing practical survival support and the only valid criterion for successful drug treatment. Long-term participation in drug-free therapeutic communities was proclaimed as the 'royal road to recovery'. There was general opposition to drug-substitution treatment from politicians, medical professionals and authorities, researchers (scientists), therapists, counsellors, and social (drug) workers (Gerlach and Schneider, 1991; Kalke, 1997a). Methadone-maintenance treatment was considered to be medical malpractice. However, there were a few general practitioners (GPs) who ignored the legal regulations and prescribed methadone to opiate addicts, but most of these lost their medical licence in court as a result of evidence presented by medical experts. As a result, some GPs began prescribing legal substitute opioids such as codeine or dihydrocodeine, as these substances were not restricted by law. Other doctors followed this example and, over many years, in fact until February 1998, codeine was

prescribed to large numbers of addicts through a loophole in the narcotics regulations.

In the mid-1980s, the emergence of a variety of factors finally provoked demands for alternative, harm-reduction approaches to the treatment of drug addiction. These factors included:

- HIV/AIDS;
- increasing addict criminality;
- increasing mortality rates among drug users; and
- the narrow range and lack of attractiveness of abstinence-oriented services.

However, it was only after several pilot programmes showed methadone-maintenance treatment (MMT) to be effective that the Gesetzliche Krankenversicherung (GK — German Social Health Insurances (SHI)) approved this treatment modality and introduced, in 1991, the Neue Untersuchungs- und Behandlungsmethoden-Richtlinien (NUB-Richtlinien — new guidelines for diagnosis and treatment). These guidelines were drawn up by the Bundesausschuß der Ärzte und Krankenkassen (Federal Association of Physicians and Public Health Insurance Organisations). The German Narcotics Act was revised in 1992. The guidelines only concern the reimbursement of treatment costs by the public health insurers. (For a detailed description of the German healthcare and insurance system, see Weil and Brenner, 1997, and Busse et al., 1999.)

Current situation

Compared with 1997, the number of first-time registered users of so-called 'hard drugs' (opiates, cocaine, amphetamines, ecstasy) increased by 1.7 % in 1998 to a total of 20 943. The Bundeskriminalamt (Federal Bureau of Criminal Investigation) reported a slight decline (1.3 %) in first-time registered heroin users in 1998 compared with 1997 (amphetamines: + 20.2 %; cocaine: + 10.6 %; ecstasy: – 25.5 %) (Bundeskriminalamt, 1998a). In 1997, 240 554 criminal offences were committed by users of hard drugs. According to investigations by the German

police, 1 criminal offence in 13 was committed by hard drug users in 1997 (Bundeskriminalamt, 1998b).

Drug-related deaths have been registered since 1969. Table 1 shows the annual figures from 1969 to 1998. Drug-related deaths increased from 0 in 1969 to 623 in 1979. After 1979, mortality rates decreased and remained relatively stable over the next 10 years. Since 1989, drug-related deaths have increased dramatically, reaching their highest level in 1991 with a figure of 2 125. From 1992 to 1997, death rates decreased again. However, the 1998 figures once again showed a slight increase in drug-related deaths.

TABLE 1: DRUG-RELATED DEATHS IN GERMANY (1969–98)

YEAR	NUMBER OF DRUG-RELATED DEATHS	YEAR	NUMBER OF DRUG-RELATED DEATHS	YEAR	NUMBER OF DRUG-RELATED DEATHS
1969	0	1979	623	1989	991
1970	29	1980	494	1990	1 491
1971	67	1981	360	1991	2 125
1972	104	1982	383	1992	2 099
1973	106	1983	472	1993	1 738
1974	139	1984	361	1994	1 624
1975	195	1985	324	1995	1 565
1976	344	1986	348	1996	1 712
1977	392	1987	442	1997	1 501
1978	430	1988	670	1998	1 674

Source: *Jahrbücher zur Frage der Suchtgefahren*, Bundeskriminalamt.

It is estimated that about 20 % of all injecting drug users (IDUs) are HIV positive. The percentage of infection rates differs between various regions and study settings. The annual number of AIDS cases among IDUs decreased from 228 in 1989 to 125 in 1997. Regarding the routes of infection, intravenous drug use made up 14 % of all diagnosed AIDS cases in 1998 (and 12 % in 1997) (Robert Koch Institut, 1998, 1999).

While the rate of new HIV infections has stabilised over recent years, there is yet another serious challenge to the drug aid system. The rates of infection with different forms of the hepatitis virus

have long been underestimated and have now reached alarming proportions. Recent studies on hepatitis among IDUs suggest that about 50 % become infected with hepatitis B and 70–90 % with hepatitis C (Bätz, 1997).

Despite strong restrictions on substitution treatment (described below), the number of patients receiving methadone maintenance funded by public health insurance (SHI) increased from about 1 000 in April 1992 to around 20 900 in April 1998. The data presented in Table 2 give an overview of the growth in methadone substitution in the 11 old federal states of former West Germany since the implementation of the new guidelines. The latest data available on the number of SHI-funded substitutions in the eastern parts of Germany date back to 31 December 1996. According to Zerdick (1997), the number of methadone patients was 4 in Brandenburg, 4 in Mecklenburg-Western Pomerania, 31 in Saxony, 2 in Saxony-Anhalt and 5 in Thuringia.

TABLE 2: GROWTH OF THE NUMBER OF METHADONE PATIENTS IN STATUTORY (PUBLIC) HEALTH INSURANCE (SHI) IN GERMANY (1991–98)

YEAR (RANDOMLY SELECTED DATES)	NUMBER OF PATIENTS (¹)
October 1991	Introduction of the NUB guidelines
April 1992	c. 1 000
July 1992	c. 1 500
October 1992	c. 3 100
March 1993	c. 4 500
April 1994	c. 9 700
April 1995	c. 13 500
April/June 1996	c. 19 000
April 1998	c. 20 900

(¹) All figures relate to the old German federal states.
Source: Weber (1998a).

The total number of methadone patients, including all those without public health insurance, increased from about 1 000 in 1991 to an estimated 45 000 in April 1999. The figures mentioned above suggest that a large proportion of methadone patients

receive treatment without public health insurance support. Methadone patients without health insurance either pay for their medication or receive funds from the social welfare system. It is estimated that the total number of patients in codeine or dihydrocodeine treatment decreased over 15 months from 25 000–30 000 in early 1998 to approximately 15 000 by April 1999, due to a change in the *Betäubungsmittel-Verschreibungsverordnung* (regulations on the prescription of narcotics) in February 1998 (see ‘Legislation on substitution treatment’ below). Since practitioners who prescribe methadone and/or codeine/dihydrocodeine need not notify the local health authorities, the total numbers of patients in substitution treatment can only be estimated. It must be pointed out that, currently, no reliable monitoring and registration system exists. Proceeding from the prevalence estimate of 100 000–200 000 opiate users (including controlled and recreational users), the estimated total number of 60 000 substitution patients suggests that at least 33 % of all heroin users participate in substitution treatment, and perhaps even 60 %.

It is estimated that at least 90 % of patients receive their medication from doctors in independent 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 GPs, 20 % specialists in internal medicine and 6 % psychiatrists (Gerlach and Caplehorn, 1999). While the majority of methadone prescribers had less than 10 maintenance patients, a few treated up to 100 addicts (particularly specialist surgeries). Weber et al. (1997) have reported similar data (Table 3). In their survey, 80.3 % of doctors had less than 15 methadone patients. In major cities such as Berlin, Bochum, Cologne, Dortmund, Essen, Frankfurt, Hamburg, Munich and Stuttgart, there are also specialised out-patient centres for substitution treatment, some of which have over 200 patients.

Nationwide, more than 3 000 physicians (mostly GPs) are authorised to provide methadone-maintenance treatment under public health schemes, about half of which do in fact prescribe methadone.

TABLE 3: PROPORTION OF DOCTORS' OFFICES WITH REGARD TO THE NUMBER OF PATIENTS TREATED WITH METHADONE (DATA COLLECTED FROM 895 METHADONE-PRESCRIBING DOCTORS IN SIX WESTERN REGIONS OF GERMANY IN 1996)

NUMBER OF PATIENTS PER OFFICE	PROPORTION OF OFFICES (%)
1-4	38.9
5-9	25.5
10-14	15.9
15-19	5
20-24	5.4
25-29	2.7
30-49	4
50 or more	2.6

Source: Weber et al. (1997).

So far, there has been only one survey, carried out in the region of Westfalen-Lippe in 1996, on the attitudes and beliefs of German methadone prescribers and their knowledge of the effects of methadone. Of the 247 SHI-approved doctors included in the survey, around 50 % supported and 25 % strongly supported abstinence-oriented policies. The strength of support that doctors gave to these policies probably reflects the domination of the abstinence paradigm in German addiction-treatment services. Their attitudes and relative lack of knowledge of the basic pharmacology of methadone are probably due to the country's relatively short experience with methadone maintenance. These attitudes are likely to affect adversely the quality of care given to heroin addicts (Gerlach, 1999; Gerlach and Caplehorn, 1999).

Provision can be made for methadone patients travelling for holiday or business reasons to continue treatment. Patients are allowed to receive take-home medication for seven days, after six months of compliant behaviour in treatment. In cases where continued (daily) methadone administration is required, doctors can refer the patient to a methadone-prescribing colleague near the place they intend to stay.

There are some 50 000 prisoners in Germany, 30–50 % of whom were IDUs at the time of imprisonment. Despite rigid controls, around 50 % of all imprisoned IDUs continue using drugs. It is estimated that the drug-using population in prisons is at least 10 000. However, these are only rough estimates, since there are no clear (generalisable) data available. Also, no information is available on the number of methadone patients in penal institutions. Only 6 out of the 16 federal states provide methadone treatment in prisons (Berlin, Bremen, Hamburg, Hesse, Lower Saxony and North Rhine-Westphalia). Entry criteria vary between states, and substitution treatment is not available in all of the prisons of these states (Keppler and Stöver, 1997).

Legislation on substitution treatment

The German Narcotics Act was passed in 1971 and modified in 1982. Several amendments have since been passed. This act has priority over all other regulations regarding narcotics. Drugs/substances are assigned to three categories.

- Schedule 1 lists all non-prescribable and non-marketable drugs (e.g. heroin).
- Schedule 2 contains marketable but non-prescribable drugs and their vegetable substances (e.g. *Papaver bracteatum*, *Erythroxylum coca*).
- Schedule 3 lists all marketable and prescribable drugs, such as morphine, opium, methadone, codeine, dihydrocodeine, LAAM and buprenorphine. Cocaine, which is used as an anaesthetic, is also categorised under Schedule 3 but must not be prescribed to drug users as a substitute in medical maintenance.

Regarding substitution treatment with methadone, it was only in 1992 that an amendment to the regulations on the prescription of narcotics was introduced which clarified the position of methadone prescribers. The latest modification of these regulations (effective from 1 February 1998) entitles doctors to prescribe, per patient, the following maximum quantities of narcotics over a period of 30 days:

- 3 000 mg of methadone;
- 1 500 mg of levomethadone;
- 30 000 mg of codeine and dihydrocodeine;
- 150 mg of buprenorphine; and
- 2 000 mg of LAAM.

These maximum quantities can be exceeded only if necessary for medical reasons. Since February 1998, substitution treatment with codeine or dihydrocodeine is now officially treated in the same way as methadone. However, codeine and dihydrocodeine are regarded as inappropriate medications for maintenance purposes ('second-choice substitute substances') and their use is limited to those (very few) patients who physically cannot tolerate methadone. Unfortunately, as these are only interim regulations for codeine treatment, the old regulations remain legally in effect. Initially, they were to be phased out in July 1998, but were extended until the end of 1998. Finally, they were extended until 1 January 2000, because it was impossible to transfer all codeine patients to methadone-maintenance treatment before that date.

The main rules regarding substitution treatment, as documented in Section 5 of the regulations, are summarised below.

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

- treatment of opiate addiction with the goal of step-by-step recovery to abstinence, inclusive of improvement and stabilisation of the general health status;
- treatment of patients addicted to opiates who have to undergo medical treatment for serious medical illnesses; and
- reduction in the risks of opiate addiction during pregnancy and after delivery.

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

- the patient is eligible for substitution treatment;
- substitution treatment is embedded in a comprehensive treatment concept incorporating the necessary accompanying psychiatric, psychotherapeutic or psychosocial care;
- the doctor works towards the realisation of necessary accompanying treatment and care;
- 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; and
- the patient sees his/her doctor at least once a week.

Doctors are obliged to document all relevant patient and treatment data. Upon request, doctors must show their files 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 laws on narcotics come under criminal law. A doctor who violates the regulations on the prescription of narcotics may face a fine of up to DEM 50 000 (EUR 25 000) or a prison sentence of up to five years.

Substitute substances must not be prescribed for parents to administer. The substitute may be dispensed and/or taken under supervision in a GP's surgery, or in a hospital, pharmacy or other facilities approved by the relevant state authorities.

It is possible to take home medication for up to seven daily doses after six months in treatment:

- when the maintenance dose has been fixed;

- when the patient does not use other substances in quantities that do not allow for responsible self-administration of the substitute; or
- when the patient uses the substitute as directed (for a detailed commentary on the new regulations on the prescription of narcotics, see Ulmer, 1998).

Additional guidelines (NUB guidelines) for SHI-funded substitution treatment have been drawn up by the Federal Association of Physicians and Public Health Insurance Organisations which regulates the reimbursement of treatment costs. These guidelines may be ignored where patients have no public health insurance.

Compared with the regulations on the prescription of narcotics, the core of the NUB guidelines is discrimination according to indications. The SHI have not approved heroin addiction per se as an indication for methadone maintenance. The guidelines provide seven indication categories. SHI-funded methadone maintenance is possible if one of the following criteria is met:

- drug dependence in the case of life-threatening conditions of withdrawal;
- drug dependence in the case of severe illness (e.g. cancer);
- drug dependence with pain that has to be treated with opioids;
- drug dependence in case of AIDS;
- drug dependence of patients needing to undergo medical treatment for serious illness but who cannot be withdrawn from drugs at the same time ('bridging' or interim substitution);
- drug dependence during pregnancy, in childbirth, and up to six weeks after birth; and
- drug dependence in cases of severe illness for which the commission considers methadone administration to be indicated as part of the treatment plan.

Doctors are required to control maintenance patients' urine and to monitor polydrug use. There are no rules regulating frequency of urine sampling. In practice, during the first weeks of treatment, doctors usually control their patients' urine once a week. The NUB guidelines require that continued collateral use of other drugs (no substances listed) must result in the termination of treatment.

All doctors seeking to provide SHI-funded methadone-maintenance treatment need to be authorised to do so by the regional branches of the Kassenärztliche Vereinigung (KVs), an association of medical doctors recognised by the German health insurance system. The doctors must have received sufficient training in pharmacology and drug addiction provided by special training programmes. The mode and scale of these programmes vary enormously between the different branches of the association. While several of them accept participation in a one-day seminar, others expect doctors to participate in a three-day training course. Training covers topics such as:

- opioid dependence and the role of methadone;
- understanding and caring for the methadone patient;
- assessment and management; and
- clinical practice dosing procedures.

There have been criticisms that substitution-treatment training in the different branches of the association is inadequate. A study conducted in the region of Westfalen-Lippe came to the conclusion, among others, that 'many doctors had surprisingly little knowledge of the effects of methadone' (Gerlach and Caplehorn, 1999).

Depending on the number of methadone-treatment providers in a given area, doctors can be authorised to treat 10, 20, 30 or up to 50 patients funded by the SHI (Zerdick, 1999). There are no such limitations given in the regulations on the prescription of narcotics. Thus, doctors who are approved to treat 10 SHI patients may have, for example, another 20 methadone patients funded by social welfare or paying for treatment themselves.

Doctors treating methadone patients according to the NUB guidelines also have to meet the regulations on the prescription of narcotics and the Narcotics Act. While NUB patients have to be registered with the regional KVs, other patients need not be. It should be noted that the regulations and guidelines given above drastically limit a doctor's choice of medical treatment. There are no such rigid regulations for any other disease or treatment modality.

Despite the fact that the NUB guidelines are effective nationwide, there are still variations between the federal states in the organisation and delivery of methadone treatment and accompanying psychosocial care (Bühringer et al., 1995). There are, for example, state-specific agreements and contracts in Berlin, Hamburg and North Rhine-Westphalia.

On 26 April 1999, the Federal Association of Physicians and Public Health Insurance Organisations passed the Anerkannte Untersuchungs- und Behandlungsmethoden-Richtlinien (AUB-Richtlinien — guidelines for recognised diagnosis and treatment methods), which were approved by the Secretary of State for Health.

Substitution clients

Entry criteria for methadone patients have already been described above. In short, while SHI-funded patients and most patients supported by social welfare have to suffer from illnesses other than drug addiction itself to be accepted for substitution treatment, it is sufficient for patients paying for treatment out of their own pockets to be diagnosed as being addicted to heroin. There are no regulations regarding the length of addiction and the minimum age of patients. In general practice, drug users will be accepted for treatment when there is a documented history of drug use of about one to two years and when they are (at least) 18 years old.

The total number of 60 000 patients in substitution treatment, together with the high retention rates reported in several German studies, speaks for the acceptability of MMT among the patients. In North Rhine-Westphalia, for example, the retention rates were 87 % after one year, 66 % after three years, 53 % after five years and 48 % after seven years (Ministerium für Arbeit, Gesundheit und Soziales des Landes Nordrhein-Westfalen, 1998). An evaluation of methadone-maintenance treatment in Hamburg showed retention rates of 84.1 % after three years, 77 % after four years and 71.2 % after five years (Raschke et al., 1996).

Both the regulations on the prescription of narcotics and the NUB guidelines demand mandatory participation of patients in psychosocial care, although there is no empirical evidence of the necessity for psychosocial support for all patients (Ullmann, 1996; Gerlach, 1997). However, these regulations do not provide any instructions on the frequency, mode and scope of psychosocial-care provision and, to date, there are no nationwide standards of how to organise and structure accompanying support. 'Psychosocial care' is a collective name for a number of different areas. These may include, for example:

- legal advice;
- managing financial problems (e.g. debts, rents);
- recreational activities;
- crisis intervention;
- (psychotherapeutic) group sessions;
- assistance with finding accommodation and jobs; and
- augmenting poor school and vocational qualifications (learning new skills).

Psychosocial care is not funded by the SHI. There are great variations in psychosocial provision between different states and communities, along with variations in quality and funding. While in Hamburg, for example, psychosocial care is paid for by the municipality, in other regions accompanying support is only partially state funded (e.g. North Rhine-Westphalia) and sometimes even has to be provided by the resources available (drug agencies, drop-in centres) without any funding at all.

The labour market is not easy to access for methadone patients, due to a high general unemployment rate (10.7 % in April 1999) and negative attitudes towards methadone patients on the part of employees. Also, the socio-demographic and biographical characteristics of MMT patients (e.g. low school and vocational qualifications, criminal records) reduce the chances of finding employment. Although there are several educational and vocational projects (e.g. in Bielefeld, Frankfurt, Ludwigshafen and Munich), accompanying support regarding education and employment is still not generally available. There is great demand for further action in this field.

There has been little research on the subjective views of patients participating in substitution treatment. The main disadvantage of methadone maintenance reported by patients is mandatory daily attendance at a doctor's surgery, a pharmacy or other dispensing site over the first months of treatment ('take-homes' can only be granted after six months in treatment). Patients living in rural areas or regions with low provision of substitution treatment, in particular, are worst hit by this regulation. Due to a lack of availability of, and access to, substitution treatment in their neighbourhood, these patients often have to make long and time-consuming journeys to their doctor or dispensing pharmacy. In such cases, day-to-day life is determined, to a great extent, by these obligatory appointments. In a study of randomly selected MMT patients in North Rhine-Westphalia, 86.7 % ($n = 113$) reported that they wished to have more rights within their treatment settings (Gerlach and Schneider, 1994). Patients interviewed in a Hamburg survey ($n = 182$) described the following as disadvantages of methadone-maintenance treatment:

- 'inner void', loneliness or boredom (67 %);
- numerous obligations (55 %);
- confronting reality (42 %);
- lack of euphoria (37 %); and
- loss of former 'scene contacts' (11 %) (Raschke, 1994).

Pharmacy activity

Dispensation of methadone in pharmacies is backed by the umbrella organisation of the German associations of pharmacists, the Bundesvereinigung Deutscher Apothekerverbände (BDA). Since the introduction of the new regulations on the prescription of narcotics on 1 February 1998, methadone may be legally dispensed via pharmacies. In Hamburg, however, local pharmacies have been involved in dispensing methadone since the introduction of MMT in 1988, due to state-specific regulations.

According to a study conducted in 1996, 80 % of all Hamburg methadone patients received their medication in pharmacies. Pharmacy dispensing is patient-friendly and saves methadone

patients long or time-consuming journeys to, and/or periods of waiting in, doctors' surgeries (because they can choose a pharmacy in their own neighbourhood) and makes flexible dispensing hours available to them. Nearly all the patients interviewed (95 %; $n = 451$) were satisfied with their pharmacy and its setting ($n = 451$). Also, 77 % of the pharmacists involved in methadone dispensing had a positive opinion of their customers. Fears that methadone patients would steal, use violence or harass not only the pharmacist but also other customers had proved to be wrong (Kalke, 1997b). So far, the Hamburg study on the dispensing of methadone in pharmacies is the only one that has been conducted in Germany. Except for Hamburg, where methadone dispensing takes place in pharmacies in almost 100 % of cases, methadone is usually dispensed on-site in GPs' surgeries (90 %).

Needle exchange or purchase of new syringes is possible at all drop-in centres, at most drug aid services and many AIDS support agencies. Moreover, in major cities there are also vending machines. Due to the wide range of these services, pharmacies play only a minor role in needle exchange. In fact, pharmacies do not exchange used needles for new ones. They sell insulin syringes, but, as many pharmacies sell only packs containing 10 insulin syringes costing DEM 6–10 (EUR 3–5), they are less attractive to drug users than other services.

Substances prescribed

Methadone is the substance most frequently prescribed in substitution treatment. As described above, there is an estimated total number of 45 000 methadone patients. In contrast to other countries, there are two forms of methadone available in Germany, the racemic ⁽¹³⁾ mixture (d,l-methadone), which has only been available since 1 February 1994, and levomethadone (l-methadone or purified methadone known as polamidon). Table 4 provides data on the quantities of methadone and levomethadone ordered by pharmacies between 1989 and 1996. In line with the increasing

⁽¹³⁾ Racemic refers to a mixture of different isomeric forms of the same substance. Racemates are different optically active forms of a molecule that are either turning to the left or right.

numbers of methadone patients (Table 2), there was a corresponding increase in consumption quantities. According to the regulations on the prescription of narcotics, the maximum dosage of methadone to be prescribed over a period of 30 days is 3 000 mg of d,l-methadone or 1 500 mg of l-methadone respectively. This suggests an average maximum daily dosage of 100 mg of racemic methadone in maintenance. The maximum quantities may only be exceeded if medically necessary. However, some patients are receiving more than 300 mg daily (Ullmann, 1999).

TABLE 4: QUANTITIES (KILOGRAMS) OF RACEMIC METHADONE, LEVOMETHADONE AND CODEINE ORDERED BY PHARMACIES IN GERMANY (1989–96)

YEAR	RACEMIC METHADONE ⁽¹⁾	LEVO-METHADONE	TOTAL QUANTITY OF METHADONE PER YEAR	CODEINE/DIHYDRO-CODEINE
1989	—	10	10	—
1990	—	20	20	38
1991	—	36	36	242
1992	—	70	70	1 061
1993	—	107	107	2 616
1994	174	133	307	4 014
1995	353	129	482	6 020
1996	419	140	559	5 631

⁽¹⁾ Approved as a Schedule 3 substance on 1 February 1994 (available on the German pharmaceutical market since that date).

Source: Schinkel (1998).

Apart from maintenance treatment, methadone is also used during detoxification in qualified detoxification units. The doses are gradually reduced over a period of one to three weeks. Detoxification is accompanied by psychological and social-care provision.

Since February 1998, codeine or dihydrocodeine can only be prescribed to those patients who cannot be treated with methadone (i.e. patients who physically cannot tolerate methadone). However, these are interim regulations for codeine treatment which, in effect, leave the former regulations in place (patients

need not be switched to MMT). As mentioned above, these provisional regulations were extended until 1 January 2000. This situation has caused considerable uncertainty among many codeine prescribers and their patients. There are no studies yet on the consequences of this development, but experiences reported from Frankfurt show that there were 'panic reactions by single physicians who terminated codeine treatment from one day to the other, despite the provisional regulations ... Some of their patients were located on the streets where they bought black market codeine and/or methadone, others switched back to heroin ... Other patients were immediately switched to methadone by their physicians, regardless of their non-tolerance of methadone. These patients also switched to black market codeine and/or heroin and no longer showed up at their GPs' (Weber, 1998b).

The maximum daily dosage of 1 000 mg of codeine in maintenance may be exceeded if medically necessary. There are patients receiving more than 2 000 mg daily. As is the case with methadone patients, doses may vary considerably between individual codeine patients. Table 4 above presents data on the quantities of codeine/dihydrocodeine ordered by pharmacies between 1990 and 1996.

Naltrexone, an opioid antagonist that hinders, or drastically decreases, the effect of opiates taken, is also used in substitution treatment, but only on a small scale. There are no estimates available on the number of naltrexone patients.

A heroin trial is scheduled to be initiated in Germany in 2001. Buprenorphine has now been approved by the Federal Institute for Drugs and Medical Devices. Data are not yet available on the use of buprenorphine.

LAAM was first used within the setting of a controlled, randomised multi-centre study in 1998 (Finkbeiner, 1999). The overall results have not yet been published. It is expected that LAAM will be more widely used in the future.

Injectable prescribing

By law, substitute substances cannot be prescribed in injectable forms.

Surveillance

No data provided.

Problems

Methadone-related deaths and diversion

In 1998, a few cases of iatrogenic methadone deaths (i.e. deaths caused by the doctor) were reported for the first time in the early days of MMT. Servais and Erkens (1998) investigated six cases of methadone-related death in which the initial dose of methadone was too high (overdoses). Two patients, who died on the first day of treatment, were prescribed 100 mg of racemic methadone. Another patient, who was given 75 mg on the first and second days, died on the second day. Three deaths occurred with l-methadone: 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 in charge of these cases had started treatment with initial doses recommended for racemic methadone, probably not knowing that l-methadone is twice as strong as racemic methadone. In another three deaths, methadone had been prescribed to non-opioid-tolerant patients.

According to the Federal Bureau of Criminal Investigation, methadone was detected in 240 of a total of 1 674 drug-related fatalities in 1998 (compared with 100 in 1997). It remains unclear how many of these deaths can be attributed to methadone and how many of the deceased were enrolled in MMT. Methadone was detected, often together with cocaine ('cocktail fatalities'), in

approximately 25 % of all 1998 deaths registered in Berlin and Stuttgart.

Schmoldt et al. (1999) investigated 78 of the total number of 132 drug-related fatalities in Hamburg in 1998. Methadone was detected in the blood in 46 of the 78 deaths investigated. No heroin was detected in the blood of 38 dead persons, which led the authors to the conclusion that these cases were 'methadone fatalities'. The study findings have to be looked at with caution, since no data are provided on the extent of collateral use of cocaine, benzodiazepines or alcohol. Furthermore, the question arises as to whether it is appropriate to infer a lethal effect from methadone levels in the blood. In an earlier paper, the same team of investigators reported that the highest methadone blood levels were found in non-fatalities (Heinemann et al., 1998). Moreover, the majority of 'methadone deaths' occurred with individuals not enrolled in MMT.

Several experts have already voiced the opinion that an apparent increase in diversion to the black market is due to the latest change in take-home regulations (before February 1998, take-home doses for up to three days were possible after one year of participation in treatment; since February 1998, take-home doses for up to seven days are possible after six months of compliant behaviour in treatment). Even if these experts are right, this says less about the take-home regulations and more about lax prescribing practices of the doctors in charge of treatment. The demand for black market methadone also clearly demonstrates that the admission criteria regarding MMT are still too rigid, leaving many drug users either untreated or treating themselves with (black market) methadone.

Evaluation

Methadone treatment has been comprehensively evaluated in Germany. On account of different methodological approaches, different evaluation periods and different sample sizes and sample populations, the research results are only partially comparable. Project-specific findings are not provided here. However, the

following important common aspects regarding the overall results — despite the heterogeneity mentioned above — can be presented (Poehlke et al., 1997).

- The average age of methadone patients is above 30 years. The duration of heroin use before starting MMT is between 10 and 12 years on average.
- More than two thirds of the patients had received treatment in inpatient, drug-free therapeutic communities (usually several attempts at treatment) prior to MMT but could seldom stay in treatment as long as expected. One third of the few who left regular therapy relapsed into heroin use.
- Methadone treatment shows considerably higher retention rates than therapeutic communities (around 65 % of clients leave therapeutic communities within the first four months of treatment).
- 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 stabilises 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 untreated heroin users.
- There is also a reduction in the use of illegal drugs. The decline in illegal use of opioids comes about in a linear way: final cessation is dependent on the duration of participation in treatment. After one year in MMT, positive urinalysis ceases with 80–90 % of methadone patients. With 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 become totally abstinent (including from methadone). At present, no follow-up studies are available on the stability of abstinence. However, experiences so far demonstrate that methadone treatment (detoxification or maintenance-to-abstinence) which is limited in time usually results in a relapse into illegal opioid use and physical as well as psychological instability.

There has been very little research regarding codeine or dihydrocodeine treatment. The main reason for this is that project funding usually comes from the State. The conservative government which was in power for 16 years, until 1998, was very reluctant to promote maintenance therapy, and codeine/dihydrocodeine treatment would have been regarded even less favourably, as it had always been considered as a loophole in narcotics regulations or as ‘grey substitution’ (where codeine patients did not have to be notified to the local health authorities and psychosocial care was not mandatory), ‘with the connotation of being at best semi-professional and semi-legal’ (Weber, 1998b). Only one important study on the effectiveness of codeine/dihydrocodeine treatment has been undertaken, the results of which suggest that the outcomes of treatment with codeine can be favourably compared to methadone (Degwitz et al., 1996; Krausz et al., 1998). This means that codeine- or dihydrocodeine-substitution treatment should be further investigated in clinical and controlled trials.

There has been a remarkable lack of qualitative research on the subjective views of patients participating in substitution treatment (one exception was a study by Gerlach and Schneider, 1994). The attitudes and views of participants in treatment should be carefully studied, because it can be assumed that orienting treatment philosophies, policies and settings towards patients’ needs might result in more successful outcomes.

Information in this chapter was updated by the EMCDDA.

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Athanassios Douzenis, OKANA, Athens

Introduction

Greece was late in introducing substitution treatment for opiate addiction for historical reasons. From the 1960s, the treatment of addictions was considered unimportant, since opiate addiction was viewed as a small problem that did not present a serious threat to society. As the number of opiate addicts increased, therapeutic communities, which had been specifically set up for addiction treatment, emerged as the main treatment option. Heavy emphasis was placed on abstinence, which, in turn, influenced public opinion. As a result, abstinence-oriented treatment was considered the only option that could deal successfully with addiction.

In recent years, the number of addicted individuals has increased. Addiction and its treatment have attracted enormous publicity and media exposure. Recent research shows that the majority of people consider drug addiction to be the biggest single social problem in Greece. The HIV epidemic intensified public fears. It became obvious that the treatment offered by the therapeutic communities did not attract the 'heavy injecting heroin users', who refused to enter this type of treatment.

Substitution treatment became possible in July 1993 when a law (2161/93) regulating the use of psychoactive substances was passed unanimously by the Greek Parliament. Until then, methadone treatment, or possession of methadone, was illegal in Greece and incurred severe penalties. The same law established the national organisation against drugs, OKANA, a self-regulated, legal entity which comes under the jurisdiction of the Ministry of Health and Welfare.

In particular, the goals of OKANA are as follows:

- to plan, promote and effect interministerial coordination and implementation of national policy concerning the primary, secondary and tertiary prevention of drug dependence;
- to undertake scientific research into the drug problem at national level, provide valid and reliable information and educate the public; and
- to establish and operate effectively the community drug-prevention centres, treatment units, vocational training centres and socio-professional rehabilitation programmes.

Strategy

In the field of primary prevention, OKANA intervenes in two ways. First, the organisation implemented a three-year plan of action (1997–99) which aimed:

- to establish 83 community drug-prevention centres at the prefectural level (26 centres planned for the Sanitary Prefecture of Attika — the region in which Athens is situated — and 57 for health districts outside Greater Athens; 36 of these centres have already been established, on a three-year contract, with the financial support of OKANA);
- to offer scientific support, and provide and update educational material; and
- to carry out scientific and financial supervision of the primary-prevention activities implemented in the community by designated prevention agents.

Second, OKANA has established a training centre for the prevention of drug use and the promotion of health with the cooperation of the University Mental Health Research Institute (UMHRI) in Athens, the Greek focal point in the EMCDDA's Reitox network. The objectives of this collaboration are:

- to train prevention agents from the local authorities who will implement prevention programmes under the supervision of

OKANA (130 health professionals have already been trained); and

- to produce educational materials which will be put at the disposal of the community drug-prevention centres (*Standing on my own two feet* has already been published for secondary education teachers and *Communication within the family* for parents).

Also in the field of primary prevention, OKANA cooperates with the following government ministries, both to deal with the problem and to coordinate activities more effectively:

- the Ministry of National Education and Religion, for planning and implementing training programmes for teachers and producing educational materials;
- the Ministry of National Defence, in order to address use-related problems and self-destructive behaviours in general in the armed forces;
- the Ministry of Public Order, for training police officers in primary-prevention interventions;
- the Ministry of Merchant Marine, for training harbour police officers;
- the Ministry of Justice, in the running of a therapeutic centre for drug-addicted prisoners; and
- the Ministry of Culture, supporting the cultural and sports events which are part of the prevention activities.

Substitution

Development of substitution services

In the field of secondary prevention, OKANA developed two pilot therapeutic programmes, in Athens and Thessaloniki, in January 1996. The substitution-treatment unit in Athens caters for 200 clients and the substitution-treatment unit in Thessaloniki (the second largest city in Greece) caters for another 100 clients. Neither unit offers maintenance treatment, as their orientation is towards abstinence.

The aims of the Greek substitution programmes are:

- harm reduction;
- intensive treatment with psychosocial and medical supports; and
- abstinence.

The opening of these units received much publicity and attracted a vast number of applications from injecting heroin users. In order for a client to receive methadone, he/she has to abstain from opiates, cocaine and benzodiazepines. The clients receive methadone in liquid form under the supervision of a nurse. Urine samples are collected under supervision and every client of the unit gives a urine sample at least once a week. Psychotherapy of a supportive nature is offered.

The aim of every treatment unit is to meet the needs of its clients and treat them in the most comprehensive way. The treatment offered is multidisciplinary. The full-time staff consists of three psychiatrists, one pharmacist, one pathologist, five social workers, four psychologists, five nurses and nine administrative members of staff (secretaries, guards, cleaners and a computer programmer). The psychiatrists in the team prescribe any psychiatric medication deemed necessary and take special account of the dual diagnosis clients. Physical problems are dealt with by the resident pathologist, who prescribes accordingly or refers the patient to another hospital. Clients have to attend weekly meetings with their key worker, who is either a social worker, psychologist, nurse or psychiatrist. The clients also attend group-therapy meetings and relapse-prevention groups. Clients who continue to use illegal substances are given a formal warning. If they ignore this warning, they are detoxified from the methadone.

On the basis of the recommendations of an external evaluation, OKANA decided to underline the abstinence orientation of the substitution programmes in Greece by setting a time limit of two years for clients to receive methadone. If clients do not achieve detoxification from methadone within these two years, they are put on slow compulsory detoxification that can last for up to six months.

Current situation

In February 1997, a team of external experts evaluated the programmes. This evaluation committee consisted of a professor of psychiatry, a professor of criminology and the Greek coordinator to the EU for combating drugs. The evaluation committee's conclusions were so positive that OKANA decided to establish two more substitution (methadone) units (also in Athens and Thessaloniki). Overall, the four therapeutic programmes offer 650 places, 400 in Athens and 250 in Thessaloniki. In June 2000, a new unit for long-term methadone (maintenance) treatment started in Athens with a capacity for 200 clients. The unit plans to raise its numbers to 600 by the end of 2001.

Following the opening of the new substitution units, OKANA was inundated with applications for treatment from heroin users. In 2000, there have been 3 000 applications for treatment in Athens. So far, only 1 120 of these clients have been invited to participate in the programme and 980 have received methadone. In Thessaloniki, there have been 980 applications and, of these, 560 have been invited to participate; 420 have received methadone.

Clearly, the demand for treatment is enormous. OKANA and the units themselves are subject to considerable pressure to accept clients who are obviously in great need.

Substitution clients

All opiate users are encouraged to apply for methadone treatment in Greece, but, because of the great demand and the limited number of places available, the units are unable to offer treatment to all applicants. Some reasons for not availing of the programme when a place is offered are as follows:

- some clients are not in the country when they are called;
- others have been sent to prison; and
- a small, yet important, minority die before they are called.

Clients must fulfil the following criteria to enter the methadone programme:

- must be at least 22 years of age;
- must be using heroin daily;
- must have previously attempted a therapeutic programme (unsuccessfully); and
- must show no evidence of any psychopathology that would make treatment in an open unit impossible (i.e. overtly violent or criminal behaviour).

Almost all of the applicants fulfil these criteria.

At present, the substitution units operate a waiting list. Applicants who fulfil the abovementioned criteria are accepted on a first-come, first-served basis. As a result, they usually have to wait for two or more years to enter the programme. OKANA only accepts applicants for immediate treatment if they are:

- HIV positive;
- suffering from metastatic cancer or gangrene (threatening immediate loss of a limb) or bacterial endocarditis;
- pregnant injecting heroin users who have completed the first trimester of pregnancy; or
- related to a client receiving methadone or married to a patient in the methadone unit (if living together).

Pharmacy activity

In Greece, methadone is dispensed legally only in the substitution units of OKANA. Pharmacies are not permitted to dispense methadone.

Primary-care involvement

In Greece, primary care is not involved in the substitution treatment of opiate-addicted individuals. General practitioners (GPs) are not allowed to prescribe methadone.

Substances prescribed

OKANA is planning to introduce the use of LAAM and buprenorphine in the substitution-treatment units. This will involve some changes in the legal classification of these drugs, which is proving cumbersome. However, these substances are expected to become available for use in the substitution-treatment units in 2001.

OKANA also uses the opioid antagonist naltrexone in its substitution programmes for clients who have successfully completed withdrawal from methadone. Naltrexone is believed to enhance the client's chances of remaining opiate free. It is also used for clients who have applied for substitution treatment but have not yet entered the programme because of the long waiting list. Occasionally, clients who have managed to stop using opiates — by their own efforts — request help and support from the units. These clients are offered naltrexone and psychological support.

At the end of the programme, clients are required to attend OKANA's rehabilitation unit for up to another year. The aim of this unit is to ease the client's social reintegration and continue psychotherapy.

Injectable prescribing

Injectable prescribing is illegal in Greece.

Surveillance

The amount of methadone given to patients is strictly controlled by the Greek State (the Greek 'monopoly of substances'). Every three months, each unit submits detailed records of methadone dispensed. They also submit similar records to OKANA about the naltrexone used.

OKANA's substitution programmes are evaluated externally by an evaluation committee. Internal checks are provided by specialists in the field of psychotherapy and addiction who do not work in the substitution units. OKANA seeks the committee's opinion at every stage of service development.

Problems

The main problem that the substitution units face on a daily basis is the overwhelming demand for treatment. Drug users come into the units asking for treatment, and staff (and OKANA) have to deal with their frustration and anger when they are told that there is a waiting list.

Problems arising from clients demanding to continue receiving methadone indefinitely are fairly recent. The demand for methadone-maintenance programmes is gaining momentum. Problems can also arise because of the differences in therapeutic approach between the various treatment units. This has been addressed by developing a set of common rules for all units and by trying to improve the services offered in the units.

Evaluation

OKANA aims in the next three years to set up a system that will identify gaps in information in order to support and provide the various treatments it oversees. It has recently set up a research and evaluation department. Information on the evaluation of the substitution programmes is expected to be published in 2001.

SPAIN

*Marta Torrens, Hospital del Mar,
Instituto Municipal de Investigación Médica, Barcelona*

Introduction

General health services in Spain are financed by the Ministry of Health and are free to everyone. They include hospital stays, outpatient services and medication, which are free in hospitals and partially paid (60 %) in outpatient treatment clinics. Drug-related treatment is also covered, including hospitalisation and medication related to HIV infection. The Constitution of 1978 divided Spain into 17 'autonomous communities' and two 'autonomous cities'. Each of these may develop its own policy on health to varying degrees. In some autonomous communities, health provision falls directly under the Sistema Nacional de Salud (National Health Service), while, in others (such as Catalonia and the Basque Country), it falls under the administration of their own autonomous health service. Some of these autonomous administrations contract private clinics and other services for public use.

The Ministry of Social Services finances the social services in Spain, but, in some autonomous communities, these services also depend on the autonomous administration departments, which constitute a different network of health services. Links between health and social services are maintained through individual professionals working in both networks. In general, health services have social workers who liaise with social services. Furthermore, health and social services are provided by the private sector, although these represent less than 15 % of all services.

Strategy

Due to major political changes in Spain in the 1970s, illicit drug problems appear to have arrived later than in other west European countries. Serious concerns in this area do not seem to have

developed until the late 1970s, when there was a marked increase in intravenous heroin consumption. In response to this growing drug problem, a number of services were developed in the large cities, but there was little overall integration between general public health services and services which had developed in response to drug-abuse problems.

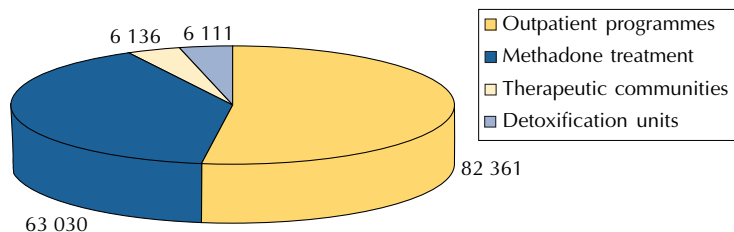
In 1985, the Plan Nacional sobre Drogas (National Plan on Drugs — the Spanish focal point in the Reitox network) was established, with the aim of developing a network of services. Various institutions, including the Ministries of Health, Justice and Education, autonomous administrations (through their own plan on drugs) and non-governmental organisations (NGOs) developed the plan. More than 90 % of all services for drug addicts were developed after 1986. Autonomous plans on drugs were developed by the autonomous administrations to facilitate the provision of resources to address drug addiction in every region. Some large cities, such as Madrid and Barcelona, developed their own local plan on drugs.

The majority of drug services fall under the public health sector and are either organised through the public health system or by non-profit-making NGOs. Probably less than 1 % are in the private sector. These services are funded through the health service and/or through the autonomous or local plan on drugs which contracts the individual providers. Each autonomous plan has its own priorities in planning and financing drug resources, according to the situation in different regions of the country regarding drug use. In most autonomous communities, new services provided for drug addicts were found to generate a parallel network for addiction-related problems. In a few autonomous communities, addiction problems were treated by the mental health services.

From 1990, in response to the HIV epidemic, a variety of harm-reduction strategies, including substitution treatments and needle-exchange programmes, were gradually implemented. These varied in timing and extent between communities. As described below, extensive substitution treatments have been developed over recent years. At the end of 1996, the number of patients admitted to methadone-treatment programmes accounted for

27 % of the total number of admissions to the various drug-treatment services (Figure 1).

FIGURE 1: NUMBER OF PATIENTS IN THE VARIOUS DRUG-TREATMENT SERVICES IN SPAIN (1998)



Substitution

Development of substitution services

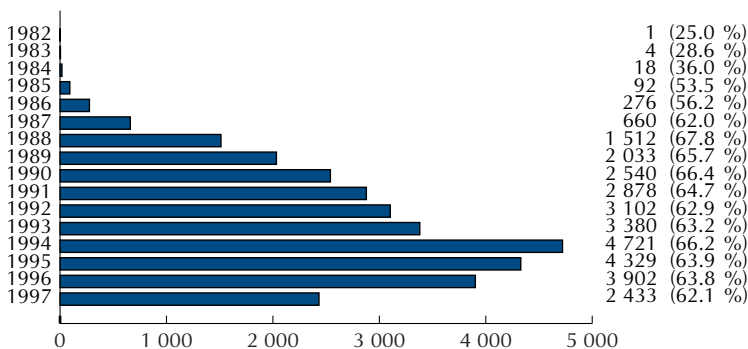
The history of substitution services in Spain is linked to changes in legislation regarding the use of opioids. The heroin epidemic began in Spain in the late 1970s and, at that time, opioid-maintenance treatment was only available for pain relief in terminally ill patients. Later, in 1983, legislation approved the use of methadone in the treatment of opioid dependence, and it then became possible to obtain methadone prescription both in the public and private sector. Methadone was also dispensed in pharmacies. At that time, about 5 000 patients were in methadone treatment. However, the majority of prescribing by doctors was located within the private sector and concern was expressed that, in some cases, this was for personal gain.

In response to this situation, subsequent legislation in 1985 in the form of the Orden Ministerial 1985 (Ministerial Order 1985) restricted the prescription of methadone within the private sector. This new legislation decreed that methadone treatment had to be

prescribed by doctors working in the public sector, in specially licensed centres (prescribing centres). The doctors were required to propose patients for methadone treatment to an 'autonomous commission' which constituted representatives of the autonomous and national administrations. This commission assessed every new case. Once approved, the subject had to receive methadone in a centre designated for the administration of methadone only (a dispensing centre) run by the relevant autonomous administration. The results of this legislation were a highly restrictive policy towards the prescription of methadone over a long period of time (only about 1 000 patients were registered in 1986 and 1987).

However, because the HIV epidemic hit drug addicts in Spain so hard (Figure 2), and because of the growing evidence that harm-reduction strategies were effective in decreasing both the spread and morbidity of HIV infection, changes were brought about in the national drug strategy.

FIGURE 2: NUMBER OF CASES OF AIDS AMONG INJECTING DRUG USERS IN SPAIN ACCORDING TO YEAR OF DIAGNOSIS

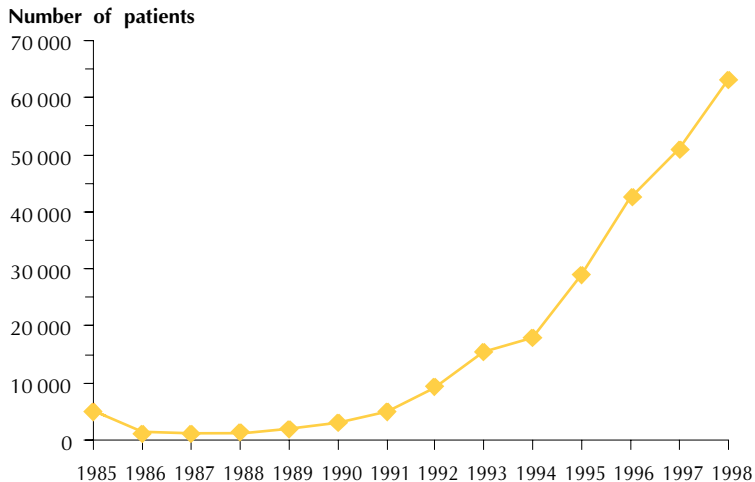


Source: National register of cases of AIDS (31 March 1998).

Legislation in 1990 in the form of Real Decreto 75/1990 (Royal Decree 75/1990) substantially modified the regulations governing opioid-maintenance programmes. The new law made it easier for patients to be admitted to methadone-treatment programmes.

Criteria for admission included a diagnosis of opioid dependence and the fact that patients must have tried and failed on at least one other previous intervention. Exceptions were made if patients were pregnant or if there was evidence of HIV infection or serious systemic disease. In these instances, treatment could be automatically initiated by doctors working in autonomous commission centres licensed for prescribing and dispensing methadone. All the licensed centres had to be public facilities or run by non-profit-making organisations. Under this new legislation, the number of patients in methadone maintenance increased significantly (Figure 3). National and autonomous plans for drugs encouraged provision of methadone programmes in most of the country and many centres for drug addicts included methadone among the treatment options.

FIGURE 3: NUMBER OF PATIENTS ADMITTED TO METHADONE TREATMENT IN SPAIN (1985–98)



Although this new law was much more permissive, the long waiting lists demanded another change in the legislation in 1996 in the form of Real Decreto 5/1996 (Royal Decree 5/1996) making admission to methadone-treatment programmes easier.

A diagnosis of opioid dependence was now the only requirement for enrolment. In addition, autonomous administrations could license private doctors and pharmacies to prescribe and dispense methadone, respectively.

Current situation

Methadone is currently available in every Spanish autonomous community, although the distribution of centres and their organisation are somewhat different in each community. In some communities, both methadone prescribing and dispensing are carried out at the same centre, whereas in other communities these activities are allocated to different centres or sometimes even to different networks (from specific drug-addiction to general health networks). At the end of 1997, a total of 631 independent centres were offering methadone treatment throughout the country:

- 44 % were of the 'prescribing and dispensing' type;
- 40 % were 'dispensing only'; and
- 16 % were 'prescribing only'.

Prescribing and dispensing centres were those offering a variety of treatment, including methadone provision (i.e. dosage, treatment duration, urinalysis, counselling, dispensing). Prescribing-only centres were those offering most of the aforementioned facilities except dispensing. Dispensing-only centres were those which were exclusively involved in providing the patients' daily dose of methadone.

At present, most prescribing-only and prescribing and dispensing centres are located in specific addiction services where other treatment modalities for drug addiction are also offered (i.e. naltrexone, drug-free programmes, detoxification, etc.). The majority of dispensing-only centres are located in primary healthcare services. Mental health centres also have some involvement. Current figures regarding the involvement of the private sector are unavailable, but, in general, there are few institutions involved (in Catalonia, only 3 % of methadone-related activities are found in the private sector).

Most of the centres (83 %) are totally or partially financed by the relevant autonomous community administration. They are generally managed at the autonomous administration level, although about 13 % are run by non-governmental organisations (mainly the Red Cross).

In prescribing-only and prescribing and dispensing centres, the ratio of staff to client is around 1:58. Treatment with methadone accounts for 40 % of all the treatment places for drug addicts. Nevertheless, at the end of 1997, in 33 % of centres there was still a waiting list for inclusion on a methadone programme, with a mean waiting time of 60 days.

There is a facility for patients in methadone maintenance to move around within Spain. Arrangements have to be made by the patient's original centre with the centre the patient will be moving to next, and this is usually done very easily. Contact has to be made by phone or fax, and specific data have to be supplied, including the following:

- patient's name;
- methadone dosage;
- take-home privileges; and
- length of time to be spent in the new location.

A list of the centres is provided by both the National Plan on Drugs and the autonomous plans on drugs. Subjects with special circumstances, such as those who are hospitalised for medical illness or committed to prison, are able to continue methadone treatment.

From the time when methadone-treatment programmes were first available up to 31 December 1997, a total of 87 828 patients had received substitution treatment. At the end of 1997, there were 51 000 patients on methadone, most of them men (83 %), and the mean age was 29 years. Positivity to HIV was found in 43 % of cases, to hepatitis B virus in 63 % and to hepatitis C virus in 68 %.

Legislation on substitution treatment

Since 1996, only a definitive diagnosis of opioid dependence is required for enrolment on a methadone-treatment programme. There are no restrictions on dosage nor on duration of treatment. Each autonomous regulatory authority, through its plan on drugs, authorises specialised centres, private doctors and pharmacies to be involved in methadone-treatment programmes. Services are required to report to the autonomous authority when an individual enters and leaves the programme. This information is collated into a national report of the Sistema Estatal de Información en Toxicomanías (SEIT — State System of Information on Drug Addiction). This information-gathering system covers any form of drug prescribing and is not specifically methadone-related, although methadone is by far the most commonly used drug for substitution.

There are no published national or autonomous guidelines for methadone services. Also, there is no specific legislation about urine controls and take-home regulations.

The National Plan on Drugs supported two national studies on methadone practices in Spain which were conducted in 1994 and 1997.

Substitution clients

Under current legislation, Spanish drug policy on treatment with opioid agonists is not restrictive, and diagnosis of opioid dependence is the only criterion for entry to a methadone-treatment programme. However, when the specific policy of different centres was assessed, it was found that pregnancy, diagnosis of AIDS and other severe physical illnesses were the most important criteria for enrolment, whereas absence of HIV infection or a patient's self-request were less frequently considered. Most of the centres considered that violence or drug use and trafficking in the centre were sufficient reason for the patient to be discharged from the programme. In 5 % of the centres, the provision of methadone is only

abstinence oriented, in 17 % provision is not abstinence oriented and in 78 % both approaches are offered.

General medical care is almost universally offered in methadone-treatment programmes, although in more than 50 % of the centres these services are provided at a different institution. This care would include:

- physical examination;
- laboratory tests;
- diagnosis of HIV, hepatitis B and C virus infection;
- detection, prophylactic and treatment of tuberculosis;
- diagnosis of sexually transmitted diseases; and
- pregnancy tests.

Patients are usually referred to primary-care physicians for an initial evaluation. Mental healthcare (pharmacological treatment, counselling, psychopathological assessment, individual and group psychotherapy) and social services (liaison with legal and labour resources) are provided in the same centre, in most cases.

Sixty-five per cent of the centres use urinalysis to detect illegal use of drugs, mainly heroin (in 99 % of the centres) and cocaine (in 93 % of the centres). Urine screening is generally performed under direct supervision, between once and four times a month.

Pharmacy activity

New regulations on substitution treatment in 1996 permitted pharmacies to be involved in dispensing methadone, but only a few currently do so. In these instances, public drug-addiction centres prescribe the methadone and the autonomous administration pays the pharmacy for every patient receiving methadone (very few pharmacies are involved in administering methadone prescribed by private doctors). More pharmacies are involved in needle-exchange programmes, particularly in the Basque Country.

In 1998, the Programa Nacional para Prevención del SIDA y Dispensación de Metadona en Farmacias (National Programme

for AIDS Prevention and Methadone Dispensing in Pharmacies) was promoted by the Delegación del Gobierno para el Plan Nacional sobre Drogas (State Office for the National Plan on Drugs), the Plan Nacional del SIDA (National Plan on AIDS) and the Consejo General de Colegios Oficiales de Farmacéuticos (General Council of Official Colleges of Pharmacies). The aim is to stimulate the implementation of needle-exchange programmes and methadone dispensing in pharmacies.

Primary-care involvement

In general, primary-care centres have very little involvement in methadone-treatment programmes. Most patients are treated in specific drug-treatment centres. The one exception is Andalusia (in the south of Spain), where most methadone is provided in the primary healthcare setting (such as dispensing centres). In some communities, such as Catalonia, some primary-care centres are involved in needle dispensation and/or needle-exchange programmes.

Substances prescribed

At present, methadone is by far the most frequently prescribed drug for maintenance treatment. LAAM is not available in Spain. Buprenorphine is marketed as a very small dose (tablets of 0.2 mg) and, in general, is not used for maintenance treatment.

Methadone is more often administered as an oral solution (syrup) or in tablet form. Most centres (91 %) do not use the maximum dose of methadone and, in 78 % of the centres, the mean daily dose of methadone was ≥ 60 mg (mean dose measured against number of patients/centre was 69 mg/day). Methadone is dispensed every day under direct supervision. Take-home treatment is also provided by all centres.

One autonomous community (Andalusia) is currently planning experimental substitution treatment with heroin. Some experimental clinical trials with buprenorphine have also been performed. A

national study of LAAM, commissioned by the National Plan on Drugs, is also under discussion.

Injectable prescribing

Although the legislation only recommends the use of oral methadone, other forms of administration are not forbidden. At present, however, there is no injectable prescribing of opioids for maintenance.

Surveillance

National data on drug-related problems in Spain are regularly published in the *Memoria anual del Plan Nacional sobre Drogas* (Annual report of the National Plan on Drugs), in the SEIT reports and, recently, in the reports of the Observatorio Español sobre Drogas (Spanish Observatory on Drugs). Also, autonomous plans on drugs regularly publish their own reports on drug-related matters.

Recent data regarding the drug-use situation in Spain are available from different sources, including the following surveys:

- encuesta domiciliaria sobre drogas 1997 (1997 survey on the use of drugs among the general population);
- encuesta sobre drogas en la población escolar 1996 (1996 survey on the use of drugs among the school population);
- encuesta a consumidores de heroína en tratamiento de 1996–97 (1996–97 survey of heroin addicts in treatment); and
- encuesta domiciliaria sobre consumo de drogas 1999 (1999 survey on the use of drugs among the general population).

The following treatment indicators were reported on by the SEIT:

- start of new treatments for opioid or cocaine abuse in outpatient centres for drug addiction;
- emergencies related to heroin and/or cocaine use; and
- mortality related to heroin and/or cocaine acute reaction (overdose).

Other studies are available in the field of drug addiction, such as on the following:

- characteristics of patients in methadone-maintenance treatment in Spain (1997 study);
- confiscations of illicit drugs (opiates, cocaine, cannabis, crack, LSD, ecstasy, speed);
- number of arrests due to drug trafficking;
- number of fines for drug consumption;
- level of distribution of alcoholic beverages;
- analysis of the usefulness of alternative treatments to imprisonment; and
- number of juridical processes due to drug trafficking.

Figures on the use of services and trends in service utilisation for inpatient, residential and community or ambulatory services, according to the *1997 Annual report of the National Plan on Drugs*, are shown in Figure 1 above.

Problems

Outpatient centres are generally well accepted by their local neighbourhood (mean of 7 on a scale of 0–10), although dispensing centres rated lower than other types of centres (mean 5.7).

It is estimated that around 30–50 % of prisoners are drug addicts. The 1990 law included a paragraph on methadone use in prisons and, in August 1997, all the prisons except two had already developed methadone-maintenance programmes. Data of August 1997 showed that 11 605 (27 %) prisoners were enrolled in methadone treatment. Most cases (86 %) were men, with a mean age of 29 years. Seropositivity to HIV infection was found in 66 % of the cases, to hepatitis B virus infection in 79 % and to hepatitis C in 70 %. Most subjects (84 %) received a daily dose of ≥ 60 mg of methadone. Methadone-maintenance programmes were not abstinence oriented; they prescribed a mean dose of ≥ 60 mg/day and there was no time limit on treatment. In most centres, when treatment for tuberculosis was indicated, antituberculous agents were administered together with methadone. When subjects are

discharged from prison, they are referred by the prison to continue methadone maintenance in an outpatient centre.

Evaluation

The National Plan on Drugs promoted two studies (in 1994 and 1997) on the characteristics of current methadone-treatment programmes in Spain. Moreover, other studies on factors influencing retention rates in methadone-maintenance programmes, such as health-related quality of life and usefulness of plasma levels of methadone in clinical practice, have been carried out. Evaluation studies of methadone-treatment programmes are currently under way in some autonomous communities (e.g. Andalusia), as well as cost-efficiency studies of different levels of healthcare methadone-maintenance programmes.

FRANCE

Marc Auriacombe, Université Victor Segalen, Bordeaux II

Introduction

France holds an original stand regarding substitution treatment for opiate-dependent subjects. Until 1994, less than 1 000 subjects were considered for treatment by specific substitution treatments, mainly involving methadone. At the start of 1999, it was estimated that a realistic minimum of 60 000 such subjects might have been receiving treatment. The total population of opiate-dependent subjects in France is estimated at between 150 000 and 300 000. Hence, somewhere between 20 and 40 % of opiate-dependent subjects in France might be under substitution treatment at any given time. Also noteworthy is that the majority of these subjects are under buprenorphine treatment and not methadone treatment, as is the case in other European countries.

Until recently, most healthcare providers in the field of substance abuse believed that the use of medication in general, and especially of opiate agonists, was undesirable for helping drug-dependent subjects achieve abstinence. Although this attitude is still quite prevalent, it is changing.

Strategy

The healthcare system for treating substance abuse in France is organised differently to the general French healthcare system. The standard French healthcare system (Fielding and Lancry, 1993) is organised on the basis that patients pay for medical services (consultation, laboratory investigations, medications) and are reimbursed through a universal State medical insurance (social security). The level of reimbursement can range from 40–60 % of expenses. For a limited number of conditions considered chronic and expensive (i.e. diabetes), or acutely expensive (i.e. myocardial infarction), the State medical insurance will cover 100 % of the

expenses. Patients may also pay voluntarily for private medical insurance that will cover those expenses not reimbursed by the State medical insurance. In the general healthcare system, treatment providers (medical doctors, nurses, etc.) are paid according to two modalities. In private practice (most of the office-based system), healthcare providers are paid directly by patients. In the public system (mostly inpatient and hospital-based), healthcare providers are employed by the State and receive a salary.

The healthcare system for substance abuse is not paid for through the universal State medical insurance. Instead, the State allocates an annual budget for this which is paid directly to private organisations that care for substance users. Consequently, treatment for substance abuse is considered to be free (providers are completely paid for by the State, so patients have nothing to pay, directly or indirectly) and anonymous (potential patients do not need to reveal their identity for the sake of reimbursement, as there is nothing to pay).

However, these obvious advantages have some drawbacks. One is the fact that these organisations are entirely dependent on State money, which makes the system extremely vulnerable. Another drawback is that many State-approved substance-abuse healthcare centres employ psychologists and social workers (less expensive) but no medical doctors or nurses (more expensive). A consequence of this has been a lack of interest in a medical approach to substance-abuse problems and consequent neglect of the somatic consequences of drug use such as infections (e.g. hepatitis and AIDS). These problems are taken care of by the general healthcare system, constituting hospital-based specialists and office-based general practitioners (GPs). In some instances, the general healthcare system has encouraged the use of opiate agonists for the care of heroin addicts. A consequence of this situation is a hiatus between the two systems regarding the use of medication and opiate agonists in the care of substance abusers. Opiate agonists are only considered useful for the prevention of infectious complications resulting from intravenous drug use, whereas they are considered contraindicative in the treatment of substance (particularly opiate) dependence. This results in an underuse of opiate agonists in substance-abuse treatment programmes and, even when they

are used, they are often not integrated into a comprehensive substance-abuse treatment plan.

Since methadone was only available to the substance-abuse specialist, it has always been, and still is, little used — less than 50 subjects received methadone in 1993 and less than 5 000 in 1996, for an estimated 150 000–300 000 opiate-dependent subjects (Facy and Verron, 1989). This helped fuel the search for an opiate agonist that could be used by practitioners other than psychiatrists and substance-abuse specialists (i.e. mainly interns and GPs). From 1988, buprenorphine was available in 0.2 mg tablets and it has since been used in limited experimental substance-abuse treatment programmes (Daulouède and Tignol, 1993; Carpentier, 1994).

Substitution

To date, four pharmacological agents are used for substitution treatment in France:

- codeine;
- morphine sulphate;
- methadone; and
- buprenorphine.

However, only the last two are officially approved for such use. Thus, the two main substitution agents currently used in France are methadone and buprenorphine, but these fall under very different regulations. Methadone can only be used for treatment by substance-abuse specialists and buprenorphine is primarily prescribed by GPs. Since these two treatment possibilities are so different, from a regulatory and social perspective, they will be described separately.

Methadone

Methadone treatment was introduced in France in 1972 as an experimental drug. Of the four State drug-dependence treatment

centres that were offered access to this then new treatment, only two — located in Paris — accepted. Each centre was authorised to treat a maximum of 50 patients at one time. Although the initial report on the impact of methadone treatment, published in 1975 (Denicker et al., 1975), was encouraging, the status and accessibility of methadone treatment remained unchanged until 1993 (Ministère de la santé et de l'action humanitaire; Olié et al., 1991; Laqueille, 1992).

In 1992, the Ministry of Health initiated some changes. State drug-dependence treatment centres were encouraged to apply for authorisation to offer methadone treatment (Ministère des affaires sociales, 1992), and a request for approval of methadone as a medication was filed through the Agence du médicament (the French medication approval authority). Methadone was licensed as a standard approved medication for the temporary treatment of severe pharmacodependent subjects in 1995. Following this, the original request procedure for access to methadone for State drug-dependence treatment centres was dropped, and all medical doctors working in such centres were authorised to prescribe methadone to as many patients as necessary (Ministère des affaires sociales, 1995). There are three restrictions on centres offering methadone treatment:

- methadone must initially be administered within the treatment centre;
- this centre must own a safe; and
- urine testing must also be carried out.

Another advance in treatment provision is that the general practitioner who initiates methadone substitution can have the treatment delivered in a community pharmacy. Once he decides that the patient is stabilised, he can authorise any GP to continue the initial prescription privileges for that patient.

Since 1995, the number of methadone treatments has increased dramatically due to a change in regulations. The number of patients treated was reported to be between 5 000 and 6 000 in 1998 in official documents from regulatory bodies (e.g. Observatoire français des drogues et des toxicomanies, the French

focal point in the EMCDDA's Reitox network). However, by dividing the amount of methadone sold by the average daily dose (60 mg), the estimated number of subjects treated was 659 in early 1996, 1 862 at the end of 1996 and 2 345 at the end of 1997 (Lert et al., 1998). The estimate for 1999 was approximately 6 000 methadone patients.

A nationwide survey of the first 5 000 such patients was attempted by the Institut national de la santé et de la recherche médicale (Inserm — the National Institute for Health and Medical Research). In April 1998, a preliminary report was released (Facy, 1998) which showed that 5 360 subjects had been admitted for treatment since 1993. Of these:

- 3 963 had at least one follow-up report;
- 1 744 were in treatment for less than 12 months; and
- 659 had been in treatment for more than two years (and 155 of these for more than three years).

This report stated that, overall, patients have a positive outcome over time.

Buprenorphine

Since methadone treatment was so restricted, and State treatment centres initially were not very eager to have such treatment extended, substitution treatment evolved outside specialist drug treatment. Buprenorphine began to be used in university-based, research-oriented settings (Auriacombe et al., 1992, 1997; Auriacombe and Tignol, 1997) and by individual GPs who were concerned about the lack of availability of methadone treatment and the reluctance of most specialists at the time to change such availability (e.g. Carpentier et al., 1994; Mucchielli and Reisinger, 1997).

Hence buprenorphine, in its analgesic form, was trialled for substitution treatment of opiate-dependent subjects. Since the initial results were encouraging, and also based on preliminary National Institute on Drug Abuse (NIDA) funded clinical trials (Segal and

Schuster, 1995), sublingual tablets of buprenorphine (of 0.4, 2 and 8 mg) were registered to be used exclusively for opiate-dependent subjects by the French medication approval authority in 1995. Following this, in February 1996, buprenorphine was marketed under the brand name of Subutex®.

Since 1996, the regulations for prescribing buprenorphine to opiate-dependent subjects were quite different to those for methadone (Ministère des affaires sociales, 1996). Any GP, regardless of speciality and whether practising privately or publicly, can initiate buprenorphine treatment. The prescription may be delivered at any pharmacy. The only restrictions are that the prescription must be written on a special prescription form, the same as that used for prescribing controlled substances such as morphine. The prescription cannot be for more than 28 days at one time, and, unless requested otherwise, the pharmacist is allowed to hand over 28 days' treatment at one time. However, prescriptions for shorter time periods are encouraged, and it is possible to request daily supervised delivery at the pharmacy. Some of the doctors who were involved in the initial trials for buprenorphine treatment in the late 1980s have produced clinical guidelines (e.g. Tignol et al., 1998). However, these are not currently widely accepted. According to pharmacy-based surveys, most treatments are unsupervised and treatment is delivered for periods of more than a week (Auriacombe and Tignol, 1997). Urine testing for those treated with buprenorphine is not encouraged.

On account of this very relaxed approach, buprenorphine treatment for opiate-dependent subjects is very accessible, and it is estimated that in 1999 as many as 50 000 subjects were receiving treatment at any given time. This estimate is calculated on the basis of the quantity of buprenorphine sold by the company to pharmacists and the average dose prescribed, which, according to a few limited surveys conducted by motivated GPs, is between 8 and 12 mg daily (De Ducla et al., 2000). Based on these calculations, the number of subjects ranged between 2 800 and 4 300 at the beginning of 1996, between 21 000 and 32 000 at the end of 1996 and between 34 000 and 51 000 at the end of 1997 (Lert et al., 1998).

It was estimated in the autumn of 1996 that approximately 24 000 patients had been prescribed buprenorphine, which represents approximately 15 % of the total addict population in France. In June 1997, it was estimated that up to 40 000 patients were being prescribed buprenorphine. The average prescribed dose seems to be 8 mg daily.

Within two months of the launch of Subutex®, patients on low-dose (0.2 mg) analgesic tablets (Temgesic®), which were prescribed when substitution was indicated, had transferred to high-dose buprenorphine tablets (Subutex®), as demonstrated by the decrease in Temgesic® sales and the growth in Subutex® sales. However, the most interesting change was that addicts who were treating themselves with over-the-counter codeine (so-called 'wild' substitution) transferred to medical substitution with prescribed buprenorphine. This was indicated by a 5–15 % decrease in codeine sales five months after the launch of Subutex®.

Pharmacy survey

In June 1996, four months after the launch of Subutex®, a face-to-face survey of 2 646 pharmacies was conducted, in order to determine levels of substitution-treatment prescription as well as to gather information about subjects using Subutex® (Picard, 1997). The survey gathered the following data.

- Close to 60 % of the pharmacies had delivered Subutex®, morphine sulphate, codeine or methadone to drug addicts during the previous month, compared with 10 % some years before; 30 % had specifically delivered Subutex®.
- Approximately 40 % of pharmacies had previously supplied only 1–3 subjects, whereas 40 % now supplied 6–20 subjects.
- Those pharmacies supplying large numbers of addicts were, in general, working with drug subjects in the AIDS-prevention and needle-exchange programmes, whereas those pharmacies with few subjects were new to substitution dispensing.
- When asked specifically about Subutex® prescription, few pharmacies had more than three patients taking Subutex® and

almost 50 % had none of the 20 000 patients currently treated with this medication.

- The most popular medication taken by Subutex® patients prior to its launch was codeine, followed by low-dose analgesic buprenorphine (Temgesic®).

The survey also revealed information about the prescribing practices of the many GPs that were now treating heroin subjects. During the induction phase, Subutex® was prescribed to be taken daily in 40 % of all cases. The length of time for which it was prescribed on one prescription was usually one week in 39.3 % of cases. However, 20.6 % of prescriptions were written for four weeks. It is possible that some of these patients had previously been treated with Temgesic® and that this was not, in fact, an induction phase but a continuation of the earlier maintenance therapy. During the maintenance stage of Subutex® therapy, four-week prescriptions were the most common (38.4 %), at daily doses of 2–6 mg, which is relatively low. Once-daily treatment occurred in over 50 % of cases, but 25 % almost never took the medication daily. This is a cause for concern, since daily administration appears to be an important condition for successful treatment. Communication between GPs and pharmacists was not as good as originally hoped, since, in 40 % of cases, the GP did not contact the pharmacist prior to the patient presenting the prescription. Also, the prescribing GP should have specified on the prescription the particular pharmacist to be used, but this only occurred in 30 % of cases.

The survey also addressed the problem of diversion. When Subutex® was launched, its street value was FRF 100 (EUR 15) for an 8 mg tablet retailing at FRF 25 (EUR 4). In 1999, this street value dropped to FRF 30 (EUR 4.5), indicating a high level of legal availability of the drug and also its low euphoric effects compared with heroin. Pharmacists felt that, in 80 % of cases, Subutex® was used in the prescribed way and that 70 % of prescriptions were not resold. From these data, it can be estimated that a minimum of 10–15 % of subjects injected Subutex® intravenously. Overall, patient compliance was considered to be good in 71 % of cases

and both pharmacists and subjects expressed a positive opinion about the treatment programme. Results from a survey in October 1996 indicate that this figure had since risen to 74 %.

Reports of adverse effects

Since June 1997, some reports have emerged of adverse effects of buprenorphine treatment. The most important of these was a report of six deaths thought to result from the combined use of buprenorphine injected intravenously with benzodiazepines and alcohol (Tracqui et al., 1997). All six subjects used illegally obtained buprenorphine and were not included in a comprehensive treatment programme. These deaths underline the importance of making buprenorphine available in a way that reduces diversion, as this is often associated with abuse of other potentially lethal drugs. However, it should also be noted that, during an 18-month period when the number of buprenorphine prescriptions reached over 40 000, the number of overdoses reported decreased from over 500 deaths annually to less than 300 (Office central pour la répression du trafic illicite des stupéfiants, 1998).

Another reported adverse effect concerns increases in liver enzymes among subjects treated with buprenorphine (Réseau des centres de pharmacovigilances, 1997). There have been a number of different clinical responses to this phenomenon, including cases where the buprenorphine treatment has been continued and a secondary reduction of liver enzymes has been observed. Overall, the incidence of liver enzyme increase currently reported does not appear to be higher than that reported with non-liver-toxic medications. These reports, however, highlight the need for close monitoring of patients receiving buprenorphine treatment, as over 75 % of opiate drug users in treatment in France have tested positive for the hepatitis C virus.

Development of substitution services

Traditionally, specialist substance-abuse treatment providers in France have been reluctant to offer substitution prescription. Non-specialists, particularly GPs, were explicitly discouraged from treating substance-abusing or dependent individuals, as these were considered to be unreliable and manipulative. Prescribing to such individuals was considered non-therapeutic. Some changes have occurred since the early 1990s, but the process of change in attitude is still ongoing.

Current situation

The population of France currently stands at 60 million. It is estimated that the country has between 150 000 and 300 000 drug-dependent subjects. Approximately 40 000 subjects a year will request help from the State drug-abuse treatment centres. The average age of subjects is 25–30, and two thirds are male. Overall, 20 % are HIV positive. However, this number is believed to be dropping over time. Two thirds appear to be hepatitis C positive.

Legislation on substitution treatment

There was a dramatic change in legislation between 1990 and 1995 (current legislation was set in place in 1995). All GPs working in substance-abuse State-approved centres may now prescribe methadone. There are no regulatory requirements for a GP recruited in such centres. Buprenorphine may be prescribed by any GP and delivered in any pharmacy. There are no licensing requirements for prescribing either methadone or buprenorphine, and there are no consensus guidelines but only individual initiatives. The only limitations are those determined by the regulations as described above. In 1996 and 1997, two-day training sessions were organised for GPs, pharmacists and other health professionals, which were funded by the State. However, this initiative was discontinued. Urine controls (also State funded), at a clinically determined frequency, are required of subjects treated at methadone-treatment

centres. Although urine testing is possible for buprenorphine-treated subjects, and some local guidelines specifically recommend such testing, it is discouraged by the regulatory bodies.

Minimal evaluation of subjects treated with methadone is implemented. However, appropriate support for data collection and quality control is not available. For buprenorphine treatment, no standard evaluation is undertaken. However, individual research initiatives conduct evaluations of either methadone or buprenorphine and sometimes both.

Substitution clients

There are no explicit entry criteria for methadone or buprenorphine treatment, except that the client is expected to adhere to the regulations. Consequently, buprenorphine is much more accessible. Subjects treated with buprenorphine are generally younger and better socialised than those treated with methadone. Polydrug use is increasing among all clients, whether or not they are treated with methadone or buprenorphine.

Pharmacy activity

Pharmacists are mainly involved in buprenorphine treatment. Over two thirds of all pharmacies deliver buprenorphine. Pharmacy involvement is generally received positively.

Primary-care involvement

GPs are the main prescribers of the estimated 50 000 buprenorphine-treated subjects. Half of these subjects are cared for by 12 % of GPs. It is estimated that 11 000 GPs have prescribed buprenorphine (20 % of all GPs), half of whom treat over 20 000 of these subjects. GPs, pharmacists and other professionals have been encouraged to organise themselves into networks to facilitate

professional support and offer more comprehensive treatment plans to patients prescribed buprenorphine.

Substances prescribed

Buprenorphine and methadone are regularly prescribed for the treatment of opiate-dependent subjects. Morphine sulphate prescription, although tolerated, is illegal. There are no data available regarding the number of subjects using morphine sulphate. Clinical observation suggests that most morphine sulphate prescription is diverted to intravenous injecting.

Injectable prescribing

Injectable prescription is not accepted practice in France. However, it is estimated that 10 % of those treated with buprenorphine, and most of those receiving morphine sulphate prescription, probably regularly divert their prescription to the intravenous route.

Prisons

Treatment by either methadone or buprenorphine can be continued in prison. Such treatment can also be started in prison.

Surveillance

A survey is conducted every year in November of all substance-dependent subjects that request help from the healthcare system (whether substance-abuse specialised or not and regardless of which substitution treatment is used) to collect data on the following:

- socio-demographic characteristics;
- drug use;
- medical and infectious status; and
- treatment regimen.

Problems

There are currently three main problems in the area of substitution treatment in France. For buprenorphine, there is the lack of control and specialist involvement, particularly of psychiatrists; diversion to intravenous injecting; and its availability on the street market. For methadone, only a small number is willing to use this treatment and there is lack of funding. Finally, most substance-abuse specialists are still slow to accept methadone or buprenorphine as treatments that can be integrated into a comprehensive substance-abuse treatment plan. This is a major problem in terms of facilitating contact between specialists and buprenorphine-prescribing GPs with difficult-to-treat patients.

Evaluation

Some work has been undertaken both locally and nationally on evaluating substitution treatment.

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IRELAND

Joe Barry, Baggot Street Hospital, Dublin

Introduction

Ireland is a parliamentary democracy with a population of 3.5 million. Historically, it has been one of the poorer countries of western Europe, but there has been a period of sustained economic growth, colloquially referred to as the ‘Celtic tiger’, over recent years. Ireland has been one of the 11 countries to join the single European currency. For almost the past decade, the country has been governed by a variety of centrist coalition multiparty governments.

The health service is funded out of general taxation. At central level, the Department of Health and Children is the government department responsible for the health services and for policy development in the area of health and personal social services. Health and personal social services are managed and delivered by health authorities, of which there are eight in the country. The largest health authority, in population terms, is the Eastern Regional Health Authority (which replaced the former Eastern Health Board on 1 March 2000), which comprises the counties of Dublin, Wicklow and Kildare. The total population of this health board region is 1.2 million, of which 1 million live in the county of Dublin.

Strategy

Illicit opiate use became a public health problem in Dublin in the early 1980s, and throughout that decade the dominant form of healthcare response was one of abstinence. In 1991, the Department of Health embraced the ‘harm-reduction model’ of treatment for opiate use because of the relatively high HIV seroprevalence in Dublin’s injecting drug users. This shift in policy was made explicit by the publication, in 1991, of the government

strategy to prevent drug misuse. One provision of this strategy was to set up a national drug-misuse database. This is being maintained by the Health Research Board (the Irish focal point in the Reitox network).

While a national drug-treatment centre had existed in Ireland throughout the 1980s, explicit responsibility for the development of the new strategy was vested in the local health board, the Eastern Health Board. Development funding for the harm-reduction approach to drug services was given to the body. Most coordination efforts after the 1991 government strategy to prevent drug misuse were in the area of substitution treatment. There was little in the way of a coordinated response in relation to primary prevention or rehabilitation.

As a result of the growing recognition of the link between poverty and opiate use, and also of the multisectoral nature of problem drug use, this national strategy was succeeded by a new strategy which was published in 1996. This was the report of the Ministerial Task Force on Measures to Reduce the Demand for Drugs. This strategy document was published in two parts. The list of recommendations presented in the two parts of this report were more explicit than those in the 1991 publication, and it could be argued that it was a more political document. The five-year interval since the production of the government strategy document had afforded an opportunity for the experiences of the developing harm-reduction model to be evaluated. An external evaluation of the Eastern Health Board's response to its coordinating role had been published in 1995, prior to the writing of the ministerial task force report.

The main recommendations of the ministerial task force were subdivided into different government department responsibilities. The overall structural changes are dealt with in more detail below. The government provided expanded funding for evaluative research in relation to substitution treatment, as a result of which some evaluation studies are currently in progress and some have been completed. The government has also made available extra funding to one third-level institution to run a Master's course in addiction studies. Recommendations on the treatment side include expanding

locally based treatment centres. This was recommended by the external reviewers and considerable success has been achieved in this regard. They also recommended that the Methadone Prescribing Protocol in relation to methadone prescribing in primary care should be expanded, evaluated and strictly regulated, which, in turn, has been carried out. The ministerial task force report made a commitment to eliminate treatment waiting lists during 1997. It also recommended that a telephone helpline be established.

Major deficiencies in the area of rehabilitation were detected at that time and it was acknowledged that a coordinated approach and priority status should be given to developing rehabilitation services. As a result, a lengthy list of recommendations was compiled in relation to primary prevention. There had long been concern that the education sector was not responding in an appropriate fashion to the opiate epidemic, despite the fact that the Health Research Board had shown that the age at which people began injecting was consistently dropping and that the concentration of opiate addiction was confined to a limited number of districts of Dublin.

Under the new arrangements, the Office of the Taoiseach (Prime Minister) coordinated government policy on drug misuse on the demand-reduction side. Epidemiological evidence in the strategy document highlighted the concentration of opiate use in 12 areas of the capital city of Dublin, and local drug task forces were established in each of these areas. Another task force was established in the northern suburbs of the city of Cork (the second largest city in Ireland). A sum of IEP 10 million (EUR 12.6 million) was made available to develop locally based responses to problem drug use in all of these 13 task force areas.

Task forces comprise independent chairpersons, full-time coordinators, six representatives of the various statutory organisations, six representatives of community groups and two representatives of voluntary drug-treatment agencies. The brief of these task forces is to promote consensus and develop imaginative responses to opiate use in the areas of prevention, early intervention and rehabilitation. Treatment remains the responsibility of the Department

of Health and Children and the health boards. A formal evaluation of the task force working processes has recently been carried out by management consultants.

Most of the initiatives in relation to problem drug use in Ireland are concentrated in Dublin, where most opiate use takes place. Other health boards are in the process of setting up local drug strategy teams to address drug use in rural Ireland.

Level of central planning and direction

The task force process has been very much a consensus approach. Due to the informal nature of Irish society in general and the close physical proximity of the inner-city drug problem areas and central government offices, there is substantial direct personal contact between civil servants, officials of the health boards and other authorities and task force members.

A degree of flexibility has been allowed in the evaluation of the drug services by task forces, while at the same time standardised methods of evaluation are being put into place. As well as the task force in each area, each statutory arm of the State (i.e. health services, public housing authority, employment and training organisations, the education sector and the criminal justice system) have their own statutory responsibilities, which are complemented by task force responsibilities.

Trends in funding

There has been a marked increase in funding of drug services. As well as the annual IEP 10 million (EUR 12.6 million) granted to the local drug task forces, the Eastern Health Board's budget for drugs increased from IEP 750 000 (EUR 952 000) in 1992 to IEP 14 million (EUR 17.8 million) in 1997. A service plan for the board costing IEP 17.6 million (EUR 22.3 million) was approved for 1999.

The overall thrust of Ireland's response is that substitution treatment is well funded at an outpatient and inpatient level.

Substitution

As well as substitution treatment provided by general practitioners (GPs), there has been a rapid expansion of substitution therapy (i.e. methadone maintenance, stabilisation and detoxification) in more structured treatment settings. These treatment settings are classified in two ways:

- addiction centres, where a full range of treatment responses, including methadone dispensing, are available; and
- satellite clinics, where methadone is prescribed.

Attempts are currently under way to standardise admission criteria to treatment services (an outline of the criteria for acceptance on methadone programmes is given in Table 1).

Development of substitution services

While methadone treatment was available in a limited fashion in the 1980s, it became widely available after the publication of the government strategy to prevent drug misuse in early 1992. Until that year, there were only two locations in the city where methadone was available, and, in both situations, this was in strictly controlled dispensing clinics. While there were no official figures, it was estimated that less than 10 GPs were prescribing methadone, and these were not linked to any formal drug-treatment service. When the government strategy was published, one of the recommendations was that a protocol for the prescribing of methadone by GPs would be instituted. This protocol was published in 1993.

In spite of the fact that the Methadone Prescribing Protocol was published in 1993, the vast majority of primary-care doctors were still reluctant to become involved in this type of work. There were

TABLE 1: CRITERIA FOR ACCEPTANCE ON TO A METHADONE-MAINTENANCE PROGRAMME — POLICY No 6

Methadone maintenance

The following are the criteria for inclusion of a person on a methadone-maintenance programme.

- They must meet physical, emotional and behavioural criteria for addiction as set down by the 10th edition of the International Classification of Diseases.
- They must be aged over 18, but those between the ages of 18 and 20 will require a more extensive investigation before being commenced on methadone. This would require an extensive drug history going back more than two to three years, which will need careful clarification.
- They must have an extensive one-year history of intravenous drug use.

Special cases that need not meet the above criteria for admission will include the following:

- patients who are HIV positive;
- partners; and
- patients who are pregnant.

These patients will be offered detoxification, maintenance or inpatient services as appropriate.

Young people, 18 years or younger

Young persons under the age of 18 will need their parents to attend and give parental consent. There should be a history of at least one failed detoxification, usually two or three preferably at inpatient level. However, where patients have a very long history that can be verified, this condition may be waived.

Young persons 18 years or younger will require very careful assessment and consideration at team meetings and will need the formal decision of a consultant psychiatrist before commencing methadone maintenance.

Dosages above 80 mg can only be offered after consultation with the consultant psychiatrist.

approximately 600 GPs in the Dublin area and, by the end of 1993, there were 15 prescribing methadone.

A revised version of the Methadone Prescribing Protocol was published in 1997, following a pilot evaluation of the initial guide-

lines. There has been a gradual increase in the number of doctors prescribing. The guidelines for 1997 recommend that 'no doctor should prescribe methadone unless they have undergone training organised by the Irish College of General Practitioners'. Two levels of prescribing doctors were established:

- level 1, where doctors could have up to 15 patients and do not initiate methadone treatment; and
- level 2, where a higher level of training is required and doctors could have 35 patients on their list (if in a partnership, level 2 doctors could have a combined total of 50 patients).

From time to time, individual GPs have been brought before the Fitness to Practise Committee of the Medical Council and have been censured for their prescribing practices.

Current situation

A study is being carried out in 2000 on the 350 people who entered substitution treatment in 1993, when the system was first set up, and on the first 150 people admitted to the then Eastern Health Board's inpatient detoxification and stabilisation unit. A cross-sectional survey has been carried out on hepatitis B and C seroprevalence and HIV seroprevalence in the cohort of drug users who were in maintenance treatment with the Eastern Health Board in the autumn of 1997. A mortality study is currently being carried out on the cohort of people who have entered substitution treatment since 1993.

Legislation on substitution treatment

New methadone regulations came into effect in October 1998. The impact of the new legislation is being evaluated in 2000. In September 1998, approximately 700 persons who were in treatment with four GPs were absorbed into the structured services and an evaluation of the care of these 700 patients is currently being carried out. The thrust of the new legislation is two-pronged:

- a more controlled environment for the prescribing and dispensing of methadone should be developed; and
- the number of patients that individual GPs can treat should be limited.

GPs do not require a specific licence. The relevant health board maintains a register of those doctors who are approved to prescribe. This approval is only granted after the doctor has undergone training organised by the Irish College of General Practitioners in conjunction with the relevant health board. At an operational level, this process is run by a combination of health board management, the Public Health Department and the psychiatrists and GPs who work in the health board drug service. The process is open to audit. Persons on methadone are recorded on a central treatment register and new software, which has recently been installed, will enable the process of substitution treatment to be more accurately monitored and researched. The Minister for Health is statutorily responsible for the monitoring of prescribing and health boards carry this out at an operational level.

Substitution clients

The entry criteria to substitution treatment are published and disseminated. Many who are addicted to opiates use other substances, in particular benzodiazepines and alcohol, and stabilisation of benzodiazepine use is often more difficult than that of opiate use.

Pharmacy activity

The situation with regard to the control of pharmacies is linked to the control of GPs. The Pharmaceutical Society of Ireland has been represented on all initiatives related to the prescribing and dispensing of methadone over the last five years and their recommendations are incorporated into the regulations and guidelines. Training is organised by the Pharmaceutical Society in conjunction with the regional health boards. The new regulations provide for

a range of pharmacy involvement, including daily supervised consumption, daily dispensing, biweekly dispensing or weekly dispensing.

Primary-care involvement

There has been one formal evaluation of GP prescribing; its findings were very favourable. Non-medical primary care is not as systematically available as medical primary care, but counselling support is provided by the health boards.

Substances prescribed

All substitution is provided by means of methadone. Opiate addiction is the only form of addiction for which substitution treatment is provided. Benzodiazepine, amphetamine or other addictions do not lead to substitution treatment. The average dose of methadone prescribed is 55 mg.

Injectable prescribing

There is currently no injectable prescribing in Ireland.

Prisons

There are just over 2 500 prisoners in Ireland's 15 prisons. A fact sheet produced by the Department of Justice in 1996 estimated that over 40 % had a history of serious drug misuse (i.e. opiate use). In theory, prison policy is to provide the same level of substitution treatment within prison as without, but in practice this does not happen. There is one detoxification unit and one small maintenance clinic in the largest prison. A major prevalence study of blood-borne viruses in the Irish prison population was carried out in 1998. Prevalence data from this survey have been published recently (Allwright et al., 2000).

Surveillance

National statistics are collected by the Health Research Board. In addition, the Eastern Regional Health Authority maintains a national methadone-treatment list.

One capture–recapture study has been carried out, and this examined anonymised data from the central methadone-treatment list, police data and acute hospital-discharge data.

Problems

Community acceptance

One of the main difficulties faced by service providers is the negative societal attitude to opiate users. It is generally felt that the opiate problem needs to be particularly bad in an area before the community accepts that there is a need to provide a related service. This has serious implications in that the time interval from initiation into drug use to access to treatment services is lengthened, with consequent risk of damage to health and spread of infection, in particular hepatitis C.

In common with other countries, Ireland has experienced a history of community resistance. There are currently 52 locations where methadone is prescribed through clinics run by health boards, which is a considerable improvement on the situation in autumn 1996 when the Ministerial Task Force on Measures to Reduce the Demand for Drugs was established. In two of the larger clinics, there have been attempts to curtail the activities of the clinic through legal action. One of these cases was based on private property rights to a shared laneway, while the other was related to the problem of nuisance congregation of drug users. The Eastern Regional Health Authority, together with the three area health boards, follows a proactive policy of consultation with communities to try to reach consensus. A clinic is only opened when a balance of public opinion in favour of this is achieved.

Evaluation

A number of major evaluative studies are under way at present, some of which have been completed. These include:

- an evaluation of the first 150 inpatients in the detoxification unit;
- a five-year follow-up of the first 350 patients in outpatient methadone maintenance;
- a four-year follow-up of the first 150 patients in inpatient detoxification and stabilisation;
- an assessment of the care process for 700 patients referred to health board services as a result of regulatory changes in 1998;
- an analysis of the first decade of first-time needle-exchange patients;
- a review of the level of care of female users at a city centre clinic;
- an evaluation of outpatient satellite clinics; and
- a study of seroprevalence of blood-borne viral infections in methadone patients.

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ITALY

*Marina Davoli, Fabio Patrino and Antonella Camposeragna,
Osservatorio Epidemiologico Regione Lazio (OERL), Rome*

Introduction

Italy is a constitutional republic composed of regions with autonomous administrative and legislative capacities. The parliament consists of two chambers, which are directly elected by the people. The government consists of the Prime Minister, the ministers and the Council of Ministers. Drug-treatment policies fall under the jurisdiction of the Ministry of Health and the Ministry of Social Solidarity.

Funding of the National Health Service is managed at regional level and is based on a per capita quota. A special annual national fund for interventions on drug issues was established in 1990. The regions decide on the level of integration of resources and on the mechanisms of funding.

Regions are divided into local health districts which supervise and coordinate projects funded by the Fondo Nazionale per la Lotta alla Droga (National Fund for the Fight against Drugs) and promote specific interventions in their own territories. All interventions are conducted by both public and private services.

Strategy

The national system of drug services is organised through servizi per le tossicodipendenze (SerT — public treatment centres (PTCs)) and non-governmental organisations (NGOs). The PTCs operate on an outpatient basis, and health districts may have one or more outpatient clinics. Apart from these public drug-treatment services, there is a growing number of private organisations, which are predominantly residential or therapeutic communities, although the number of drop-in centres has increased recently.

The national drug strategy for Italy is defined by the 1990 legislation on drugs, and in subsequent acts which have been passed each year. The legislation deals with demand-reduction strategies, prevention, treatment and rehabilitation. Supply-reduction strategies are also included in the legislation, but these fall under the jurisdiction of the police. Great emphasis is placed on prevention in this legislation, especially for students and young people in recreational environments.

Harm reduction has only been explicitly mentioned and promoted in recent years. Both public services and NGOs provide treatment and rehabilitation. Partnership between public and private services is encouraged. The development and organisation of public and private drug services is carried out at regional level. Considerable autonomy is afforded to the PTCs and even more to the private treatment centres.

There were 518 PTCs and 1 348 NGOs in Italy at the end of 1997. However, the majority of clients are treated by the PTCs. This varies between regions, from a minimum of 68 % to a maximum of 98 % of all treated clients.

Substitution

Development of substitution services

The development of the national system of drug services is closely related to the legal regulations which were in force at different times. Subsequent to a law passed in 1954 (1041/54), those caught using illegal drugs were punished regardless of the type and quantity of the substance, and the law permitted their compulsory referral for detoxification in psychiatric hospitals.

Therefore, during the 1960s and 1970s, when drug use had become a prevalent problem, the laws against the use of illegal drugs were quite strict. However, there was a clear change of direction with a law passed in 1975 (685/75). This law decriminalised possession of small quantities of drugs, including opiates, for personal use. It also stated that drug addiction was to be

managed as a medical condition and that the drug addict had a right to seek help for his/her condition and his/her social rehabilitation, within the appropriate healthcare or other services. Also, the provision of methadone to opiate addicts became permissible and specific treatment services were developed. Up to 1993, substitution treatment was only given in public treatment centres. However, since 1993, methadone has also been prescribed by general practitioners (GPs).

The first services for drug treatment were implemented in the 1980s. At the same time, medical doctors were prohibited from prescribing morphine. PTCs have developed more effectively in some regions than others, with huge variations in treatment offered across the country.

The number of PTCs increased from 475 in 1991 to 518 in 1997, while the number of NGOs increased from 1 249 in 1993 to 1 348 in 1997.

Current situation

Table 1 shows data concerning clients of treatment services (according to the annual report of the Ministry of Health), the number of drug-related deaths and the estimated number of drug users (using the mortality multiplier method — MMM) ⁽¹⁴⁾. The number of drug users was estimated from the mortality rates, calculated on a cohort of drug users enrolled in PTCs and NGOs in Rome during the period 1980–95.

The rise in the numbers of drug users recorded was probably partly due to improved monitoring by the Ministry of Health's surveillance system and to an increase in users attending treatment services. Prevalence of drug users (estimated using the MMM) continued to increase until 1992, stabilising afterwards with a prevalence of around 200 000 users.

⁽¹⁴⁾ The mortality multiplier method for estimating the prevalence of drug use involves determining the annual number of drug-related deaths in a given setting (e.g. a city) and assuming these represent a proportion (e.g. 2 %) of the total number of active users in that setting. The proportion is usually based on studies of the annual mortality rate amongst groups of drug users.

TABLE 1: ESTIMATED PREVALENCE OF DRUG USERS IN ITALY

	1990	1991	1992	1993	1994	1995	1996	1997
Drug users in treatment services ⁽¹⁾	67 500	92 853	103 805	104 742	113 735	123 828	129 884	138 218
Number of drug-related deaths (police)	1 161	1 383	1 217	888	867	1 195	1 566	1 153
Number of drug-related deaths (ISTAT, ICD-1 304)	1 094	1 180	1 093	760	809	—	—	—
Mortality rate for overdose (1 000) ⁽²⁾	8.9	7.4	6.2	4.3	4.9	5.9	—	—
Estimated number of drug users ⁽³⁾	130 449	186 891	196 290	206 511	176 938	202 542	—	—

⁽¹⁾ Source: Ministero della Sanità, 1996.

⁽²⁾ Mortality rate among drug users enrolled in PTCs and NGOs, Rome, 1980–95.

⁽³⁾ Multiplier formula.

One of the main limitations of these data is that they refer to prevalence of heroin use, which still represents 90 % of clients attending treatment centres. Data on prevalence, spread and risks related to consumption of other substances are limited. The only available data come from prevalence studies on selected areas of the population and from information on confiscated drugs provided by the police authority.

In 1994, a survey was carried out on a sample of 35 000 18-year-old males undergoing an army selection test. Data on drug use were collected by a self-administered questionnaire and urine analysis. Fifteen per cent of the sample declared they had used cannabis, 2.8 % had used amphetamines or ecstasy, 2.7 % cocaine or crack, 2.5 % heroin or opiates and 1.9 % hallucinogens. Four per cent of the sample tested positive in the urine analysis. Of these, 86 % tested positive for cannabis, 4.7 % for opiates, 4 % for cocaine and 2 % for amphetamines (Rezza, 1994). From 1994 to 1996, a harm-reduction integrated programme was carried out in Rome (Verster et al., 1996). One of the outreach units involved in the programme surveyed a section of the population

aged, on average, 26 years. Of this sample, 34.6 % reported use of cocaine in the previous three months, 20 % ecstasy and 14 % LSD.

In a study evaluating the efficacy of interventions for HIV prevention conducted in Rome in 1997–98 among secondary-school students (Bargagli et al., 1999), information was gathered concerning substance use. Of this sample:

- 35 % reported using cannabis at least once;
- 9.5 % had used sedatives;
- 5.5 % had used ecstasy;
- 3.7 % had used LSD;
- 3.4 % had used stimulants;
- 0.5 % had used heroin; and
- 9 % had used cocaine.

All the available data show a stabilised prevalence of heroin use from 1990 to date, but it is difficult to evaluate both the trends and health effects regarding other substances.

Legislation on substitution treatment

In the 1970s, substitution treatment was offered by medical doctors. Morphine and methadone were offered, both in oral and injectable form. The first regulatory approach to substitution was initiated by a law passed in 1975 (685/75) which established that specialised public treatment centres should be developed in each health district. In 1980, the Ministry of Health pronounced that GPs would no longer be allowed to prescribe substitution treatment. Since then, substitution treatment has only been offered by PTCs.

A law passed in 1990 (309/90), which united in one text the existing Laws 685/75 and 162/90, defined general guidelines for provision of substitute drugs and criteria for admission to the methadone programmes. This law was open to a wide range of interpretations. In practice, some PTCs prescribed no methadone at all, others gave the minimum required for a detoxification pro-

gramme lasting three weeks, and others gave it for longer periods with higher doses. Nonetheless, the official view remained that methadone maintenance alone was not allowed but that it should only be provided in conjunction with psychosocial interventions. Eventually, in June 1993, parts of Law 162/90 were abolished by a national referendum. A clarification was provided by specific guidelines produced by the Ministry of Health in September 1994:

- methadone prescription should be personalised according to the needs of the client;
- methadone can be prescribed over a protracted period of time, in order to avoid relapse and to help reduce the rate of HIV infection; and
- medical doctors can prescribe methadone, but always in collaboration with the local PTC (and after the PTC has established a diagnosis).

Substitution clients

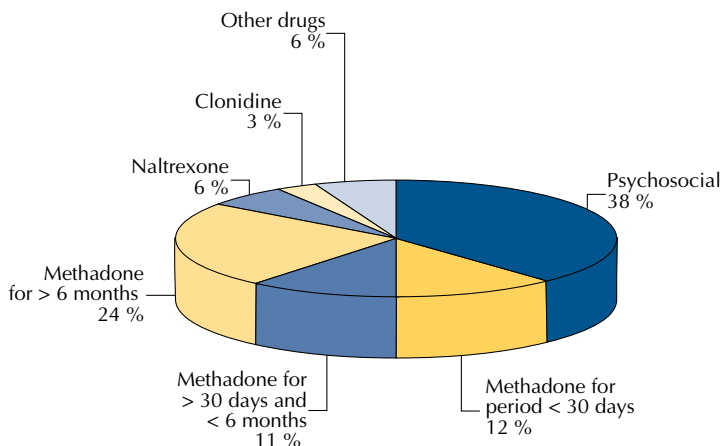
The number of drug users treated increased from 93 000 in 1991 to about 140 000 in 1997 (Ministero della Sanità, 1999), corresponding to a prevalence of 24.1 per 10 000 inhabitants in 1997. The male/female ratio is 6:1. The average age increased progressively from about 28 years to 31 for prevalent cases and from 26 to 28 for new users.

In 1997, the majority of clients in treatment (87.5 %) used heroin as the primary drug, whereas, in 1992, heroin was used by 91.2 %. This negative trend is completely different for cocaine, which was used by 1.3 % of clients in 1991 and by 2.3 % in 1997. Other common features of heroin users are:

- they usually inject;
- they also use other drugs (cannabis and benzodiazepines); and
- they are older than new clients.

Clients in the care of public treatment centres were generally treated pharmacologically (62 %), as shown in Figure 1.

FIGURE 1: TYPE OF TREATMENT OFFERED BY PTCs IN ITALY (1997)



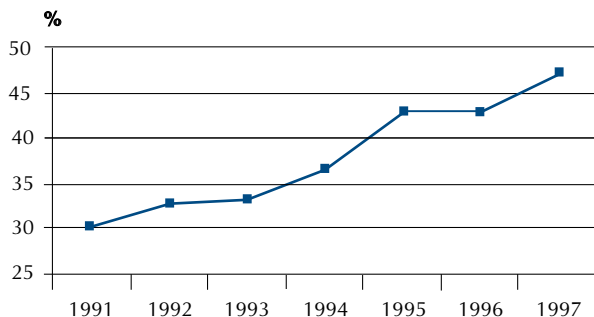
Source: Ministero della Sanità (1999).

In 1997, about 50 % of clients of PTCs were offered methadone treatment, half of them on a maintenance schedule. The proportion of clients on methadone progressively increased from 30.3 % in 1991 to 47.2 % in 1997 (Figure 2).

Data from the Ministry of Health do not provide information on methadone dosage. Since 1995, the drug-addiction surveillance system in the Lazio region has collected individual data on methadone dosage (D'Ippoliti et al., 1998). In 1997, the average dose of methadone prescribed to people on maintenance was 44 mg.

As far as prevalence of HIV infection among treated drug users is concerned, in the period 1991–97 the percentage of HIV-positive clients was continually decreasing: in 1991, of 51 256 clients tested, 28.8 % were positive, while in 1997 this figure was 15.7 % of 76 096 people tested. If we classify clients according to gender and time spent in the care of PTCs, it is clear that, even if the trend is decreasing, new male clients are less likely to be infected, whereas 'old' (or longer-term) female clients represent the greater proportion of people infected.

**FIGURE 2: PREVALENCE OF CLIENTS OF PTCs
ON METHADONE TREATMENT IN ITALY (1991–97)**



Source: Ministero della Sanità (1999).

Hepatitis B is widespread among PTC clients: in 1997, of 68 062 people tested, 43.6 % were positive, while in 1991 this figure was 50.9 %. Data regarding hepatitis C have been collected since 1997, when 67.3 % of patients tested positive in a sample of 66 467. There were no obvious differences between men and women.

Pharmacy activity

In Italy, pharmacies only have limited involvement in the provision of services for drug users. They mainly sell injection equipment. Some pharmacies keep a syringe-exchange machine on the wall outside the pharmacy. In Rome, a special programme on overdose prevention started in 1999, one element of which is that pharmacies sell syringes together with an information leaflet. Also, the pharmacies will be encouraged to sell naloxone to heroin users without medical prescription.

Primary-care involvement

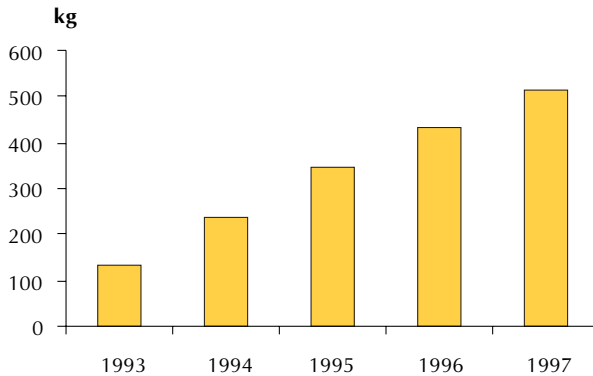
There is only occasional medical involvement in primary care and no specific training has been proposed.

Substances prescribed

Oral methadone has been the only substance authorised for drug treatment, but, in 1999, new legislation allowed prescription of sublingual buprenorphine.

Figure 3 shows the trends in methadone consumption in drug dependency during the period 1993–97. These data confirm the increased consumption of methadone which has been observed in PTC clients.

FIGURE 3: CONSUMPTION OF METHADONE IN ITALY (1993–97)



Source: International Narcotics Control Board (INCB).

Injectable prescribing

No injectable substitution treatment has been authorised.

Prisons

The problem of drug users in prison has been evident since 1990: drug users represent about 30 % of all prisoners. More than half the drug users in prison are there for violating laws regarding drugs (mainly dealing and trafficking).

Provision of substitution treatment is virtually non-existent (as of December 1997, only 500 drug users out of the total 14 000 in prison were on methadone treatment).

Surveillance

Since the second half of the 1980s, two surveillance systems have been collecting data on drug users attending treatment centres: one is run by the Ministry of Internal Affairs and the other by the Ministry of Health.

Every three months, the Ministry of Internal Affairs collects data on the number of drug users registered at public treatment centres and therapeutic communities on a specific day (point prevalence). The Servizio Centrale Antidroga del Ministero degli Interni (Central Anti-Drug Office of the Ministry of Internal Affairs) keeps regular records of the number and characteristics of those people who have died of drug-related causes. This source also provides data on the following:

- the quantity and kinds of drugs seized;
- the number of criminal charges brought for drug dealing and trafficking and for drug-related theft; and
- the number of people reported to the authorities for possession of drugs.

The Ufficio Centrale per le Dipendenze da Alcool e Droga del Ministero della Sanità (Central Office for Alcohol and Drug Dependence of the Ministry of Health) gathers data about the following:

- the number of drug users attending public treatment centres;
- their demographic characteristics;
- type of drug used; and
- treatments followed.

Other sources of information on drug addiction are the Ministry of Justice, which provides data on drug users in prison, and the Ministry of Defence, which collects data on the number of drug users identified when called up for military service or while serving.

All these surveillance systems are based on aggregated data. One of the major problems is double counting, as some regions have their own surveillance systems based on individual data. A national system based on individual data is currently being developed.

Problems

The most critical problems of community-based services is the shortage of personnel and poor structural organisation. Italy is now reorganising its health system and minimum quality criteria will be established for both private and public services.

Another critical problem of these services is the heterogeneity of treatment offered, with the consequent inequalities across the country. A lack of continuity of treatment between the healthcare system and prison is also a major problem.

Finally, most services still have an abstinence-oriented ethos, with consequent resistance to substitution-treatment programmes, especially on a maintenance basis.

Evaluation

The first large-scale study of treatment outcome for heroin users ever conducted in Italy is the 'Valutazione efficacia dei trattamenti per la tossicodipendenza da eroina' (VEdeTTE — 'Evaluation of effectiveness of treatments for heroin dependence'). It was

commissioned and funded by the Ministry of Health and coordinated by the Osservatorio Epidemiologico Regione Lazio (OERL — Department of Epidemiology of the Lazio Region), the Health Authority and the Department of Public Health of Torino University.

Special efforts were made to inform workers in the drug services, policy-makers and researchers of the objectives and methodology of the study and its relevance to the planning and implementation of effective treatment programmes at national level.

VEdeTTE is a prospective, longitudinal, cohort study on a multi-centre cohort of heroin users entering 130 public treatment centres for drug addiction in 13 Italian regions. Local and national coordinating groups have been identified for the management of the study. The objective of the study is to evaluate the effectiveness of different treatments for heroin dependence offered in PTCs in order to:

- prevent mortality from overdose, injury and poisoning; and
- retain clients in treatment.

Enrolment of patients in the study, which began between September 1998 and March 1999 in all participating PTCs, will continue for 18 months. Two years after the beginning of the study, checks will be made to ascertain whether the patients are still alive. A questionnaire and a form for collecting data on treatments were specifically designed for the purposes of the study. The questionnaire, to be administered on enrolment, gathers information on potential confounders, such as:

- socio-demographic characteristics;
- severity of dependence;
- previous overdoses and treatments; and
- physical and psychiatric health status.

All therapeutic interventions are recorded using a standardised form.

A pilot study involving 1 000 heroin users enrolled in 20 PTCs across 13 different regions was carried out between November

1997 and January 1998. The protocol and instruments for collecting data for the VEdeTTE study have been prepared on the basis of the results of this pilot study. The estimated number of people that will be enrolled is more than 10 000.

An Italian project, which is part of the COST A6 programme ⁽¹⁵⁾, aims at producing guidelines for treatment evaluation in the field of drug abuse.

In 1998, the Cochrane collaborative review group on drug and alcohol was implemented. Its editorial base is in Rome at the Department of Epidemiology of the Lazio Region. The other editors collaborating in the review are based in the following:

- the National Addiction Centre, London, UK;
- the Department of Public Health, Torino University, Italy;
- the National Drug and Alcohol Research Centre, Sydney, Australia;
- the Drug and Alcohol Services Council, Adelaide, Australia; and
- the University Victor Segalen, Bordeaux II, France.

The main objective of the group is to produce, disseminate and update systematic reviews on the effectiveness of interventions in drug and alcohol abuse.

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LUXEMBOURG

Simone Dietz, Jugend–An Drogenhëllef, Luxembourg

Introduction

Luxembourg is a constitutional monarchy with a population of 429 000 (as of 1 January 1999). The country's main characteristics are as follows:

- economic prosperity;
- low unemployment;
- 13 % of the population are non-natives (mainly of Portuguese origin); and
- 25 % of the working population do not live in Luxembourg.

Medical care in Luxembourg is very accessible. Payments from health insurance are very high. Only a few people have no health insurance, and they are covered by the well-developed social services. However, there is no systematic and organised collaboration between health and social services. Health services are based on a liberal system and social services are private or financed by the government via NGOs. Collaboration between the two remains difficult.

Strategy

The first specialised services for those with drug-related problems were created at the end of the 1970s. Private initiatives at that time prepared the ground for current drug-treatment structures. During the 1980s, the drug problem increased and, in parallel, so did social pressure. The Jugend–An Drogenhëllef (JDH — Youth and Drug Assistance), a counselling service for young people and drug users initially financed by the Ministry of Family, was the first specialist outpatient institution for those with drug-related problems.

At the end of the 1980s, hepatitis and AIDS prevention became prevalent and outreach work, a methadone programme and needle-exchange activities were initiated in 1989 with the help of the Ministry of Health. In the mid-1990s, the Centre de prévention des toxicomanies (Centre for the Prevention of Drug Addiction) was established and the methadone programme extended.

The low-threshold service known as ‘Camionnette–Scene Contact’ (a specially equipped van near the central railway station offering hot drinks, needle exchange, human contact and counselling) was created at the beginning of the 1990s.

In 1997, a new agency was developed in collaboration with Médecins sans frontières which works with minors experiencing drug problems and conflicts with the law.

A counselling service has been operating in the north of the country since February 1999. This project was developed with advice from local institutions and in close collaboration with the municipality.

There is a distinct trend towards developing low-threshold services (rooms in which to take drugs under medical supervision, emergency lodgings, heroin programmes, etc.).

It is current policy to develop an integrated approach, by which low-, middle- and high-level services are parts of a general strategy, with a complementary perspective. Strategies of harm reduction and health prevention for drug users, on the one hand, and a therapeutic approach, on the other, are not seen as mutually exclusive.

Several ministries are responsible for drug policy: the Ministries of Justice and Health are responsible at one level and the Ministries of Family, National Education and Youth at a second level. An interministerial working group coordinates the activities of these different ministries.

The small geographical size of Luxembourg facilitates reciprocal contacts between citizens and policy-makers. The relevant schemes rely more on cooperation than confrontation.

Substitution

Development of substitution services

The pilot phase of the methadone programme began in April 1989, evolving from a project entitled 'SIDA et toxicomanie' ('AIDS and drug addiction'), offering a total of 15 places. The initial results of the pilot project were encouraging and, in 1992, the capacity of the programme was extended to 25 places. This small project had a long waiting list (up to one year in 1994) and high admission criteria. Also, the death rate among drug users peaked in 1994. This situation induced the Ministry of Health to extend the programme to 100 places in 1995 and to 160 places in 1996.

At the beginning of the programme, only one doctor (a psychiatrist) was prescribing methadone at the JDH. The expansion of the programme required services to be decentralised. Pharmacies became involved in the preparation and distribution of methadone, and general practitioners (GPs) became responsible for monitoring drug users and for prescribing, in their own consultation room. This rationalisation phase was an important transition period in the programme's development. A disagreement between the doctors' association and the Ministry of Health hampered this process but, fortunately, these difficulties have been resolved. There is currently a network of over 40 physicians prescribing methadone in Luxembourg. These doctors have to agree to the prescribing guidelines.

At first, substitution treatment was firmly structured by the fact that the national methadone programme had the monopoly of prescription. The methadone programme now constitutes a network composed of the following:

- staff (psychologist, social workers, male nurse, educator, secretary);

- prescribing doctors (general practitioners and psychiatrists who signed a 'work convention' with the Ministry of Health);
- pharmacists; and
- the Commission méthadone (Methadone Commission).

The Methadone Commission is composed of representatives of GPs, pharmacists, the Ministry of Health and the staff of the methadone programme. The commission meets regularly to make decisions in the following areas:

- applications for admission;
- staff proposals for changes to the programme; and
- solutions to problems that cannot be resolved by the staff alone.

Since the pilot project was established in 1989, substitution treatment with methadone has gradually evolved and developed.

Current situation

In 1999, 186 drug users participated in the national methadone programme (Table 1).

The staff of the methadone programme is composed of one psychologist (responsible for the methadone programme) working half-time, three and a half social workers, a nurse, an educator and a half-time secretary. The psychologist and one and a half social workers provide the therapeutic framework. The programme's centre is open between 6 a.m. and 5 p.m. from Monday to Friday. Two members of staff supervise the distribution of methadone in the morning to about 40 clients. The rest of the staff work from 9 a.m. to 5 p.m. In 1998, 186 clients participated in the methadone programme. Many of them had their key worker, social assistant or therapist and one of the two other staff in the JDH counselling centres for drug users in Luxembourg.

A GP visits the centre weekly and prescribes treatment for about 35 clients. However, some of these 35 clients do not have to be seen by the doctor every week because they have been stabilised for several years.

TABLE 1: METHADONE PROGRAMME DATA FOR LUXEMBOURG (1999)

GENDER		
Male	131	70.5 %
Female	55	29.5 %
Total	186	100 %
SOCIAL SITUATION		
Employed	75	40 %
RMG ⁽¹⁾	36	19.5 %
Paying rent	18	10 %
Receiving unemployment benefit	9	5 %
Receiving social aid	2	1 %
Student	1	0.5 %
Without any revenue	45	24 %
Total	186	100 %
NATIONALITIES		
Luxembourgish	137	75 %
Portuguese	24	13 %
Italian	10	5 %
French	5	3 %
Belgian	3	1.5 %
Cape-Verdian	3	1.5 %
Spanish	2	1 %
German	2	1 %
Total	186	100 %
AGE		
< 20 years	1	0.5 %
20–24 years	20	10.5 %
25–29 years	54	29 %
30–34 years	61	33 %
35–39 years	34	18 %
> 40 years	16	9 %
Total	186	100 %
DURATION OF DRUG DEPENDENCY		
< 3 years	4	2 %
3–5 years	30	16 %
6–10 years	85	46 %
11–15 years	44	24 %
> 15 years	23	12 %
Total	186	100 %
GEOGRAPHICAL ORIGIN		
North	41	22 %
South	83	44.5 %
East	7	4 %
West	1	0.5 %
Centre	54	29 %
Total	186	100 %

(1) Guaranteed minimum revenue.

The centre for the methadone programme (in two locations) is situated near the railway station opposite the counselling centre. This geographical position has the advantage of being close to the station and the disadvantage of being close to the 'drug scene'. The fact that it is opposite the counselling centre and that the methadone programme is run by the whole organisation, the JDH, facilitates collaboration between the two services. Useful collaboration with a general hospital has also been set up in order to be able to admit pregnant women to the programme. Additionally, meetings are organised to facilitate collaboration with other specialist institutions. Staff members have to be mobile in order to be able to:

- visit clients who are hospitalised;
- visit clients who are in prison; or
- organise meetings with the other services to ensure follow-up.

This collaboration may not be perfect, but much effort has been expended on improving it.

The development and maintenance of an effective collaboration network benefit both the centre and the clients. There have been difficulties regarding collaboration with GPs (partly due to the fact that the centre does not have a doctor on the staff), although the GP who counsels in the centre does a lot of networking: for instance, collecting the medical data of drug users who are in treatment with other doctors in the methadone programme. These data will be included in the JDH's next evaluation, which will be completed in 2001.

Staff have already collected medical data from 92 patients out of a total of 186. Of these 92 patients, 5 (18 %) are HIV positive, 44 (48 %) are hepatitis B positive and 55 (60 %) are hepatitis C positive. Two suicides occurred during 1998. Also, 124 of the 186 patients who participated in the methadone programme in 1998 have been convicted of drug offences at least once in their lifetime.

Legislation on substitution treatment

To date, the methadone programme does not have a legal framework. Officially, it is tolerated and relies on verbal commitment. In fact, the law actually prohibits contributing to the maintenance of addiction, and substitution could be considered just that. In August 1997, the Ministers for Health and Justice introduced a bill which would provide a legal framework for the methadone programme. Since then, the two ministers involved have retired and a new legislative period has begun under which no changes have occurred. The current situation obviously makes it difficult to enforce guidelines for treatment.

Those doctors who have signed a convention with the Ministry of Health benefit from a verbal contract. This convention determines the conditions of prescribing:

- the rules of the methadone programme have to be respected;
- collaboration with the methadone programme has to be ensured;
- special training has to be undertaken; and
- meetings organised by the methadone programme have to be attended.

The Ministry of Health controls prescribing by demanding that doctors use a special prescription form. In serious cases of abuse of prescribing practices, the Ministry of Health can withdraw the prescription forms and make a complaint to the medical committee. The doctors' association and the Ministry of Health have signed an agreement which regulates the prescription of narcotic substances.

Luxembourg has two kinds of substitution treatment: one in the official programme (for maintenance treatment) and one outside the programme. The latter is used for short substitution treatments, such as detoxification. In Luxembourg, about one third of substitution patients are in the methadone programme and the remaining two thirds are out of the programme. Another function of the agreement between the doctors' association and the Ministry of Health is to structure these treatments. The three JDH services, the

two counselling services and the methadone programme, can opt to support and work with the prescribing doctors if they wish.

Luxembourg's Reitox focal point (the Directorate of Health at the Ministry of Health) has conducted a study on the attitudes and practices of GPs treating drug-addicted patients. The results, published in the 1998 report by the Réseau luxembourgeois d'informations sur les stupéfiants (RELIS — Luxembourg information network on drugs and drug addiction), show that 29 % of the doctors received special training of between 1 and 15 days maximum; 71 % of doctors felt that they were insufficiently prepared.

The methadone programme normally organises training, but only a few doctors are interested. All the doctors are invited to collaborate with JDH staff, since it is generally felt to be more constructive to work in a medical psychosocial team and to have its support. However, it seems that this collaboration is not necessarily desirable for some of them. Collaboration with doctors is useful for an efficient follow-up of the client, and it is also useful for the good working of the methadone programme. Guidelines which are developed by JDH staff are often the result of suggestions made by the clients themselves and our collaborators.

New concepts are discussed by the Methadone Commission and are then disseminated to all JDH collaborators. Meetings are organised for the clients and collaborators to facilitate debate and exchange of opinions.

Substitution clients

A drug user who wants to be admitted to the national methadone programme must be interviewed by a social worker or a therapist from the counselling service for assessment (for instance, to ascertain if substitution is really the best solution in the light of his/her specific social situation and past treatment). After this, an admission questionnaire is passed on to the Methadone Commission, where his/her possible admission is debated. The two main entry criteria are:

- confirmed opiate addiction; and
- minimum age of 18 years.

An earlier entry criterion of having undergone two trials of abstinence-oriented therapies has now been discontinued.

Once admitted to the methadone programme, the applicant is registered and receives an anonymous M-number. He/she is also registered with the Ministry of Health via the special prescription form. A treatment contract has to be signed by a representative of the methadone programme, by the prescribing doctor and the client himself/herself. This contract sets out the obligations of the applicant and details of the services provided by the centre. In the first four months of treatment, weekly urine controls and visits to the doctor are mandatory. When a client can prove abstinence for at least four months, he/she is rewarded (for instance, instead of having to attend every day for his/her prescription he/she can do so only three times a week). After the first four months, the client is allowed to decide for himself/herself whether or not to undergo urine controls. If the doctor or a member of staff believes a urine control will be useful, it will be carried out. For young parents, urine controls remain mandatory.

A client decides with his/her doctor how long he/she will stay in the programme; there is no time limit whatsoever. There are three situations where treatment will stop:

- if the client is violent;
- when a deterioration of the client's situation since the beginning of treatment shows that substitution is not an adequate solution; and
- when it is estimated that methadone is only one substance in a panoply of substances consumed by the client.

One of the biggest problems is the polydrug user, a problem to which an adequate solution has not yet been found. In such cases, two substitutions are offered; one for opiate addiction and one for benzodiazepine addiction. In the latter, periodical qualitative urine controls are carried out. Nevertheless, when the polydrug use is too compelling, the treatment is stopped.

The JDH offers many services, ranging from support with traditional therapies to social aid such as help for urgent problems and assistance in searching for employment or accommodation. Even clothing is supplied, if needed. The JDH also has the facility to organise groups to discuss specific problems. Whenever a patient is a parent, psychosocial care is obligatory.

Twice a year, the clients are invited to complete a questionnaire for the organisation's statistics and evaluation programme. At the same time, the client is interviewed to evaluate his/her current situation.

Pharmacy activity

Since decentralisation in 1994, about 35 pharmacists have participated in the distribution of methadone. They are involved in the treatment and can benefit from psychosocial support if they wish. They are invited to participate in training programmes organised by the methadone programme.

The pharmacists who participate in the distribution of methadone also sell needles, and thus sometimes have a dual role. Harm reduction is often the major aim (AIDS and hepatitis prevention), making the distribution of sterile needles vital.

Primary-care involvement

Currently, of the prescribing doctors who participate in the methadone programme, 90 % are GPs (40 out of a total of 225), 5 % are medical physicians and 5 % are psychiatrists. As can be seen, GPs are very involved in substitution treatment. As stated above, an agreement between the doctors' association (a group of doctors who created a working group to debate substitution treatment) and the Ministry of Health outlining guidelines for substitution treatment is in preparation.

Prior to the expansion of the methadone programme in 1994, only a few doctors were involved in the treatment of drug users. At that time, doctors could prescribe substances such as dihydrocodeine without being monitored through the use of the special prescriptions.

In 1994, there were no professional bodies offering advice because few doctors were interested in drug-related medical problems. However, a working group of about 12 doctors has now been created. An important point is that specialised training and supervision are paid for by the Ministry of Health to encourage doctors to participate in substitution treatment.

For most doctors in Luxembourg, the practice of working in a network is new, because of the country's tradition of a liberal medical system. Organising meetings to discuss clients (for pooling information or case management) is not usual practice, because these meetings are not paid for. Nevertheless, such practices could be of considerable benefit to many patients. Unfortunately, this deficiency shows that social medicine does not exist in Luxembourg.

Substances prescribed

The substitution substance most often prescribed for opiate addiction is methadone (95 %). It is prescribed in syrup form for the clients who are in the national methadone programme. All other drug users receiving substitution treatment receive their methadone in tablets. The dosage for long-term substitution is between 40 and 80 mg, with a maximum of 150 mg.

The situation regarding other substitution substances is as follows.

- Dihydrocodeine was often prescribed before the expansion of the methadone programme in 1995. Now it is only prescribed in very few cases.
- LAAM and palfium are not prescribed in Luxembourg.
- Buprenorphine is sometimes prescribed and this will probably increase in the future (dosage 8–16 mg).

- Dezitramide (20–40 mg) is sometimes prescribed to clients who cannot tolerate methadone.
- Mephenon (methadone in pill form) is often prescribed in Luxembourg. Its pharmacological action is equal to that of methadone.
- Clonazepam (6 mg/day), bromazepam (up to 36 mg/day) or lorazepam (up to 7.5 mg/day) are the substitution benzodiazepines most often prescribed for benzodiazepine addiction.
- Frazodone chlorhydrate (50–200 mg/day), fluoxetine (20–40 mg/day) or any other antidepressant drugs are prescribed for amphetamine addiction.

Usually detoxification proceeds gradually and might take several years. If a client desires a more rapid withdrawal, his/her dosage will be reduced by about 10 % every 14 days. More rapid detoxification is possible but remains difficult.

Injectable prescribing

Luxembourg does not have any injectable prescribing. The August 1997 bill proposed a heroin programme, but the retirement of the Ministers for Health and Justice involved (see above) engendered a blocked situation.

Surveillance ⁽¹⁶⁾

Established in 1994, RELIS is based on a standardised data protocol which includes 24 core items and over 60 sub-items. Ninety-five per cent of the items in the Pompidou Group Protocol (a list of treatment-demand indicators) are integrated into the standard protocol. A second protocol, namely the ‘actualisation protocol’, is completed each time a previously known drug addict is re-registered after a period of one year following the previous registration. This registration system allows for updated quality data and efficient follow-up of the institutional careers of drug addicts.

⁽¹⁶⁾ The surveillance section was compiled from selected writings of Alain Origer, Head of the Luxembourg national focal point of the EMCDDA’s Reitox network.

RELIS relies on a mechanism known as the 'institutional contact indicator', a data-providing network which includes all specialised drug-treatment institutions, law-enforcement agencies and custodial institutions. Efforts are currently under way to encourage the participation of GPs and emergency services in the information network.

In terms of prevalence estimation and assessment of the impact of specific demand-reduction or law-enforcement interventions, as well as in terms of planning new institutions or addressing gaps in drug care, RELIS is a reliable monitoring tool which operates on a national basis and is regularly updated.

RELIS became operational in 1994 and currently relies on a multi-sectoral network which includes:

- specialised treatment centres;
- general hospitals;
- counselling centres;
- legal bodies; and
- penal institutions.

In order to avoid duplication and to allow for follow-up of drug users' careers, RELIS operates on a nine-digit numerical code which is obtained by combining the three variables (attributors), namely:

- gender;
- date of birth (e.g. 10051967); and
- country of birth.

This results in a Luxembourg Reitox focal point proper code (calculator). This technical device was developed by the focal point itself. The method is very time- and cost-effective, because it relies on a simple Hewlett Packard calculator that runs an attributor-to-code transcription programme on a 27-step algorithm.

It is not possible to extract information on the person to whom the code relates and the transformation key is unknown to participating field institutions and to all members of the focal point. Even if the calculation algorithm were to be discovered, he/she would be unable to do a backward calculation. Each contact person in the participating field institutions disposes of the calculator and produces the code himself/herself. The reliability of this system, in terms of data protection, has recently been acknowledged by the Commission nationale d'informatiques et de liberté (National Commission for Informatics and Liberties) of France.

One of the main assets of RELIS is that no personal data can be inferred directly from the identification code. The inputting and encoding procedures are carried out at the level of the field institutions. In this way, the focal point receives individualised data (reporting protocols) without nominative information or attributors on the persons thus registered, which is undoubtedly one the major preoccupations of field institutions.

The information gathered by this system and the results of research coordinated by the national focal point contribute to the political decision-making processes in Luxembourg as well as to the drafting of new action plans in the area of drug abuse. At the European level, Luxembourg's national focal point collaborates with the other national centres of the Reitox network. This collaboration focuses, among others things, on:

- implementation of an interregional drug-treatment reporting system (TRANS-RELIS), which includes border regions of Belgium, Germany and France;
- active collaboration in establishing the Reitox network's IDA/EMCDDA project; and
- analysis of procedures to improve national drug monitoring systems within the European Union.

TABLE 2: SOME DATA FROM THE RELIS STUDY AND THE ANNUAL REPORTS OF THE SPECIALIST SERVICES IN LUXEMBOURG (1996–98)

SPECIALIST INSTITUTIONS	1996	1997	1998
Counselling JDH-Lux (ambulatory service)	308 persons	244 persons	270 persons
Counselling JDH-Esch (ambulatory service)	175 persons	166 persons	183 persons
Methadone programme	128 persons	158 persons	186 persons
Camionette (low-threshold specialist service)	6 456 contacts	8 734 contacts	8 525 contacts
Neuro-psy hospital (specialised service for inpatient detoxification)	250 admissions	226 admissions	251 admissions
Residential community (Manternach)	58 admissions	62 admissions	39 admissions

Comments and remarks

The numbers of counselling clients have varied only slightly over the years. Low-threshold services are being increasingly solicited. The residential community had 39 admissions in 1998 and it ran a full house with a waiting list during some periods. Over the period 1998–99, the work concept of the residential community has been usefully modified.

Many drug users go to other countries (Belgium, Germany, France and Italy) for residential treatment, because of the limited number of places offered in Luxembourg.

Problems

A number of the residents in the neighbourhood of the treatment centres encounter considerable problems with the services, mostly due to the following factors:

- the centres are situated near the railway station;
- prostitution is practised in this area; and
- the area is still a residential one.

Unfortunately, the residents no longer feel safe. They have formed a local organisation but this is unlikely to bring about the closure of the centres. Staff hold regular meetings to discuss strategies for dealing with these problems.

As regards the situation in Luxembourg's prisons, 36 % of prisoners in 1997 were imprisoned for drug-related offences. Clients who are in methadone treatment before their detention continue their treatment during remand and, in cases of a long prison sentence, undergo slow detoxification. A prisoner is allowed methadone before his/her release.

Evaluation

An evaluation of the methadone programme will be undertaken in late 2000.

THE NETHERLANDS

Han Kuipers, Trimbos-Instituut, Utrecht ⁽¹⁷⁾

Introduction

The Netherlands is one of the smaller countries of Europe, yet it is also one of the most densely populated and urbanised countries in the world. For almost two centuries, the political system has been a democratic one. The members of the Houses of Parliament of the national government represent the people, while the judiciary oversees the implementation of the laws.

In the Netherlands, there is an extensive and comprehensive healthcare system. In practice, the system has two pillars:

- a considerable network of facilities for general healthcare; and
- a more extended network of facilities dedicated to specific health tasks and social work (for instance, mental healthcare and addiction care).

These facilities are funded by the Ministry of Health, health insurance companies and funds controlled by private organisations (foundations and associations) founded for this specific purpose.

Strategy

Drug laws

The first Opium Act of 1919 was a direct result of the Netherlands attending the first International Drug Conference in The Hague (1912). Opiates were strongly forbidden, except for registered use for medical and scientific purposes. In 1928, the Opium Act was amended for the first time (cannabis was included in this revision)

⁽¹⁷⁾ The Trimbos-Instituut is the Dutch national focal point in the EMCDDA's Reitox network.

and for the second time in 1953. In 1976, the act was fundamentally changed:

- a distinction was made between hard and soft drugs (unacceptable versus acceptable health risks); and
- the philosophy of reducing the health risks of users (harm reduction) was formally accepted.

Since 1976, the Netherlands has had its own drug policy. Prior to that, the country was committed to a number of international treaties, such as the 1961 UN Single Convention on Narcotic Drugs.

The Opium Act is a penal law, and Dutch penal law recognises two kinds of criminal act: criminal offences (crimes) and minor offences (misdemeanours). In relation to drugs, processing, production and trade other than for medical and scientific reasons are major offences. The only minor offence in the area of drugs is possession of small quantities of cannabis (up to 30 mg) other than for personal use. Dutch penal law is strongly influenced by a principle of expediency, which means that the public prosecutor decides whether or not prosecution is necessary. The public prosecutor is bound by a comprehensive set of guidelines.

The Netherlands is still party to a number of international treaties. All three United Nations conventions in the area of drugs have been ratified by the Dutch Parliament and some elements have been integrated into Dutch law. Besides these UN conventions, the country is also committed to a number of European treaties, the most important of which is the Treaty on European Union (Maastricht Treaty), and other treaties where EU Member States cooperate on issues such as police activity and money laundering.

Since the 1980s, and particularly in 1995, when a government paper entitled 'Continuity and change' was introduced, a number of measures to reduce public nuisance caused by drug users and drug tourists have been implemented to reduce the burden on the judicial system. These policy changes have aimed at addressing unwanted outcomes of the drug policy formulated in the 1970s.

Philosophy and objectives

Availability of drugs is a reality in open western societies. Recognising that drugs are probably here to stay, the Netherlands Government acknowledges the importance of prevention, treatment and harm reduction for the individual and his/her environment, and for society as a whole. The underlying premise is that the harmful effects of drug use do not depend solely on the properties of the substance, but also on the characteristics of the user, the reasons for use and the circumstances under which the drug is taken. Any policy ignoring such complex interrelations is bound to fail. The government attaches great value not only to legislation, but also to social control and social support. It believes that prevention, treatment and harm reduction are better ways of containing drug use and its associated problems than repression alone.

The national cannabis policy is based on the assumption that people do not switch from soft to hard drugs because of the properties of the substances in question, but rather because of social and economic factors, such as the availability of both types of drugs in criminal settings. According to this hypothesis, such a transition can be prevented by separating the soft and hard drug markets. At the same time, the government is actively fighting the wholesale transporting, trafficking and manufacturing of hard drugs and is also increasingly taking measures against the large-scale cultivation and sale of cannabis.

Responsibilities

The Minister for Health, Welfare and Sport (HWS) and the Minister for Justice are jointly responsible for national drug policy. The former coordinates this policy and is responsible for demand reduction (health policy in general, drug prevention, drug treatment and harm reduction). The Minister for the Interior is responsible for matters related to local administration and the police and the Minister for Justice for the enforcement of criminal law and partly for probation and aftercare services.

Objectives

Current drug policy in the Netherlands has four objectives:

- prevention (demand reduction) and treatment;
- harm reduction for drug users;
- reduction of the supply of drugs; and
- maintenance of public order.

This policy is carried out in close collaboration with healthcare services (including addiction care), social-care professionals, judicial authorities and those responsible for public order and safety, such as the police. The main policy instruments are:

- separation of markets for soft and hard drugs;
- decriminalisation of the use of soft drugs;
- monitoring of changes in drug use and the consequences of drug use;
- establishment of a highly diversified and extensive professional network of healthcare and social services and institutions offering treatment and care for drug users;
- prevention of problem drug use through information and education targeted at both the general public and specific groups;
- rehabilitation of (former) drug users;
- prevention of marginalisation and criminalisation of drug users, to prevent them becoming outcasts or sources of infection;
- reconciling the interests of crime control with those of public order, public health and public welfare;
- implementing severe penalties for the trafficking of hard drugs and larger quantities of soft drugs; and
- financing research into the effectiveness and efficiency of addiction treatment, care services and prevention programmes.

Nuisance policy

In 1993, the cabinet concluded that the nuisance caused by hard drug addicts required a separate policy. The integration of various measures and the cooperation between the municipalities,

addiction-care facilities, the police and legal systems have been the core of nuisance policy.

From the wide range of projects and facilities that have been set up, some appear to function well, although others have been disappointing or have led to unexpected results. The intramurale motivatie centra (intramural motivation centres), and, in part, the projects that encourage addicted prisoners to be treated, are examples of this. An important conclusion is that no policy can be truly effective unless there is a degree of coherence and compatibility between the facilities. To prevent a situation arising where a client is not accepted by any of the facilities, continuous monitoring will be essential, which, in turn, requires a coordinated approach and supervision of the various facilities.

A review study on the effectiveness of recommending treatment or of compulsory treatment in cases of addiction-related nuisance concluded that the benefits of these responses may well turn out to be small and probably short lived. Little evidence can be found in the international research literature on the effectiveness of the large-scale application of recommending treatment (Rigter, 1998, 1999). Small-scale measures stimulating treatment for these addicts might be considered.

Recent actions

Since 1997, the Unit Synthetische Drugs (Synthetic Drugs Unit) has been operational in the Netherlands. Its main objectives are:

- to improve the national collation of information on synthetic drugs and their precursors and to improve the use of this information for judicial purposes;
- to provide support to local public prosecutors, police teams and special investigation teams in their investigations into synthetic drugs and their precursors; and
- to make national and international inquiries, independently of, or in cooperation with, others, into synthetic drugs.

This unit is expected to expand to a staff of about 50 professionals with statutory power of investigation. Members come from the Economic Surveillance Department of the Ministry of Economic Affairs, the Customs Department, the Ministry of Finance's Fiscal Intelligence and Investigation Department, the Royal Netherlands Military Constabulary, the Central Criminal Intelligence Service and the Public Prosecution Department.

In 1997, the Minister for Health, Welfare and Sport announced plans to establish a coherent national monitoring system, the Nationale Drug Monitor (National Drug Monitor), covering existing projects and a number of new initiatives. The main reason was the need for sound and comparable information on the effects of drug policy measures and developments in use, treatment and care. The general objective of this monitoring system is to improve the existing, divergent monitoring practices by creating a harmonising and coordinating framework. This will enable policy-makers and researchers to better compare data from various sources and to process and interpret such findings. It is aimed at illicit drugs, but also includes alcohol, tobacco and other addictive substances. Prevention and harm-reduction activities will be covered. The main purpose is to yield reliable data at national level, although local and regional information relevant to national policy should also be considered. The National Drug Monitor went into effect in 1999 and published its first annual report in October 1999.

In 1998, a government paper was published by GGZ Nederland (the Netherlands Mental Health Organisation) to stimulate quality and innovation in addiction care. Core competencies of addiction care should be enhanced. Recently established development centres in three areas are intended to stimulate this. These areas are prevention, care and social addiction care (e.g. nuisance projects, user rooms, supported living, or harm reduction). A starting conference for the Nederlands Ontwikkelcentrum Preventie (Development Centre for Prevention) was organised by three addiction-care organisations that have volunteered to initiate this quality-enhancement process. Several others are willing to join the activities. Further initiatives are expected during 2000.

The addiction-care system

There are 16 instellingen voor ambulante verslavingszorg (IAVs — institutions for ambulatory addiction treatment and care), formerly known as consultatiebureaus voor alcohol en drugs (CADs — consultation bureaux for alcohol and drugs). These offer a wide range of treatment, such as pharmacotherapy, psychotherapy, group therapy and other forms of counselling. These 16 IAVs have some 130 branches throughout the country. Originally, there were around 60 low-threshold facilities for social care, such as street-corner work, shelter, methadone programmes, social and work-rehabilitation projects, day programmes and crisis interventions. Most of these facilities have merged with the CADs to form the present IAVs. One of the historical tasks of these is the aftercare of discharged prisoners. Police, prosecutors and judges may refer drug users to one of the institutions. In such cases, the social worker functions as a probation officer.

Inpatient treatment is provided by 19 addiction clinics (in an intramural setting). Of these 19 institutions, 3 are independent, 8 are part of a psychiatric hospital and 8 are part of an institution for integrated (in- and outpatient) care for addicts. The treatments offered can be short- or long-term interventions. Short-term interventions are directed at averting a crisis or at detoxifying the client. A long-term intervention generally comprises a detoxification programme (3 to 12 months' therapy). During the 1990s, a number of new formats of inpatient treatment were developed:

- living at home;
- living between home and hospital;
- daytime treatment (offered by some institutions); and
- intramural motivation centres.

In 1996, 10 addiction clinics were granted funding by the national government to establish these intramural motivation centres with a total of 136 places. These facilities are time-out centres for problem drug users for whom regular clinical treatment is not yet appropriate.

In 1997, there were 20 verslavingsbegeleidingsafdelingen (addiction guidance departments), formerly the drugsvrije afdelingen (drug-free departments), with a total of 446 places. More than half of these facilities are located in detention centres and the rest are in prisons.

Funding and budget

Implementation of the national drug policy and the addiction-care system is financed by income from the social security acts, taxes and health insurance companies. Relevant social security acts are the Algemene Wet Bijzondere Ziektekosten (General Law for Special Disease Management) and the health insurance funds. In 1997, the Ministry of Health's overall budget for addiction issues (including alcohol) was over NLG 66 million (EUR 30 million).

The municipalities fund the IAVs. The total budget available for local and regional ambulatory treatment and care, and also for preventive and harm-reduction activities, was more than NLG 110 million (EUR 50 million) in 1997. Also, the Ministry of Justice allocated NLG 33 million (EUR 15 million) to the institutions for probation and aftercare services. Local methadone-maintenance programmes and low-threshold facilities received NLG 70.5 million (EUR 32 million). The maximum budget for supplying methadone was fixed at NLG 5 million (EUR 2.3 million) in 1998. In 1997, NLG 4.21 million (EUR 1.91 million) was spent on methadone supplies, and the actual costs in 1998 came to NLG 4.6 million (EUR 2.1 million). In 1999, the budget for supplies was again fixed at NLG 5 million (EUR 2.3 million).

The institutions that offer inpatient treatment are financed on the basis of the General Law for Special Disease Management. In 1997, the budget for specialised addiction clinics was NLG 147 million (EUR 67 million). Most treatment costs for addicted clients are mandatorily covered by public health insurance.

Substitution

Development of substitution services

The history of substitution services has been well documented by a number of authors (Driessen, 1990; van de Wijngaart, 1991). According to some sources, substitution treatment started in 1968 in Amsterdam. The objective of this first methadone programme was abstinence for heroin addicts. The format of the programme was derived from Dole and Nyswander's (1966) experiment in the United States. Only a few addicts attended this first programme, due to the fact that there were relatively few heroin users at that time. This situation rapidly changed during the 1970s and, from 1972, a number of institutions offered methadone programmes to clients.

From the beginning, the consultation bureaux for alcohol and drugs were involved in substitution. In 1976, the Health Council advised general practitioners (GPs) to stop prescribing methadone to drug addicts because of the risks involved, such as manipulation by the clients and improper use of prescriptions. In Amsterdam, many GPs ignored this advice.

Surveys of methadone prescription and the availability of substitution programmes at a national level were conducted in 1978, 1982 and from 1989 to 1990. Local data are available in the big cities, such as Amsterdam and Rotterdam, which have their own registration system.

During the 1970s, the IAVs were relatively independent. One of the consequences of this was that there was considerable variation in the way methadone was provided, depending on healthcare workers' attitude towards methadone. The main treatment methods were the short-reduction, or detoxification, model, or a longer-reduction model. Intake criteria hardly existed and there were no general guidelines for determining dosage.

In 1977, the Ministry of Health published a paper as an attempt to formulate policy principles and to provide some points of reference for everyday practice for those working in the field. As a

result, new methadone programmes were set up whose main objective was to improve the social functioning of a client. Thus, reduction of heroin by means of methadone in order to achieve abstinence had been replaced by the goal of maintenance. A study carried out in 1982 (Buisman, 1983) confirmed this: 87 % of the institutions reported that improving social functioning was their main goal. Furthermore, they invested much energy into keeping clients in the programme.

The admission criteria for methadone programmes were never very specific during the 1980s and 1990s: being addicted to heroin for more than six months was (and still is) qualification enough to enter a programme.

The present situation is not very different to that in the 1980s. Methadone programmes are offered by all IAVs, which means that every region has its own programme. Big cities such as Amsterdam and Rotterdam, and also The Hague, have their own approach, which is quite similar to the other regions. Almost all programmes are to be considered as maintenance programmes. The structure of the programme is clear to the client, and it is quite easy for an opiate addict to enter a programme. To reach specific categories of clients, the methadone mobile bus has been introduced in a number of cities.

Substances prescribed

In the Netherlands, a few experiments have been conducted to look for alternatives to methadone. At the beginning of the 1990s, an experiment with morphine was conducted in Amsterdam with some positive results. This could be considered as an alternative for a very small category of clients. LAAM substitution was not a success, as drug addicts simply refused to participate in the project. The same goes for clonidine: clients were not interested in this alternative, so the experiment failed.

In a recent experiment, palfium was offered in combination with methadone to 53 chronic opioid addicts (mean age of 43 years and a mean maintenance use of methadone of 21 years). Heroin

use was reduced for 60 % of the clients and most of the others stopped using palfium. Using palfium for a longer period (in a maintenance programme) is mainly effective when clients have a more or less normal social situation (housing, partner, family contacts).

Heroin supply

After a long period of preparation, the government, in 1997, approved to start an experiment with heroin on strictly medical grounds. The structure of the experiment is quite similar to the Zurich experiment. The selection criteria the drug addicts have to meet before entering the programme are very strict, and only serious problem drug users with a long history of unsuccessful treatment are allowed to enter it. The first report on the experiment describes the problems experienced during the first six months. The results show that, despite many negative perceptions, it is possible to organise and carry out such a complex experiment.

Current situation

The current situation is much the same as it was at the beginning of the 1990s. The 16 IAVs (see 'The addiction-care system' above) and the Municipal Health Service in Amsterdam and Groningen are the main providers of methadone treatment. A very few GPs prescribe methadone to a small number of clients.

Almost all IAVs offer a maintenance and a reduction programme. Over two thirds of the clients attend maintenance programmes. One exception relates to programmes in detention centres, where addicted prisoners who will spend more than a few weeks in detention are obliged to follow a reduction programme.

According to the national registration data, in 1999 more than 11 000 addicts were attending methadone programmes provided by the IAVs, compared with 8 000 clients registered in 1988. More than 75 % of all methadone clients live in the four big cities of the

Netherlands: Amsterdam, Rotterdam, The Hague and Utrecht. The number of prescriptions supplied per month is about 16, which means that clients visit the institution four times a week for their supplies. The average dose of methadone supplied is 35 mg. This figure has been fairly stable over the years.

A large majority of the population using methadone is male (over 80 %), with an average age of over 30 years in 1997 and just under 30 years in 1988. This figure is still rising: in Amsterdam the average age was 37.8 years in 1997. This means that there are less 'new' heroin addicts and it could also mean that maintenance programmes do maintain the addiction: a considerable number of clients have been in the programme since the mid-1980s.

More than a quarter of all clients using methadone are members of ethnic minorities. This figure has remained stable for the last 10 years. A majority of these are from the former Dutch colonies of Suriname and the Dutch Antilles. A minority were originally Moroccan or Turkish but have lived in the Netherlands for many years. These minorities, in total, constitute around 5 % of the population. This means ethnic minorities are over-represented in the drug-using population in the Netherlands.

Legislation on substitution treatment

The Opium Act prohibits the use of methadone and other opiate substitutes such as clonidine and palfium. The first Opium Act of 1919 (see 'Drug laws' above) regulated the production, transport, trade and application of opium and its derivatives. This act was amended in 1928 and 1953 in response to prevailing international attitudes to drugs, dominated by the United States. The 1953 amendment meant that drug use became a criminal offence. The 1976 amendment was a political response to the actual situation in the Netherlands at that time with regard to the use of cannabis and opiates: production, transport and trade in opiates are still forbidden. Production and use of cannabis for private (recreational) purposes were classified as a misdemeanour and were no longer a criminal offence. Heroin and cocaine are not classified as medical drugs, so only formal use within a scientific setting is allowed,

whereas methadone is classified as a medical drug and can therefore be prescribed by any doctor. The rules of prescribing are covered by the *Wet op de Geneesmiddelenvoorziening* (Law on the Provision of Medicines), and this is controlled by the Ministry of Health. Clients in the substitution programmes are registered at national level (see National Alcohol and Drugs Information System under ‘Surveillance’ below).

A number of studies have been carried out, but these are almost always statistical surveys. Only Driessen’s (1990) study can be considered as an evaluation of methadone programmes in the Netherlands. The conclusions of this study are rather disappointing: there is still much variation in the way different institutions run their methadone programmes. There are no clear guidelines for determining dosage. The differences identified seem to bear no relation to any particular philosophy or treatment objective. The majority of methadone programmes are well organised, but a considerable number of institutions do not have any serious intake criteria or medical examination requirement.

Related to this evaluation of methadone programmes, Driessen (1992) also carried out a study on clients of the programmes. The main results of this study are:

- the majority used methadone for a long period (on average eight years);
- most clients used other substances in addition to methadone;
- morbidity is two times higher than in the same age group in the general population; and
- many clients suffer infectious diseases related to drug use and report more psychological problems than the same age group in the general population.

Most of these results are applicable to general drug use rather than to the specific use of methadone.

The first results of methadone maintenance in the Netherlands were recently published by Driessen et al. (1999). Two and a half years after the first tests, 8 % of the methadone users were found to be abstinent. For more than half of the clients (57 %), a less-

ambitious goal had been achieved: prevention of further deterioration of the physical, psychological and social situation of the addict; in other words, their situation had remained stable. For 26 % of clients, their situation had improved and for 17 % it had worsened. The authors conclude that methadone maintenance is successful when abstinence is not the primary goal. However, the optimal dose has still not been determined in the Netherlands, and a combination with counselling might be more effective.

Surveillance

The Netherlands has a system of national registration of clients of the IAVs called Landelijk Alcohol en Drugs Informatie Systeem (National Alcohol and Drugs Information System) which accumulates considerable data on clients. Most clients of methadone programmes are registered with this system, and there are other national registration systems which cover clients of the gemeentelijke geneeskundige en gezondheidsdienst (GGD — municipal health services). Clients receiving inpatient treatment at intramural institutions for addiction care are registered with an inpatient register of the Patiëntenregister Intramurale Geestelijke Gezondheidszorg (PIGGZ — Netherlands Mental Healthcare Organisation).

Duplicating the records of those who attended an IAV as well as a municipal health service used to be a problem, but in the 1980s the registration systems were modified to overcome this.

Problems

There are two main problems relating to substitution treatment.

- A maintenance programme cannot exactly be seen as treatment. The client is still addicted and, more problematically, he/she is dependent on his/her methadone supplier. The original objective of maintenance was to improve the social functioning of addicts, so that they could be stimulated to make changes in

their lives, such as finishing school, starting vocational training or applying for a job.

- Another problem is the lack of longitudinal studies on the effects and effectiveness of substitution programmes. As stated before, one study of this started recently and the results are not yet available.

Evaluation

Some studies have already been mentioned in the text, and an extended list of references is given below under the heading 'Further reading'.

Information in this chapter was updated by the EMCDDA and by André van Gageldonk of the Trimbos-Instituut.

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AUSTRIA

Gabriele Fischer, University of Vienna, Vienna

Introduction

Although the increasing illicit drug consumption in the 1970s was recognised as a social problem in Austria, abstinence-oriented therapy was the only legal option in the medical treatment of addiction until 1987 — the year when the Substitutionserlass (Narcotics Maintenance Decree) was issued. Withdrawal therapy was carried out with a variety of neuroleptic drugs, tranquillisers and antidepressants. In 1998, the principle of providing maintenance therapy for opiate dependence was anchored in the Suchtmittelgesetz (Narcotic Substances Act).

Strategy

The Austrian ‘drug strategy’ ⁽¹⁸⁾ has a number of fundamental objectives in addressing opiate dependence and provision of treatment:

- prevention;
- maintenance therapy;
- harm reduction;
- social reintegration;
- abstinence-oriented therapy; and
- repression.

A federal law regulates the therapy options, and the individual provinces are responsible for the implementation of these options. This situation leads to significant variations in the implementation of drug treatment in the various provinces. In some parts of Austria, an opiate addict must submit a written application to a

⁽¹⁸⁾ Austria does not have an official national drug strategy as such; however, seven of the nine provinces do have a formal drug strategy where these objectives are listed. These aims are also in line with the objectives of the 1998 Narcotic Substances Act.

special commission prior to being admitted to one of the maintenance programmes, whereas, in Vienna, it is solely the responsibility of the attending physician or care unit to decide who is suitable for maintenance therapy.

Substitution

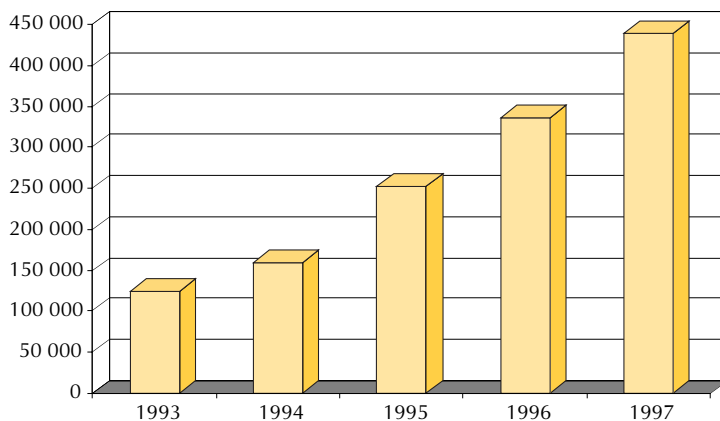
Development of substitution services

For a long time, outpatient or inpatient detoxification treatment was the only legal option in the treatment of opiate dependence. However, the effectiveness of maintenance therapy in other European countries, and the increasing awareness of risk factors such as HIV infection, led to a gradual acceptance of maintenance therapy.

In 1985, the first treatment trials were carried out with methadone tablets at the Department of Psychiatry at the University of Vienna. Since the official Narcotics Maintenance Decree of 1987, methadone has been available only in liquid form. Initially, treatment of opiate dependence with opioids was offered only in the specialist departments of hospitals (primarily psychiatric wards), but, over the years, an increased demand for therapy resulted in the establishment of a number of facilities with various strategies.

‘Outreach services’ are the first level of care for drug addicts. Support and harm reduction are important for patients who are not particularly motivated to change their life circumstances. The social workers at the Verein der Wiener Sozialprojekte (Association of Social Projects, Vienna) not only operate a base in one of the underground stations in Vienna, which has been a meeting-point for drug addicts for many years, but also a bus that travels to other parts of Vienna on a fixed schedule. The main emphasis of the bus is a syringe-exchange programme. In 1997, 438 661 syringes were exchanged for sterile instruments (Figure 1).

FIGURE 1: NEEDLE EXCHANGE IN VIENNA, AUSTRIA (1993–97)



Sources: Drug Coordination, city of Vienna (1993–96); Association of Social Projects, Vienna (1997).

So-called ‘street workers’ make contact with addicts at known meeting-points and offer advice, help and medical care in order to form a basis of trust. These street workers usually cooperate very closely with low-level facilities.

The next level of care are the ‘low-level facilities’, such as the *Ganslwirt*. The *Ganslwirt* not only offers patients psychiatric and medical care for their substance dependence and consequent physical problems, but also provides facilities for washing clothes, receiving cheap meals and participating in leisure activities; there are also a few beds available. Social workers offer help with financial problems and official matters.

The next stage, the so-called ‘high-level facilities’, requires that patients understand the nature of their condition, since their visits are scheduled by appointment only. Only patients with strong motivation to undergo treatment are allowed to follow the therapy regime. Multiprofessional teams, consisting of physicians, social workers, psychotherapists and nursing staff, provide patients with medical treatment and also try to improve patients’ whole life situation where possible.

One example of such a facility is the Drogenambulanz Klinische Abteilung für Allgemeine Psychiatrie (drug-addiction outpatient clinic at the Department of General Psychiatry), University of Vienna (<http://www.akh-wien.ac.at/drogenambulanz>; e-mail: drogenambulanz@akh-wien.ac.at). This clinic was established in 1967 and was originally only open for a few hours each week. In 1995, Gabriele Fischer became medical director of the drug-addiction outpatient clinic and expanded it. Currently, three psychiatrists, two social workers and two psychologists are employed there, in collaboration with nurses (who also work in other outpatient clinics of the Department of General Psychiatry) and interns.

TABLE 1: DRUG-ADDICTION OUTPATIENT CLINIC: TREATMENT DOSES OF SYNTHETIC OPIOIDS USED FOR MAINTENANCE THERAPY, AUSTRIA (1998)

	MEAN/DAY	STANDARD DEVIATION	RANGE
 Methadone			
Total (n = 436)	60.96	29.34	16–150
Females	58.68	33.60	15–200
Males	61.18	23.76	15–200
 Mundidol retard® (¹)			
Total (n = 17)	470.00	210.27	300–700
Females	240.00	207.85	120–600
Males	670.59	95.58	120–700
 Vendal retard® (²)			
Total (n = 255)	651.34	234.38	300–1 200
Females	635.52	237.75	300–1 200
Males	666.67	230.04	300–1 200
 Kapanol retard® (¹)			
Total (n = 225)	452.63	186.80	100–900
Females	443.41	192.65	150–900
Males	459.46	182.04	100–900
 Subutex® (³)			
Total (n = 102)	9.12	3.40	2–16
Females	8.46	3.52	2–16
Males	9.83	3.10	2–16

(¹) Morphine sulphate.

(²) Morphine hydrochloride.

(³) Buprenorphine.

FIGURE 2: NUMBER OF PATIENTS AND TREATMENT EPISODES AT A DRUG-ADDICTION OUTPATIENT CLINIC, AUSTRIA (1994–98)

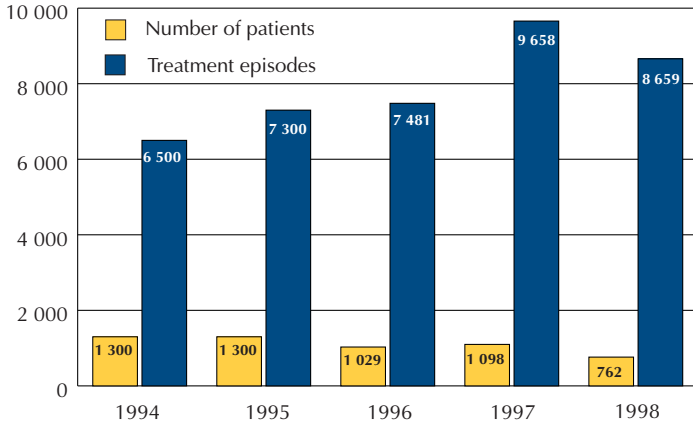
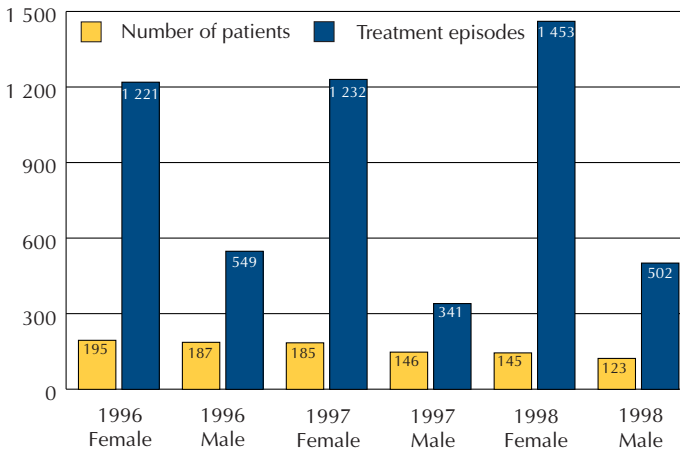


FIGURE 3: GENDER DISTRIBUTION OF PATIENTS WITH PSYCHOSOCIAL SUPPORT AT A DRUG-ADDICTION OUTPATIENT CLINIC, AUSTRIA



In 1998, 448 male and 307 female patients received medical and sociotherapeutic care at the clinic (Table 1; Figures 2 and 3). In addition, a number of physicians involved in research trials also work there.

The relatively high percentage of women patients is explained by the fact that a special programme for pregnant women with substance dependence was established in 1995. In close cooperation with the Department of Gynaecology and Obstetrics and the University Children's Department, the women receive multi-professional care during pregnancy and after delivery. Neonates suffering from neonatal withdrawal can be treated in the collaborating children's clinic.

Since 1991, all prisons in Austria have been offering maintenance therapy with synthetic opioids during a prison sentence. The prison in Favoriten (Vienna) has specialised in the treatment of addicts, and patients can also acquire job qualifications in the form of an apprenticeship there. Social and psychotherapeutic approaches are offered in addition to medical treatment.

'Abstinence-oriented facilities' can only be used by patients after successful physical detoxification, which is usually performed in psychiatric departments. Subsequently, a long-term therapy programme tries to facilitate the social and vocational rehabilitation of patients. This therapy usually lasts for between six months and two years, and is offered in therapeutic housing communities. Most of these facilities are within an hour's drive of Vienna (such as the Grÿner Kreis, Anton Proksch Institute), but there are also a few in the western parts of Austria (such as the Stiftung Maria Ebene). Group-therapy sessions, individual therapy, sports and regular work are all part of the programme.

Current situation

Austria has tried to prevent open drug scenes developing (such as existed in Switzerland some years ago) by increasing deployment of police. A further focus of police work is to attempt to stop drug dealing and smuggling. Possession of even small quantities of

illegal drugs is a criminal offence, although criminal proceedings can be avoided if the offender agrees to undergo counselling or treatment. This aims at avoiding criminalisation of those patients who buy or possess drugs solely for their own use. However, the distinction between persons who only use drugs themselves and those who smuggle and deal in drugs is quite limited when it comes to addicts becoming minor dealers or drug couriers in order to finance their own addiction. This can be seen from the fact that convictions for dealing or possessing small quantities of illegal drugs (paragraph 16 of the Suchgiftgesetz (SGG — Narcotic Drugs Act)) were twice as high as those for larger quantities (paragraph 12) (Table 2). (The Narcotic Drugs Act of 1971 — revised in 1980 and 1985 — was the predecessor of the 1998 Narcotic Substances Act.)

TABLE 2: DRUG-RELATED CONVICTIONS IN AUSTRIA (1997)

DRUG-RELATED CONVICTIONS		14–19 YEARS	20–24 YEARS	25–30 YEARS	31–35 YEARS	> 35 YEARS	TOTAL
Total	Male	453	1 166	712	469	479	3 279
	Female	68	190	113	81	66	518
Narcotic Drugs Act, paragraph 12 (¹)	Male	84	275	217	152	175	913
	Female	14	41	27	17	24	123
Narcotic Drugs Act, paragraph 16 (²)	Male	380	888	480	300	279	2 327
	Female	54	148	85	63	40	390

(¹) Suchgiftgesetz (SGG), paragraph 12: Professional possession and dealing.

(²) Suchgiftgesetz (SGG), paragraph 16: Possession and dealing of small amounts.

Source: Österreichisches Statistisches Zentralamt (ÖSTAT) — Austrian criminal court statistics from the Austrian statistical office.

As in most countries, the drug problem is concentrated in the major cities. Also, the opening of the borders in the east of Austria to the countries of the former Warsaw Pact has led to increased smuggling and thus to cheaper drugs. In 1987, 33 kg of heroin were confiscated, but by 1997 this figure had risen to 102 kg. During the same period, the amount of cocaine confiscated rose from 72 to 87 kg. Cannabis is the most frequently confiscated drug and is also the most common reason for criminal charges under the 1998 Narcotic Substances Act. Confiscation of amphetamines and ecstasy is also on the increase. Ecstasy was first discovered in

Austria in 1994, and, since then, the number of tablets confiscated has increased eightfold (Table 3). Most of those convicted are aged 20–24, followed by people aged 25–30, with a strong male dominance (Table 2 above).

TABLE 3: SUBSTANCES CONFISCATED IN AUSTRIA (1988–97)

SUBSTANCE	1988	1989	1990	1991	1992	1993	1994	1995	1996	1997
Cannabis (kg)	205	192	320	12 166	248	546	394	697	517	915
Heroin (kg)	50.5	100.5	72.3	102.8	78.2	104.8	80.2	47	81.3	102
Cocaine (kg)	14.4	20.9	41.2	84.4	58.1	83.9	52.6	55.3	72.7	87
Amphetamines (kg)	0.1	0.1	0.2	0.3	0.4	0.3	0.7	1.6	3.7	7.9
LSD (tablets)	1 092	3 237	418	906	3 847	28 201	1 543	2 602	4 166	5 243
Ecstasy (tablets)	—	—	—	—	—	—	3 003	31 338	25 118	23 522

As a result of greater freedom in travelling and the varying economic situations in Europe, immigration to Austria has considerably increased, primarily from the former eastern bloc countries, as well as the former Yugoslavia and Turkey. Refugees (and their children) who have fled their home countries for political or economic reasons represent a steadily growing section of the patients in drug-counselling facilities.

Legislation on substitution treatment

From 1987, the Narcotics Maintenance Decree regulated the treatment of opiate addiction with synthetic opioids. Until this decree was revised in 1998, physicians were entitled to use any oral opioid licensed in Austria for the treatment of severe pain. Unfortunately, there are no standardised qualification requirements for physicians treating drug addicts with opioids. Since special qualifications are not required, the quality of therapy depends greatly on the commitment and motivation of individual physicians to undergo further training. There are no regulations as to how often urine samples should be analysed for drug toxicology, and, although concurrent psychosocial care is recommended, it is only mandatory in the case of young patients. At present, there is a strong emphasis on concurrent psychotherapy, whereas

psychosocial care, combined with medical care, has been proven to be more relevant for patients in rehabilitation.

Since the decree was revised, it is still possible for any general practitioner to prescribe methadone, but prescription of oral slow-release morphine for maintenance is now reserved for specialist clinics.

The law defines methadone as the substance of choice in substitution treatment. From a medical point of view, this must be regarded critically, as it shows that treatment of substance dependence is still strongly governed by social attitudes and political views. Therapy guidelines should be based purely on medical considerations, as with other diseases. In the event of strong side effects, such as depressive symptoms or extreme weight gain, or in the case of pregnancy or patients with HIV infection, slow-release morphine should be the substance of choice.

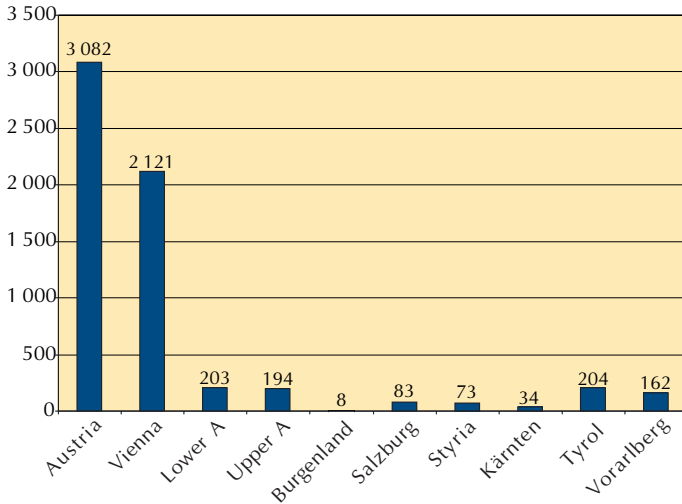
Most patients are prescribed their opioid with a so-called 'narcotic long-term prescription'. This allows them to obtain a fixed daily dose of the maintenance substance for 30 days. Once the prescription has been issued by a physician, it must be endorsed by a medical officer from the health authority. He/she checks that the prescription is formally correct and that the patient is a resident of the relevant district. This is to prevent a patient from obtaining more than one long-term prescription.

Daily opioid issue at the pharmacy is a legal requirement, although exceptions can be made for those patients who are unable to go to the pharmacy every day because of their working hours or because of physical problems. At weekends, the synthetic opioids are usually issued on Fridays. However, in the case of well-stabilised patients without relapse, it could be argued that issuing opioids for several days can and should be used therapeutically. This could enhance patients' self-confidence and help develop responsibility for handling their own problem.

The attending physician must report all patients undergoing maintenance therapy to the Suchtgiftüberwachungsstelle (Substance Monitoring Authority). In 1998, 3 082 such cases were reported

(Figure 4). However, it should be mentioned that this figure is incomplete, since not every physician reports his/her patients.

FIGURE 4: NUMBER OF OPIOID-MAINTAINED PATIENTS IN AUSTRIA (1998) (PAIN TREATMENT NOT INCLUDED)



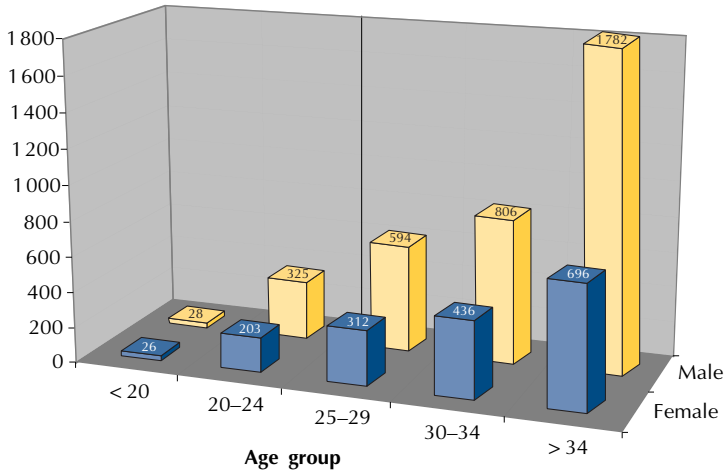
NB: Data incomplete.
Source: Substance Monitor, Ministry of Health.

Substitution clients

Patients who meet the criteria of the 10th edition of the International Classification of Diseases (ICD-10) for opiate dependence can be included in a maintenance therapy programme. Adolescents must prove that detoxification has been attempted before being accepted on a maintenance programme. In 1998, 3 082 patients were enrolled in maintenance therapy, most of them (2 121) in Vienna (Figure 4). This is due not only to the fact that major cities have more drug addicts, but also because the criteria for inclusion in a therapy programme can be very strict in some provinces. Therefore, many drug addicts outside the cities either do not undergo therapy or they try to access it in Vienna. One remarkable phenomenon is that the age of patients in main-

tenance therapy is fairly high. The majority of patients of both sexes are aged over 34 years (Figure 5).

FIGURE 5: AGE DISTRIBUTION OF OPIOID-MAINTAINED PATIENTS IN AUSTRIA (1997)



NB: Data incomplete.

In order to make comprehensive rehabilitation possible, the Arbeitsmarktservice (Labour Market Service) has for some years offered special services for drug addicts. In addition, there are a number of private and public associations that offer vocational training and further education.

Virus infections

In Austria, the number of individuals who are HIV positive can only be estimated, since only those who are actually suffering from AIDS are registered. Unlike hepatitis C, HIV infection does not have to be reported. In 1997, 76 persons were reported with AIDS, 17 of whom were injecting drug users.

In total, the HIV infection rate in Austria is fairly low compared with other European countries. However, since only estimates are available, figures are not provided here.

The situation with regard to hepatitis C infection is quite different. In a study at the drug-addiction outpatient clinic at the Vienna General Hospital, hepatitis C antibodies were found in 80 % of a random sample of 197 patients. Since, according to estimates, up to 40 % of patients with hepatitis C infection develop liver cirrhosis, this disease is likely to become a major challenge for the health system.

Pharmacy activity

Pharmacies play an important role in maintenance therapy. The prescription must be deposited with the pharmacy, and the patient takes his/her opioid under supervision at the pharmacy. The pharmacist records whether the patient has received his/her drug on the prescription every day. Since the pharmacist is in contact with the patient every day, he/she is often the first to notice any worrying changes in behaviour. The pharmacist, therefore, can be an important link between the physician and the patient. In future, pharmacists should be integrated more actively into the treatment programme. Education events organised by the Österreichische Apothekervereinigung (Austrian Pharmacists' Council) have led to a clear increase in understanding and a decrease in bias with regard to maintenance patients.

Primary-care involvement

The involvement of general practitioners in maintenance therapy varies considerably from one province to another.

The national health insurance and the Ärztekammer (Medical Council) run a joint scheme which acknowledges that the treatment of drug addicts is a special service. If proof of participation in an education event is furnished by a general practitioner, an

appropriate fee is paid for the treatment of drug addicts. Unfortunately, these education events do not follow standardised treatment procedures. The aim of this scheme is to encourage greater involvement of general practitioners in maintenance therapy. Many general practitioners are overtaxed by the demands of the psychiatric disorders which can accompany drug addiction; addicts are sometimes difficult patients. It is often feared that other patients might be deterred from attending a general practitioner who treats addicts. Some doctors accept a small number of substitution patients, or only patients that they know well, while others treat too many and find it difficult to cope, which can lead to prescribing benzodiazepines. Only estimates and no conclusive data are available about how many maintenance patients are treated by general practitioners.

Substances prescribed

Methadone: Racemic methadone is used exclusively in liquid form. The recommended daily dose is 60–100 mg. In exceptional cases, more than 100 mg a day may be prescribed, especially for patients with a physical disorder where additional drug therapy leads to enzyme induction in the liver. Methadone is administered with syrup, partly in order to prevent intravenous consumption and partly to improve the taste.

Oral slow-release morphine: Morphine sulphate and morphine hydrochloride, with an action of 12–24 hours, are used. Recommended daily doses range from 200–600 mg. HIV-positive patients, especially those on combination therapy, often require a higher dose. Until recently, slow-release morphine was licensed only as a drug for treating severe pain, but a preparation has now been licensed specifically for maintenance therapy. Further such opioids will be submitted for licensing in the near future.

Buprenorphine: This partial morphine agonist has been used in low doses for pain therapy for some time. At the drug-addiction outpatient clinic, tablets of 2 and 8 mg (Subutex®) are being used for maintenance therapy in clinical trials. The average recommended daily dose is 8–12 mg. Buprenorphine has been licensed in Austria since 1999.

LAAM: This is already licensed but hardly used in Austria.

Injectable prescribing

Under the 1998 Narcotic Substances Act, opioids for injection are not permitted. Oral maintenance therapy is used in order to avoid the health risks associated with unsupervised injecting. It also avoids promoting the mystique and seduction associated with the ritual of preparing and administering the injections.

Surveillance

In Austria, no special surveillance system for substitution treatment has been defined.

Problems

A significant problem in the treatment of drug addicts results from the fact that substance dependence is still regarded by the public as a vice and not as a disease. Treatment is still not possible on a purely medical-scientific basis, as it is too strongly associated with public opinion and political views.

The Austrian media present the statistics on drug-related deaths as a measure of the success or failure of political policy (Table 4). Although, since 1995, there have been efforts to differentiate between overdose and other causes of death, these statistics remain a problem. The high degree of co-morbidity in addicts with depression, anxiety and other psychiatric disorders is ignored.

A correlation between death and efficacy of treatment is not made in any other disease.

TABLE 4: DRUG-RELATED DEATHS IN AUSTRIA (1989–97)

AGE	1989		1990		1991		1992		1993		1994		1995		1996		1997	
	ABS.	%	ABS.	%	ABS.	%	ABS.	%	ABS.	%	ABS.	%	ABS.	%	ABS.	%	ABS.	%
Up to 19	6	7	4	5	2	2	22	12	32	14	34	13	33	14	24	10	20	12
20–24	14	17	13	16	22	19	40	21	63	28	55	22	40	16	47	20	38	22
25–29	29	35	21	25	36	31	42	23	38	17	42	17	46	19	36	16	26	15
30–34	22	27	27	33	39	34	47	25	56	25	65	26	62	26	54	24	33	19
35–39	8	10	16	19	13	11	25	13	32	14	42	17	41	17	45	20	30	17
40 or over	3	4	2	2	4	3	11	6	5	2	12	5	19	8	24	10	25	15
Total	82	100	83	100	116	100	187	100	226	100	250	100	241	100	230	100	172	100
Female	n.a.	n.a.	14	17	24	21	33	18	39	17	40	16	45	19	36	16	29	17
Male	n.a.	n.a.	69	83	92	79	154	82	187	83	210	84	196	81	194	84	143	83

Source: Department VIII, Ministry of Health.

Another problem is the lack of scientifically obtained epidemiological data. Very few studies have been conducted investigating the prevalence of addiction (of legal and illegal substances) in Austria. The data provided by the Ministry of Health (currently part of the Federal Ministry of Social Security and Generations) must be considered incomplete, and the World Health Organisation (WHO) gives estimates based on ‘official’ data.

Differences in how the 1987 Narcotics Maintenance Decree is interpreted make the development of an adequate nationwide care network difficult. Patients in all the federal provinces should have equal access to maintenance therapy.

Physicians who are permitted to prescribe opioids for the treatment of opiate addicts should have to prove that they are suitably qualified. General practitioners can only cope with a limited number of patients in an oral maintenance programme, depending on the severity of the disease.

Currently, a strong emphasis on psychotherapeutic care can be observed. However, psychotherapy is only helpful once a patient is medically and socially stable, and once there is evidence of strong motivation for change (only about 10 % of patients are suitable for psychotherapy). Thus, a phased therapy plan is more useful than the concurrent therapy approach which frequently leads to years of 'wrong' treatment being provided. The national health insurance pays for medical and psychotherapeutical care, but not for psychosocial care, which constitutes a very important part of treatment for stabilising patients. A disease that leads to discrimination must not be subject to discriminatory treatment.

Evaluation

In Austria, there is no public funding for the evaluation of patients enrolled in substitution programmes.

PORTUGAL

Rodrigo Coutinho and José Godinho, Serviço de Prevenção e Tratamento da Toxicodependência, Lisbon

Introduction

Portugal became a parliamentary and democratic republic on 25 April 1974. It is one of the most socioeconomically disadvantaged countries in the EU, with considerable deficiencies in educational and professional training and significant asymmetries of development between the coastal and inner areas. The main cities are densely populated, and a high proportion of the population is very deprived, with living standards far below the European average. This situation generates serious social problems, such as increased trafficking in, and consumption of, illicit drugs.

The number of heroin users in Portugal is unknown, although some empirical estimates suggest that there are around 50 000 (approximately 5 in every 1 000 of the overall population). However, recent research of local prevalence suggests this number may be much higher (around 100 000).

Recent years have witnessed the development of social policies which have brought about some improvement in the situation, either through the social security system, of which the most recently implemented measure was the minimum guaranteed income, or through incentives by non-governmental organisations (NGOs).

In 1979, the Serviço Nacional de Saúde (SNS — National Health Service) was created, whose aims were:

- to provide universal and free access to integrated healthcare (primary and specialised);
- to promote good health; and
- to monitor and prevent disease.

In 1990, the Lei de Bases da Saúde (Basic Health Law) was passed, which aimed at promoting a universal healthcare system consisting of the SNS, private entities and independent professionals. This system would, in principle, offer free healthcare to everyone.

The healthcare centres and hospitals are the local and regional bodies responsible for providing healthcare to the population. These are administered by the Ministry of Health.

The Ministries of Health and Social Solidarity collaborate on health and social security, both at a regional level (through the regional health administrations and the social security) and at a local level (through the provision of social service workers in the healthcare units).

Strategy

In Portugal, the coordination structure for addressing the drugs problem is ensured at the highest political level by the Conselho Coordenador da Estratégia Nacional de Luta contra a Droga (Council for the Coordination of the National Drug Strategy). This interdepartmental political body, chaired by the Prime Minister, includes all Portuguese ministers working on drugs. It determines the national drug policy and the plans for its implementation.

The Secretary of State of the Presidency of the Council of Ministers is the member of government appointed to oversee the implementation of all drug-related political decisions, in particular the Estratégia Nacional de Luta contra a Droga (National Drug Strategy) adopted on 26 May 1999.

The execution of the national policy on drug addiction is guaranteed by the Instituto Português das Drogas e das Toxicodependências (IPDT — Portuguese Institute for Drugs and Drug Addictions), which was restructured on 18 May 2000. The IPDT replaced the former national drug-prevention programme — ‘Projecto VIDA’ — on 18 August 2000. The president of the IPDT also took over the coordinating functions previously performed by the coordinator of ‘Projecto VIDA’.

The Comissão Técnica de Acompanhamento (Technical Support Committee), one of the IPDT bodies, consisting of directors-general and heads of department in the various ministries involved in the field of drug addiction, plays an important coordinating role at national level. The IPDT also ensures the functioning of a national information system on drugs and drug addiction and constitutes the Portuguese focal point in the EMCDDA's Reitox network.

In addition, the Conselho Nacional da Droga e da Toxicodependência (National Drug Council) exists as an advisory body to the Prime Minister. This involves representatives of over 20 social, political and religious organisations and provides expert opinions on request.

In 1999, PTE 17 billion (EUR 85 million) was allocated to the ministries and public services implementing actions against drugs, PTE 7 billion (EUR 36 million) of which went to the Ministry of Health's Serviço de Prevenção e Tratamento da Toxicodependência (SPTT — Service for the Prevention and Treatment of Drug Addiction) set up in 1990.

Local and regional authorities and NGOs also promote some services and intervention measures.

Treatment

The following excerpt from the publication *Estratégia nacional de luta contra a droga* (1999) (1999 *National strategy against drugs*) outlines key points in Portugal's treatment activities:

'Drug-addiction treatment reveals specific features characteristic of each drug in particular and general features which are common to all addictions.

Heroin is the addiction substance that is responsible for more than 95 % of requests for specialised help. That is why the therapeutic structures of this area have been specially adapted to the treatment of heroin addicts. It is also in the

heroin-related field that the psychopharmacological therapeutics are most developed.

The treatment of drug addicts in Portugal is carried out by public services and by a high number of both profit-making and non-profit-making private organisations, which demonstrate the engagement of civil society in this sphere. It comprehends a set of differentiated or specific interventions, according to the treatment phase or the problem posed by each case. The technical, multidisciplinary teams reflect the diversity of this intervention. They are made up of physicians, psychologists, social service workers, nurses, psychosocial workers, physiotherapists, occupational therapists, etc.’

Substitution

Development of substitution services

The Portuguese substitution programme started in 1977 in Oporto. The Centro de Estudos e Profilaxia da Droga/Norte (CEPD/Norte — Study Centre on Drug Prevention/North), which ran the programme, was the responsibility of the Ministry of Justice, and this centre along with the CEPD/Centro (CEPD/Central), in Coimbra, and the CEPD/Sul (CEPD/South), in Lisbon, were the only institutions exclusively engaged in the drug-addiction field. The CEPD/North, using methadone as the substituting substance, was the only unit using opioid substitution until 1992. While primarily meant for users living in the Greater Oporto area, this programme also served a limited number of patients in the central and southern regions.

In 1987, the Centro das Taipas in Lisbon was created, an institution specialising in the treatment of drug addicts. This centre consisted of a consultation service, a day centre and an inpatient detoxification unit. This facility, which was the responsibility of the Ministry of Health, was the first in the network of centres specialising in treating drug addiction which now covers the whole country. These units, called centros de atendimento a toxico-

dependentes (CATs — centres of assistance to drug addicts), are administered by the SPTT and, since 1990, have included the former study centres on drug prevention. With the exception of the Boavista CAT (the former CEPD/North — Boavista is an area of Oporto), the CATs developed a drug-free therapy strategy, as they had not adopted a substance-substitution approach from the start.

However, the increase in numbers of drug addicts (including an 'explosion' at the beginning of the 1990s), together with the growth of AIDS and hepatitis C among this population, has led to a change in attitude. Since 1992, methadone-substitution programmes have been extended to several CATs. The Leiria (Centre) and Olhão (Algarve) CATs were the first to join this therapeutic model, but now most of the others have substance-substitution programmes. In 1994, the Taipas CAT started a substitution programme with LAAM, becoming the first European centre to use this substance. LAAM has the advantage of needing to be taken only three times a week, thus avoiding Saturdays and Sundays, and is currently prescribed in several centres throughout the country (Almada, Gaia, Gondomar, Lisbon, Oporto, Setúbal, etc.).

To date, substitution services in Portugal have been the sole responsibility of the State and dependent on the authorisation of the SPTT. In 2000, the only substitution services which are not dependent on the SPTT are the psychiatric services of Santa Maria Hospital in Lisbon, S. João Hospital in Oporto and the Sines Health Centre.

The intervention model adopted varies from centre to centre, but, overall, the programmes are medium or high threshold. With the exception of occasional activities in a slum area in Lisbon, there are no true low-threshold programmes (risk and harm reduction). The main goal of the current drug-addiction intervention policy is expansion of the substitution programmes in order to meet the growing demand. The possibility of developing risk- and harm-reduction programmes in the worst-affected areas is currently under study. Some of the resulting programmes are likely to be implemented by non-governmental organisations duly authorised by the SPTT.

Current situation

Most areas of Portugal currently run substitution programmes, the most developed being located in the main urban centres of the coastal areas (Lisbon and the Tagus Valley, Oporto and the Algarve). With the exception of the Boavista CAT, which has 20 years of experience in substitution programmes, all the Portuguese centres (having only recently introduced substitution programmes) prioritise abstinence, offering the following therapeutic services:

- individual and group psychotherapies;
- family therapy; and
- therapy with an opioid antagonist.

Until 31 December 1998, 74 312 users had been treated by the CATs. Of this total, 24 164 were treated in 1998. In December 1998, 3 984 users were currently in substitution (3 475 on methadone and 509 on LAAM). The average age of clients was 30–35 years; 75–80 % were men and 20–25 % were women. Until 31 December 1999, 102 062 users had been treated by the CATs. Of this total, 27 750 were treated in 1999. In December 1999, 6 040 users were currently in substitution (5 343 on methadone and 697 on LAAM).

Until now, the substitution programmes and non-opioid therapies have mostly been carried out in the CATs (with the exception of the programmes in Santa Maria Hospital in Lisbon and S. João Hospital in Oporto). Some CATs assign other institutions, namely the healthcare centres, to administer their programmes. Currently, an experimental programme is in progress in which some pharmacies cooperate in the administration of methadone to fairly stabilised patients who are being treated by the CATs. In all cases, methadone is always administered under the supervision of qualified staff. Unlike some methadone centres in other countries, the CATs have a limited number of available places. The number of patients in each centre varies according to its capacity and the availability of staff. There are long waiting lists for substitution programmes in the urban centres, and efforts are being made to increase the response ability of treatment centres.

It is not possible to assess the staff/client ratio in substitution programmes, since the staff are often involved in other therapeutic interventions and psychosocial staff may not be directly involved in the administration of the programme.

Some centres are open seven days a week, so that medicine can always be taken on the premises. Centres which are open on weekdays and closed at weekends arrange for the substitute to be administered by a member of the family or by another institution (either a State institution or an NGO).

Despite some difficulties (partly caused by the fact that services are currently being computerised), there is collaboration between all the SPTT services, allowing for patients to move between centres, provided this is arranged in advance. The centres also treat clients from other countries who are staying in Portugal for limited periods, once this is arranged in advance and essential clinical information is forwarded.

Surveys of drug problems

It has been estimated that approximately 5 in every 1 000 of the total population are heroin users, but research on local prevalence suggests this number may be much higher. Two prevalence surveys conducted in 1997 and 1998 in the Setúbal region were based on the capture–recapture method. Setúbal is situated 50 km from Lisbon and has a population of 103 534; it is considered to be one of the worst-affected regions of Portugal.

The first survey, carried out in Setúbal in 1996 as part of a European project, estimated a prevalence of 1.82 % of heroin addicts in the 15–54-year-old age group in this city (EMCDDA, 1997). This estimate is probably on the low side, since the authors only surveyed two medical sources, one of which was quite small.

A second survey conducted in the Setúbal district in 1995–97 aimed at estimating the overall prevalence of heroin consumers in the city. Three medical sources were used for data gathering, and

the results point to a prevalence of 4.07 % of heroin addicts in the overall population (confidence interval (CI) 95 %; 2.56–7.13 %).

Despite the consistency of the survey model and the high number of consumers surveyed (1.04 % of the overall population), it is probable that some factors, such as the three-year duration of the research (1995–97), may have led to an inflated estimate (Godinho et al., 1998). These two surveys show a very high prevalence of heroin addicts in the Setúbal region, and it is probable that there is also a high number of addicts in other urban areas, such as Lisbon and Oporto.

In the years 1995–97, the SPTT centres conducted 26 532 first consultations (7 460 in 1995; 9 889 in 1996; 9 183 in 1997) (GPCCD, 1998). These figures suggest that the underlying amount of heroin use is very high, since the centres have a low response ability (there are long waiting lists in many units). Also, drug addicts usually only seek help after several years of consumption, hence the high average age (27) of the patients (Félix da Costa and Freire, 1998). Research shows that clients have been using for four years on average when they visit the centres for the first time (Godinho and Costa, 1997). Injectable drugs are consumed by 50–60 % of the patients that seek help (Godinho and Costa, 1997; Félix da Costa and Freire, 1998).

A recent study (forming part of an international study) surveyed 2 033 15–16-year-old youngsters attending the 10th, 11th and 12th grades in public schools. The results suggest that Portuguese students show a lower consumption than the European average in all drugs, including alcohol and tobacco (ESPAD, 1997).

Legislation on substitution treatment

The SPTT, operating under the Ministry of Health, is the only service authorised to provide substitution substances (methadone or LAAM), apart from the psychiatric services of Santa Maria Hospital, S. João Hospital and Sines Health Centre. Most experts agree that there is a pressing need to increase the response ability regarding substance substitution, a view shared by the government.

A serious effort is currently under way to expand the existing programmes, through the creation of new units and an increase in the number of places available in the existing units. A study is also being conducted on risk-reduction programmes and an experimental programme is being carried out in a Lisbon slum area.

Substitution programmes have to be authorised by the direcções regionais and the Direcção de Acção Médica (regional directorates and Directorate for Medical Action) of the SPTT. Prescription of the substitutes is the responsibility of clinicians authorised by the SPTT. Currently, substitution is only authorised in State services, mostly those belonging to the SPTT. Although specific training is not compulsory, only clinicians who are experienced in the treatment of drug addicts are authorised to prescribe substitution substances. The possibility of allowing non-profit-making private institutions (NGOs) to conduct substitution programmes is currently being considered.

The substitution programmes must comply with a set of procedures laid down by the regional directorates and the Directorate for Medical Action. Programmes must specify the following:

- the narcotic to be used;
- the population to be addressed;
- the mode of administration and treatment (residential or ambulatory);
- the duration of the programme;
- admission criteria;
- criteria for exclusion and discharge of patients;
- the psychotherapeutic model to be used; and
- the people in charge of the programme, including the prescribing doctors.

There are no compulsory guidelines for treatment. However, patients are not encouraged to take the substitution substance for administration home, although some programmes can make special arrangements for this to occur. Most of the programmes are of medium or high threshold, and there are periodical controls on illicit drug consumption, with accompanying psychosocial support. The frequency of these controls and of the psychosocial sup-

port, as well as the sanctions, depends on the type of programme being followed. In most cases, good compliance with intake of the prescribed substitute, an absence of aggression and availing of improved psychosocial support are sufficient conditions for the patient to be retained on the programme, despite evidence of some consumption of illicit drugs. The duration of the programme and size of dose administered vary according to the needs of the patient; there are no restrictions regarding the maximum prescribed dose or duration of the programme. The patients undertaking this programme must be registered, and treatment records are kept. Most of the programmes are not yet computerised, so there is as yet no exchange of information between the institutions.

Substitution clients

There are no compulsory admission criteria. However, the following criteria are generally a basis for admission:

- age over 18 (except if HIV positive);
- HIV positive;
- pregnancy;
- long years of addiction and several failed treatment attempts;
- psychiatric morbidity;
- evidence of severe medical disease; and
- lack of social and family support leading to a bad prognosis for therapy (the goal of which is abstinence).

Clients are generally agreeable to treatment, as it is usually provided when other attempts have failed. However, as is often the case in other countries, dependence on a substance and, in a way, on an institution, can lead to the client wanting to stop treatment early or disregard the rules of the programme.

Most programmes include relevant psychosocial support (provided by a social worker) and psychotherapy. Although the social support is limited, social workers play an active role in liaising with the families, securing lodgings and food subsidies and seeking employment. This support is generally well received. After

some time has been spent in treatment, patients are often less receptive to psychotherapy, probably because the treatment leads to a greater degree of calmness and a consequent desire to avoid confrontation with the therapist concerning changes in lifestyle. Considerable efforts are made to maintain patients in regular psychological care, particularly during the process of change. Some programmes exercise sanctions if the patient does not comply with the psychotherapeutic support. However, these sanctions are seldom applied in cases where there is an overall improvement in the patient.

Some programmes prefer to take heroin users who are not significantly dependent on other drugs, but the majority accept patients who regularly consume other substances. Although heroin is the main illicit drug in Portugal (apart from cannabis), there are currently a significant number of heroin addicts who use cocaine as a secondary drug (30–50 %). Regular consumption of cocaine, as revealed by many patients, generates problems, since it frequently occurs during the substitution treatment. Abuse of alcohol and benzodiazepines is also a frequent problem with these patients.

Substitution programmes in Portugal do not have a restricted time limit but operate on a case-by-case basis.

Pharmacy activity

A national network of pharmacies covers the whole of Portugal, and pharmacists play an important role in drug-addiction interventions. Pharmacies are private institutions, owned and run by pharmacists. From 1993 onwards, through a protocol between the Associação Nacional de Farmácias (ANF — National Association of Pharmacies) and the Comissão Nacional de Luta contra a SIDA (CNLCS — National Commission for the Fight against AIDS), all pharmacies and some mobile outlets located in high-drug-use areas have started a needle-exchange programme. The programme consists of free provision (in exchange for a used syringe) of a kit containing a syringe and a needle, a sterilised towel, a condom and a leaflet entreating the addict to give up drugs. Apparently, this programme was well received by drug addicts and

led to a decrease in syringe sharing (Félix da Costa and Ferraz de Oliveira, 1997). There are currently 2 000 pharmacies involved in this needle-exchange programme. The number of syringes exchanged in the pharmacies increased between 1994 and 1997, as the following figures show:

- 2 440 705 in 1994;
- 2 853 005 in 1995;
- 2 913 915 in 1996;
- 3 250 185 in 1997;
- 3 049 065 in 1998; and
- 2 992 165 in 1999.

The pharmacists' willingness to cooperate in the needle-exchange programme and treatment of drug addicts has made it possible to establish, through an agreement between the SPTT and ANF, an experimental programme of methadone provision by pharmacists to patients who are undertaking substitution treatment in a CAT, provided they are stabilised and are not too problematic. This measure aims at lessening the overload of the CATs and allows patients to take their medication close to home. This experimental programme involves a small number of pharmacies, and allows each pharmacy a maximum of five patients in treatment. As this programme only started in 1998, no assessment has yet been made. The pharmacists involved in the programme were given specific training by SPTT workers and they receive continual support from the CATs' technical staff.

Primary-care involvement

The SPTT, created in 1990, is a specific drug-addiction service. This service is a vertical structure operating under the jurisdiction of the Ministry of Health, on a par with the primary-healthcare services, and is not part of the National Health Service. The SPTT guarantees free treatment and anonymity.

The decision to create a vertical structure stemmed from the need to respond quickly and efficiently (which the existing structures of the SNS were unable to do), taking into account the seriousness of

the problem at hand. After some initial problems, links were established between the various services, allowing for a complementarity of tasks that was extremely necessary to tackle this problem. This collaboration can take a variety of forms, including the following:

- staff from the CATs provide support and consulting to the health centres;
- some general practitioners (GPs) work part-time in the CATs or in the health centres in the field of drug addiction; and
- training is regularly provided by CAT staff members to the healthcare service personnel.

Substances prescribed

The only substitution substances prescribed in Portugal are methadone and LAAM. There are no restrictions regarding dose or duration of treatment. These substances are usually used in substitution programmes, and in detoxification programmes for pregnant women, either as part of an inpatient or ambulatory regime. Some detoxification units use low doses of methadone in the first three or four days of treatment, so as to reduce the withdrawal symptoms. However, it is not usual practice to use methadone in detoxification programmes; alpha 2 agonists, sedatives and analgesics are the preferred medications. Tramadol, a strong analgesic which acts on the opioid receptors, is currently very much in use in abstinence treatment, apparently with good results.

In Portugal, there are no substitution therapies for abuse of other substances.

In 1998, 63 177 kg of methadone and 3 759 kg of LAAM were used in substitution treatment. Most of the methadone is administered as a 10 mg/ml oral solution and is prepared by the Laboratório Militar (Military Laboratory). Some centres administer methadone in tablet form (5 and 40 mg). There is no injectable methadone. LAAM is administered as a 10 mg/ml oral solution

and is imported from the United States. In 1999, 81 856 kg of methadone and 6 074 kg of LAAM were used in substitution treatment.

Injectable prescribing

There is no prescribing of injectable substances in Portugal.

Surveillance

Data referring to methadone- and LAAM-maintenance programmes are provided by local facilities to the SPTT, but these data solely concern the number of clients and the administration site.

There is no national registration and data cannot be exchanged.

Problems

The problems usually identified by the services are the lack of human resources (technical staff) and logistic problems.

Accessibility (in terms of distance and extended schedules) is essential for the maintenance of these programmes. Since there are no mobile dispensing units, many people are forced to travel long distances. This problem has not yet been overcome.

To date, the centres have not experienced serious problems with the communities who live close to the dispensing facilities, since efforts are made to spread dispensing over the day or refer patients to health centres, pharmacies or even their homes (with the support of the family) for administration of treatment.

Evaluation

In Portugal, there have been few studies evaluating substitution treatment.

Patrício et al. (1996) carried out a preliminary evaluation of the LAAM programme at the Taipas CAT. Although the sample was relatively small, it clearly showed that 60 % of patients in the programme were totally abstinent from using heroin and cocaine. Apparently, there was also an improvement in their social and professional activities. Viegas et al. (1997) carried out a retrospective study on the patients attending the Boavista CAT. In this study, the retention rates over time were assessed at around 50 % in 24 months. This study suggests that the retention rate is higher when high doses of methadone are used. Padre-Santo et al. (1998) conducted an initial assessment of the substitution programme at the Setúbal CAT and found:

- a high retention rate;
- a decrease in the consumption of heroin over time; and
- an apparent improvement in the quality of life of the majority of the patients.

It is generally felt that better assessment of the substitution programmes is needed. The following points deserve special attention:

- retention rates over time;
- abstinence from drug consumption;
- social and professional integration;
- reduction of delinquent behaviour;
- improvement of general health; and
- relationships of patients with the programmes.

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FINLAND

Veikko Granström, Hesperian Sairaala, Helsinki

Introduction

The total population of Finland is 5.2 million, of which 1.5 million live in the Greater Helsinki area. Only approximately 90 000 foreigners live in Finland and ethnic minorities are very small. Relatively few variations in nationality, religion and languages, and a fairly even distribution of income, contribute to making the Finnish community very homogeneous.

National administration (parliament) is responsible for legislation, general order in the country and the funding of services. Local administration is responsible for organising and funding the social services and health services, mostly with money allocated by parliament. Private funding of services is very limited. The social and health services are separate in most municipalities and generally compete for funding. However, at local level, there is considerable cooperation. Drug services are provided by both the social and health authorities, often in collaboration, although occasionally one buys services from the other.

Strategy

In Finland, a decree on the treatment of opiate addicts with certain medicines (buprenorphine, methadone and levo-alpha-acetyl-methadol) was issued on 1 July 2000. Prior to this, treatment had been regulated by the Ministry of Social Affairs and Health.

These earlier regulations had defined treatment of opiate addicts with medication in two categories:

- detoxification treatment — treatment with medication (in practice, buprenorphine) aimed at withdrawal from opiates, the length of which is a maximum of one year; and
- substitution treatment — treatment with medication (in practice, methadone) for patients who have failed to withdraw from opiates after detoxification treatment (using normal treatment protocols); in Finland, the term ‘maintenance treatment’ was not recognised, but neither was there a ‘drug-free’ target for substitution treatment.

The 2000 decree defines the treatment of opiate addicts with medication according to three categories:

- detoxification treatment — treatment with medication for a maximum of one month aimed at freedom from drugs (the wording of the earlier regulations had been ‘withdrawal from opiates’);
- substitution treatment — treatment with medication for more than one month aimed at freedom from drugs; and
- maintenance treatment — treatment with medication for more than one month aimed mainly at reducing drug-related harm and improving the addict’s quality of life.

Until recent years, the drug situation in Finland had been reasonably good. In an article in 1997 (Poikolainen, 1997), it was stated that ‘the number of drug misusers in need of health and social welfare services can be estimated at 1 200–2 400’. However, other estimates are higher, and it is possible that heroin users exceed 2 000. During the last three to four years, it seems that more drug users, particularly heroin users, have sought treatment and that the use of amphetamines has increased.

Until recently, HIV infection and hepatitis C were not very prevalent in Finland. There have probably been less than 1 000 reported cases, and a coincidence of HIV and heroin addiction was found in less than 20 cases at the end of 1998, although that number had risen to 90 at the end of 1999 and is still rising. Studies suggest that some 60 % of injecting drug users are infected with hepatitis C and about 3 % with HIV (Leinikki, 1999; Turpeinen et al., 1999).

Substitution

Development of substitution services

Due to the limited use of heroin in Finland to date, the history of substitution services is short and sparse. It has two principal phases. During the years 1974–96, there were at most 15 patients in a methadone-maintenance programme in Helsinki. The patients, who were all ageing, had used prescribed opiate painkillers, a practice which was subsequently stopped by the authorities. Methadone doses were low, there were no rehabilitation services and no urine controls.

The second phase began by establishing a new programme, in August 1995, in the psychiatric outpatient clinic of Hesperian Hospital in Helsinki. Since December 1997, this has been a separate outpatient substitution therapy clinic. Almost all substitution patients in Finland are on this programme, which is described below.

The drug question has not generated much interest in Finland, both in terms of users themselves and treatment, because the situation has not been particularly remarkable. Given the current environment, it could be a good time to develop suitable treatment programmes.

Current situation

Substitution therapy is still in its early stages in Finland. There were about 70 patients in methadone-substitution therapy and 20 patients in buprenorphine detoxification therapy at the end of 1999.

Under the previous regulations, assessment for treatment (evaluation of the need for substitution treatment) was available only in three university hospitals and the subsequent substitution treatment was then to be undertaken in other social and healthcare units qualified for the task.

However, in practice, there was, and still is, only one full-time unit offering substitution treatment (according to the new decree, for substitution, but in effect mainly for maintenance treatment). There are also some psychiatric hospital departments that have participated in the substitution treatment of some individual opiate addicts.

It should also be mentioned that the new decree emphasises that treatment should be moved from the treatment assessment units to a unit that is situated nearer to the patient (e.g. a local health centre). This unit should operate in cooperation with the assessment unit. Also, according to the new decree, in certain cases patients demonstrating good cooperation can be allowed up to seven take-home doses of medication.

TABLE 1: ARRANGEMENT OF SUBSTITUTION THERAPY IN HELSINKI, FINLAND

METHADONE SUBSTITUTION	BUPRENORPHINE DETOXIFICATION
Assessment: University Hospital of Helsinki	Assessment: Substitution therapy clinic of Hesperian Hospital, Helsinki
Treatment: Substitution therapy clinic of Hesperian Hospital, Helsinki	Treatment: Kettutie A-polyclinic, Helsinki Detoxification clinic, Helsinki

Substitution therapy is only used for heroin addiction in Finland. Substitution therapy in Helsinki can be divided into long-term (open-ended) methadone substitution, in an outpatient setting, and long-term detoxification with buprenorphine, in either a hospital or an outpatient setting. In other parts of Finland, there have been a few individual cases of patients treated with methadone and buprenorphine in a variety of settings. As in Helsinki, most of this work takes place in psychiatric units. Very few patients have been treated in general practice.

Therapy at the Helsinki substitution-treatment clinic (with methadone) is quite intensive, consisting of daily visits to the clinic, counselling therapy approximately once a week, an 'own-nurse' system and urine control on average four times a month.

The average dose of methadone was 145 mg in 1998 and the maximum dose approximately 270 mg. Retention of patients is more than 90 % in a half year, and heroin-positive samples are found in about 10 % of urine controls. Only three of the patients were infected with HIV.

In Helsinki, there is intensive collaboration between health and social services in substitution therapy cases. No sanctions are used in the treatment. For example, positive urine samples are seen as a sign of addiction disease, requiring renewed efforts in therapy (such as raising the methadone dose). If patients actively use heroin and/or amphetamines, it is considered too great a risk to give them take-home methadone and so this has been limited.

Continuity of care has not yet been a problem during the three and a half years of the programme. Four patients of the substitution-treatment clinic continued receiving methadone substitution while in prison in 1998.

The Ministry of Social Affairs and Health regulations refer to LAAM as a substitution substance, but it is not used in Finland. It is estimated that around 170 opiate addicts have been receiving buprenorphine.

Substitution clients

Assessment for substitution treatment with methadone takes place at the five university hospitals in Finland, mostly in Helsinki University Hospital (in its Clinic of Psychiatry). This means spending two weeks as an inpatient. During the assessment period, patients are detoxified from heroin.

Entry criteria for substitution treatment are as follows:

- must be over 20 years of age;
- must have used heroin for more than four years; and
- attempts at detoxification must already have been made.

Relative contraindications are the massive use of amphetamines or benzodiazepines.

Almost all patients are accepted for treatment, which in Helsinki takes place in the substitution therapy unit of Hesperian Hospital.

Issues for the future

It has been decided that treatment slots (vacancies) in the Helsinki substitution therapy clinic will be increased to 90 by the end of 2000. Some new minor methadone and buprenorphine programmes for 1–5 patients have been started in other parts of the country. Substitution therapy using buprenorphine is planned, despite difficulties in its use in long-term detoxification.

In Helsinki, there is a growing interest in research in the area of substitution treatment and national research data would indeed be very valuable. One area of interest would be to investigate when substitution treatment can finish for a patient. It may ultimately be necessary to establish a maintenance treatment programme (aiming only at harm reduction) and this is now a possibility with the new legislation of July 2000.

Surveillance

Names of doctors in charge of units giving substitution treatment must be announced to State officials. Otherwise, surveillance is the same as in healthcare in general.

Problems

There is a lack of treatment slots in the country as a whole, especially in smaller locations. It is also problematic organising treatment for HIV-positive drug users.

Evaluation

No evaluation data are available, due to the short history of substitution treatment in Finland and its very concentrated organisation. National evaluation of treatment has not yet been carried out, and local evaluation information has not yet been collated.

Information in this chapter was updated by the EMCDDA.

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SWEDEN

*Marlene Stenbacka, Beroendecentrum Nord, Karolinska Hospital,
Stockholm*

Introduction

Rehabilitation of drug users in Sweden takes place in public hospitals and care institutions, as well as in private institutions and family-care units (Socialstyrelsen, 1993). In addition, municipal authorities often fund private institutional care. Furthermore, there are special detoxification and rehabilitation units in the psychiatric clinics, and some of these clinics also run methadone-maintenance programmes.

In some municipalities, special departments and institutions are available for drug users suffering from HIV infection or AIDS, or for those with mental problems. The social services play an important role in the rehabilitation of drug users, in collaboration with the medical services. It is the social services which are responsible for the care and treatment of drug users. Some municipalities also have specialised drug-care units. Collaboration between social service drug-care units and the prison and probation services is often good.

Remand centres and prisons play a very important part in drug-treatment activities in some municipalities. Special teams at the remand centres consist of representatives from the social services, the prison and the probation service. They educate the inmates about AIDS and encourage them to undergo HIV testing and to take part in different therapies.

However, methadone-maintenance treatment is not available in prison since one of the inclusion criteria for maintenance treatment is that the patient shall not be in custody, under arrest or in prison at the time of admission.

Some municipalities have set up specialised outpatient teams targeting young people who are at risk of developing maladjusted behaviour. Other municipalities have set up drug-prevention programmes. Social workers try to come into contact with young people in different settings in order to offer support and guidance. Some municipalities also have outpatient teams for alcohol and drug misuse. Sometimes, the drug users are offered institutional care. Admission to treatment is voluntary.

Drug users who are taken into compulsory care often have a long history of compulsive drug misuse and a poor social situation. The decision to admit an addict to compulsory care is taken by the county administrative boards. Compulsory care is provided in special institutions run by the municipalities and county councils.

Methadone maintenance for chronic opiate users, which is the main substitute treatment for drug abuse allowed in Sweden, was developed at the end of the 1960s by Lars-Magnus Gunne and co-workers at Ulleråker Hospital in Uppsala (Dole and Nyswander, 1965, 1976; Dole et al., 1968, 1969), mostly following the original guidelines of Dole and Nyswander (Gunne and Grönbladh, 1981, 1988, 1989; Grönbladh and Gunne, 1989). A small number of opiate abusers are treated with buprenorphine.

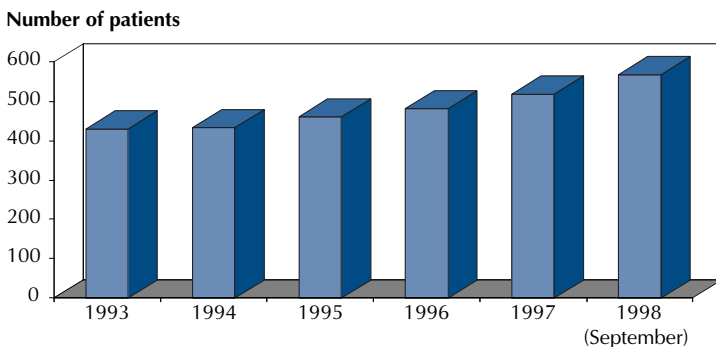
Since Sweden only had a few severe opiate users at that time, the number of patients in methadone treatment was small (Gunne and Grönbladh, 1981). Heroin began to spread on the black market during the second half of the 1970s and, since then, it has been the dominant opiate drug. Before that time, most opiate abusers had used morphine, although there were also a few who used raw opium and morphine base, dissolved for intravenous self-administration. About 100 opiate users were in the methadone programme in Uppsala in 1979 (Grönbladh and Gunne, 1989).

A survey was carried out in 1968 which identified 200 opiate users in the whole country. When a similar study was repeated in 1979, the number had increased to 3 000, mainly heroin users (Olsson et al., 1981). A nationwide survey in 1992 (Olsson et al., 1993) estimated the number of heavy drug users at between 14 000 and 20 000. Of these, 77 % were using multiple drugs, mostly alcohol,

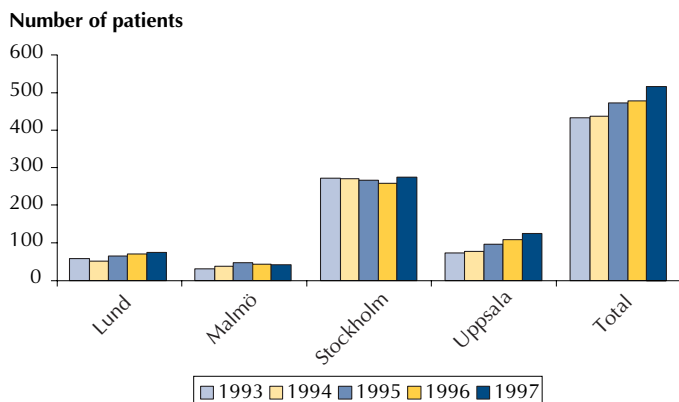
sleeping pills and tranquillisers (Alkohol-och narkotikautvecklingen i Sverige, 1998). Amphetamine was the most common drug (82 %). Heroin was used by one third of heavy drug users. This means that there were 5 000–7 000 heroin users in Sweden at that time. More recent reports indicate that heroin smoking is increasing, especially among immigrants (Alkohol-och narkotikautvecklingen i Sverige, 1998).

Since 1965, the Swedish drug market has been dominated by intravenous amphetamine use (Bejerot, 1975; Alkohol-och narkotikautvecklingen i Sverige, 1998) and most heroin users have a previous history of amphetamine use, often in combination with other drugs. Polydrug use is a problem when opiate users enter methadone treatment (Alkohol-och narkotikautvecklingen i Sverige, 1998). Although methadone patients often stop using heroin during methadone treatment, they may start or continue using other drugs, such as alcohol or benzodiazepines, as well as methadone (Grönbladh and Gunne, 1989). In September 1998, 567 opiate users in Sweden received methadone treatment (Lund had 81 patients, Malmö 61, Stockholm 291 and Uppsala 134) (Figures 1 and 2). In March 2000, the number of methadone patients increased to 612 (Lund 84, Malmö 60, Stockholm 321, Uppsala 147).

**FIGURE 1: TOTAL NUMBER OF METHADONE PATIENTS
IN ALL SWEDISH PROGRAMMES
(LUND, MALMÖ, STOCKHOLM AND UPPSALA) (1993–98)**



**FIGURE 2: NUMBER OF METHADONE PATIENTS
IN ALL SWEDISH PROGRAMMES
(LUND, MALMÖ, STOCKHOLM AND UPPSALA) (1993–97)**



Strategy

After an evaluation of the Uppsala programme (Grönbladh and Gunne, 1989), the Socialstyrelsen (Swedish National Board of Health and Welfare) approved methadone treatment for opiate users (Socialstyrelsen, 1981, 1987). Since 1983, methadone treatment has been a regular form of treatment for opiate users, but with special restrictions and guidelines enforced by the Swedish National Board of Health and Welfare (Socialstyrelsen, 1972, 1981, 1983, 1987, 1988, 1990, 1991).

The Swedish National Board of Health and Welfare has published guidelines for methadone treatment, including instructions regarding the following:

- maximum number of patients in treatment;
- inclusion criteria; and
- number of programmes.

In 1993, the Swedish National Board of Health and Welfare decided that not more than 150 patients could receive methadone

treatment in Sweden. This limit on the number of patients has since been increased on four occasions:

- to a maximum of 300 patients in 1988;
- to a maximum of 450 patients in 1990;
- to a maximum of 500 patients in 1994;
- to a maximum of 600 patients in 1997; and
- to a maximum of 800 patients in 2000.

The criteria for acceptance onto a methadone-treatment programme in Sweden have changed little over the years. Based on the American methadone programmes introduced by Dole and Nyswander, they are supervised by the Swedish National Board of Health and Welfare. The acceptance criteria are as follows:

- a history of at least four years of intravenous opiate misuse;
- earlier attempts at drug-free treatment judged to be of negligible value to the patient;
- aged at least 20 years;
- opiate as the dominant drug;
- must not be in prison when admitted to the programme (Dole and Nyswander, 1965; Gunne and Grönbladh, 1981; Grönbladh and Gunne, 1989; Socialstyrelsen, 1990; Eklund et al., 1994).

During the entire methadone-treatment period, the patient should have support from a social worker from the social welfare services (from the drug-dependence unit).

Since 1990, the National Council of Methadone-Maintenance Treatment has played an important role in the follow-up of methadone treatment. Council members are representatives of the following bodies:

- methadone programmes;
- social services;
- drug-dependence units of hospitals; and
- the Swedish National Board of Health and Welfare.

Members meet twice a year to discuss policy, statistics from the programmes and important matters to do with funding and recruitment of new patients.

Substitution

National register

Since 1995, the Swedish National Board of Health and Welfare has been collecting data from the methadone-maintenance programmes. This register contains basic information about the patients themselves, their drug-use history, reasons for ending treatment and extent of treatment periods.

The methadone programme in Uppsala

The first Swedish methadone programme started in January 1967 in Uppsala and is one of the oldest in Europe. The programme, which grew slowly in the first few years, recruited patients from all over the country. When raw opium, morphine base and, eventually, heroin were introduced into the country in the mid-1970s, opiate misuse increased and more opiate users fulfilled the criteria for methadone treatment. After a waiting period, patients who had applied for treatment were admitted to Ulleråker Hospital in Uppsala. Treatment started with a drug-free month, during which time the patient was given information about treatment and detoxification. A thorough evaluation was made of the patient's medical, social and psychological status, and a schedule was determined for methadone dosage. During this investigation and adjustment phase, the patients also met with the methadone programme's outpatient team, a unit which was created in January 1976. The patients obtained their methadone and gave urine samples at a pharmacy near their homes. Treatment is largely based on the American model, which has been further refined and adapted to suit Swedish conditions under the guidance of Professor Gunne.

A three-year follow-up of the programme has shown that a great number of clients (80 %) were at work or studying. A study of 46 patients who were in treatment in 1975 showed that criminality decreased from 52 % prior to treatment to 13 % after 18 months in treatment. By 1980, 16 % had left the methadone programme voluntarily and 37 % had been excluded for breaking the rules (Grönbladh and Gunne, 1989).

The methadone programme in Stockholm

In 1985, a methadone programme started in Stockholm. This programme has more patients than the other three programmes (Lund, Malmö and Uppsala) and is part of the Beroendecentrum Nord (Central Clinic for Dependence Disorders). The programme offers outpatient treatment to opiate users, but it is also possible, if necessary, to give inpatient care to the patients. The programme advocates close and personal support in the treatment of patients, and collaboration between healthcare and social welfare.

A social welfare study in Stockholm identified 2 500 drug users between October 1993 and March 1994 (Berglund et al., 1994). Of these, 284 were opiate users in methadone treatment and 714 opiate users in contact with social services. It is unclear whether these persons met the criteria for admission to methadone treatment. This study also showed that 37 % of the 284 patients in treatment and 10 % of the 714 opiate users who were not in treatment were HIV positive. The methadone patients were somewhat older (median age of 39 years) than the users who were not in treatment (median age of 33 years). Of the patients in treatment, 44 % used only methadone. The most commonly used drugs besides methadone were benzodiazepine, heroin and alcohol. One hundred methadone patients (35 %) used intravenous drugs. Seventy-five per cent of the methadone patients lived in their own apartments compared with 25 % of the non-treated opiate users.

The methadone programmes in Lund and Malmö

In 1988, the Swedish National Board of Health and Welfare decided to establish a further methadone programme. In 1989, the methadone programme in Lund had five patients in treatment and in May 1990 the programme was formally established. A controlled case study was undertaken in Lund (Andersson, 1981) which included 21 methadone patients and a control group of 21 non-treated opiate users. After one year, the following facts were identified by the study:

- 14 methadone patients had stopped using illicit drugs, compared with 2 in the control group;
- 13 patients in the methadone group had work, compared with 2 in the control group; and
- 1 methadone patient and 4 from the control group had died during the follow-up period.

In 1990, another programme started in Malmö, in the south of Sweden. Most of the patients had started methadone treatment in Uppsala but then continued in Malmö.

A descriptive and analytical evaluation of all four methadone-treatment programmes in Sweden was finished in 1997 (Stenbacka and Romelsjö, 1997; Stenbacka et al., 1998). One aim of this evaluation was to analyse social characteristics, substance use and psychological and physical health before and during methadone treatment, as well as the effect of methadone on criminal behaviour, inpatient care and mortality. An interview and a study based on register data were performed as part of the evaluation. The study included 655 patients (465 men and 190 women) who were treated at any time between the start of the methadone-treatment programme and 1993. The evaluation of the Stockholm patients also included a comparison with a group of injecting opiate users who were aged 20 or older and had at least four years of documented intravenous opiate use, but who had not received methadone treatment. As part of the evaluation, interviews were conducted with a total of 209 methadone patients enrolled in 1993–94: 135 in Stockholm, 26 in Uppsala, 24 in Malmö and 24 in Lund. They were asked questions about the following:

- their relationships with family and friends;
- employment/education status;
- financial situation;
- mental and physical health; and
- drug-use and treatment history, both before and during their current treatment.

Of the 655 patients in the register study, 257 (195 men and 62 women) had been compulsorily discharged and had not returned to methadone treatment, 48 (40 men and 8 women) had undergone at least two periods of methadone treatment and 312 (203 men and 109 women) had remained in continuous methadone treatment. Thirty-eight patients had died while enrolled in a methadone-treatment programme.

In all programme units, most patients (male and female) reported marked improvement with regard to the following areas:

- housing;
- employment/educational activity;
- social relations;
- health;
- family relations;
- use of alcohol; and
- use of narcotic drugs.

In six out of the seven areas mentioned above, 38 % of patients showed a significant improvement.

The annual mortality rate in Stockholm's methadone programme was 1 % for both men and women, compared with 2 % for both sexes in the control group and 4 % in the group of patients who had been discharged from treatment (5 % of men and 1 % of women) (Stenbacka and Romelsjö, 1997). A follow-up of mortality among methadone patients until 1993 showed that 29 of the methadone patients in Stockholm had died: 17 of these during treatment and 12 after being discharged from the methadone programme.

In Uppsala, the oldest programme, 67 patients had died: 16 during treatment and 51 after discharge. In Lund and Malmö,

4 patients had died: 3 during treatment and 1 after discharge. In Stockholm, HIV/AIDS ($n = 10$), narcomania (overdose of narcotics, $n = 7$) and liver cirrhosis ($n = 5$) were the most common causes of death. After discharge, 5 persons died of narcomania. In Uppsala, methadone narcomania ($n = 18$) was the most common cause of death, then came accidental death/suicide ($n = 14$), liver cirrhosis ($n = 4$) and intoxication with benzodiazepines ($n = 4$). After leaving methadone treatment, 15 persons died of narcomania and 8 persons by suicide. These diagnoses were the most common causes of death.

The number of hospital admissions declined markedly for patients in the Stockholm and Lund programmes, where reliable hospitalisation data are available. Data of this kind for Uppsala and Malmö are lacking for the period under observation.

The annual rate of inpatient care among methadone patients in Stockholm decreased from 1.3 admissions per year before treatment to 0.6 during methadone treatment, with a greater decrease for women. This was associated with time spent in treatment and did not decrease further for those who were more than two years in treatment. The rate was 1.7 admissions per year for those who stayed for less than a year, less than 1 for those who stayed more than two years and 0.3 for those who stayed longer (more than six years).

HIV-positive patients consumed a greater amount of inpatient hospital care than HIV-negative patients, which may partly be due to AIDS and its complications. There was a marked decrease in inpatient-care admission among HIV-negative patients during treatment. However, the number of treatment days decreased during treatment for both the HIV-positive and HIV-negative women but only for HIV-negative men (Stenbacka and Romelsjö, 1997; Stenbacka et al., 1998).

The rate of hospitalisation with a diagnosis of HIV/AIDS was higher for the methadone patients, especially during treatment, than for the control group. There was an increase in the incidence rate of admissions for treatment of other infectious diseases in men and a decrease in women. In all, 20 % of the men and 13 % of the

women in the control group had been treated in hospital for alcohol diseases, compared with 10 and 4 %, respectively, prior to treatment among the methadone patients (Stenbacka et al., 1998).

A significant reduction in convicted crimes was observed among both women and men during treatment, compared with the time prior to treatment. The rate of convicted crimes among all four programmes was highest in Stockholm (2.2 crimes per year) and lowest among the Malmö patients (1.7 crimes per year). During treatment, the number of convicted crimes decreased to 0.3 in Malmö, 0.5 in Lund and Uppsala and 0.6 in Stockholm. In all programmes, the reduction was significant for both sexes. Similarly, there was a decline in the number of detentions (arrests or remands in custody) among patients in Stockholm, where data on this subject were available. No such improvement occurred in the control group.

The patients who had difficulty adjusting to methadone treatment and who were involuntarily discharged showed an increase in recorded criminal behaviour but were convicted of fewer crimes after discharge than before entering the treatment. Nearly 40 % of 655 methadone patients were involuntarily discharged during the whole period under study (1966–93). On the other hand, consumption of inpatient care in hospital showed a marked increase after discharge from treatment.

The methadone patients in Lund, Malmö, Stockholm and Uppsala, 1993–98

The number of patients in methadone treatment increased from 430 in 1993 to 567 in 1998. Lund had 81 patients, Malmö 61, Stockholm 291 and Uppsala 134 in September 1998. About one third of the patients in all the programmes were female.

The decision to request methadone treatment often came from the patients themselves, or through family members, doctors or social workers (Stenbacka and Romelsjö, 1997). The intake of new patients increased from 109 in 1993 to 128 in 1997 (Figure 3).

The proportion of new admissions to methadone programmes is highest in Stockholm (57 % in 1997) compared with 16 % in Lund, 8 % in Malmö and 20 % in Uppsala (Figure 4).

FIGURE 3: TOTAL NUMBER OF NEW PATIENTS ADMITTED TO THE METHADONE-MAINTENANCE PROGRAMMES IN SWEDEN (1993–97)

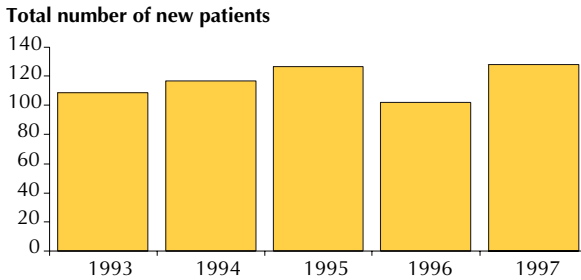
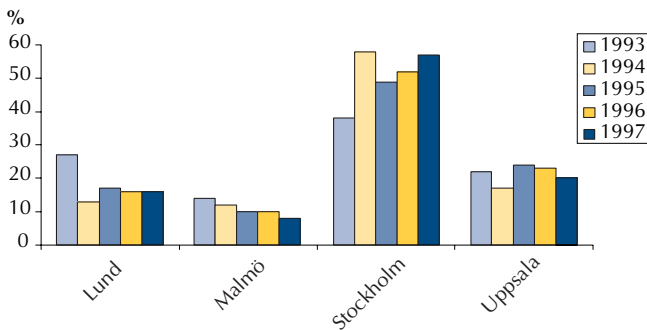


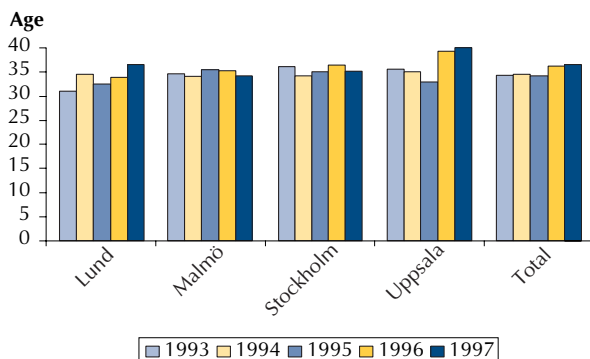
FIGURE 4: PROPORTION OF NEW ADMISSIONS OF OPIATE MISUSERS TO ALL SWEDISH METHADONE PROGRAMMES (LUND, MALMÖ, STOCKHOLM AND UPPSALA) (1993–97)



The average age on commencement of methadone treatment increased from 34.5 years in 1993 to 36.5 in 1997. The age was somewhat higher in the Uppsala methadone programme in 1996

and 1997. One reason for this could be that the Uppsala programme has accepted about 30 patients with long-term physical pain. These patients are generally somewhat older than the heroin users when they apply for methadone treatment (Figure 5).

FIGURE 5: MEAN AGE AT ENTRANCE TO ALL SWEDISH METHADONE PROGRAMMES (LUND, MALMÖ, STOCKHOLM AND UPPSALA) (1993–97)



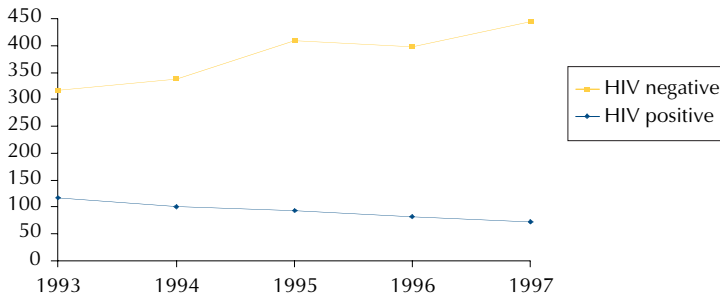
The age of initiation of intravenous opiate use was investigated in 1997 in 205 methadone patients. The results show that nearly 50 % had started using intravenous drugs at 19 years of age or younger, 21 % were between 20 and 24 and the rest were 25 or older (Andersson, 1981). These figures agree with the self-reported age of commencement of opiate use (mean age = 21 in 1997) in the Uppsala and Malmö methadone programmes. In Stockholm, the average age recorded in 1997 for intravenous opiate use was approximately 27 years.

In Lund, Malmö and Uppsala, 235 patients were receiving methadone treatment on 1 December 1997. A one-year follow-up of these patients showed that 7 % had been discharged. In Stockholm, 14 % of 279 patients had 'dropped out' of treatment during the same period. One explanation for the higher rate of

drop-out among the methadone patients in Stockholm could be that many of the drug users in Sweden live there.

The proportion of HIV-positive patients in methadone treatment has decreased in Sweden. In 1993, 117 persons were HIV positive and this number decreased to 73 in 1997 (Figure 6). One reason for this reduction is that a great number of these patients had died during the previous five years. Another reason is that a high proportion of the drop-out patients are HIV positive.

FIGURE 6: HIV STATUS AMONG METHADONE PATIENTS IN ALL PROGRAMMES IN SWEDEN (1993–97)



The methadone programme in Stockholm has most patients with HIV-positive diagnoses, followed by the programme in Uppsala. Very few patients were HIV positive in Lund and Malmö. A reduction in HIV-positive patients has been observed both in Stockholm and Uppsala (Figures 7 and 8).

Drug use other than methadone treatment seems to be the most common reason for discharge from a programme (Figure 9). In the Stockholm programme, voluntary interruption of treatment (the patient fails to attend appointments or does not take medication, etc.) and manipulation of methadone doses seem to be more common than in the other programmes.

Mortality decreased from 19 persons in 1995 to 4 in 1997 (Figures 10 and 11). However, most of those who died after being discharged from treatment suffered from HIV-related diseases.

FIGURE 7: PERCENTAGE OF HIV-POSITIVE PATIENTS AMONG METHADONE PATIENTS IN ALL SWEDISH METHADONE PROGRAMMES (LUND, MALMÖ, STOCKHOLM AND UPPSALA) (1993–97)

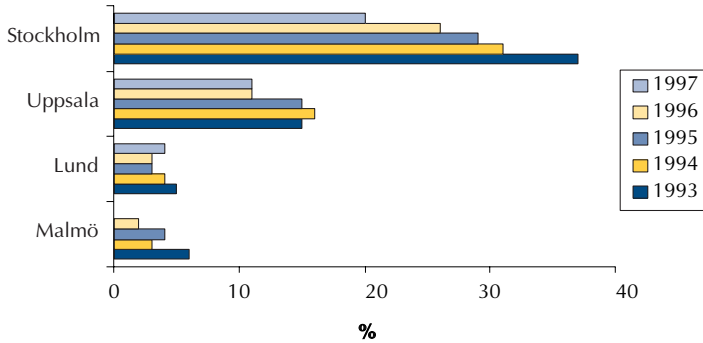


FIGURE 8: PERCENTAGE OF HIV-POSITIVE PATIENTS IN METHADONE TREATMENT IN STOCKHOLM (1993–97)

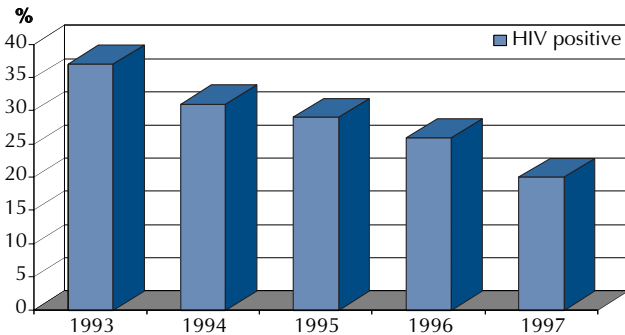


FIGURE 9: REASONS FOR DISCHARGE FROM METHADONE TREATMENT AMONG ALL PATIENTS IN SWEDEN (1993–97)

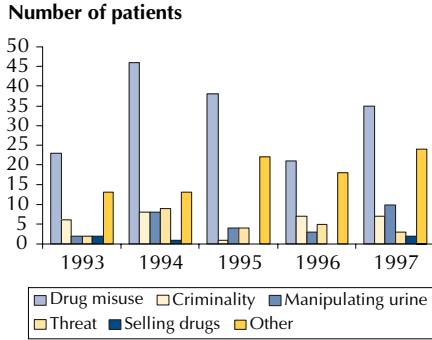


FIGURE 10: NUMBER OF PATIENTS WHO DIED DURING METHADONE TREATMENT IN ALL SWEDISH METHADONE PROGRAMMES (LUND, MALMÖ, STOCKHOLM AND UPPSALA) (1993–97)

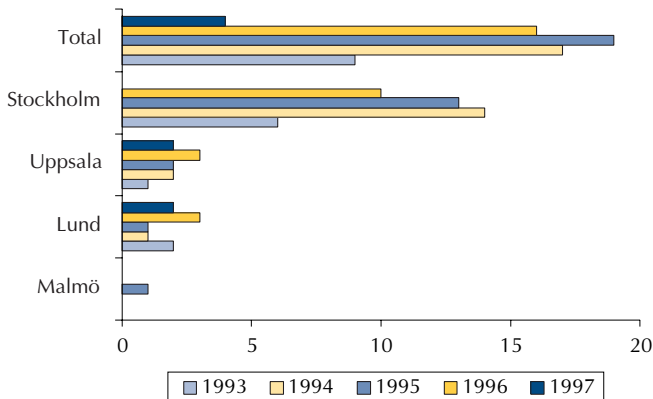


FIGURE 11: HIV STATUS AMONG 31 PERSONS WHO DIED AFTER BEING DISCHARGED FROM METHADONE TREATMENT IN STOCKHOLM (1995–97)

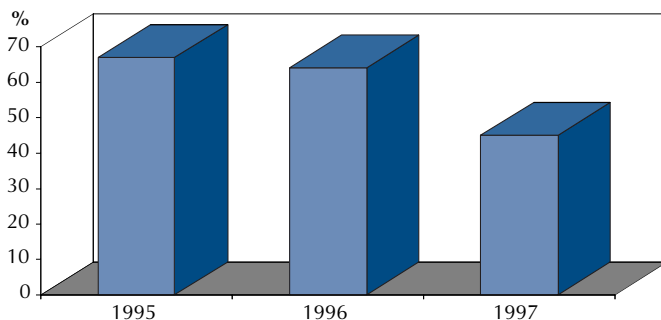
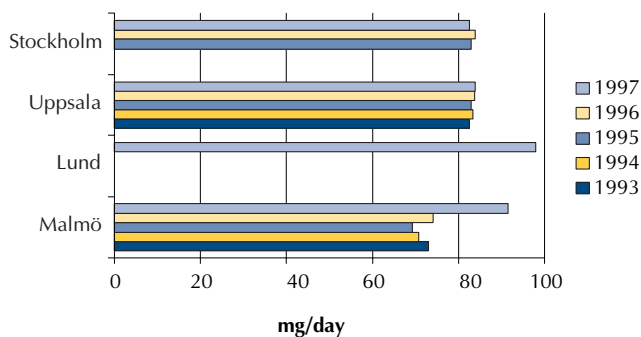


FIGURE 12: METHADONE DOSE (MEAN MG/DAY) IN ALL SWEDISH PROGRAMMES (LUND, MALMÖ, STOCKHOLM AND UPPSALA) (1993–97)



Methadone doses seemed to be highest in Lund (98 mg/day). In the Malmö programme, the mean dose increased from 69.3 mg/day in 1995 to 91.5 mg/day in 1997 (Figure 12).

Controversy

Many studies have demonstrated positive outcome results of methadone-maintenance treatment. Despite this, there has been a negative public attitude towards methadone treatment in Sweden, especially before the AIDS epidemic. When it became known that injecting heroin users are an important risk group for transmission of HIV, attitudes towards maintenance treatment changed in a positive way. Today, maintenance treatment is more accepted as a medical treatment for chronic opiate misuse than it was 10–15 years ago.

Methadone-maintenance treatment in Sweden is provided in four specialised programmes. One of the reasons for the strict regulation of the programmes is to limit the chances of methadone being diverted to the black market.

Surveillance

In 2000, the Swedish National Board of Health and Welfare began collecting data from all the methadone-maintenance programmes in the country.

Methadone conferences where staff from all the programmes report current data and discuss future plans and directions of the programmes also take place a few times a year.

A longitudinal study is being carried out on a cohort admitted to treatment in 1989 and 1991 and followed up to 1999 according to retention in treatment, mortality, hospitalisation, occupation, criminality, etc.

Problems

One problem encountered in substitution treatment in Sweden is a shortage of personnel for the methadone-maintenance programmes, particularly a lack of trained nurses. Another problem is that county councils are often not willing to pay other communities

to perform the treatment if a patient wishes to move from one programme to another.

Evaluation

In Sweden, as in many other countries, evaluation of the effects of methadone-maintenance treatment on different outcome measures has been a priority. However, few studies have investigated if it is the methadone itself or other treatment factors, or a combination of these, which is significant for a good outcome. More evaluations of the 'black box' of treatment and treatment strategies are needed.

Summary and conclusions

One must assume that opiate users who apply for methadone treatment do so voluntarily. It is fair to believe that they would like to see various improvements in their lives and are motivated to try to change their behaviour to this end (Ball and Ross, 1991; Bell et al., 1992; Ward et al., 1992). Treatment of patients who are thus motivated could partly explain good outcome during methadone treatment.

Due to successful treatment outcome, the number of methadone patients in Sweden has increased. The Swedish National Board of Health and Welfare offers treatment for 600 patients at present. Four methadone programmes (in Lund, Malmö, Stockholm and Uppsala) offer substitute treatment to chronic opiate users. Stockholm is the largest programme, with 297 opiate users in treatment and the highest number of HIV-positive patients. The Uppsala programme is one of the oldest in Europe and accepts a new category of methadone patient, those with chronic pain disorders. An evaluation of the methadone programmes in Sweden (Stenbacka and Romelsjö, 1997) has shown that the incidence of criminality, inpatient care, illicit drug misuse and mortality decreased during methadone treatment, as compared with the time prior to treatment. However, an increase in criminality, inpatient care and mortality occurred after discharge from treatment.

Most patients report improvements in many areas during treatment. Thus, retention in treatment is important for the health of the patient, for a reduction in criminality, inpatient care and mortality and for public health in the community in general.

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UNITED KINGDOM

*Michael Farrell and Samantha Howes,
National Addiction Centre, London*

Introduction

The United Kingdom is made up of England, Wales, Scotland and Northern Ireland. The principle of universal access to healthcare, free at the point of delivery, is enshrined in all settings, but there is some substantial variation between regions. For example, in Northern Ireland, there is no separation between health and social services. Over the past two decades, there has been much debate about the funding of health services, and the UK remains one of the countries in Europe with the lowest per capita expenditure on healthcare.

The use of primary care as a gatekeeper to secondary-care services is regarded as conferring a unique level of efficiency of service utilisation. However, despite the overall limits on spending, debate continues around value for money, priorities in healthcare delivery and overall strategies for cost containment, in a manner similar to most European Union Member States.

Strategy

The core of the UK's national drug strategy for the past three decades has been a combined approach to drug prevention and drug treatment, with a blend of demand-reduction and supply-reduction strategies. In a recent comprehensive spending review, it was estimated that 75 % of resources were directed towards enforcement and supply-reduction approaches, 13 % towards treatment and 12 % towards prevention.

As part of a move towards improving integration and coordination of services, a national action called 'Tackling drugs together' (1995) launched a three-year strategy which established drug-

action teams in 105 localities in England and Wales; a separate system was established in Scotland and Northern Ireland. These bodies were charged with improving links between drug-prevention and drug-treatment activities and reported to a national drugs-coordination unit (based at the Office of the Lord President of the Privy Council) which was responsible for improving central government coordination of the drug strategy. In 1998, this approach was modified with the introduction of a national anti-drugs coordinator ('drug tsar') and deputy anti-drugs coordinator and the production of a further 10-year drug strategy entitled 'Tackling drugs to build a better Britain: the government's 10-year strategy for tackling drug misuse'. These new positions had more political profile and public exposure than their predecessors, who were professional civil servants (UKADCU, 1998).

The main aims of this strategy are as follows:

- to tackle the supply of drugs;
- to improve drug prevention;
- to improve treatment, particularly for young people and for prisoners; and
- to establish a robust information framework for measuring progress.

The primary department responsible for drug policy remains the Home Office, which oversees drug enforcement and control. The Home Office also houses the Drug Prevention Advisory Service (formerly the Drug Prevention Initiative).

Health and health promotion are the responsibility of the Department of Health, which provides a substantial budget, calculated on the basis of local demographic factors, to over 100 local health authorities. These have responsibility for organising and delivering primary and secondary healthcare to populations usually in the range of one quarter of a million people. The health authority can set its own local priorities, but must work within the framework of central guidance. The National Health Service (NHS) has undergone many transformations and reorganisations since its inception in 1948. In the 1990s, the NHS and the Community Care Act established a separation between the

purchaser and the provider of health services, and between health and social care, which placed much of the responsibility for social care with local authorities. The resulting division and loss of protected funding for residential psychosocial services resulted in major changes in the residential sector:

- shorter-term funding (giving rise to annual financial problems);
- substantial overall reductions in residential services; and
- considerable expansion in daycare and other non-residential services.

A recent key change in the health services has been the promotion of primary-care as the shaper of services. Primary care is currently being reorganised into groups which will have overall responsibility for the purchasing of all health services, both primary and secondary (Gerada and Farrell, 1998).

Substitution

Development of substitution services

There were few drug problems in the UK in the early part of the 20th century, except for a brief flurry of activity in the 1920s. In 1922, the Rolleston Committee (a departmental committee under the UK's Department of Health, which supported the use of opiate-substitution treatment for the chronic management of opiate addiction) produced a report confirming the role of treatment in response to addiction. Problems first arose in the 1960s, when a small number of doctors prescribed large quantities of heroin for some of the 'flower-power' generation, the newly evolving youth drug culture of the day. A significant black market grew out of this form of prescribing (Spear, 1994). At that time, however, the majority of doctors wanted as little contact as possible with addicts. The growth of a market in prescribed heroin and cocaine resulted in the establishment of the Brain Committee in 1966. This interdepartmental committee, chaired by Lord Brain, recommended the creation of a network of specialist clinics for the delivery of drug treatment as well as the establishment of the UK Dangerous Drugs Act. Subsequently, the right of general

practitioners to prescribe heroin and cocaine was restricted and drug-dependence units with specialist doctors to prescribe for addicted patients were established.

At this stage, the problem remained quite small, with between 3 000 and 5 000 heroin addicts using services. Most of those entering the newly established clinics for treatment were started on methadone; a smaller group were prescribed heroin and a much smaller group cocaine. The size of the clinic population remained fairly stable, with two thirds on methadone and one third on diamorphine or other opiates, and had a turnover of approximately 50 % per annum.

During that period, there appears to have been limited clinical commitment to methadone maintenance and a growing interest in short-term opiate detoxification. The growth of the use of illicit drugs continued through the 1970s but remained relatively stable until the heroin epidemic, which began at the end of the decade. Between the late 1970s and the early 1980s, there was a large increase in the availability of smokable heroin and injectable heroin in all parts of the UK, except Northern Ireland. This problem continued throughout the 1980s. The second half of the 1990s saw the gradual spread of the drug culture to all areas of the United Kingdom, including Northern Ireland. National and local surveys indicated high rates of non-dependent drug use by young people and a lower age of drug initiation.

There was no specialist service for drug misuse prior to 1968, when the Dangerous Drugs Act specialist services were established. There were three phases of service development:

- 10 % of services were developed before 1970;
- 19 % of mainly residential rehabilitation services were developed in the 1970s; and
- the majority of services (71 %) were established after the central funding initiative in 1984.

It has been argued that the increase in HIV and AIDS has stimulated the development of the public health model of drug services (Stimson, 1996). The public health implications of HIV spreading

among drug users precipitated a large range of proactive strategies, such as increased funding for the expansion of community drug services and the development of a wide network of needle-exchange programmes.

MacGregor (1994), as part of a review for the Task Force to Evaluate Services for Drug Misusers (1996), reported that, in the decade since the previous review, there had been a process of merging and consolidating services, with over 475 services identified. Of these services, 95 were residential or inpatient and the rest were statutory or voluntary sector community-based drug agencies.

Current situation

There have been no specific national surveys on drug misuse in the UK, but other national surveys have included questions on drug misuse. Sexual health and lifestyle surveys (Johnson and Williams, 1993; Farrell et al., 1998a) indicate that less than 1 % of the population has ever injected drugs, but that 2 % of London's population may have injected drugs. It is estimated that there are approximately 150 000 opiate injectors in the UK and that there may be a sizeable number of amphetamine injectors; it is hard to obtain reliable data on this population. There is significant variation in the route of administration of heroin, with between 30 and 60 % of those attending services reporting smoking heroin. There is currently a large heroin- and amphetamine-using population, and a separate large section of the young population are involved in hallucinogen use. Up to 30 % of the population report use of cannabis, but a smaller proportion report regular use of cannabis. A growing problem with cocaine use is emerging, both among the opiate-addict population and separately. There is also a growth in new markets for crack cocaine. The size and extent of this problem are not yet clear, but a significant shift of service responses will probably be needed to cater for the crack-cocaine-addict population.

The number of new people entering services for opiate-addiction treatment in the UK continues to grow as does the number of

young addicts entering these services. The number entering with stimulant-type problems remains a small fraction of the overall number but has grown at a substantial rate over the last few years. There is considerable concern about the lack of access to current drug services for amphetamine users (Farrell et al., 1998b; Klee, 1997). The general perception is that this is a worsening drug problem.

Major growth has been observed over the past decade in the number of people attending for treatment, rising from 8 000 in 1984 to 43 372 in 1996. The majority of these have had opiate problems (see below). Most were prescribed methadone, and there has been a considerable expansion in the consumption of this substance (Table 1). There are no clear data on the numbers receiving short-term versus long-term methadone. A small number of people (approximately 250) are prescribed heroin, and this number has remained stable over the decade. The services available consist of:

- community drug teams/outpatient services;
- inpatient and residential treatment units; and
- day centres.

TABLE 1: NUMBER OF METHADONE PRESCRIPTION ITEMS DISPENSED IN THE COMMUNITY IN ENGLAND (1991–96)

YEAR	NUMBER OF PRESCRIPTION ITEMS (1 000)					
	TABLETS	MIXTURES	LINCTUS	INJECTIONS	OTHERS	TOTAL
1991	38.3	403.3	6.8	39.0	3.1	490.5
1992	47.7	495.0	5.3	54.5	4.7	607.0
1993	62.4	598.2	4.2	70.1	0.3	735.1
1994	77.3	682.4	4.0	81.7	0.7	846.0
1995	94.9	787.0	3.5	84.2	1.4	970.9
1996	97.8	891.0	3.1	83.1	1.0	1 076.1

NB: The data cover all prescription items dispensed by community pharmacists, dispensing doctors and prescriptions submitted by prescribing doctors for items personally administered. The data cover all prescriptions for methadone hydrochloride and do not identify those solely for drug addicts.

Source: Statistics Division 1E (1998).

The population attending these services tend to be over-represented in terms of socioeconomic deprivation, unemployment, low level of educational attainment and polydrug abuse.

Methadone-prescribing services are integrated, in most settings, with community-based multidisciplinary teams which aim to provide a range of psychosocial interventions, such as:

- brief interventions;
- motivational interviewing;
- cognitive behavioural and relapse prevention; and
- addressing legal, housing and financial problems.

Such activities may emanate from community drug teams, which have their own medical staff, or from shared-care services with primary-care involvement. There has been considerable emphasis on developing shared-care services and promoting primary-care involvement in drug services (Gerada and Farrell, 1998).

The UK has a wide network of methadone-prescribing services, the majority of which are integrated into the mainstream of drug services and linked also to primary-care services. Probably 95 % of methadone prescribing occurs off-site. Prescriptions are brought to community pharmacists, the substance is dispensed by the pharmacist and consumed at home. There is considerable geographic variation in levels of methadone prescribing, with regions such as Merseyside having high levels and other regions, such as Oxford, having low levels. Most of this activity occurs through community drug services, which are, in essence, specialist services or secondary-care services. A substantial amount of prescribing by general practitioners (GPs) is associated with these community drug teams. Up to 20 % of GPs are involved in methadone prescribing, but over 80 % have no desire to be involved in substitute prescribing. A small number of practitioners are involved in prescribing dexamphetamine sulphate for the management of amphetamine addiction. There is a substantial amount of benzodiazepine prescribing, with up to 30 % of clients of some services reporting use of benzodiazepines. Overall, the majority of service utilisation lies in the community-based services.

Legislation on substitution treatment

Any doctor in the UK may prescribe methadone for the purposes of treating addiction and there is no limitation on this treatment. The doctor is obliged to complete the prescription on a controlled drug prescription form and to complete a database form which is then incorporated as part of both the regional and national data set on treatment activity. This legislation applies nationally. The Home Office drugs inspectorate partnership with the police regularly inspects chemists to ensure that the requirements for prescribing are adhered to by both doctors and chemists. Improper procedures can be pursued through the Home Office inspectorate.

The Home Office 'Addicts index' collates data on drug users throughout the UK who come into contact with a medical doctor. The 1973 misuse of drugs regulations (notification of, and supply to, addicts) required that all doctors notify the 'Addicts index' of patients whom they considered to be addicted to one of 14 notifiable drugs, including heroin, methadone and cocaine. In 1997, the 'Addicts index' was closed and information is now collated by the new 'Regional drug-misuse database' (RDMD), which collates similar information but includes other drugs, such as ecstasy etc. However, data from the 'Addicts index' contained valuable information on the prescribing practices of doctors treating drug misusers in the UK.

Substitution clients

Between 1995 and 1996, the total number of addicts notified to the Home Office increased by 17 % (6 200 additional addicts). This equates to 743 addicts per million of the UK population in 1996, compared with 636 in 1995 and 583 per million in 1994. Around 40 % of notifications each year are of new addicts joining the register.

Heroin was the most common drug of addiction for addicts notified to the Home Office. However, in 1996, a record number of people (18 617) were reported as dependent on methadone (alone or with other drugs). Due to the method of reporting to the data-

base, it is unclear whether the methadone is prescribed or if it comes from illicit sources, although it is thought that the increase may reflect the expansion of medical services providing methadone on prescription. The overall trend is of a substantial increase in the proportion of addicts reported as dependent on methadone. This trend is most apparent amongst re-registered addicts, where the number of addicts dependent on methadone has increased overall from around 25 % in 1987 to 50 % in 1992, 58 % in 1995 and 55 % in 1996. This probably reflects increased prescribing of methadone in the treatment of heroin addiction.

Age and sex of notified addicts

Since 1991, new addicts notified to the Home Office have been getting younger. In 1996, the average age of a newly notified addict was just under 26. Three quarters of new addicts were under the age of 30. In 1996, there was a 35 % increase in the number of newly notified addicts under the age of 21 compared with 1995. New addicts aged 21–24 and 25–29 rose by 22 % in 1996 compared with 10 and 5 % respectively in 1995.

Males account for about three quarters of all notifications across all age groups. On average, females are one year younger than male addicts.

Guidelines for the management of drug dependence

Guidelines for the management of drug dependence have been established since the mid-1980s. These are advisory guidelines specifically aimed at general practitioners. They recommend that general practitioners be involved in the short-term prescribing of substitute drugs, as well as less-complicated methadone maintenance. In both the specialist service deliveries and the community service deliveries, there are no regulations as to how frequently a patient must attend and there is no limit to the size of client population the service may have. Prescriptions are generally valid for 14 days and it is recommended that, in the early stages, all drugs

be dispensed on a daily basis and that the consumption be supervised until stability has been achieved. Doctors are free to exercise their clinical judgment. There are no specified dose limits, but practitioners generally dispense doses ranging between 20 and 100 mg. In oral methadone, a mixture of 1 mg/ml is the normal requirement. Most of the services have behavioural contracts.

An updated version of the guidelines was launched in late March 1999 and these recommended a move towards tighter monitoring and supervision of methadone in the early phases of treatment. There are also proposals for new legislation to restrict the prescribing of injectable medication and certain other medications to specialists and authorised licence holders.

Pharmacy activity

Alongside the increase in notifications of drug users to the Home Office 'Addicts index', there has been an increase in the number of prescriptions dispensed in the community for methadone hydrochloride in its various forms. Table 1 above shows the number of items dispensed in England for different forms of methadone in the period 1991–96.

In the UK, there have been two comparable surveys of pharmacy activity throughout England and Wales, the first in 1988 and the second in 1995. Table 2 shows a large increase in the percentage of community pharmacies involved in the provision of services for drug misusers.

TABLE 2: PERCENTAGE OF COMMUNITY PHARMACIES INVOLVED IN SERVICE PROVISION TO DRUG MISUSERS IN ENGLAND AND WALES

ACTIVITY	1995 (%)	1998 (%)
Dispensing controlled drugs	23	50
Selling injecting equipment	28	34
Needle-exchange scheme	3	19

Source: Sheridan (1998).

Substances prescribed

The data described below are taken from the 1995 national survey of community pharmacies (Sheridan et al., 1996; Strang and Sheridan, 1998). The data draw on a sample of 3 693 methadone prescriptions dispensed across the UK and provide details of the type and dose of methadone prescribed and the dispensing arrangements used. The data also show wide variations in prescribing practices across UK health authorities.

Type of methadone prescribed

Across the whole sample, 79 % of all prescriptions were for oral methadone, 12 % were for tablets and 9 % were for methadone ampoules.

Dispensing arrangements

Guidelines from the UK Department of Health (1999) advise doctors to instruct dispensing pharmacists to provide methadone in instalments (for example, daily dispensing). The survey showed that GPs prescribed with longer intervals between pickups than hospital doctors.

More than one third (37 %) of all prescriptions examined in the study were for weekly or fortnightly pickup, with 38 % being for daily pickup. Tablets and ampoules were less likely to be dispensed on a daily basis. However, there was considerable variation across the UK in dispensing arrangements. For example, the proportion of prescriptions dispensed daily was 16 % in one region compared with 65 % in another.

Doses prescribed

Prescriptions for up to and including 50 mg of methadone accounted for 67.9 % of the total prescriptions dispensed. Doses

TABLE 3: DISTRIBUTION OF METHADONE DOSES BY THE TYPE OF METHADONE DISPENSED IN ENGLAND AND WALES

	DAILY DOSE OF 50 MG OR LESS	DAILY DOSE OF 100 MG OR MORE
Percentage of oral methadone mixture prescribed	71.2	1.5
Percentage of methadone tablets dispensed	58.4	6.1
Percentage of methadone ampoules dispensed	52.6	8.0

of methadone dispensed varied according to the type of methadone prescribed, with oral mixtures being most likely to be prescribed at the lower dose range (Table 3).

Public versus private sector prescribing

The data for private prescriptions revealed considerable differences compared with those for public prescriptions:

- they were significantly more likely than NHS prescriptions to be for tablets or ampoules;
- they were for substantially higher doses; and
- they were collected on a weekly or fortnightly basis.

Eighty per cent of all private prescriptions were from the London area.

Primary-care involvement

Shared-care participation has been identified as an important development area (Task Force to Evaluate Services for Drug Misusers, 1996). Although limited in number, well-implemented initiatives show that it is possible to deliver opioid maintenance treatment in a general-practice setting for many patients, provided there is ongoing case management and active collaboration with a specialist service. The difficulty of delivering services to drug users in non-metropolitan areas, where specialist services may

have a limited capacity, underscores the importance of further developing reduction and maintenance treatments in the primary-care setting. There is a major policy emphasis on expanding primary-care involvement in the management of drug dependence. This includes strategies to provide further financial support for general-practitioner involvement and provision of financial support to develop shared-care strategies between primary-care and specialist services.

Two studies have been conducted comparing primary-care and specialist service intervention. One randomised study reports similar outcomes in both settings (Task Force to Evaluate Services for Drug Misusers, 1996) and Gossop et al. (1997, 1998, 1999) report, as part of the 'National treatment outcome research study' (NTORS), similar levels of performance between specialist and primary-care methadone treatment.

Prisons

There has been considerable expansion in the growth of methadone detoxification for prisoners, but only a limited amount of methadone maintenance (Singleton et al., 1999).

Overall surveys indicate that half of the women and a third of the men who were identified as drug dependent in the year before entering prison received help for their drug problem during the time of imprisonment. Also, a substantial proportion had some contact with help agencies during their prison stay. Those with opiate dependence were more likely to receive help in the community and were also more likely to receive help in prison, but dependent stimulant users also reported significant levels of access to help within the prison setting.

Substitute prescribing is one of the most common forms of treatment delivered by community treatment agencies. There is a low level of continuity between community methadone treatment and prison methadone treatment. Data indicate that, for those who are sentenced, there are reasonable levels of contact with outside specialist agencies.

Service expansion for drug users within prisons has changed significantly in the recent past, with the development of a range of treatment programmes as part of the new strategy. There is a strong recognition of the links between acquisitive criminality and drug dependence. Recent work on a national treatment cohort (Gossop et al., 1998) identified high rates of active offending among those newly entering drug-treatment services. It has been obvious for some time that there is a considerable drug problem associated with the prison setting.

It has been acknowledged that the level of HIV seroprevalence among the drug-injecting population in the UK has remained low (at 1–2 %) (Stimson, 1996), with London figures running at between 6 and 10 %. This is seen as resulting from a successful HIV-prevention strategy supported by broad-based community services and needle-exchange programmes. All of these services are funded through the National Health Service and are free at point of access. There is a small private treatment sector in London which mainly focuses on prescribing injectable methadone and amphetamines, because of the limited prescribing of these drugs within mainstream services.

Injectable prescribing

There is considerable variation between injectable and oral methadone prescribing, with some regions reporting up to 10 % of injectable prescribing and some reporting minimal injectable prescribing (Sheridan et al., 1996; Ford and Ryrie, 1999). Heroin prescribing occurs within the specialist services, where the cost has effectively limited the amount of such prescribing. Further studies are exploring the desirability of injectable prescribing and two studies have recently been completed. The first, a descriptive outcome study of those on injectable methadone and diamorphine, reported positive outcomes (Metrebian et al., 1998) and the second is a small pilot randomised study of injectable versus oral methadone (Strang et al., forthcoming).

New medications

The UK has a history of problems with buprenorphine but further research into its utility in the management of opiate dependence is being considered. Subutex® is now available to clinicians. One study of buprenorphine as a detoxification agent is in progress in the UK, but no studies on treatment with LAAM have been conducted to date. Considerable interest is also shown in further evaluating the role of dihydrocodeine in the management of mild opiate dependence.

Issues of diversion

Due to the mode of dispensing in the UK, a considerable amount of diversion of prescribed medication occurs. Methadone costs GBP 10 (EUR 16) per 100 ml on the black market. To date, this diversion has not been a major political issue, but there are rising numbers of first-treatment episodes for methadone only and there has been anecdotal evidence of deaths from recreational methadone use. However, a continuing rise in the number of opiate- and methadone-related deaths has resulted in a degree of alarm around this issue and calls for more supervision of prescribed methadone (Fountain et al., forthcoming).

Surveillance

The new drug strategy is commissioning a range of monitoring projects to provide an information framework. These include school and household surveys. The topic and approach to surveillance continues to be a subject of debate (Hickman et al., 1998; Judd and Fitch, 1998).

Problems

The most critical problem facing community-based services is restricted funding and consequent inability to expand services to meet treatment demand.

Many services report difficulties in engaging primary-care services in the treatment of drug users. Continuity between the criminal justice system and the healthcare system is seen as a clear problem, and resources have been invested in an attempt to improve the links between them.

Services for very young people are very sparse and there is a lack of clarity on the legal situation concerning managing young people under the age of 16 with methadone. It is currently being recommended that services for young people be developed in all localities.

Considerable interest exists in the issues of dual diagnosis (Johnson, 1997) and ethnic minorities (Khan, 1999).

Evaluation

A major study is being conducted as part of the Task Force to Evaluate Services for Drug Misusers. This study recruited over 1 000 patients, half of whom were in methadone treatment, and is following their progress over five years. The study is providing valuable information about the reduction in criminal offending associated with methadone treatment and has resulted in a positive response to the further development of methadone-treatment programmes.

Other, smaller-scale, studies have been conducted and there is currently a new national research initiative to develop further treatment evaluation studies. New studies commenced in early 2000.

Finally, two major independent bodies have recently published reviews of current drug policy (Police Foundation, 2000; Royal College of Psychiatrists, 2000). Both have called for increased funding for treatment and a better focus on the health needs of drug users, along with other recommendations for changes in drug policy. Also, both suggest that more resources be expended on research and evaluation.

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Contributors

BELGIUM

Juan Tecco

Isy Pelc

Service de psychiatrie et de psychologie médicale

Hôpital Brugmann

Place A. Van Gehuchten 4

B-1020 Brussels

Tel. (32-2) 477 27 24/477 27 05

Fax (32-2) 477 35 19/477 21 62

E-mail: Juan.tecco@chu.brugmann.be

DENMARK

Peter Ege

Municipality of Copenhagen

Socialoverlæge, Socialdirektoratet

7. Kontor

Bernstorffsgade 17, 2.

DK-1592 Copenhagen V

Tel. (45) 33 17 36 07

Fax (45) 33 17 37 31

E-mail: Peter.Ege@faf.kk.dk

GERMANY**Ralf Gerlach**

Institut zur Förderung qualitativer Drogenforschung,
akzeptierender Drogenarbeit
und rationaler Drogenpolitik (INDRO e. V.)
Bremer Platz 18–20
D-48155 Münster
Tel. (49-251) 601 23
Fax (49-251) 23 45 77
E-mail: ndro@muenster.net

GREECE**Athanasios Douzenis**

OKANA
19, Aristotelus Street
GR-104 33 Athens
Tel. (30-1) 825 37 63–9
Fax (30-1) 825 37 60
E-mail: Okatina2@otenet.gr

SPAIN**Marta Torrens**

Hospital del Mar
Instituto Municipal de Investigación Médica (IMIM)
Paseo Marítimo, 25–29
E-08003 Barcelona
Tel. (34) 932 21 10 09/10-4631/932 21 64 47
Fax (34) 932 21 05 41/932 21 32 37
E-mail: mtorrens@imim.es

FRANCE**Marc Auriacombe**

Laboratoire de psychiatrie
Université Victor Segalen, Bordeaux II
121, rue de la Bechade
F-33076 Bordeaux Cedex
Tel. (33) 556 56 35 86
Fax (33) 556 01 19 32/556 56 35 15
E-mail: marc.auriacombe@labopsy.u-bordeaux2.fr

IRELAND

Joe Barry

Eastern Health Board
Baggot Street Hospital
18 Upper Baggot Street
Dublin 4
Ireland
Tel. (353-1) 660 05 21
Fax (353-1) 660 63 52
E-mail: joebarry@tcd.ie

ITALY

Marina Davoli

Fabio Patruno

Antonella Camposeragna

Annette Verster

Osservatorio Epidemiologico Regione Lazio (OERL)
Via Santa Costanza, 53
I-00198 Rome
Tel. (39) 06 51 68 64 06
Fax (39) 06 51 68 64 63
E-mail: oss.epid.reg.lazio@agora.stm.it

LUXEMBOURG

Simone Dietz

Service de pédopsychiatrie
Centre hospitalier
4, rue Barblé
L-1210 Luxembourg
Tel. (352) 44 11 61 01
Fax (352) 44 13 29
E-mail: sec.pedopsy@chl.lu

THE NETHERLANDS**Han Kuipers****André van Gageldonk**

Trimbos-Instituut

PO Box 725

3500 AS Utrecht

Netherlands

Tel. (31-30) 297 11 00

Fax (31-30) 297 11 11

E-mail: agageldonk@trimbos.nl**AUSTRIA****Gabriele Fischer**

University of Vienna

Wiener Allgemeines Krankenhaus

Department of Psychiatry

Währinger Gürtel 18–20

A-1090 Vienna

Tel. (43-1) 404 00 35 43

Fax (43-1) 404 00 35 00

E-mail: Drogenambulanz@akh-wien.ac.at**PORTUGAL****Rodrigo Coutinho****José Godinho**

Serviço de Prevenção e Tratamento da Toxicdependência (SPTT)

Av. Columbano Bordalo Pinheiro, 87–4°

P-1070-062 Lisbon

Tel. (351) 213 12 93 80

Fax (351) 213 12 93 89

E-mail: sptt@esoterica.pt**FINLAND****Veikko Granström**

Hesperian Sairaala

Välskärinkatu 12

FIN-00260 Helsinki

Tel. (358-9) 47 16 37 12

Fax (358-9) 56 13 11 31

E-mail: veikko.granstrom@sll.fimnet.fi

SWEDEN

Marlene Stenbacka

Beroendecentrum Nord
Karolinska Sjukhuset
Hus M4, Plan 4
Magnus Huss
S-171 76 Stockholm
Tel. (46-8) 51 77 48 12
Fax (46-8) 51 77 66 15
E-mail: marlene.stenbacka@bekl.cso.sll.se

UNITED KINGDOM

Michael Farrell

Samantha Howes

National Addiction Centre
4 Windsor Walk
Denmark Hill
London SE5 8AF
United Kingdom
Tel. (44-20) 77 40 57 01
Fax (44-20) 77 40 5764/77 40 57 30
E-mail: spjemff@iop.kcl.ac.uk

Project coordinators

National Addiction Centre (NAC)

Department of Demand Reduction
4 Windsor Walk
Denmark Hill
London SE5 8AF
United Kingdom
Tel. (44-20) 77 40 57 01
Fax (44-20) 77 40 57 29

**Osservatorio Epidemiologico
Regione Lazio (OERL)**

Via Santa Costanza, 53

I-00198 Rome

Tel. (39) 06 51 68 64 83

Fax (39) 06 51 68 64 63

**European Monitoring Centre for Drugs
and Drug Addiction (EMCDDA)**

Margareta Nilson

Petra Paula Merino

Ulrik Solberg

Demand Reduction Department

Rua da Cruz de Santa Apolónia, 23–25

P-1149-045 Lisbon

Tel. (351) 218 11 30 00

Fax (351) 218 13 76 43

E-mail: Margareta.Nilson@emcdda.org

Petra.Paula.Merino@emcdda.org

Ulrik.Solberg@emcdda.org

PRACTICAL INFORMATION

European Monitoring Centre for Drugs and Drug Addiction
(EMCDDA)

Rua da Cruz de Santa Apolónia, 23–25
P-1149-045 Lisbon

Tel. (351) 218 11 30 00

Fax (351) 218 13 17 11

E-mail: info@emcdda.org

Website: <http://www.emcdda.org>

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