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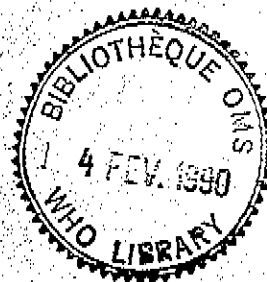
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# THE USES OF METHADONE IN THE TREATMENT AND MANAGEMENT OF OPIOID DEPENDENCE

Edited by Gossop, M.; Grant, M.; & Wodak, A.

from background papers prepared for  
WHO Meeting on the Use of Substitution Drugs  
in the Treatment of Opiate Dependence



WORLD HEALTH ORGANIZATION  
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## PART I

## ISSUES, PROBLEMS AND NATIONAL EXPERIENCES

1. Introduction and background

This review looks at the use of methadone in the treatment of opioid dependence in a number of countries. It was developed from background papers prepared by participants at a meeting held at WHO Geneva in December 1988, WHO Working Group on the Use of Substitution Drugs in the Treatment of Opiate Dependence. The list of participants at the meeting is attached as an annex. A report of the discussions held at the meeting has already been issued and is entitled "Options for the Use of Methadone in the Treatment of Drug Dependence".<sup>1</sup> The diversity of the experiences with opioid use in recent years is evident from the summaries of countries from different regions, and from its earlier history.

Methadone was first synthesized in Germany in the 1940s, during the second world war. The chemical formulation is d,l-4,4-diphenyl-6-dimethyl-amino-3-heptanone, with the one isomer being the active component. The name methadone was coined by the Council on Drugs of the American Medical Association in 1947. Early clinical trials demonstrated that methadone is a potent analgesic which possesses many of the pharmacological actions of morphine. In 1949 Isbell and Vogel<sup>2</sup> showed that it also has a marked dependence liability. The drug can produce analgesia, sedation, respiratory depression and euphoria. A single dose of five to ten milligrams of methadone gives analgesia which is comparable in intensity and time course to 10 to 15 mg of morphine. When taken orally in sufficient dosage, methadone has been used to suppress the opioid withdrawal syndrome for between 12 and 24 hours.

The concept of using legal opioid drugs in the treatment of drug dependence dates back at least one hundred years. In the 19th century, the king of Siam decreed that opium should be dispensed by the state to opium-dependent persons. At the turn of the century, the Spanish dispensed legal opioids to indigenous Chinese in the Philippines. This practice was discontinued by the United States of America, after it took control of the Philippines in the Spanish-American war. The practice was terminated not as the result of any considered analysis of the advantages and disadvantages, but because the legal provision of opioids became politically unacceptable. In the early 1920s, American use of morphine in maintenance clinics was terminated when American courts ruled that physicians could not use this drug to maintain opioid dependents. In the United Kingdom, the Rolleston Commission in 1924 ruled that physicians could dispense heroin and morphine in maintenance clinics to treat opioid dependence. This policy was changed in 1967 to limit its use to specially licenced practitioners, because poor prescribing procedures were felt to have led to an increased abuse of heroin and consequent increases in heroin dependence.

The short term medical prescription of methadone to opioid dependent patients was first used in the United States of America in the 1940s to assist patients in their withdrawal from illicit drug use. Although this methadone-assisted detoxification/treatment was effective in modifying or reducing the withdrawal symptoms in the short term, patients commonly encountered protracted withdrawal sickness and most relapsed to illicit drug use after the administration of methadone was stopped. In the early 1960s, Dole and Nyswander<sup>3</sup> began to prescribe methadone on a daily basis over much longer

1 World Health Organization (1989) Options for the use of methadone in the treatment of drug dependence. Geneva, WHO (unpublished document WHO/MNH/DAT/89.2).

2 Isbell, H. & Vogel, V.H. (1949) The addiction liability of methadone and its uses in the treatment of the morphine abstinence syndrome, Am. J. of Psych., 105, 909-914.

3 Dole V.P. & Nyswander, M. (1965) A medical treatment for diacetylmorphine (heroin) addiction. J. of Am. Med. Ass., 193, 146-150.

periods, in order to assist the addict to reduce illicit drug use and to achieve improved levels of psychosocial functioning. The results of these early studies involving methadone maintenance treatment were regarded as encouraging, and with a relaxation in the legal constraints on doctors to prescribe opioid drugs to drug dependent persons, similar programmes were started in other cities in the United States of America and Canada (1963), in Sweden (1966), and the Netherlands (1968).

Unfortunately, in these early methadone maintenance programmes insufficient attention was given to measures which would optimize the manner in which methadone was used in treatment, and prevent the diversion of methadone into illegal channels. Due to widespread over-prescribing and misuse of methadone by physicians, there were instances of diversion of methadone to the black market and its subsequent abuse. As a consequence of such problems, in the early 1970s many governments introduced restrictive amendments to their drug legislation governing methadone treatment for drug dependent persons. In Canada and the USA, these regulations provided guidelines for the use of methadone by physicians in the treatment and rehabilitation of drug dependent persons, and also included measures to prevent the misuse of methadone and its diversion from licit to illicit channels. Following the early use of methadone in the USA and Canada in the 1960s, methadone was introduced for the treatment of drug dependent persons in the United Kingdom (1968), Australia (1970), Hong Kong (1972), France (1973), Italy and Switzerland (1975).

## 2. National perspectives on opioid abuse

### 2.1 THAILAND

Current drug dependence problems in Thailand can be traced back to the smoking of opium that has existed in the country for several centuries. However, current problems have their roots in more recent events. After 1959, and in the wake of the enactment of the opium-ban law, heroin dependence evolved from the older pattern of opium dependence. Because of the new legislation, the opium dependent population was put under pressure to seek treatment. The first heroin epidemic probably lasted only 3-4 years but it was sufficient to attract attention from the government and the public. The opioid seizures by law enforcement authorities in 1961 included 8 cases of the illicit stimulant, amphetamine sulphate, indicating that a problem involving the abuse of amphetamines already existed. However, there was no indication of a heroin problem at that time. Around the end of the 1960s and the beginning of the 1970s, the use of ganja, opium, heroin and amphetamine rapidly increased and continued to rise during the 1970s. This second epidemic was so extensive and prolonged that drug-related social deterioration was seen as a real threat to the security of the public as well as the national (or government) administration. Drug dependence was declared the priority problem of the country. The Narcotics Control Board (NCB), chaired by the Prime Minister, was created in 1976 as the national coordinating committee responsible for national policy making and coordinating the implementation of all interventions. The Office of the Narcotics Control Board (ONCB) serves as the secretariat of the NCB, enabling for the first time the systematic and centralized compilation of information and statistics related to drug abuse and dependence and implementation of interventions.

Three decades after the declaration of the opium ban law on 9 December 1958, the pattern of drug use in Thailand increasingly involves multiple drugs, including analgesics, antihistamines, industrial solvents, and stimulants, as well as the well established drugs like ganja, opium and heroin. Opium and heroin dependence are still regarded as the most serious drug problems, with stimulants probably the next major concern. Consumption of stimulants by night workers, truck and taxi drivers and other labourers is thought to be quite common, although the true extent of use is not precisely known. The population of drug users is recognized to be diverse.

Similarly, the extent of opioid dependence in the general population is not known. Some data can be obtained from drug abusers in contact with treatment services, and from convicted drug offenders. Between 1985-1987 there were 53,000-57,000 annual drug-related

admissions to the treatment services in the whole country. For the convicted drug offender population, end of the year statistics from the Correction Department, Ministry of Interior, showed about 10,000 inmates annually. Problems of opioid dependence were found in all parts of the country, but there were definite regional differences in the distribution of opium and heroin dependence within the population. Opium dependence prevailed in the northern and upper parts of the north-eastern regions while heroin dependence was common in Bangkok, the central and the southern regions. A summary of trends in drug dependence in Thailand has been recently reported.

## 2.2 SPAIN

Estimates of the numbers of intravenous drug users in Spain vary between 60,000 and 100,000. The mean age of initiation of consumption is 19.8 years and the ratio of males to females is 4:1. The initial route of administration for 52% of subjects is inhalation, but most individuals subsequently go on to use the intravenous route. Ninety-five percent of IV-users share syringes and needles. Seventy-two percent of male and 50% of female IV-users have a non-injecting sexual partner, whereas 5% of men have sex with other men.

## 2.3 MEXICO

Home surveys have shown heroin abuse to be most prevalent in the metropolitan area of Mexico City (at a level of 0.1%), followed by two cities in the northern part of Mexico at the border with the United States, where levels of heroin consumption varied between 0.02 to 0.4%. Other opioids such as codeine or propoxyphene napsylate (Darvon) were also used illegally, particularly in the north-west and central regions, where the consumption ranged between 3 to 9%. These opioids were mainly used by young women aged 14 to 17, and this was considered a sign of the freedom with which these drugs are consumed with or without medical prescription. Interestingly, it was found that there is a province in the same central region (Michoaca) where heroin consumption did not occur at all. Nevertheless, we have to bear in mind that home surveys could underestimate the number of drug abusers, particularly users of heroin and morphine, because of the possible legal repercussions and social stigma.

Studies carried out among high school and university students have indicated that the use of opioids among students 14 to 19 years old in Mexico City increased from 0.9% in 1978 to 1.3% in 1980. In 1976, the use of heroin at a national level among students was reported as being 0.23%, while in 1986 it had gone up to 0.5%. The highest consumption in 1976 was found in the central region of the country, while in 1986 it occurred in the northern region. The consumption of other opioids also rose from 0.5% in 1976 to 0.7% in 1986.

Toxicological tests with drugs confiscated in 18 cities between 1975 and 1979 indicated that opioids (natural, synthetic, and semi-synthetic) were the second most frequently used drugs after cannabis. Between 1976 to 1980, tests carried out on 26,738 patients in hospitals and emergency rooms in Mexico City, showed that only 0.17% were opioid users. A study carried out from 1970 to 1976 in specialized centres for the integration of the youth in the whole country reported that heroin consumption occurred in 4% of the studied population, 97% of whom had used heroin for the first time when aged 18 to 20. Another study carried out in two communities south of Mexico City showed a heroin consumption rate of 3.7% in one community (a suburban area), and in another, with a large floating population and considered to be a high risk, the highest drug consumption was of opioids (10.3%).

## 2.4 NIGERIA

Since the 1980s, the abuse and trafficking of opioids has risen rapidly to reach epidemic proportions in Nigeria. In 1987, more Nigerians were arrested abroad for trafficking in drugs such as heroin and cocaine than all other African nationals. An increasing number of Nigerians are being arrested at Lagos International airport with increasing weights of drugs despite the existence of stiff penalties, and the drugs are now freely

sold in the streets of the main cities. The government has responded by passing severe anti-drug measures, but without legislating for the treatment of drug dependent persons.

In the current socio-economic circumstances, it has been suggested that the government should subsidize the cost of detoxification/treatment on an in-patient basis using clonidine, naltrexone and benzodiazepines to achieve a rapid detoxification. It is felt that opioids should not be prescribed by doctors on an out-patient basis in order to control unsanctioned opioid use.

## 2.5 PAKISTAN

Pakistan has seen dramatic changes in the nation's problem with heroin abuse during the last decade. In 1980 there was virtually no heroin problem in the country. However, the introduction of the technology for producing heroin from local opium crops led to a sudden and massive increase in the availability of heroin, and a consequent rise in the numbers of heroin abusers. By 1988 some national estimates were pointing to as many as 700,000 drug dependent persons in the country. The problem is almost exclusively a male phenomenon, with the majority of cases involving young men between the ages of 20-30. All areas of the country appear to be affected but the problem is especially prevalent in the major cities. Karachi is particularly badly affected. Pakistan currently has a large Afghan refugee population, but this group does not appear to be badly affected.

The predominant pattern of heroin abuse involves smoking, either by "chasing the dragon", which entails heating the heroin and inhaling the vapours, or by smoking the drug with tobacco in a cigarette. A relevant and important feature of the national problem is that Pakistan does not have a tradition of intravenous drug use and consequently, self-administration of heroin by injection is extremely uncommon in Pakistan today.

## 2.6 YUGOSLAVIA

Although drug abuse in Yugoslavia has not assumed alarming proportions, its incidence has certainly been registered in larger urban areas. According to data from the annual reports received from the republics and autonomous provinces, the total number of drug dependent persons receiving treatment varies from 2,000 to 4,000 (Table 1). This number, however, is unlikely to be accurate as the true extent of drug abuse is impossible to ascertain, either because records are incomplete or not available at all, or because parents and milieux will often conceal the existence of dependence, which is regarded as one of the worst vices. Some 10,000 or 12,000 persons in Yugoslavia are estimated to be using various types of narcotic drugs on either a regular or occasional basis.

TABLE 1

ANNUAL ESTIMATES OF NUMBERS OF OPIOID ABUSERS IN TREATMENT  
(Yugoslavia)

1980	1981	1982	1983	1984	1985	1986	1987
659	1030	1649	1489	2099	2615	3931	3832

The opium poppy has been grown in Yugoslavia for almost 200 years. Opium collection by incision in plant capsules had been practiced until 1973, when this method was prohibited by law and the industrial extraction of opium alkaloids from the harvested plants introduced. This industrial opium poppy processing method is of special importance, since the Macedonian opium was reputed to be of exceptional quality and in great demand on the illicit market.

As a traditional producer of opium alkaloids, and also in view of its geopolitical position, Yugoslavia is vitally interested in an organized effort on the part of the international community to control the production, trade and consumption of opioids, as well as in the undertaking of measures for reduction in demand, and reduction in production, trafficking and distribution of illicit drugs. Accordingly, Yugoslavia has been actively participating in all international activities almost from the very beginning of the establishment of the international narcotics control system.

At present, the problem of illicit opiate use is not particularly pronounced in Yugoslavia. Therefore, the basic thrust of action taken to combat illicit opioid use is primarily focused on all forms of prevention. It is the view of some drug experts in Yugoslavia that the factors underlying the occurrence and development of drug abuse are very diverse, and that no specific prevention measures exist. For this reason, it is believed that such efforts should encompass all activities which can contribute to the prevention of illicit opioid use. Organized social structures in the areas of education, information, social welfare, the judiciary, health care, the system of national defence, customs and law enforcement organs have a major role to play in this respect.

The measures and activities that have been undertaken, either within specific regions or cities, or as part of various social services, have been coordinated through the Federal Commission on Narcotic Drugs. However, these measures were not sufficiently uniform or synchronized, and often those in charge of the various programmes have worked from different basic principles and towards different objectives. Therefore, in 1983, the Assembly of the Socialist Federal Republic of Yugoslavia entrusted the Commission with the task of establishing common basic principles for combating drug abuse.

The document which was produced to that end was entitled, The Joint Programme Principles of the Struggle for the Prevention and Control of Drug Abuse. It lays emphasis on the prevention of drug abuse, i.e., on all measures involving preventive action by various social structures. The programmes which will be adopted within individual socio-political communities, regions or cities or as part of various social services should proceed from the basic premises contained in that document. The measures taken so far have resulted in certain improvements, both as regards the prevention of illicit traffic and production of opioids in the country, as well as in terms of stronger involvement of all concerned and the organs and organizations responsible within the various social bodies. It is generally acknowledged that education and upbringing constitute the most important link in the prevention of drug abuse.

### 3. Methadone and its uses

The use of methadone has been proposed as a form of substitution therapy and generally only been considered in countries with significant levels of intravenous heroin use. A clear distinction must be made between the uses of methadone as

- (i) a detoxification agent, and
- (ii) a maintenance drug.

In both cases methadone is used as a substitution drug, most often for heroin, but the two types of use differ so greatly in terms of their practice and in terms of their wider implications that they must be clearly and explicitly separated. (This distinction is illustrated and discussed in greater detail in Part II, National Case Studies, USA.)

In some countries such as India and Pakistan, methadone is not available for any medical purposes. Some countries such as the Federal Republic of Germany, Austria and Norway prohibit or limit the use of methadone as treatment for drug dependent persons. In France, it has been an unpopular and little used treatment option. Some countries such as USA, Australia and Canada permit its use with certain governmental control and regulation. Still other countries such as the Netherlands allow methadone to be used more freely with relatively few guidelines or restrictions. In certain countries such as Myanmar, opium is

sometimes used rather than methadone. In addition, many countries permit the use of methadone for the short-term detoxification of drug dependent persons but not for maintenance treatment.

In some countries, where methadone is not made available for the treatment of opiate dependence, alternative detoxification methods are used. In Pakistan, for instance, the detoxification of heroin dependent persons is often carried out using "symptomatic treatment", which is a general approach involving the use of a variety of different drugs to treat the most severe withdrawal symptoms separately, or alternatively by prescribing clonidine. Opium tablets and other preparations containing opium have also been used as substitution drugs during detoxification. Opium itself has been used both with and without symptomatic treatment to control withdrawal symptoms in heroin dependent persons.

The wide variety of international approaches and diverse range of conditions is also well-illustrated by the experience in Pakistan, where there is an official ban on the use of opium except for tablets manufactured by the Punjab Excise Department. These tablets are supposed to contain 250 mg. of opium, however, their strength has been found to be variable as determined by laboratory analysis of random samples. Another problem that has arisen with regard to the use of opium tablets has concerned the unreliability of supply. On those occasions when a legal supply of opium has not been available, it has sometimes been necessary to resort to illicit supplies of opium, increasing the problem of variable purity as well as introducing further risks associated with the possibilities of harmful and unhygienic constituents. Doubts have also been raised about the dangers of creating an increased risk of opium abuse as a result of socially sanctioning its use in treatment centres. A recent national clinical trial was commissioned by the Government of Pakistan in conjunction with UNFDAC to investigate the effectiveness of various detoxification methods.

There are fewer than 30 government-run detoxification centres in Pakistan. Treatment centres run by NGOs and by the private sector are a relatively new development. With a few exceptions, most of the centres are inadequately supplied with personnel and equipment. Data is collected from most centres and monitored by a central office of the Pakistan Narcotics Control Board.

#### 4. Policy and practice of methadone use

The availability of methadone for use varies considerably from country to country. The practice and the pattern of methadone use in each country is related to several factors. These include:

- (i) the size of the opioid abusing population;
- (ii) the extent of social and legal problems associated with the abuse of opioid drugs;
- (iii) the level of knowledge among professionals and policy makers about drug problems and appropriate responses;
- (iv) prevailing professional and public attitudes concerning the management and treatment of drug dependent persons;
- (v) the attitudes toward ethical and moral aspects of prescribing an opioid drug such as methadone to drug dependent persons; and
- (vi) the political and economic aspects of drug dependence problems.

It is not surprising, therefore, that the manner and the extent to which methadone is used varies considerably. At the most general level, countries need to decide:

- (a) whether methadone should be used at all in the treatment of opioid dependent persons; and
- (b) whether methadone should be used in the long-term treatment and management of opioid dependent persons.

The coordination of methadone treatment involves many factors besides the administration of methadone to patients. These include its relationship to other forms of treatment, policies and procedures, the types of facilities required for delivering the treatment (e.g. inpatient or outpatient facilities), support services, urine testing facilities, and the number and types of treatment staff required. Qualifications for treatment staff can differ greatly from programme to programme, and the special training of staff has been of particular concern in some countries, especially where inadequate training has been associated with problems associated with methadone. An additional issue concerns whether the treatment should be voluntary or should involve coercion. In some countries, all patients undergoing treatment for opioid dependence are registered with the central authorities, a practice which raises questions of patients' confidentiality. Another sensitive area involves policies concerning the assessment of new patients applying for treatment. In addition to the two general questions raised above, there are many other specific questions that arise with regard to clinical practice:

- (c) If methadone is to be prescribed, how should the process of selection separate the most appropriate person for methadone from others best suited for drug-free treatments?
- (d) What are the comparative advantages of long-term methadone detoxification and short-term methadone maintenance?
- (e) How should the most appropriate drug dependent person be selected for detoxification or methadone maintenance?
- (f) How can treatment approaches be optimally matched for different patients?
- (g) Can different treatment approaches be used with different patients at the same time within one treatment setting?
- (h) How should the optimal duration of treatment be decided for a specific patient?
- (i) How should a combination of different treatments be established for each patient?

#### 5. Methadone maintenance in relation to HIV and AIDS

Methadone maintenance was a contentious treatment modality in some countries at the time when the epidemic of HIV infection began to spread among injecting drug users. The Swiss experience with methadone provides some interesting perspectives. Switzerland was one of the first European countries to be affected by HIV infection, and the rate of increase of AIDS cases has been the steepest of all European countries. In the second half of 1987, the incidence rate was 20 cases of AIDS per million population. As in other European countries, injecting drug users have been one of the major risk groups and have shown the highest rates of increase, probably due to a lesser potential for self-help and hygiene improvement when compared to homosexual/bisexual males. The total number of AIDS cases in Switzerland by the end of September 1988 was 605, with one quarter being intravenous drug users. The rate of increase among this group was 350% within 12 months.

A number of controversial issues have been tackled and have led to changes and development of policies regarding HIV transmission among drug injectors. Previously, the availability of syringes and needles in Switzerland was restricted; in some Cantons

doctors were even prosecuted for furnishing syringes to intravenous drug users. Since 1987, this policy has been completely changed. Free syringes and needles are available in outpatient and youth advisory centres. They are also available at low prices in pharmacies. Some institutions prefer one-to-one exchange rather than distribution of syringes, because of the high number of used syringes discarded in public places.

Survival help, including shelter for homeless drug users and specialized medical assistance, has become a major component of streetwork. In some major cities there is still a public debate on whether this type of survival help should be provided in the midst of the drug scene, as it is argued that this may make the drug scene all the more attractive. An alternative option is decentralization of assistance with outreach work extending into the drug scene.

In Switzerland, methadone maintenance has been available in the majority of Swiss Cantons since 1978. A specific policy paper on methadone treatment was published by a national expert group in 1984. At that time, methadone maintenance was considered to be a second priority treatment approach reserved for those drug users who, for whatever reason, could not benefit from drug-free, abstinence-oriented treatment. Accordingly, the indications for methadone maintenance were restrictive and specialist approval was required.

This policy was first changed in the Canton of Zurich 1987. Methadone maintenance is, according to new regulations, available for intravenous drug users who have been properly assessed with regard to their opioid dependence, health status, medical history and capacity for complying with the treatment programme. The responsibility for notification and treatment lies with a physician, who is obliged to report all treatments to the Cantonal Health Authority. Those reports are periodically evaluated. This change resulted from parliamentary initiatives which sought to make methadone maintenance available, especially for drug users who were HIV-positive or had AIDS; subsequently, it was argued that drug users should be able to prevent themselves becoming infected.

The regulations for treatment itself have not been changed. Physicians are obliged to control methadone intake which is administered in non-injectable solutions, to care for all medical and psychosocial problems of their methadone patients (eventually in collaboration with specialized agencies) and to control concomitant drug use by regular urine analysis. These regulations are upheld with the intention of preventing poly-drug use among methadone patients, which would not only endanger them, but also reduce the effectiveness of HIV prevention by methadone maintenance.

Outpatient advisory and treatment centres as well as residential, long-term, abstinence-oriented treatment programmes have been adapted to the changing needs of clients. Increased medical help, availability of sterile syringes and condoms, professional advice on how to protect oneself, HIV-testing and discussion of test results are new elements which have been integrated into the therapeutic programme. Reinforcing information and continuing instruction of colleagues is a priority, considering the high prevalence of seropositivity among the clientele (up to 90%). In prison, new approaches are being discussed, including the introduction of methadone maintenance. Distribution of sterile syringes to incarcerated drug users has been rejected by authorities.

A quite different situation exists in France, where methadone prescribing has traditionally been unpopular and little used. It is, however, accepted that the problem of HIV infection among drug abusers requires that the national approach be reconsidered. Hitherto, the question of substitution therapy or methadone prescribing was not posed in the same terms. The question must be considered from two sometimes contradictory angles: the treatment of individual IV drug users, and public health. From the standpoint of public health it is clear that the progression of the epidemic must be prevented. But it is not enough simply to say this, or even to provide the means - bleach, disinfectant, sterile syringes or condoms - to prevent contact with the virus; it is necessary to ensure that these materials are used. Difficulties have been encountered in efforts to increase the utilization of condoms, and with efforts to achieve changes in sexual behaviour of citizens who may be described as "responsible". This may be because the modes of infection involve intimate behaviours and attitudes to enjoyment. Attempts at prevention have

generally proved to be futile unless accepted by the persons concerned. The risk that the most marginal and exposed groups of the population would go underground if measures of segregation were introduced has often been raised. There are unresolved questions regarding the enlargement of programmes arising not from the needs of drug dependent persons but from those of AIDS patients. If patients believe that programmes exist primarily to interrupt virus transmission rather than to assist individuals, they may avoid treatment centres, feeling that these are inappropriate or unsympathetic to their needs and demands. In France, practitioners have always preferred an approach stressing the individual rather than the symptom. This applies not only to drug dependence, but is true for the whole approach to public psychiatry, which has undergone major changes in the post-war years.

#### 6. Assessment procedures and admission criteria

In most countries where methadone maintenance programmes have been established, there is generally broad agreement about the importance of establishing policies, regulations for the programmes, and criteria for admission to methadone treatment. There are considerable differences in programmes from one country to another, and sometimes from one unit to another within the same country.

In the United States, the original Dole-Nyswander programme in New York in the early 1960s selected only candidates with a history of at least four years heroin dependence, a minimum age of 21, absence of alcohol or other drug problems, and an history of repeated failure in other treatment modalities. Treatment began with six weeks of hospitalization. The original programme was followed by rapid expansion of methadone programmes, which brought several modifications in the programme's criteria: the minimum age was reduced; the required duration of heroin use was reduced; drug experimenters were accepted; and immediate outpatient treatment was soon adopted.

In 1974, the Narcotic Addict Treatment Act became operative in the USA. The revised criteria for admission may be summarized as follows:

- (i) current physical dependence on heroin;
- (ii) a history of heroin dependence for at least one year before admission;
- (iii) all drug dependent persons under 18 years of age must have evidence of two previous detoxifications or other residential treatments; and
- (iv) no admission before the age of 16 without special permit.

These regulations are still valid, and in some States the regulations are more restrictive.

In Canada, the Narcotic Control Act became operative in 1961 and was revised in 1971. The latter provides more restrictive regulations concerning methadone maintenance. It implemented a diagnostic procedure, including a series of daily urine tests before admission, as well as daily consultations during the first phase. It also included strict regulations relating to treatment procedure. As a consequence, there was a considerable drop in the total number of methadone patients. The reasons for the new regulations were to prevent the diversion of methadone to the street, to prevent primary methadone dependence and to give priority to drug-free treatment programmes.

Australia introduced national guidelines in 1981 which included a minimum age of 18. In New South Wales, which has always been considered to have a majority of the opioid dependent cases in Australia, the regulations prior to revision in 1985 required physical dependence upon opioids, age greater than 18 years and a documented history of opioid use for longer than 2 years. Exclusion criteria including poly-drug abuse and presence of psychiatric conditions were partially relaxed after 1985.

In Europe, the first methadone treatment programme was set up in 1966 in Uppsala, Sweden, which adopted the original criteria of Dole-Nyswander (from New York during the 1960s). From the early part of this century in the United Kingdom, the prescription of opiates including heroin, was at the discretion of any physician. In 1965 the Brain committee restricted the prescription of heroin to specialized clinics, but no formal criteria for admission to the clinics were specified. In Italy the minimum age for admission to a methadone treatment programme is specified (e.g. 16 years), no history of prior treatment is required, and in many instances methadone maintenance is the treatment of first choice. Minimal criteria are also applied in certain parts of Holland, whereas in Denmark methadone maintenance programmes are reserved only for the most chronic heroin users. These different criteria and regulations can create problems when addicted persons from one country seek methadone treatment in an adjacent country (e.g. maintained patients may not be able to carry methadone across national borders or may not be able to find any clinic which can provide methadone).

Various screening procedures at admission have been developed. The standard requirements are for a medical and psychiatric examination, and for a history of substance abuse and previous treatments. A few programmes require the patient to be hospitalized for initial screening and for determining the appropriate dosage of methadone, (San Antonio, USA and Uppsala, Sweden). In several countries, a number of programmes test for physical dependence by administration of Naloxone to precipitate withdrawal. In other assessments, the patient's dependence upon opiates is tested through a series of urine tests in conjunction with the Naloxone test (e.g. Addiction Research Foundation, Toronto, Canada).

#### Policy Fluctuations Regarding Methadone: Spain as an Example

The Spanish experience with methadone is of interest as an example of a country which introduced methadone with few restrictions but subsequently found it necessary to progressively increase regulations to reduce deleterious consequences. The use of methadone in the treatment of intravenous heroin dependent persons has been controversial in Spain. A good deal of debate has occurred involving treatment professionals, associations of relatives of drug abusers, and institutions and agencies with direct and indirect involvement in the problem.

The manner in which methadone has been used in clinical practice has tended to fluctuate, often with rapid changes, and there is no direct relationship between the location of methadone programmes and areas with high levels of drug problems. This suggests that the use of methadone in Spain has been strongly influenced by factors unrelated to the pharmacology of methadone or its therapeutic efficacy.

Between the early 1970s and 1983, profound political changes occurred in Spain. The State Administration was reformed, leading to the restructuring of the different Administrations, and the creation of new ones. Against such a background of socio-political change, it became clear that certain groups of young people were beginning to use and become dependent upon certain drugs, and, because of its severe consequences, problems associated with the abuse of heroin were particularly noted. Previously, the phenomenon of widespread illicit drug use had been almost unknown in Spain. Several Administrations were unable to respond effectively to the new situation in terms of solving or at least diminishing the harmful consequences of drug use. As a result, other institutions and organizations attempted to deal with these problems.

At the same time, some Administrations, mostly local ones in the first instance, created specific services and resources designed to meet the new social situation. However, because there was no existing infrastructure to support the establishment and development of such responses, not enough attention was paid to the regulation of the centres and to the evaluation of the efficacy of the different systems. The provision of methadone was recorded on a document overseen by the medical colleges. This system was then widely used within numerous programmes of maintenance on methadone and extended to private care systems. Some maintenance programmes consisted of no more than the pre-

scription of a substitute drug without any kind of adjunctive therapy or psychological support (tilidine was also used as a substitute drug for a time).

The development of methadone treatment services was haphazard. In some cities it became so widely accepted that it represented the primary method of treatment, and was chosen by drug dependent persons in preference to drug-free programmes. At the same time, methadone began to be diverted from treatment programmes and from legitimate therapeutic uses with the development of a black market in methadone. Money obtained from the sale of methadone was often used to acquire heroin.

In 1983, the Ministerio de Sanidad y Consumo passed a regulation on prescription, use and consumption of methadone in the treatment of opioid dependent persons. This was the first time a Ministerial Order had dealt with such issues. The Ministerial Order referred to the necessity of designating an individualized treatment schedule and made such treatment services dependent upon the approval of the relevant Public Health Services. The true aim of the Ministerial Order was to incorporate the use of methadone within a wider therapeutic approach to the problem, in which methadone was not considered a therapeutic modality per se, but a practical weapon.

In an attempt to prevent the diversion of methadone to the illicit market, the Ministerial Order made recommendations regarding the form in which methadone was to be administered and the time schedule for prescribing the drug. The extent to which this regulation was acted upon varied greatly. Thus, whereas in some cities it had the effect of decreasing the number of patients in treatment services and introducing elements of control and strictness, in other cities it had little impact and the problems surrounding the abuse of methadone remained unchanged.

In 1983 there were few other resources for treatment of injecting drug users, and the existing ones required those patients who were anxious to receive some help to wait for a long time. Within this context, the administration of methadone continued to be the only feasible treatment option.

On October 31, 1985, as a result of further developments in the situation and the experience accumulated after 1983, the Administration was prompted to pass a new Ministerial Order addressing the problem of current demands as well as dealing with some of the service issues related to clinical practice. A new Ministerial Order (1985) attempted to define more precisely the various factors to be taken into account in order to implement an effective methadone programme. When this second Ministerial Order was promulgated, the "Plan Nacional sobre Drogas" had already been approved by the Government. With respect to the care of IV-drug abusers, this "Plan Nacional sobre Drogas" contained a series of guidelines which were directed to the provision of public care services to the whole drug addict population. Within such a legal framework, it was thought advisable to review the systems of prescription and dispensing of methadone so that the maintenance programmes would come to occupy an appropriate place among the broader range of public care options.

The main innovation introduced by the Ministerial Order concerned the definition and regulation of programmes. The order established that a Parity Commission Central Administration-Autonomous Administration must be created in each Autonomous Community to supervise the observance of the requirements of the resolution regarding the custody and disposition of methadone. Currently, Parity Commissions have already been established in all the Autonomous Communities and have proved to be useful instruments for regulating conflicts which previously existed in each Community.

The Ministerial Order also clearly stated that the consumption of methadone must take place at the treatment centre (at least during the first 3 months of treatment). This measure was expected to achieve two results: first to ensure that methadone was not diverted to the black market, and second to ensure that the dose prescribed by the therapist was properly administered. In addition, an annex was included that provided a detailed statement of individual therapeutic schedules. These guidelines included assessment prior to admission covering:

- (a) Physical and psychological condition as well as family, job, and social situation;
- (b) detailed history of drug use and dependence.

Monitoring during treatment included a therapeutic schedule with duration, dose schedule, psychological and social care, and laboratory analyses.

The Ministerial Order also specified the characteristics of the patients who were to be considered for admission to these treatments: age of at least 18 years; opioid dependence of at least 3 years duration; and previous attempts in at least two drug-free treatments. Exclusion criterion were: presence of severe psychiatric disorders; poly-drug use dependence; and severe organic complications.

Some of the Parity Commissions have established studies and strict follow-up procedures for patients on methadone maintenance programmes. Such treatment centres may be created only in those cities in which there are a large number of opiate abusers. Patients who have been considered to be suitable candidates for methadone treatment in a public centre require approval of their protocol by the corresponding Parity Commission, and must appear in person at the dispensing centre each day, when methadone will be administered and must be ingested on the premises. Where relevant, a urine specimen will be collected for objective evidence to confirm that there is no current illicit drug consumption. This measure is regarded as temporary, but currently such services are still needed in order to progress toward the normalization of a treatment that is outside traditional views of therapeutic practice.

The negative experiences of Spain are not unique. On the basis of previous trials with methadone, several countries have adopted a negative attitude (e.g. Federal Republic of Germany, Austria and Norway), or at least a discouraging attitude (e.g. Denmark, France and Ireland). In other countries, for example Spain and Italy, attitudes were initially liberal or permissive but were modified after negative experiences, and stricter regulations were adopted. Others have adopted relatively liberal policies from the beginning, but with certain regulations regarding the manner in which the drug should be prescribed. Some countries have tried to find a pragmatic compromise by accepting methadone maintenance but with relatively restrictive regulations (e.g. Sweden).

Differences in attitude are partly based on experience, especially experience with negative consequences. However, many negative attitudes reflect value orientations and the ideology of leading professionals and/or politicians.

## 7. Substitution drugs and goals of treatment

The pre-eminent goal for the treatment of people who are dependent upon opioids is generally regarded as the achievement of a state of enduring abstinence from drugs. However, it is increasingly recognized that other goals may also be applicable to the treatment of people with drug problems. Examples of other goals would include the reduction of social or physical harm associated with drug abuse. However in the early 1980s there has been growing support for the notion that the achievement of a reduction in harm without necessarily achieving abstinence was all that could be accomplished with many individuals and at particular stages in the lives of some injecting drug users, and that these achievements were preferable to the alternative of continued uncontrolled illicit drug use. The advent of an epidemic of HIV infection in the 1980s has also resulted in renewed interest in public health objectives for methadone programmes, with the achievement of abstinence considered a more long-term goal.

The attempt to attract or enlist drug dependent persons into treatment through the offer of prescribed methadone has often been seen as a lower-level and less attractive goal to abstinence, even when the intent has been to establish an initial stabilization of users' life-styles by reducing intoxication, withdrawal symptoms and drug-seeking beha-

viour. Proposals to accept goals which fall short of complete abstinence have proved controversial in a number of countries. The specific applications of methadone in treatment may include the use of methadone for short-term detoxification which takes place within one month or long-term detoxification which may take up to six months, as well as short-term (from six to twelve months) or long-term (more than twelve months) maintenance prescribing of stable doses of methadone. The definition of "short-term" and "long-term" is, inevitably a somewhat arbitrary affair, and any such definitions are open to dispute. The terms are used here as previously suggested by Arif and Westermeyer (1988).<sup>4</sup>

In most Western countries, the most frequently applied method of treatment for illicit opiate users has been substitution therapy, the aim of which was to replace the narcotic drug by a drug having similar effects, during the first stage, and afterwards to gradually decrease the dose, applying a variety of psychological and supportive methods of treatment, until the ultimate achievement of abstinence.

The experience of Yugoslavia is an example of some of the negative experiences that may arise with the use of methadone as a substitute drug. Within a few years of introducing methadone, one type of drug problem appeared to have been replaced by another. Methadone doses were not being reduced. The accompanying measures were not yielding satisfactory results, and the consumption of methadone increased enormously. Methadone appeared in the illicit market, diverted from prescriptions, and at a price 100 times higher than the purchasing price. This problem was discussed by psychiatrists and other experts dealing with the problem of narcotic drugs at the federal level. It was concluded that methadone should not be available for the treatment of drug dependents persons, and that methadone should be administered only in cases of crisis, when the life of the drug dependent person is in jeopardy.

Basic guidelines for the medical treatment of drug dependent persons were prepared. These were, that:

- the objective of treatment and rehabilitation of drug dependent persons should be the establishment of abstinence and elimination of somatic, neuropsychiatric and acute social consequences;
- treatment should be carried out by a multi-disciplinary team (e.g. psychiatrist, psychologist, social worker, nurse);
- as a rule, outpatient treatment should be preferred;
- health care for drug dependent persons should start within primary health care, with treatment and rehabilitation carried out at all levels of health care and in specialized settings;
- drug dependent persons in conditions of physical or medical crisis should be treated in intensive care departments.

## 8. National views of service development

The following summaries indicate the variety of approaches adopted in response to a diverse range of local conditions.

### 8.1 THAILAND

Drug dependence treatment services in Thailand fall into two categories - services for volunteer cases and those for convicted drug offenders. The total number of treatment

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<sup>4</sup> Arif, A. & Westermeyer, J. (eds) (1990) The Role of Methadone in the Management of Opioid Dependence. New York, APA Press (in preparation).

service units reported to the national information system in 1983, 1984 and 1985 were 80, 90 and 92 respectively.

The agency responsible for the administration of the drug dependence treatment in Thailand is the Department of Medical Services in the Ministry of Public Health. Until November 1988 there were 142 treatment service units, with 44 units located in Bangkok. The central, northern, north-eastern and the southern regions had 33, 28, 11 and 26 units respectively. A licence was needed for service delivery as required by the Treatment Service Regulation 1. The treatment services also required that all client admissions be reported, using a standard form, to the Technical Division of the Department of Medical Services. Since the majority of clients were opioid dependent, treatment services were generally designed for this group. Short term methadone detoxification with or without counselling, after care and follow-up, was provided through either in- or out-patient services in most official and private treatment units. There were 3 Buddhist temples in the provincial areas providing traditional forms of intervention, using religious vows, herbal medicine and steam baths.

## 8.2 SWITZERLAND

A national policy paper, prepared by an expert group at the request of the government, was published in March 1983. It defined the scope, aims and measures to be taken in the fields of prevention, treatment and repression. This "Drogenbericht" served as a guideline for all concerned authorities, governmental and non-governmental organizations and for the parliament. The "Drogenbericht" covered epidemiology, legislation, preventive and therapeutic approaches as well as the practice of law enforcement. All types of substance dependence, including illegal drugs, alcohol, prescription drugs and tobacco, were included. This policy paper aimed at a coordinated approach to drug related problems, at the national level as well as on the level of Cantons which are responsible for health matters. A guideline for coordinated activity became necessary as, since the early 1970s, a significant number of preventive activities, treatment institutions and agencies, rehabilitation centres and Cantonal regulations have been developed in response to persistent drug abuse and its correlates and consequences (alcoholism and misuse of prescription drugs in all age groups, illegal drug use among adolescents and young adults).

## 8.3 FRANCE

In France, care for drug dependent persons is provided by a very diverse network of facilities. These are small units belonging to the public system or to voluntary associations and connected with the Ministry of Health (or the Ministry of Justice in the case of drug dependent persons serving prison sentences). Approaches to management tend to be eclectic and include medical, psychological, educational and social components. There are also emergency reception centres, treatment centres offering consultations and admission to hospital, and short or medium stay post-treatment homes (i.e., for periods of not more than six months).

Despite many differences in theoretical approaches, the importance of a psychological approach is emphasized. There are wide differences in the overall range of facilities available in France. These respond to different individual needs or different stages in the evolution of these individuals, but there is consensus on the general approach, which is that all the work is carried out on a case by case basis. In France, the concept of a "programme" of care does not exist, perhaps explaining why methadone treatment programmes are so limited, and how methadone has been used to date in the two national centres concerned.

## 9. Control of methadone

After the ratification of the Single Convention of 1961, many countries revised their legislation regarding opioids. Often more than one revision has occurred. During the late 1960s and early 1970s, many countries introduced legislative measures to control the

prescription of opioids, including methadone to opioid dependent patients. Usually these regulations required:

- (i) the authorization of certain programmes or professionals to prescribe opioid drugs to drug dependent persons; and/or
- (ii) a central registration or notification system of drug dependent individuals prescribed opioids (e.g. Britain, Hong Kong, New York).

An analysis of the sequence of legislative changes in some countries suggests pendular movement of policy, in which there was a swing back and forth between repressive measures and "medical" priorities. Restrictions often follow the identification or perception of unintended consequences associated with earlier liberal methadone prescribing policies. On the other hand, the awareness of large numbers of opioid dependent persons outside the treatment system has often led to calls for easier access to methadone maintenance programmes and a desire to attract larger proportions of the addicted population into treatment. Changes in the characteristics of opioid abusers and the size of the addicted population have also been reflected in the frequent changes in regulations of many countries.

No country has introduced legislation which requires compulsory admission to maintenance programmes. At present, all countries which provide methadone maintenance programmes do so on a voluntary basis. However, the criminal or narcotic laws in many countries have provision to suspend a sentence in favour of sending drug dependent persons to a treatment programme. In case the treatment is not followed, or otherwise fails, the sentence has to be enforced. Methadone maintenance programmes are one of the treatment modalities regarded as an acceptable alternative to imprisonment, though this is only implemented if the drug dependent person accepts the treatment option. The person is still permitted to choose the option of imprisonment (as in Holland, Italy, and Switzerland).

#### 9.1 Authorization of agencies or individual doctors to provide treatment

In most countries, initially all medical practitioners were permitted to prescribe opioids for the treatment of drug dependent persons. This situation changed with the growth in the numbers of illicit heroin users. In some countries such as Canada, Denmark, Ireland and United Kingdom, every medical practitioner is still entitled to prescribe opioids according to their discretion. In Switzerland and Australia, a physician who wants to prescribe opioids to treat opioid dependent persons needs a special authorization.

In the Federal Republic of Germany a few pilot methadone maintenance programmes were originally authorized, and several methadone programmes are still running, especially in the North of the country. It is, however, a controversial practice and most Southern German States remain opposed to methadone maintenance programmes. The situation in Austria is similar to Germany.

Many countries prefer specialized clinics and agencies to operate maintenance programmes. In countries such as Italy, Hong Kong, Thailand and the United States of America, only specialized clinics are authorized to run maintenance programmes. It has been suggested that the practice of individual doctors is more susceptible to pressure from the addict and from others. Also, individual doctors cannot offer the whole range of psycho-social services that are often needed. In Switzerland, the evaluation of various methadone programmes suggested that the clinics and agencies which run programmes are able to provide better psycho-social care. In the light of past experience, methadone maintenance programmes are preferably administered by a team of multi-disciplinary professionals who are prepared to cover all aspects relevant to stabilization and life-style change.

## 9.2 Registration of patients and confidentiality

In order to avoid problems of patients enrolling in more than one maintenance programme at the same time, central registration (municipal, provincial or national) has been stipulated by law in various countries. Myanmar, Hong Kong, Malaysia and United Kingdom have central national notification or registration systems, whereas most other countries register their methadone patients on a lower administrative level. These registers are usually kept confidential and information is not made available to other agencies. In the treatment programme, therapists are concerned with the social behaviour and life-style of patients. This necessarily involves wider contact with people and agencies outside the clinic, e.g. relatives, employers and other key persons such as probation officers. When the patient opposes or is unhappy about such contact, the therapist is in a difficult position. This issue is not usually dealt with at a national policy level. Nevertheless, each programme has to set up policies regarding confidentiality which are in accordance with local legislation and professional practice. It is advisable to discuss these rules with patients at the time of admission.

## 9.3 Duration and termination of treatment

In many countries where methadone maintenance is an accepted form of treatment for an opioid dependent person, the treatment is available for an unlimited period of time. No country has informed WHO of any national legislation which imposes limits upon the duration of methadone maintenance. At the programme level, however, some individual programmes provide a time-limited and change-orientated model rather than indefinite maintenance models.

There are many reasons why treatment may be prematurely terminated. These include unwillingness to accept the administration of medication under controlled conditions, obligation to report current activities and to provide urine specimens, inability to cope with the challenge of recovery from drug dependence, and unwillingness to give up former contacts or change daily habits. In very rare cases side effects of methadone lead to premature termination of treatment. In addition, most programmes have rules of conduct, the breach of which may lead to the patient being discharged from treatment. These generally relate to violence on the premises, threat of violence, selling drugs, missing appointments or consultations, or being uncooperative with urine tests.

## 9.4 Methadone and driving

It is still unresolved whether patients who are "stabilized" on methadone have impaired skills and capacity for driving. In some countries, methadone maintenance patients are initially prohibited from driving, on the grounds that they are under the influence of sedative or addictive substance. In later months or years, arrangements may be made to enable patients to drive when they are stabilized medically and socially, and when no relapses have been detected for a specified period of time. This important problem has received insufficient attention and remains neglected and unresolved.

## 9.5 Referral of patients between programmes

Some patients receiving methadone are migratory and socially unstable. They may change residence, move to new jobs, to new partners or new friends, or move to try a new start elsewhere. Such changes may entail a referral to another maintenance programme.

Special problems exist where maintenance policies and regulations are not unified throughout the country, and where major differences exist from programme to programme or from province to province. Australia and the United States have made efforts towards developing a national policy. In other countries, voluntary agreements have been initiated on a national level, e.g. in the Netherlands and Switzerland. In many other countries, there is considerable lack of consistency in maintenance policies and regulations.

Problems with referral from one country to another are also reported (e.g. from the United Kingdom to the Netherlands). France exemplifies a country that has been relatively strict in controlling the ways in which methadone may or may not be used. The steady rise in heroin dependence in France during the early 1970s was met by a widely varied range of responses, and led the French public authorities to propose the use of methadone. In 1973, after a Ministerial decree had authorized the use of this substance, four units which already had several years experience with heroin dependent persons were approached about the experimental introduction of programmes (3 in Paris and one in Marseilles). Two of these units refused, as this technique was difficult to combine with their usual methods of management or because it posed ethical problems. Only two units in Paris agreed to undertake this experiment, and methadone is now one of the forms of treatment which may be offered to heroin dependent persons who present there for consultation. This experiment was conducted under the auspices of INSERM, and in 1973 a commission of INSERM specified the mode of administration and the control tests that were to be carried out. Mindful of the American experience, the commission established very strict regulations in order to avoid problems with intoxication, accidents or trafficking.

#### 9.6 Practical conditions in which methadone is now used in France

Both French programmes are limited to 20 persons who must take their methadone in the unit, except on Sundays. The rules may, however, be waived if there are compelling reasons, in particular of a professional nature. These exceptions are not a right and are discussed on a case by case basis with the patient. Methadone is administered in the form of a highly sweetened drinkable syrup to avoid, as far as is possible, the misappropriation of the drug. Methadone can thus be consumed under some degree of surveillance. It is not available on the black market and is produced solely by the central hospital pharmacy. Urine tests for opioids are carried out several times a week. The detection of synthetic opioids which can be prescribed poses difficulties. A large number of legally authorized products containing codeine and codethyline, especially antitussives, can also be legitimately purchased through pharmacies, though these can be distinguished from morphine-based drugs by urine screening. Also, it may sometimes take time to obtain the results of urine analyses.

Since 1977, the use of methadone for the treatment of withdrawal in hospital has been abandoned in favour of treatment with pentazocine, and more recently with drugs of the clonidine type. Methadone may, however, be used when serious somatic conditions occur in the course of treatment. In some cases, orally administered pentazocine has been preferred, not for pharmacological reasons, but because of the symbolic implications of the word "methadone", which tends to signal drug dependence. Also since 1977, short-term outpatient treatment has been abandoned, either because it was regarded as ineffective or because it was impossible to carry out. Treatment is prescribed for several months, and possibly even for several years. The cut-off date is not always specified when treatment is initiated, but it is nevertheless clear that there is no maintenance in the strict sense of this term and that treatment will sooner or later be stopped.

A report prepared for World Health Organization jointly by the Sainte-Anne and Fernand Widal Centres describes the position of these two prescribing centres. Given that this text was prepared some years ago, this does not take account of the most recent developments relating to HIV infection among drug abusers. However, recent views of these centres are essentially unchanged on the question of methadone. It is remarkable that, without consultation, the two centres have evolved along identical lines, although there may be differences in their theoretical justification. Both centres consider:

- that methadone is only one of several methods of treatment to be tried when the offered other alternatives have failed;
- that substitution therapy has no validity unless psychological therapy is undertaken and social problems are dealt with at the same time;

- that this approach can on no account be used to attempt to resolve the problem of drug dependence, but only the problem of individual drug dependent persons;
- that this technique is difficult to handle. Methadone is considered to demand great dedication and competence on the part of staff, and firm institutional support; and
- lastly, in 1980 it was already considered a complex task to assess the clinical advisability of treatment; in 1988, the indications for methadone appear just as problematic although identifying contraindications to methadone is considerably easier.

## 10. Monitoring and evaluation of services and responses

Following the introduction of methadone programmes in many countries, Health Departments have developed a number of different ways of monitoring service delivery.

### 10.1 THAILAND

The general importance and the benefits of an effective monitoring and evaluation system for drug dependence treatment programmes have been well recognized in Thailand at the policy making level. Unfortunately, this recognition remains an abstract statement without back-up in terms of specific allocation of resources. A similar situation exists with regard to delivery of treatment services. A treatment admission record system that gathers continuous data on all the clients admitted for treatment, exists in the Department of Medical Services. This system covers demography, selected social and economic variables, drug use pattern, treatment experience and incarceration, etc. It provides data and information which are useful in the monitoring and evaluation of the treatment services at the national level. The treatment service units of various government and private agencies, in general, do not have built-in monitoring or evaluation components. There have been a few ad hoc evaluation efforts of some treatment programmes. These were invariably follow-up studies of a cohort sample.

The treatment admission record statistics in Thailand, although seemingly simple in conception, actually provide a large quantity of information which requires a considerable expenditure of time and effort to establish and maintain. Furthermore, the data processing also requires heavy investment of resources and specific technical experience because of the size of the data base. Over a period of years there have been several changes in the variables gathered by the standard data collection form. This information yielded answers to fundamental epidemiologic questions such as who received what treatment, when and where. With the incorporation of appropriate variables in the standard form, useful direct evaluation of treatment and services could be partially obtained. These might, for example, look at questions on "the duration of drug abstinence after last treatment" in conjunction with "the identification of the last treatment service unit attended by the client." Despite the weaknesses of these data when judged by strict research criteria, they can offer some indication of relative efficacy of the treatment services. Given that the reliability of the epidemiologic data has been consistently maintained over time, they provide a useful set of indicators for treatment evaluation when considered in conjunction with the implementation record of overall drug dependence interventions.

In relation to monitoring the social and behavioural variables related to transmission of HIV infection, the trend of changes in prevalence of intravenous administration and attendance at different treatment services are examples of data already in existence. They are also potentially useful for future development of the system to monitor and evaluate the prevention and control of HIV infection.

In delivering drug dependence treatment services, most units keep some records. Since the Treatment Service Regulation requires a standard report from all treatment service units, each centre should be recording data on the client at least comparable to the

national pool of information at the Department of Medical Services. In fact, the treatment units commonly have much more extensive records on their clients and treatment interventions. These records are frequently used for reporting conventional service statistics. The potential to derive epidemiologic and evaluation information of greater depth than those already referred to (above) from the existing data on hand has rarely been exploited.

There have been periodic studies sampling populations from specific treatment service units to evaluate outcome. These studies mostly focussed on drug abstinence, though subjective reports were frequently accepted at face value without the use of objective screening methods based upon laboratory analysis of body fluid. Where objective information was available, there was often doubt about the validity of laboratory results and their interpretation. To resolve these issues requires expertise as well as appropriate technology.

Among many clinical workers there is a preoccupation with drug abstinence, which probably reflects the belief that the drug itself is the principal cause of all problems related to drug dependence. The focus of treatment outcome evaluation on drug abstinence alone may be regarded as having had some negative effects on the attitude of the therapeutic personnel. Because of the low rate of abstinence which is often found after treatment, the exclusive focus on abstinence has led to feelings of futility among many workers. In conjunction with a rejecting attitude to the drug dependent, this feeling has also led to a lack of motivation in treatment delivery. In this context there is a particular need for systematic monitoring and evaluation of the treatment intervention process and of the distant impact of treatment outcome. These are completely lacking at present.

#### 10.2 MEXICO

As opioid consumption and, particularly heroin use, is considered rather low within the overall context of drug abuse in Mexico, monitoring has mainly taken the form of estimating the prevalence of illicit drug use over time. However, the limited amount of research that has been conducted on such problems could conceal higher rates of consumption. Systematic research on drug abuse started in Mexico at the beginning of the 1970s, when it was observed that drug abuse was going beyond those groups previously identified as drug consumers, such as people living in some rural areas who use drugs as part of a ritual or as a medical resource. The same was observed among small groups such as artists and intellectuals. Since then, research on drug abuse has been attracting attention and at present an overall picture of drug abuse in the country has been obtained from different studies undertaken since 1974 in the Mexican Institute of Psychiatry, a WHO Collaborating Centre on Drug Abuse for Latin America.

Through the recently created Information Centre at the Mexican Institute of Psychiatry, it is now intended to develop a national instrument in order to systematize the data collection. This instrument has already been used in four evaluations in different parts of the country; three of these have already been reported. In these applications 1523 cases in 42 institutions were studied. Only 10 cases reported heroin consumption and seven the use of other opioids. Heroin consumption usually occurred for the first time after the age of twenty and the users were described as "experimenters", "slight" or "moderate" consumers. They reported legal and family difficulties as their main drug related problems. Opioid users were over the age of 15 and single. School level and occupation varied widely as well as social class (middle to upper class). First use tended to occur from the age of 15 onwards and the initial pattern of use was experimentation. During the first half of 1988, on the other hand, while heroin consumption occurred in 18.9% of patients hospitalized for the first time in a psychiatric hospital, in Mexico City only 0.5% of the patients studied had previously used heroin. Although the results are not exactly comparable, they are considered to be indicators of the different patterns of the use of these drugs. The recently created Information Centre at the Mexican Institute of Psychiatry is expected to systematically compile data on heroin and drug abuse in general.

At this stage, most of the studies carried out in the country have been undertaken in the central and north of Mexico and very little is known from the south and south-east where important social and cultural changes are rapidly taking place, such as development of the Caribbean coast and Cancun, a tourist resource which is becoming more and more cosmopolitan. However despite these occurrences, opioid consumption, and particularly heroin use, is not considered to be as important a problem as excessive alcohol consumption. This impression is shared by researchers, the general community and the government. The main concern regarding illicit drugs is illegal drug trafficking, as it is believed that the south-east of Mexico is on the drug traffickers route.

One of the commonest forms of monitoring is urine screening. Often there is some confusion about the real purpose of urine testing. In most countries, periodic urine monitoring is regarded as an important part of treatment programmes. This aims to detect relapse to opioid use, and abuse of other substances. Some programmes check urine in order to discharge polydrug users and relapsed patients from the programme, while others perform urine testing in order to make relapse a central issue for intervention.

No common policy exists among countries in relation to positive finding in urine samples. Whereas some programmes exclude patients after specific numbers of positive samples, others react with further psychosocial assessment, intensive confrontation, increased frequency of consultations and urine monitoring, or transfer to residential treatment.

## PART II

### NATIONAL CASE STUDIES

#### 1. NETHERLANDS

##### 1.1 Introduction

In the Netherlands there are many treatment and policy issues which have not been settled and there remains considerable variation in the dose levels at which opioid drugs are prescribed, in the use of take-home medication, in the duration of medication and in the use of additional psychosocial responses. The national debate about treatment and rehabilitation has often taken the form of a clash between opposing views on the question of how substitution drugs should be used. For example, the discussion has tended to polarize between advocates of

- medical versus non-medical treatment
- low-threshold versus high-threshold programmes
- compulsory versus voluntary treatment
- opioid prescribing versus drug-free treatment

Such polarization has not been followed by clarification of the issues or by any useful answers to unresolved questions. Currently it is not known whether low-threshold (non-restrictive) methadone programmes lead to better or worse outcomes than methadone programmes that are more focused on eliminating drug seeking behaviour of the addict. Also, we do not know whether an intensive treatment programme for drug dependent persons is likely to produce better results than a dispensary methadone programme with minimal counselling. It would be interesting to know, for example, whether or not there might be a group of addicts for whom it made little difference in terms of outcome whether they were treated in an intensive treatment programme with high levels of psychosocial intervention or in a methadone programme with minimal interventions. The absence of a dominant theory in dependence has led many health workers to use their own private 'theory' as a guideline for treating drug dependent persons.

##### 1.2 Development of treatment and rehabilitation programmes for drug dependent persons in Holland

Twenty years ago a special treatment for drug dependent persons in Amsterdam started, and heroin also became available on the illicit market. A black market in raw opium already existed and opium was being used by an estimated 200 to 300 opium dependent persons. For many previous decades, opium had only been available to the small Chinese minority who frequented gambling houses which were only open to Chinese people.

In 1968 the Jellinek clinic, an alcohol treatment centre in Amsterdam, opened an outpatient facility for individuals with drug problems. These patients came on a voluntary basis and the treatment was free of charge. Also, in the same year, a methadone programme for opioid dependent persons was started in that clinic. The goals of the treatment were to change addictive behaviour and to try to improve psychosocial functioning.

In 1970 the Youth Advice Centre operated as an information centre for drug takers and as a crisis centre for young people with drug problems. The most common presenting problem was of anxiety reactions related to the abuse of hallucinogenic drugs, and at that time, these were treated with "talking down". The primary goal of this approach was harm reduction, not behaviour changing.

By 1972 different treatment approaches for drug takers with different goals developed in the Netherlands. Some methadone programmes and drug-free therapeutic communities were primarily oriented to changing behaviour. There were also other programmes for drug dependent persons developed by the welfare system. These programmes allowed drug

dependent persons to obtain food and a place to stay, and to continue their life-style without pressure to change their behaviour. It took about five years before the effects of heroin use became visible in the form of street "junkies" with the associated criminality and harassment in certain downtown areas. From 1979 the Amsterdam Municipal Health service was instrumental in setting up a coherent helping system for drug dependent persons. Three goals were set:

- (i) Reducing the negative social effects of the drug problem
- (ii) Creating and improving conditions for a decent and acceptable existence for drug users
- (iii) Creating a preventative programme for adolescents

These goals were not primarily oriented towards "cure" or changing the addictive behaviour. Instead, the provision of care was accepted as a more important goal for those drug dependent persons who were not motivated to change their behaviour with the assistance of a treatment setting. Care, and from a public health perspective, risk and harm reduction were accepted as an alternative goal if abstinence was not possible, as with those drug dependent persons who were either not willing to enter treatment or who had had disappointing experiences with treatment. In addition, and from a public health perspective, the further goal of creating a preventative programme for adolescents aimed at health protection was adopted.

Methadone distribution can be used within an abstinence-oriented treatment system but also as a major tool in care and harm reduction or health protection. Amsterdam has various methadone programmes with different 'thresholds'.

The lowest threshold project provides methadone via a bus. Every day two rebuilt city buses take a distinct route through Amsterdam, stopping at a total of 6 different places in or nearby the 'drugscene'. In these buses, oral methadone is dispensed to heroin dependent persons who have been referred to the buses by one of the Municipal Health doctors. The precondition for participation in this methadone bus project is:

- (a) Regular contact with a medical doctor (though in practice such contact is minimal, about once every three months).
- (b) Introduction into the central methadone registration system.
- (c) No take home dosages.

From the methadone buses, drug dependent persons can be referred to an outpatient methadone clinic on condition that they are willing to change their addictive behaviour, for example to give up their illegal drug use. In 1987 about 3500 drug dependent persons received methadone from one of the municipal methadone programmes in Amsterdam.

Apart from the methadone programmes, general practitioners in Amsterdam prescribed methadone to about 1500 patients. These general practitioners can be assisted by one of the doctors from the "consultation project". The general practitioners are obliged to participate in the central methadone registration.

### 1.3 Drug-free treatment and rehabilitation

The change-oriented treatment approach for drug dependent persons in Amsterdam is mainly done by the Jellinekcentrum, and includes inpatient as well as outpatient facilities. These methadone programmes are comparable with other methadone programmes in Europe or in North-America. The goal is to change the addictive behaviour and to improve levels of psycho-social functioning. The Jellinekcentrum has outpatient detoxification and methadone maintenance programmes, and an inpatient detoxification unit. The drug-free therapeutic communities in the Jellinekcentrum are comparable with the Phoenix House or the Daytop Project in the USA. The government also funded special educational and work

projects for the more stable drug dependent persons who are participating in these projects. For example, in one special project the city of Amsterdam created 40 jobs for ex-drug dependent persons.

#### 1.4 Outreach projects to contact drug dependent persons

Three activities are undertaken in order to get in touch with drug dependent persons who do not seek help:

- (i) Street workers make frequent visits to places where drug dependent persons can be found, to give information about assistance.
- (ii) Doctors from the municipal health system visit local police stations twice each day to see arrested drug dependent persons. Medical first aid, including methadone, is given.
- (iii) A consultation team visits the general hospitals, where methadone is also very often prescribed for detoxification or maintenance.

In 1987 about 2,000 drug dependent persons were seen in the local police stations and 350 patients in the general hospitals. In Amsterdam approximately 70% of the total addict population of about 7,000 persons is estimated to be in contact with the helping system.

#### 1.5 Needles and syringe exchange

In Amsterdam the needle and syringe exchange began in the summer of 1984. In 1988 the Municipal Health Service started to make the exchange of syringes and needles available on the methadone buses as well. In 1987 approximately 700,000 needles and syringes were exchanged on 11 different locations. Conclusions from the first evaluation by Hartgers, Buning et al. (1989)<sup>5</sup> of the needle/syringe exchange programme should be qualified, since the data are based on self report, no HIV testing was performed and no follow-up data are available. Based on the present data, it can be suggested that:

- differences were found between 'exchangers' and 'non-exchangers' on a number of characteristics;
- no increase in drug use was reported by the 'exchangers';
- the exchange schemes help a certain group of IV-drug users to use drugs in a safer way with regard to HIV injection;
- the exchange schemes facilitate contact with drug dependent persons outside the methadone programmes.

Negative side effects (such as increasing number of IV-drug users, increase in drug use or reduced interest in drug free treatment) were not found in Amsterdam. On the basis of the Amsterdam experience, no definite answer can be given to the question of whether needle/syringe exchange schemes are effective tools to prevent further spread of HIV. Although safer drug use has been reported by a large percentage of the IV-drug users in Amsterdam, some are still involved in needle sharing; this group is at greater risk of becoming infected by HIV. For many other IV-drug users, the exchange serves an important role in assisting to remain free of HIV infection, or if they are already infected, to avoid infecting friends or partners.

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<sup>5</sup> Hartgers, C.; Buning, E.C. et al. (1989) The impact of the needle and syringe exchange programme in Amsterdam on injecting risk behaviour, AIDS, 3, 571-576.

Although a needle and syringe exchange may be less than 100% effective in changing the behaviour of drug dependent persons, there is in addition a very important public health issue of reducing the number of contaminated needles in the environment. Any measure that has the potential of reducing the spread of HIV infection from IV-drug users to the general population, needs serious consideration.

#### 1.6 Heterogeneity of a Dutch addict sample and implications for an integrated treatment and rehabilitation centre

Until a few years ago, drug dependent persons in treatment or rehabilitation were considered a relatively homogeneous group, who required approximately the same treatment approach. Recent studies in Holland have shown that mood and anxiety disorders were very prominent in addict groups. These studies suggested three groups of psychiatric diagnoses among drug dependent persons. About one third have no psychopathology according to DSM-III criteria, about one third have the characteristics of an antisocial personality, and one third have Axis I psychopathology according to DSM-III criteria. Because a dysthymic or mood disorder is very highly correlated with a personality disorder, dysthymic disorders were excluded in the Axis I psychopathology.

The implications of these findings are clear. The drug addict population that receives methadone is, in Holland, a heterogeneous group, in need of different approaches. Therefore, screening and diagnosis are necessary for a good matching of the clients to the different programmes. A pragmatic way of dealing with the drug problem and prescribing methadone with different goals such as care, cure and health protection or harm reduction can lead to a stabilization of the total number of heroin dependent persons and a decrease in the number of young heroin users.

Health protection or harm reduction-projects have not turned drug dependent persons away from drug-free treatment. If the attitude of the staff is mainly oriented towards change or "cure", giving needles, syringes and methadone may be seen as giving the addict a double-message. However, if the programme is primarily care-oriented, the goal of harm-reduction in the giving of needles and syringes will not be in conflict with staff attitudes. Therefore, the addict will not be receiving a double-message.

#### 1.7 Drug dependent persons with psychiatric symptomatology

It is important that treatment and rehabilitation centres identify drug dependent persons with other psychopathology. Besides methadone substitution, other clinical responses including pharmacotherapy, psychotherapy, and especially family therapy are the major therapies for the psychiatric disorders within drug abuse treatment and rehabilitation programmes. Continuity in care, with no time limit is necessary. Drug dependent persons have different psychopathological, medical and social problems, and the programme should be oriented to the special needs of the individual. An efficient treatment and rehabilitation centre for drug dependent persons with other psychopathology provides a comprehensive approach with screening and multidimensional diagnosis, pharmacotherapy, psychotherapy, counselling, social work, and educational groups. Cooperation of this centre with self help groups to establish good treatment outcome, is necessary. In the event of a relapse, it is also considered important that an addict should not be deprived of the care of the treatment and rehabilitation centre. A coordinated approach to the treatment and rehabilitation process under the supervision of a case manager is advisable. More complete details of the characteristics of Dutch drug dependent persons are given in the following tables.

TABLE II.1.1

Characteristics of 459 participants by sex, Dec 1985 - Oct 1987

	Men	Women	Total
	221	238	459
Mean age	30.7	27.6	29.1
% of Dutch nationality	80	63	71
% of German nationality	8	26	17
% with history of iv use	79	85	82
% with steady sexual partner	39	64	52
% homo/bisexual	20	-	-
% with history of prostitution in preceding 5 years	13	79	48

TABLE II.1.2

Serological tests results, study van den Hoek et al.<sup>6</sup>

<u>Serological Test</u>	<u>IV-Users (%)</u>	<u>Non-IV-Users (%)</u>	<u>Total (%)</u>
anti-HIV	118/378 (31%)	4/81 ( 5%)	122/459 (27%)
HIV-Ag	9/362 ( 3%)	1/81 ( 1%)	10/443 ( 2%)
Anti-HTLV-I	4/249 ( 2%)	0/59 ( 0%)	4/308 ( 1%)
HB-markers	199/245 (81%)	20/59 (34%)	219/304 (72%)
Syphilis-markers	16/192 ( 8%)	5/48 (10%)	21/240 ( 9%)

TABLE II.1.3

Characteristics of "exchangers" and "non-exchangers"

	Exchangers (n=73)	Non-exchangers (n=75)	Significance p
Males	66	76	n.s.
Average age (years)	31.1	28.1	<0.001
Average length of drug use (years)	12	9	<0.001
Average length of IV drug use (years)	9	7	<0.05
No contact with methadone programme in last 5 years (%)	25	50	<0.05

<sup>6</sup> Van den Hoek, J.A.R., et al. (1988) HIV Infection among Drug Users in Amsterdam: Prevalence and Risk Factors. Ned. Tijdschr. Geneeskd., No. 132, 723-728.

TABLE II.1.4

Risk level last month (df=2, p<0.001)

	Exchangers	Non-exchangers
No sharing and single use of needle (%)	74	28
No sharing, but re-use of needle (%)	17	50
Still sharing (%)	9	22

TABLE II.1.5

Frequencies life time DSM III diagnoses

	Total	Number Screened	Number Positive	DSM II Pos Positive
Mood disorders Total	(a)	199	17	8.5%
Anxiety Disorders Total	(b)	202	61	30.2%
Antisocial Personality		193	106	54.9%
Alcohol dependence		190	120	59.1%

(a): exclusion criteria used

(b): exclusion criteria used and only one positive diagnosis of possible several in a category is counted.

## 2. UNITED STATES OF AMERICA

### 2.1 Introduction

Opioid substitution therapy, the first type of treatment to be used in the United States with opioid dependent persons, began in the late 19th and early 20th centuries. This form of therapy has been administered both within in-patient and out-patient facilities. Many narcotic dependence rehabilitation programmes have gradually moved toward multi-modality interventions which offer a combination of drug substitution, psychotherapy, and group therapy.

Prior to the Harrison Act, maintenance of opioid dependent persons in the United States was left to the discretion of physicians. There were problems associated with this system and in some instances the prescribing habits of physicians aggravated the problem of dependence while producing a financial profit for the prescriber. It was not until the height of the Second World War, and in the midst of a zealous drive to purify the nation, that a campaign was mounted to strengthen the Harrison Act to prohibit maintenance prescribing for drug dependent persons. Physicians were only permitted to use opioid maintenance for an opiate addict in cases of senility or intractable pain. Physicians and pharmacists were further monitored and restricted following the adoption of a federal anti-maintenance policy in 1918. This anti-maintenance feeling was backed by leading physicians and the American Medical Association. The act of prescribing drugs to an addict was considered a form of medical malpractice that endangered society by perpetuating a criminal and immoral activity. Many of these same arguments are put forth today by those who are opposed to methadone maintenance therapy for opioid dependence.

In the late 1800s, there were more than 40 clinics scattered across the United States which were using both heroin and cocaine as maintenance drugs. Governmental drug policy and supreme court decisions were responsible for the majority of those clinics closing and after 1925 all clinics for maintenance known to the narcotic division of the Treasury Department were closed until the advent of methadone maintenance clinics.

## 2.2 Detoxification

Prior to the more recent applications use of a maintenance approach to dependence, detoxification, with or without other forms of therapy, was usually the only treatment available for the heroin addict. It is still the necessary pretreatment route to the therapeutic community, narcotic antagonist maintenance, or drug-free treatment on either an out-patient or in-patient basis.

Although detoxification is said to be used by some drug dependent persons as a means of reducing tolerance, and as such may contribute towards a "revolving door" system, for many it still remains the necessary first stage in the achievement of abstinence and the beginning of the rehabilitation process. In general, the purposes of detoxification could be stated as follows:

- (i) Ridding the body of the acute physiological dependence associated with the chronic daily use of opioids.
- (ii) The relieving of the pain and discomfort that can occur during withdrawal, especially if it is abrupt.
- (iii) The providing of a safe and humane treatment that can help the individual over the initial hurdle of stopping narcotic use.
- (iv) Providing an environment that encourages a more long range commitment to treatment and making appropriate referrals to other modalities.

Substitution therapy using morphine, codeine and thiamin in gradually decreasing doses was the principal treatment until the late 1950s when these drugs were replaced by the most widely used opioid agonist, methadone. At present, methadone is the most commonly used substance for detoxification of opioid addicted individuals in the United States. It is substituted for the opioid being abused (usually heroin) and gradually decreased on a daily basis over 5 to 21 days. The technique was first introduced by Isbell and Vogel in 1949 and has been described as the most humane, effective and manageable method currently available. Methadone is effective and well absorbed orally and is long acting in humans, making it ideal for both in-patient and out-patient management of the opioid addict. Determining beginning doses requires good assessment of post drug abuse behaviour and level of opioid tolerance. Many American programmes regard 10-20 mg as a good level from which to start, and where there are doubts about the amount and time of previous opioid use, it is best to administer the initial dose in two or three increments after a period of direct observation of the addicted subject, avoiding overdose by making sure not to exceed the initial total amount. Nodding and drowsiness after 10 or 20 mg in a tolerant addict is a sure sign of misjudgment of severity of dependence and opioid tolerance. A thorough, complete history and physical examination can, in most instances, prevent these errors.

It is not clear whether short detoxification schedules are to be preferred to detoxification over longer periods. Some clinicians in the United States of America prefer 21 day schedules on the grounds that they provide a greater opportunity for counseling and convincing the patient of the importance of follow-up care and the maintenance of a drug-free state. Other drugs have been used for opioid withdrawal, such as Zomiperac, Propoxyphene Napsylate, some of the phenothiazines, and many of the benzodiazepines. These various drugs are said to have ameliorated the discomfort of withdrawal but none have been as effective as methadone HCL for this purpose.

One of the more recent developments in detoxification involves the use of clonidine. A good deal of the research on this drug has been conducted in the United States and clonidine has been reported to be effective in many clinical trials. It has also been used in a number of rehabilitation programmes with some success. For shorter acting opioids (heroin, morphine, dilaudid, fentanyl) a 4-day schedule and lower doses can be used. There are some major side effects with the use of clonidine. Hypotension and some acute psychiatric problems have been reported. Clonidine's action on opioid withdrawal has been explained in the following way:

".... opioid withdrawal may be due, in part, to increased noradrenergic neural activity in areas such as the locus coeruleus which are regulated by both opioids through opiate receptors and clonidine through alpha-2 adrenergic receptors .... opioids administered systematically turn off the locus coeruleus by stimulation of inhibitory opiate receptor sites with reversal of this effect by the opioid antagonist, naloxone. Clonidine also inhibits the locus coeruleus but by stimulation of a different receptor, this effect being reversed by specific alpha-2 adrenergic antagonists ...."

### 2.3 Substitution treatments

Substitution or chemotherapy for the treatment of opioid dependence has enjoyed its finest hour since the "discovery" of methadone maintenance by Drs Vincent P. Dole and Marie Nyswander in 1965. It is likely that the discovery of opioid receptors and endogenous opioid peptides in 1975 has helped to increase its popularity. More importantly perhaps, the appearance of HIV infection and the awareness of the increased incidence and prevalence of HIV infection and AIDS among intravenous drug users has prompted a renewed interest in methadone maintenance treatment and contributed to its expansion as one method to reduce the spread of HIV. Dr Dole's recent honour by the Albert and Mary Lasker Foundation for his pioneering work in dependence, has put methadone maintenance or substitution therapy for opioid dependence on the front pages of newspapers and peer review medical journals. This focus has again stimulated debate about the merits and demerits of substitution therapy both in and out of government. Despite the claims for success and despite reports which offer results supporting methadone maintenance, this treatment response is still considered by some to be in the "slums" of medicine. No endorsement of its effectiveness has yet been made by the highest ranking public officials, ministers, physicians and law enforcement personnel in the United States.

Methadone maintenance as a modality has changed considerably from the classical model introduced by Dole and Nyswander in 1965. Dole and Nyswander employed very considerable "stabilizing" doses up to a maximum of 120 mg. In current practice, in order to offer such high doses, prior permission must be obtained from the Food and Drug Administration, and, if in New York, from the Division of Substance Abuse Services. The optimal daily dose of methadone for maintenance is the quantity that will hold the blood level in the 150-600 NG/ML range. This concentration range is consistent with binding to narcotic receptors when allowance is made for binding of methadone to plasma proteins and reduction in sensitivity of receptors with narcotic tolerance. As a general rule, 60-80 mg of oral methadone hydrochloride a day is given. This dose should be achieved by gradual increase over four to six weeks. Such doses are regarded as adequate and not excessive, although in exceptional cases substantially higher doses may be needed. Unfortunately, in some programmes many patients demand and receive 40-60 mgs immediately upon programme entry. Medical personnel are so occupied with a myriad of bureaucratic functions, that this kind of patient attention in most programmes is lacking. Classically, maintenance therapy has been accompanied both by common sense and vocational counseling. Counsellor/patient ratios were 15-20:1. In contrast, today those ratios are 75:1 in most programmes, and there is less interest in supportive services. Many programmes, in an effort to reduce cost, no longer monitor urine for the presence of illicit substance abuse, including morphine, clearly a deviation from the classical programme approach.

The American experience suggests that:

1. Oral methadone is effective as an agent for opioid detoxification on an in-patient or out-patient basis using schedules of 5, 7, 11, 15, 21 days or longer if desired.
2. Opioid dependent persons can be stabilized for extended periods of time on a single daily dose of methadone HCL administered orally and in dosages adequate enough to maintain a blood level of 150-600 ng/ml.
3. Dosage levels of 60-80 mg are usually adequate. However, more may be required in certain circumstances, for example, where there is an increase of the hepatic microsomal enzyme oxidizing system by interaction with other medications being taken concurrently, such as Rifampin, Phenytoin or Phenobarbital, or in the presence of liver disease.
4. Dosages should be gradually increased as tolerance develops, beginning with the dose that relieves the abstinence syndrome.
5. Levels should be reached that relieve the individual's craving or hunger for opioids but are not intoxicating.
6. Dosage levels should be increased further to a tolerance level sufficient to block the euphoriant effect of heroin.
7. Methadone maintenance should be accompanied by support services: vocational, legal, medical, psychological and social counseling as needed.
8. All uses of methadone in detoxification and maintenance programmes must be accompanied by urine monitoring for the presence of illicit substances. Urine sample collection must be under direct supervision, unscheduled and frequent in order to be effective.
9. To be effective, methadone must be taken orally every day in order to maintain adequate blood levels.

Daily supervised methadone ingestion creates an inconvenience for both patient and staff, and take home doses do not solve the problem of frequent visits when a patient's working hours and clinic hours are unmatched, especially for new programme entrants. With regard to take home privileges (regulations), if a patient is not in school or a homemaker, take home privileges are limited to one day per week. Although somewhat stringent, they were instituted in order to reduce methadone diversion. Good programme compliance (no alcohol, no illicit drugs, regular programme attendance) generally takes precedence over regulations. High levels of unemployment exist in the USA, particularly among minorities who make up 60-70% of the drug dependent population, and this must be taken into account in selection of patients and operation of the programme.

In response to the high incidence and prevalence of HIV infection among injecting opioid abusers, the Centres for Disease Control (CDC) funded, and the Food and Drug Administration relaxed regulations and permitted the Beth Israel Hospital to temporarily open an experimental methadone maintenance clinic in Harlem. This aimed to maintain drug patients without services mandated by Federal regulations. The purpose of this experimental programme was to try and relieve the long waiting list for treatment of intravenous opioid dependence among New York City drug dependent persons. It is estimated that there are 250,000 drug dependent persons in New York City, of whom only 35,000 are presently in methadone maintenance treatment. This experimental programme has now been extended indefinitely, despite much opposition to a "no frills" methadone maintenance treatment. However, some methadone maintenance programme administrators argue that such an experimental programme will further erode the public's and politicians' confidence in

this treatment modality and ultimately lead to lower funding quality. Evidence of this reaction is the recent letter written by the Chairman of the USA Congressional Select Committee on Narcotics Abuse and Control, calling for a USA General Accounting Office (GAO) evaluation of all methadone maintenance programmes. Similarly, the White House conference for a drug-free America recommended to the president of the USA that methadone maintenance treatment be evaluated for its effectiveness.

Despite these continuing debates, proponents of methadone maintenance claim that it is the most available and successful treatment to date for the treatment of opioid dependence. When the classical Dole and Nyswander technique is followed, using 60-80 mg of oral methadone daily, and maintaining 150-600 nanogram per milliliter blood level, drug hunger is reduced and rehabilitation can ensue. When lower plasma levels are maintained secondary to lower dosages being employed, patients are more likely to use illicit opioids. Cessation of illicit opioid use and elimination of drug seeking behaviour are generally considered the major goals of successful treatment in the USA.

In USA methadone programmes which are geared towards abstinence, 80-90% of patients return to some illicit opioid use within one year of completing or being discharged from a programme. Some patients do better if methadone to abstinence treatment is followed by participation in Narcotics Anonymous (NA) or Alcoholics Anonymous (AA) programmes. Either of these follow-up programmes can be replaced by regular individual or group counseling accomplishing similar results. Some programmes, in response to patients' requests to be detoxified from methadone after long periods of maintenance have reduced dosages over a long period of time (6-12 months) and then instituted antagonist therapy. An approach employing both an opioid agonist and antagonist for treatment of opioid dependence has been proposed and utilizes a sequence of Methadone, LAAM, and then Naltrexone.

#### 2.4 Levo Alpha Acetyl-Methadol (LAAM)

One answer to the problem of methadone diversion and frequent clinic visits was thought to be LAAM, a long-acting methadone derivative and opioid agonist developed in Germany in the late 1940s. It is absorbed orally with a duration of action that ranges from 48 to 72 hours. In the late 1960s and early 1970s, several teams of researchers in the United States evaluated LAAM in heroin dependence treatment programmes, and found that it was a useful opioid agonist. LAAM also offered some advantages to both patients and clinicians compared to methadone. Patients could attend clinics less frequently (three times a week) and take smaller doses of LAAM; and there was less liability for diversion. Some patients expressed a greater liking for LAAM than for methadone, reporting less anxiety, less sedation, more alertness, and less nervousness. LAAM also provided a better blockade of intravenous heroin than did methadone. Some researchers reported that LAAM was less reinforcing and prone to abuse when compared to methadone.

Despite all these favourable qualities, LAAM was unfavourably received by the treatment communities and became unpopular. Such response is not uncommon among the addict and treatment communities, where many rehabilitation workers are recovering ex-users, and anything new is not readily embraced despite its efficacy. Even at the height of its use only a very small number of patients received treatment with LAAM, and it continues to be unpopular. Despite this, some clinicians in the United States of America continue to believe that the drug has considerable potential value and that it should have a prominent place as a chemotherapeutic agent in the treatment of opioid dependence. In general, LAAM and methadone are both effective maintenance medications. Both drugs can produce dramatic reduction in heroin use in street heroin dependent persons, which may persist throughout maintenance. Both drugs produce successful rehabilitation almost equally with LAAM favoured over methadone in psycho-social improvement. LAAM has limited availability for treatment purposes and is presently only available from the National Institute on Drug Abuse (NIDA) and is not produced commercially in the United States.

#### 2.5 Opioid detoxification and maintenance with Propoxyphene Napsylate

Propoxyphene Napsylate is a mild analgesic compound derived from methadone. It has been used for opioid detoxification and maintenance by some clinicians, especially in

inner city programmes with a predominantly minority patient population, and staffed with ex-users as counselors, because of the disfavour with which methadone was viewed by patients and staff. A trial involving 280 heroin dependent persons evaluated Propoxyphene Napsylate for detoxification. A second trial involved 92 others were maintained on the drug on an out-patient basis for periods up to 240 days. Patients maintained on Propoxyphene Napsylate were found to be more likely to be abstinent at one month follow-up than methadone patients. However, doses of 800-1200 mg were considered necessary for daily maintenance and often produced disturbing side effects in many patients, resulting in high drop-out rates. The disturbing side effects included visual hallucinations, slurring of speech and seizures. As a result of the experiences with this drug, authors and researchers have concluded that Propoxyphene Napsylate is less effective than methadone as a medication for detoxification and maintenance of opioid dependent persons. However, Propoxyphene Napsylate is still employed in detoxification of special populations for weak opioid withdrawal and maintenance.

### 2.6 Mixed agonist antagonist detoxification and maintenance

Buprenorphine HCL, a partial Mu agonist and antagonist has demonstrated substantial effectiveness and promise as both a detoxification and maintenance substance for opioid dependence. Doses of 2, 4 and 8 mg sublingually have been employed in both detoxification and maintenance. Among some clinicians, it is regarded very positively and its versatility has been described as being unmatched by any presently used compound. Large doses (8 mg SC) have been demonstrated to block the effects of a 120 mg morphine challenge. Researchers at Yale University observed the ability of buprenorphine to switch methadone maintained/cocaine abusing patients from 30-35 mg of methadone to 2-4 mg of BUP (SL). These patients simultaneously ceased using cocaine and equally maintained their abstinence from other illicit opioids. This unusual finding has not been properly explained. Buprenorphin was introduced as a non-addictive analgesic and said to be 25-40 times as potent as morphine on a dose for dose basis. It also presents a milder euphoriant effect and minimal withdrawal symptoms. However, it is important to note that there have now been many reports of its potential and actual abuse from New Zealand (1983), Germany, Manchester (England) and Edinburgh (Scotland) and Perth (Australia, 1987). The drug is marketed in the USA in injectable form and as such there can be little doubt that it will be abused.

## 3. AUSTRALIA

### 3.1 Introduction

The level of intravenous drug abuse in Australia began to rise from low levels in the 1960s when American servicemen in Vietnam took rest and recreation leave in Australia. During the last 20 years the level of intravenous drug abuse in Australia has undoubtedly increased although inadequate data collection systems do not allow precise estimations of time trends to be made. Heroin has always been the preferred drug although barbiturates, amphetamines and cocaine are also injected. A recent study of IV-drug abusers in Sydney (Wolk et al, 1990)<sup>7</sup> found that 87% of subjects preferred heroin. Amphetamine use appears to be increasing considerably although carefully collected data to support this view is hard to find. The abuse of barbiturates appears to be declining and cocaine use remains low despite frequent predictions (over many years) of imminent crisis. Ingestion of heroin other than by intravenous injection is exceedingly rare. Estimates of the number of IV-abusers in Australia vary widely. The most recent official national estimate is that 30-50,000 people regularly inject drugs and that 60,000 are occasional heroin injectors. These estimates have been made with unspecified definitions and methodology.

<sup>7</sup> Wolk, J.; Wodak, A.; Morlet, A.; Guinan, J.J.; Gold, J. HIV Risk Behaviours, Knowledge and Serostatus of Sydney Intravenous Drug Users, Medical Journal of Australia, 1990 (accepted for publication).

### 3.2 Treatment for drug abusers in Australia

A very small number of Therapeutic Communities existed in the late 1960s when the first methadone maintenance unit in Australia commenced operation in Sydney in 1969. Methadone maintenance is now available in five states and one territory. One state and one territory (representing 3% of the national population) do not use methadone maintenance. During the last three years, methadone maintenance has expanded considerably across the nation. In March 1987, 5,063 patients were enrolled in maintenance programmes in Australia. At present, there are likely to be over six thousand five hundred patients in methadone programmes in Australia. In the most populous state of NSW, the growth in number of methadone patients began in 1981 when approximately five hundred patients were receiving this drug. Steady but slow increase occurred until January 1985 when eight hundred patients were receiving methadone, but by January 1986 this had increased to one thousand eight hundred. By January 1987 three thousand two hundred patients were receiving methadone in NSW. At present, over three thousand eight hundred patients are receiving methadone in NSW. This expansion can also be demonstrated by the increasing consumption (licit) of Methadone Syrup in Australia per thousand population: (see Table II.3.1).

TABLE II.3.1

Year	Methadone Syrup (grams)
1978	1.36
1979	1.44
1980	1.36
1981	1.66
1982	1.89
1983	2.10
1984	2.35
1985	3.30
1986	5.42
1987	5.34

Estimates of the numbers of drug abusers receiving drug treatment other than methadone are hard to obtain and only approximations are available. Drug free treatment has also expanded and been improved in recent years. In NSW (with 3800 methadone patients), a total of approximately 500 detoxification and residential rehabilitation (therapeutic community) beds are available. A similar proportion of methadone to non-methadone treatment services exists in other parts of the country. It is generally difficult to obtain rapid access to methadone maintenance programmes (except in one State) because demand for treatment exceeds supply of treatment. In contrast to methadone maintenance, it is often the case that therapeutic communities are not filled to capacity.

### 3.3 The national drug offensive

On 2 April 1985, the Prime Minister and the Premiers of all States met to discuss the establishment of a nationally coordinated response to the "drug problem" which was perceived to be rapidly worsening. The National Drug Offensive commenced twelve months later, with over \$A 100 million committed over a three year period. The funding was committed to a wide variety of approaches to alcohol and drugs, including law enforcement, education, treatment and research. The National Drug Offensive was comprehensively evaluated in 1988 with generally positive findings, and an additional \$A 100 million has been committed for a further three year period.

### 3.4 HIV and AIDS

The first case of AIDS was reported in Australia in 1982. A total of 1,079 cases of AIDS had been reported in Australia by 7 November, 1988 representing 64.6 cases per million. Three hundred and forty five new cases were reported in 1987 representing 2.15 new cases per 100,000 population. Of all cases reported thus far, 88% are homosexual/

bisexual males, 0.9% are heterosexual drug injectors, and 2.5% are homosexual/bisexual male intravenous drug abusers. The first Australian case involving a heterosexual IV-drug user was reported in Sydney in 1985. A study of the contents of returned needles and syringes in Sydney in December 1986 reported 3 out of 300 (3%) had antibodies to HIV. (1987). Between March and December 1987, one hundred eighty one Sydney IV-users were recruited into a study of whom 9% were sero-positive; in this study it was also found that AIDS risk taking behaviour was common, knowledge of AIDS was good, perception of risk related to injecting was high but perception of personal risk was very low. Sero-positive IV-users have been located in all capital cities by 1988 with over two hundred identified by mid 1988 in Sydney and seventeen percent of the known sero-positive cases in Adelaide are IV-users.

### 3.5 Intravenous drug abuse and HIV in Australia: responding to the epidemic

A National AIDS Task Force was established in 1983 to coordinate medical and scientific efforts against AIDS. The National Advisory Committee on AIDS (NACAIDS) was established in the same period to coordinate community services and educational responses. In 1985 a NACAIDS working party on intravenous drug abuse and AIDS was established and met frequently for over two years, generating policy papers for consideration of NACAIDS. The National AIDS Task Force and NACAIDS were replaced in February 1988 by the Australian National Council on AIDS (ANCA) which advises the Commonwealth Department of Community Services and Health. All States now also have a committee which advises State Governments on problems related to drug abuse and AIDS. AIDS is not an issue between political parties (with very rare exceptions) and major policy developments are coordinated between the Government and Opposition. A Parliamentary liaison group with cross party representation has been initiated in the Commonwealth Parliament and some of the States. At present, matters relating to drug abuse and AIDS in Commonwealth State administrations are still often being developed independently of Alcohol and Drug administrations. Although the existence of some difference of views must be acknowledged at both national and state levels between "AIDS" and "Drugs" administrators, the gap is probably narrowing. The National Campaign Against Drug Abuse has been represented on the ANCA AIDS and IV-drug abuse Working Party (now Standing Committee) for over two years.

### 3.6 Milestones in policy development: HIV and intravenous drug abuse

#### (i) Needle and syringe availability

The National AIDS Task Force first advocated increasing the availability of sterile needles and syringes in late 1984. Unofficial (and illegal) distribution began in 1985 with the overt operation of a needle and syringe exchange commencing in November 1986. In December 1986 the then NSW Government initiated a retail pharmacy needle and syringe distribution scheme. The repeal of State legislation covering availability of needles and syringes began in 1987 and is continuing. Sterile needles and syringes are distributed and exchanged in all jurisdictions in Australia except one (which represents 3% of the population). IN NSW an estimated 1.0-1.5 million needles and syringes will be distributed or exchanged from over thirty exchanges and a network of retail pharmacies in 1988. A target of nine million needles and syringes per year has been accepted for NSW. The entire spectrum of politicians' support efforts to increase sterile needle and syringe availability and this strategy also has widespread community support. Methadone maintenance treatment units make sterile needles and syringes available, but generally inform patients of the outlets for exchange or distribution. In New South Wales and other States, drug abusers can ring a drug telephone counselling service (24 hours a day) to find the nearest exchange or distribution point. Vending machines for needles and syringes are under consideration in some states

#### (ii) Education Campaigns

A series of mass media campaigns on injecting and HIV have been developed. In December 1986 for the first time, the theme was "Don't Share" with no mention being made of not using drugs. An education strategy for injectors and HIV is now being developed.

(iii) Methadone Maintenance

The increase in numbers of patients receiving methadone in Australia has already been discussed. Substantial qualitative change has also occurred with programmes becoming more liberal over the last few years. National guidelines were revised in 1985, then in March 1987 and will be revised again in early 1989. These reviews were instigated largely because of desires to maximize the contribution of methadone maintenance in efforts to contain HIV infection among drug abusers. Although the dramatic expansion of maintenance in 1985 and 1986 has been attributed retrospectively to concerns about HIV spread, it may be more accurate to acknowledge the desire at the time to use maintenance prescribing to control the epidemic of drug related crime which was considered to be occurring. Therapeutic communities have also become more liberal in recent years and recently began to make condoms available to residents. This liberalization may, however, have been influenced by the low utilization of therapeutic communities following the expansion of methadone maintenance.

A "fast track" to methadone maintenance for HIV positive drug abusers is often made available in several States, although this approach has also received some criticism. The expansion of pharmacotherapy to include Leva Alpha Acetyl Methadol (LAAM), buprenorphine and Naltrexone has been advocated for some years without any indications so far of a positive response. Methadone maintenance programmes have also been introduced into some Australian prisons and in NSW two hundred and fifty prisoners are currently receiving methadone (with the total prison population being four thousand).

(iv) Research

A national multi-centre collaborative study is investigating sero-epidemiological, behavioural and ethnographic aspects of IV-drug abuse in relation to HIV infection. The effectiveness of HIV-related education in alcohol and drug worker training is also being evaluated. A cognitive behavioural approach to reducing AIDS risk-taking behaviour among drug abusers is about to commence. A Sydney AIDS and drugs study group meets as a forum to discuss research on issues related to HIV and drug abuse, and Sydney is collaborating in the WHO multi-centre AIDS and drugs study. A proposal to evaluate the effectiveness of intravenous methadone (and possibly other injectables) in attracting drug injectors to enter treatment and to reduce AIDS risk-taking behaviour has been developed and will soon be submitted for consideration of funding. A review of methadone maintenance research literature was undertaken in 1987 to identify the most important areas for future research. Following this review, a study has commenced to develop standardized measures for pre-treatment and outcome variables covering several domains, including AIDS risk-taking behaviour.

(v) Removal of Legislative Impediments

Progress has been made in repealing some of the legislation which reduces the operation of needle and syringe exchange, but a great deal more work is required in this area.

(vi) The Relative Weighting of Efforts to Contain HIV Infection and Prevention of the Spread of IV-Drug Abuse.

This subject first began to be discussed in Australia following the influential McClelland report (Scottish Home and Health Department, 1986)<sup>8</sup>. It is probably accurate to say that the notion of giving priority to HIV containment is gaining increasing acceptance. The Australian National Council on AIDS Strategy Review states that "in the short term, the containment of spread of HIV infection should be the objective with the most important and immediate priority in health, welfare and legal policies relating to illicit drugs". Earlier drafts were less ambiguous. A clear majority of members of the ANCA Standing Committee accepts the pre-eminence of efforts to contain HIV infection.

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<sup>8</sup> McClelland, D.B.L. (Chairman) (1986) HIV Infection in Scotland. Report of the Scottish Committee on HIV Infection and Intravenous Drug Misuse. Edinburgh, Scottish Home and Health Department. Publ. No. D1600404.096.

### PART III

#### CONCLUDING OBSERVATIONS

The substitution of legal opioid drugs for illegal ones dates back at least one hundred years, with methadone now the most common form of substitution drug therapy currently used. This drug is widely used in many countries in the treatment of dependence to heroin and other opioids. It is important to distinguish clearly between the uses of methadone in detoxification and its uses as a substitute or maintenance drug. The practice and pattern of methadone use is related to many factors, including the nature of the national drug problem and experiences of any negative consequences of methadone, though other equally important factors may be related to attitudes, value orientation, ideologies and prejudices about drug issues. Often the debate has taken the form of a clash of intransigent views between proponents and opponents of methadone. In many countries at present, methadone maintenance is considered to be an important element of a comprehensive response to injecting drug use, although some controversy and unresolved problems still exist. In some countries where heroin injection is a significant problem, methadone maintenance is not considered acceptable or is only employed for exceptional cases. One of the most important and threatening developments which has revived interest in the use of methadone as a substitution drug has been the appearance and spread of HIV infection among injecting drug users. There is also evidence that this reappraisal had already begun in some countries as a result of the rapid spread of heroin problems and criminal behaviours prior to the identification of the drugs/HIV issue. Recently there has been increasing interest in the possibility that IV heroin users enrolled in methadone maintenance programmes may have lower HIV sero-prevalence than drug users who are not enrolled in treatment.

Methadone maintenance has changed considerably since the first formulations were proposed by Dole and Nyswander. Indeed, the variation in clinical practice appears to be sufficiently great for there to be a need for clarification of what is actually meant by maintenance or substitution therapy in terms of clinical practice. In addition, there are great differences between countries in the ways methadone is perceived and used to tackle drug-related problems. Some countries forbid the use of methadone for any purposes (e.g. Pakistan). Other countries use methadone extensively both for detoxification and maintenance programmes (e.g. USA). A few countries initially approached methadone with relatively liberal or permissive attitudes but adopted much stricter regulations regarding the manner in which the drug could be used after adverse experiences (e.g. Spain and Italy). Often these negative experiences were related to the diversion of methadone to illegal markets and the subsequent development of a methadone dependence problem. The changes within specific countries have often been pendular, with attitudes and practices swinging one way only to swing back again a few years later. Methadone policies have often appeared to be inherently unstable.

Insufficient attention has been given to the manner in which the effectiveness of methadone as a substitution drug might be maximized. In general, any considered analysis of the issues and procedures, and properly controlled research has been conspicuous only by its absence. Many of the most important questions about substitution therapies are seldom asked, and no convincing answers are available. Quite apart from the fundamental uncertainties about what is meant by 'maintenance' or 'substitution' and about what doses and time scales are, and are not, appropriate, there is still no consensus regarding the goals of treatment, and no agreement upon the extent to which methadone maintenance should be seen as a treatment in its own right or as a method of practical weapon for the control of social and health problems. It is not known whether low threshold, non-restrictive methadone programmes lead to better or worse outcomes compared to programmes which adopt clear expectations about the need for behaviour change; this question is obviously directly relevant to many current concerns about HIV infection among drug abusers. Also, it is unclear how the availability of substitution therapies relates to and influences the offer and acceptability of other types of treatment. In general, methadone maintenance has high acceptability with drug users as a treatment option and this is reflected in ease of recruitment into treatment and high retention. In some centres, recruitment and

retention in other treatment options is less favourable. On this question, there remains considerable confusion both about the identification of goals for the treatment and management of opioid dependence and also about how such goals are related to treatment methods. Important data are unavailable for the formulation of appropriate policy concerning the safety of maintenance treatments in relation to the driving of motor vehicles or the use of machinery.

One view was that methadone treatment units could only be demonstrated to be effective when given adequate resources. In practice, it was felt that virtually all such programmes had fewer resources than they required. The inability of current treatment units to increase the number of IV drug abusers in treatment was regarded as unfortunate. Current proposals to "liberalize" methadone maintenance treatment and to develop "no frills" approaches in which maintenance is used without adequate back-up facilities or controls are regarded as inappropriate by many workers. It is feared that under-supported and under-funded substitution treatment services may have far-reaching deleterious consequences and may undermine the effectiveness and credibility of the whole substitution approach. Current research findings suggest that methadone maintenance programmes that have adequate medical and rehabilitative services are effective in reducing intravenous drug use, whereas inadequate programmes are markedly less effective. Any move to lower treatment standards, staffing and services should therefore be resisted. Indeed, it seems necessary to improve methadone maintenance treatment in order to assist in the containment of the HIV epidemic among intravenous opioid dependent persons.

Another view was that no attempt should be made to reduce resources for abstinence-based treatment programmes. What is required is a greater diversity in or between programmes including additional less-resourced programmes with less ambitious goals and objectives for IV drug abusers who may not be willing or able to take advantage of other programmes. The need to adopt less ambitious goals could be a valuable aspect of the drive to modify HIV risk behaviours and prevent HIV infection among injecting drug users. In many countries the capacity of all drug treatment services is less than the number of drug users who seek treatment. This capacity shortfall has been of particular interest in recent years since the emergence of HIV infection and the possibility that drug injectors in treatment may have lower levels of infection than drug users who are not in treatment. Policy makers are required to make difficult decisions regarding the distribution of scarce resources, balancing the need to maintain adequate standards against the desire to provide maximum access to treatment.

There is general agreement that better monitoring and a better data base are required to guide discussion of these extremely important issues. In this context it should be noted that the effort to monitor and evaluate programmes for drug dependence treatment can be handicapped by giving so much priority to service provision that no resources are left for monitoring activities. The imbalance between policy and planning has often arisen where resources have been severely limited and because of pressing needs for technology, and infrastructure supports. Drug substitution treatments have a vital role to play in some countries as part of national and international responses to drug problems, especially because of the problem of HIV infection in drug injectors.

Finally, it should be noted that the views summarized in this document represent the particular perspectives of those who participated in the WHO Working Group. As such, they do not constitute a comprehensive global overview; nor do they represent a scientific or clinical consensus. Rather, what this document does is to bring together experiences from a range of countries in order to inform further debate on the uses of methadone in the treatment and management of opioid dependence. WHO is continuing to work in this area, both by gathering more detailed information regarding current policies and programmes and also by developing methodologies for assessing the quality of care in the treatment of drug dependence, including the use of substitution drugs.

WHO WORKING GROUP ON THE USE OF SUBSTITUTION DRUGS  
IN THE TREATMENT OF OPIATE DEPENDENCE

Geneva, 12-15 December 1988

LIST OF PARTICIPANTS

- Dr J. DUJARIN, Espace Murter, Hôpital Fernand Widal, St Denis, Paris, France
- Dr P. GEERLINGS, Amsterdam University Medical Centre, Amsterdam, Netherlands.
- Dr R. LOPEZ GODOY, Addictive Behaviour, Universidad Autonoma de Yucatan, Centro de Investigaciones Regionales "Dr Hideyo Noguchi", Merida, Yucatan, Mexico.
- Dr K. MUFTI, Post-graduate Medical Institute, Lady Reading Hospital, Peshawar, Pakistan.
- Dr M.J. KREEK, Biology of Addictive Disease Service, Laboratory of Biomedical Endocrinology, The Rockefeller University, New York, USA
- Dr A.O. ODEJIDE, Department of Psychiatry, College of Medicine, University College Hospital. Ibadan, Nigeria.
- Dr B. PRIMM, Director, Addiction Research, Treatment Corporation, Brooklyn, New York, USA.
- Dr L. SAN MOLINE, Chief, Section of Drug Addicts, Hospital del Mar, Besseig Meridim, Barcelona, Spain.
- Dr M. SKRLJ, Head, Group for Narcotics and Poisons, Ministry of Health, Belgrade, Yugoslavia.
- Dr M.-J. TABOADA, Espace Murter, Hôpital Fernand Widal, St Denis, Paris, France
- Dr A. UCHTENHAGEN, Psychiatric University Clinic, Zurich, Switzerland.
- Dr VICHAI POSYACHINDA, Institute of Health Science Research, Chulalongkorn University, Bangkok, Thailand.
- Dr A. WODAK, Director, Alcohol and Drug Service, St Vincent's Hospital, Sydney, Australia.

Representatives of Other Organizations

- Dr J. BALL, Addiction Research Center, National Institute on Drug Abuse (NIDA), Baltimore, USA.
- Dr J.R. COOPER, Associate Director, Medical and International Affairs, National Institute on Drug Abuse (NIDA), Rockville, USA.
- Mr S. di MENZA, Special Assistant to the Director, National Institute on Drug Abuse (NIDA), Rockville, USA.
- Mr N. REUTER, Program Officer, Health Assessment Policy Staff, Office of Health Affairs, Food and Drug Administration (FDA), Rockville, USA.
- Dr R.J. SAMSOM, Deputy Director-General of Health, Directorate General of Health, The Hague, Netherlands.

United Nations

International Narcotics Control Board (INCB)  
Dr S. OGUZ KAYAALP, Ankara, Turkey

United Nations Division of Narcotic Drugs (UNDND)  
Dr M. KILIBARDA, Vienna, Austria

United Nations Fund for Drug Abuse Control (UNFDAC)

Representatives of NCO's in official relations with WHO

International Council on Alcohol and Addictions (ICAA)  
Dr J.-J. DEGLON, Geneva, Switzerland

International Commission for Prevention of Alcoholism & Drug Dependency (ICPA)

WHO Secretariat

Dr A. ARIF, Geneva, Switzerland (Temporary Adviser)  
Dr M. CARBALLO, Global Programme on AIDS, WHO, Geneva  
Dr R. DIEKSTRA, Division of Mental Health, WHO, Geneva  
Mr C. GOOS, WHO Regional Office for Europe, Copenhagen\*  
Mr M. GRANT, Division of Mental Health, WHO, Geneva  
Dr I. KHAN, Division of Drug Management and Policies, WHO, Geneva\*  
Dr I. LEVAV, WHO Regional Office for the Americas, Washington  
Dr N. SARTORIUS, Division of Mental Health, WHO, Geneva  
Dr G. WEISS, Division on Drug Management, WHO, Geneva  
Mrs E. DUANE, Division of Mental Health, WHO, Geneva

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\* Invited but unable to attend.