

for policymakers

**on the effectiveness
of substitution treatment
for opiate dependence**

ANNETTE VERSTER & ERNST BUNING

Information for policymakers

**on the effectiveness of substitution
treatment for opiate dependence**

Annette Verster & Ernst Buning

EuroMethwork, 2003

Executive summary	4
Why this information on substitution treatment?	6
Acknowledgements	8
1. The health and social costs of drug dependence	9
1a. What is drug dependence?	9
1b. What is opiate dependence?	12
1c. How big is the problem of opiate dependence?	13
1d. What are the social and health consequences?	15
1e. Is there a cure for opiate dependence?	17
2. About substitution treatment	19
2a. What is substitution treatment?	19
2b. What are the aims of substitution treatment?	21
2c. What is the extent of substitution treatment in Europe?	22
2d. What is methadone treatment?	24
2e. Is methadone the only substitution medication for opiate dependence?	25
2f. Why does substitution treatment need to be given for such a long time?	27
3. About the effectiveness of substitution treatment	28
3a. What is the effectiveness for the individual?	29
3b. What is the effectiveness for society?	31
3c. What are the cost-benefits of substitution treatment?	32

3d. Is it a waste of public funds to invest in substitution treatment?	34
3e. Why are some people still critical of substitution treatment?	35
3f. Are there also disadvantages in substitution treatment?	38
3g. What are the major challenges ahead?	40
4. The delivery of substitution treatment	41
4a. Is substitution treatment alone enough?	42
4b. What is the best setting for substitution treatment?	44
4c. Should substitution treatment be available in prison?	46
4d. Is there a best way to provide treatment?	48
4e. What is the optimal dosage?	49
4f. Is urinalysis a useful tool?	51
4g. How to optimise the quality of substitution treatment?	52
Lexicon of terms	53
Useful sources: Literature, Websites	55
List of experts involved, acknowledgements	56

Opiate dependence is a phenomenon which confronts all (European) countries and it is a costly problem, both in public spending and in human suffering. Opiate dependence is considered a major contributor to poverty, crime, family disintegration and to government spending at the local and national level.

Substitution treatment has proved effective for the individual and for civil society as it improves the social, mental and physical well being of the individual and reduces public spending in health care and the criminal justice system.

Substitution treatment delivered appropriately will:

- Reduce or stop illegal drug use
- Improve physical, mental and social well-being of the patient
- Prevent and reduce infectious diseases, including HIV and hepatitis
- Reduce mortality, in particular through overdose
- Reduce morbidity
- Improve the quality of life of the patient and his family
- Reduce public spending in health care
- Reduce public spending in the criminal justice system

The benefits of substitution treatment are maximised by:

- Retaining clients in treatment
- Prescribing adequate dosages of medication (in the case of methadone usually between 60-120 mg or higher and in the case of buprenorphine 8 mg or more)

- Maintenance rather than abstinence
- Offering counselling
- Assessment and treatment of psychiatric co-morbidity
- Availability of psycho-social interventions and encouraging integration between different services.

While the efficacy of opiate substitution treatment has been well proven, there are significant challenges ahead:

Making treatment as cost-effective as possible while maintaining or improving the quality of care

Increasing the availability and variety of treatment services

Providing additional funding for opiate addiction treatment and coordinating these services with other necessary social services and medical care.

WHY THIS INFORMATION ON SUBSTITUTION TREATMENT FOR POLICY MAKERS?

Opiate dependence exists all across Europe and causes problems not only at the level of individual patients and their families, but also for civil society. Opiate dependence is a major contributor to poverty, crime, family disintegration and to government spending at local and national level.

Scientific evidence suggests that substitution treatment can help reduce criminality, infectious diseases and drug-related deaths as well as improve the physical, social and psychological well-being of the patients.

Despite the expansion of substitution treatment in Europe in recent years, there remain several challenges to be tackled, which include:

- **Lack of quality control:** Monitoring or assessment of individual programmes is needed in order to improve the quality and cost-effectiveness of treatment
- **Limited availability:** Most people with an opiate dependence today are not in substitution treatment, either because it is not available or because current treatment does not meet the needs of the patient
- **Political agenda:** Although the evidence base exists in support of substitution treatment ideological and political considerations against it often prevail
- **Lack of consensus:** There is still confusion and disagreement about the nature of addiction and about the value of substitution treatment.

WHY THIS INFORMATION ON SUBSTITUTION TREATMENT FOR POLICY MAKERS?

This booklet summarises the facts about effective substitution treatment for opiate addiction. The information provided is given in the form of frequently asked questions, which people working in the field are confronted with. We have sorted these questions into four chapters and provide answers, based on scientific evidence and current practice, which could help you when discussing the importance of implementing substitution treatment in your area.

Given the differences in historical, cultural, social, economic and political background as well as differences in how health-care is organised within Europe we have tried to remain as general as possible. One has to keep in mind the diversity in the current availability, stage and state of substitution treatment in Europe, the differences between Western Europe and Central – and Eastern Europe and even within individual countries. Although at several stages certain aspects or treatment options are recommended, we do not intend to dictate, but rather provide guidance and suggestions for good clinical practice of substitution treatment. In the end, every community needs to reach its own consensus and this booklet can be instrumental in this process. It can provide a knowledge base for implementing and sustaining drug treatment programmes that will be effective both for the individual as well as to civil society.

This booklet has been prepared with the financial support of the European Commission. It was co-sponsored by Molteni Farmaceutici, Quest for Quality, the International Harm Reduction Association and Itaca Europe. The authors have worked in collaboration with a group of experts from different national and professional backgrounds. We thank Bill Nelles, Patrick O'Hare, Edo Polidori, Marc Reisinger, Gerrit van Santen and Marta Torrens for their collaboration in the process of developing this document.

1. THE HEALTH AND SOCIAL COSTS OF DRUG DEPENDENCE

1a.

What is drug dependence?

Drug dependence is a complex condition with social, psychological and biological components. Drug users do not form a homogeneous group, because there are many forms of drug dependence, varying in types of drugs used and the level of dependence.

There are many drugs which can cause dependence, including legal ones such as alcohol, tobacco, prescribed drugs and coffee and illegal ones such as opiates (most often heroin) and stimulants (cocaine, speed, amphetamines, ecstasy).

It is important to distinguish between drug use and drug dependence. Tables 1 and 2 summarise the distinction between people who can control their drug use and people with a drug dependence or addiction.

1. THE HEALTH AND SOCIAL COSTS OF DRUG DEPENDENCE

Table 1: Drug users

Drug users who can consume drugs in a controlled way and perceive low risk, because of

Curiosity	often the reason for initial drug use
Experimentation	young people may experiment with drugs to fill in gaps in their knowledge
Adventure, risk taking	some people may be attracted by the risk they see as inherent in drug use
Improve performance & body image	this may include the use of stimulants such as cocaine and amphetamines, and performance enhancers such as anabolic steroids
Enjoyment	most people use drugs because they enjoy them
To enhance experience	this will include the use of ecstasy by younger clubbers, and mescaline by older writers (e.g. Huxley)

1. THE HEALTH AND SOCIAL COSTS OF DRUG DEPENDENCE

Table 2: Problematic drug users

Problematic drug use, people who are dependent on the drug and who have to use in order to

Avoid withdrawal	Once dependent on drugs, users will wish to avoid the extremely unpleasant physical and psychological effects of withdrawing from their dependence
To kill (emotional) pain	Some people will use drugs (generally opiates) as a means of coping with emotional pain as a form of self medication

Apart from the differences between the drugs used and the extent of the use, the way of administering drugs also differentiates users. Some drugs can only be taken orally and others can also be sniffed or injected. The most hazardous pattern of drug use is found among dependent opiate injectors who inject daily over many years. This group is faced with high levels of mortality, including that caused by HIV/AIDS, hepatitis, overdose, suicide and trauma (WHO, World Health Report, 2002)

1b.
What is opiate dependence?

Opiate dependence is a condition in which the neuro-chemistry and receptor sites of the brain change, causing the need for opiates to become as biologically driven as the need to eat or breathe.

1C.

How big is the problem of opiate dependence?

Because opiates are illegal drugs the use is often hidden, hence it is difficult to estimate the number of people using or dependent on them.

In Europe all countries have been confronted with a drug problem. The introduction of the opiate epidemic however varied across the continent:

- In the late 60's and early 70's among young people in North Western Europe
- In the late 70's and early 80's in Southern Europe
- In the 90's in Central and Eastern Europe

Some of the Northern European countries such as Sweden and Finland appear to have comparatively lower levels of heroin dependence and higher rates of amphetamine use and dependence (Farrell *et al.*, 1999).

The European Monitoring Centre on Drug and Drug Addiction (EMCDDA) provides general estimates of the number of problematic opiate users per country in European Union Member States. Portugal, Italy, Luxembourg and the UK score highest with an estimate of between six to nine per 1000 inhabitants aged 16-65. Estimates are lowest in Austria, Germany and the Netherlands, with about three problem drug users per 1000 inhabitants aged 16-65 (EMCDDA Annual Report, 2002).

1. THE HEALTH AND SOCIAL COSTS OF DRUG DEPENDENCE

Table 3: Estimated prevalence in the European Union

Estimated number of problematic drug users per 1000 population aged 16-65 in the EU in 2001:

Highest	6-9	Italy, Luxembourg, Portugal, the UK
	3-6	Denmark, Finland, France, Ireland, Spain, Norway
Lowest	2-3	Austria, Germany, the Netherlands

1d.

What are the social and health consequences of opiate dependence?

Dependence on illicit opiates is a serious condition which is associated with severe morbidity, in particular HIV/ AIDS and other infectious diseases (hepatitis B and C), and a high risk of death. In many countries, injection is a major cause of HIV infection amongst opiate users through the sharing of contaminated injection material, with the risk of spreading it to the general population through their sexual partners and through maternal transmission. In addition, opiate addiction is considered a major contributor to poverty, crime, family disintegration and to government spending. Opiate dependence can cause social, health and economic problems.

A British study by the University of York has calculated the costs of the use of illegal drugs in the UK such as heroin, crack and cocaine. These drugs are estimated to cost the nation almost 30 billion Euro a year. Serious addicts account for 99 per cent of the total social and economic costs of drugs: recreational users without a habit cost an average of €30 a year, while problem drug users cost over €16,000 a year. The annual economic costs to the health service and the criminal justice and benefits systems are estimated at between €5.6 billion and €10.3 billion. The social costs of crime to victims boost the figure to between €16.6 billion and €28.6 billion (The Observer, press release 1.12.02).

1. THE HEALTH AND SOCIAL COSTS OF DRUG DEPENDENCE

An Australian study puts the cost of drugs to society into perspective, comparing the social costs of smoking, alcohol and of illegal drugs. The calculations for the survey period, 1998-9, included both tangible and intangible costs to individuals, companies and governments. Tangible costs included hospital care, road crashes, loss of productivity and tax revenue, and increased crime and policing. The intangible costs included pain and suffering. Smoking tobacco accounted for 61%, alcohol for 22% and illegal drugs for 17% of the social costs.

ie.

Is there a cure for opiate dependence?

Opiate dependence is a chronic recurring condition and treatment is a long process. There is a range of treatment options available for opiate dependence, ranging from psycho-social interventions in residential settings (including therapeutic communities) or in outpatient settings (including self help such as AA and NA) to medically assisted treatment including substitution treatment or detoxification regimes in outpatient settings, including specialised centres and primary care. The different forms of treatment are not mutually exclusive but can operate together for patients with different needs.

Some of these options have proved more effective than others. Substitution treatment given to an appropriate standard of care has proved effective in producing many positive outcomes both for the individual and for society in that they:

- Reduce illegal drug use
- Improve physical, mental and social well-being of the patient
- Improve the quality of life of the patient and his family
- Reduce risk behaviour
- Reduce public spending in health care
- Reduce public spending in the criminal justice system.

Scientific evidence has shown that opiate addiction is best treated by a combination of continuing outpatient therapy, medication and monitoring, with the goal of retaining patients

1. THE HEALTH AND SOCIAL COSTS OF DRUG DEPENDENCE

in treatment to maximise and maintain the full benefits of treatment (UNODC, 2003). Substitution treatment and in particular methadone maintenance coupled with relevant social, medical and psychological services has the highest probability of being the most effective of all available treatments for opioid addiction (Joseph *et al*, 2000; AATOD Drug Court Fact Sheet, 2002).

2a.

What is substitution treatment?

Opiate dependence is difficult to control due to compulsive drug use and craving, leading to drug seeking and repetitive use, even in the face of negative health and social consequences. At this moment there is a wide range of treatment options available and substitution treatment is for the majority of opiate dependent people the most successful one.

Substitution treatment is a form of medical care for opiate dependence using a similar or identical substance with properties and actions similar to the drug normally used. This type of substance is called an agonist. Agonists can be substituted for the drug of abuse to provide a more controllable form of addiction. Using them alleviates many of the withdrawal symptoms often experienced by persons addicted to various psychoactive substances and reduces the health and social risks; when given in the right dosage it also reduces craving for opiates. Methadone is an example of an opiate agonist.

Another medication prescribed for opiate dependence is buprenorphine. Buprenorphine is a synthetic partial agonist-antagonist. An antagonist is a blocking agent which occupies the same receptor sites in the brain as the specific drug of abuse but is non-addicting. When someone is taking an antagonist, the effects of heroin are blocked because they cannot act on the

brain in the usual way and there is no mood-altering effect. Pure antagonists, like Naltrexone, are used when people do not want to be maintained on opiate substitutes or when leaving other drug-free treatment programmes and re-entering the community, to diminish the risk of relapse. Another opiate antagonist, Naloxone (Narcan®) is used to treat opiate overdose and to reverse coma.

The value of substitution treatment lies in the opportunity it provides for dependent drug users to reduce their exposure to risk behaviours and to stabilise their lives in health and social terms. Substitution treatment is generally considered for dependent users who find it difficult to stop their drug use and complete withdrawal. It is desirable for substitution drugs to have a longer duration of action, or half-life, than the drug they are replacing so as to delay the emergence of withdrawal and reduce the frequency of administration. This allows the person to focus on normal life activities without the need to obtain and administer drugs. Furthermore, the substitution of prescribed medication for an illicit drug helps in reducing criminal activity, supporting the process of lifestyle change.

2b.

What are the aims of substitution treatment?

The aims of substitution treatment can be summarised as to:

- Assist the patient to remain healthy until, with the appropriate care and support, they can achieve a life free of illegal drugs
- Reduce the use of illicit or non-prescribed drugs by the individual
- Deal with problems related to drug misuse
- Reduce the dangers associated with drug misuse, particularly the risk of death by overdose and of HIV, hepatitis B & C, and other blood-borne infections from injecting and sharing injecting paraphernalia
- Reduce the duration of episodes of drug misuse
- Reduce the chances of future relapse to drug misuse
- Reduce the need for criminal activity to finance drug misuse
- Stabilise the patient where appropriate on a substitute medication to alleviate withdrawal symptoms
- Improve participation in other medical care
- Improve overall personal, social and family functioning.

These goals are achieved almost from day one of treatment for many patients. Substitution treatment can be compared to other drugs that are effective in treating serious chronic conditions such as hypertension and diabetes. These conditions, like opiate dependence, are chronic, require daily treatment, and have a high risk of adverse effects if treatment is stopped.

2C

What is the extent of substitution treatment in Europe?

In Europe, substitution treatment has a long and varied history across the continent where changes in medical opinion and legislation have led to developments and changes in prescribing practices.

In the European Union action plan on drugs (2000-04), one of the five strategy targets is defined as 'to increase substantially the number of successfully treated addicts'.

Most European countries today provide some form of substitution treatment. The percentage of people with an opiate dependence actually receiving treatment varies across countries and within regions. In part this depends on the size and history of the problem per country, and in part on the political will to provide treatment on a large scale.

For example, in Italy only between 27-29% receive substitution treatment. In Spain, the percentage varies between 41 and 86%, in Germany between 33 and 63% and in the Netherlands between 40 and 47% of the heroin users receive substitution treatment (EMCDDA, 2002).

Most countries have seen a rapid expansion in the provision of substitution services, especially in Spain, France, and in some Central and Eastern European countries. The impetus for the

expansion has largely been a response to the HIV/AIDS epidemic among drug users as well as the increased evidence base of overwhelming effectiveness of substitution treatment both for HIV prevention and for opiate dependence itself. Whilst most countries have experienced few problems during this growth period, concern has been expressed in some member states. It concerns the lack of training and skills of some practitioners who are now involved in substitute prescribing. This is particularly noticeable among specialist services, including general practitioners and pharmacists. There is also concern about controls on prescribing and the risk of possible diversion of methadone onto the illegal market (Farrell *et al.*,1999).

2d.

What is methadone treatment?

Over 90% of opiate substitution in the EU is delivered in the form of methadone, apart from France, where buprenorphine prevails. It is estimated that approximately 300,000 people are on methadone in Europe, 180,000 in the United States and 20,000 in Australia. There are many countries in the world where different forms of drug substitution take place. However, the bulk of methadone treatment to date is still carried out in Europe, North America and Australia. These overall estimates would suggest that around half a million people receive this type of drug substitution globally (Farrell *et al.*, 1999; Parrino, 1999).

Methadone is a synthetic opioid agonist with a half-life of between 24-36 hours. There are several forms and formulas of methadone. The most widely used form is the liquid 1mg/1ml solution.

The principal effects of methadone are relief of narcotic craving, suppression of the abstinence syndrome, and blocking of the euphoric effects associated with heroin. Because of the often chronic nature of opiate dependence, the majority of patients requires high doses and treatment for an indefinite period of time. Methadone maintenance treatment, long term treatment, has therefore proved more effective than shorter term treatment or detoxification. Lower doses may not be as effective or provide the blocking effect. Methadone maintenance has been found to be medically safe and non-sedating. It is also a safe and effective medication for pregnant women addicted to heroin.

2e.

Is methadone the only substitution medication for opiate dependence?

The vast majority of all substitution treatment is provided by methadone, but there are some other medications available and which are also effective in the treatment of opiate dependence. Although only a minority of patients responds poorly to methadone, other substitute medications need to be available to them.

Buprenorphine

There is increasing evidence for the effectiveness of buprenorphine (Subutex® or Suboxone®) as a substitute medication. Buprenorphine is a synthetic mixed agonist-antagonist medication and not a pure but a partial opioid agonist. Its effectiveness seems comparable to methadone. Although it has not proven to be more effective than methadone, some individuals benefit from this partial agonist-antagonist. The opioid effects of this medication are limited and thus buprenorphine is less likely to produce overdose. Some countries have made buprenorphine more available than methadone, which in part may be based on overcoming resistance to providing substitution treatment. In France for example, the majority of substitution treatment is provided with buprenorphine. In 2000, there were only 5000 people receiving methadone in France against an estimated group of 80.000 receiving buprenorphine. In Austria, 35% of patients receiving

substitution treatment receive buprenorphine; compared to 5% in Portugal and 15% in Germany. Buprenorphine has been introduced in office-based medicine in Australia in 2000, and in the United States in October 2002.

Some experts prefer buprenorphine for younger drug users and methadone for older users on a long-term basis. Buprenorphine also seems better for pregnant women, because it causes fewer neonatal problems than methadone. On the other hand, methadone administration is easier to control, and in most countries it is a lot cheaper than buprenorphine (EMCDDA, 2002).

Diamorphine

Several countries have initiated trials with prescribed heroin (diacetylmorphine) as a form of substitution treatment for severely addicted patients and for people who respond poorly to methadone. Switzerland and the Netherlands have concluded the trials and published the results. The main finding of both studies was that for severely addicted, older, heroin users methadone plus heroin was more effective than treatment with methadone alone. Similar studies are currently being carried out in Germany and are to be begun in the near future in the region of Andalusia in Spain.

2f.

Why does substitution treatment need to be given for such a long time?

The chronic use of heroin causes changes in the chemistry of the brain. The biology of the brain changes and may never revert back to its pre-heroin state in a number of heroin-dependent individuals. Opiate dependence is considered a chronic relapsing condition and treatment should therefore be of a chronic nature, just like for other chronic conditions such as diabetes and hypertension.

Substitution treatment generally does not end physical dependence but allows people to live a healthy life on a legal and stabilising medication instead of an illegal and dangerous one such as heroin. Although some people stop needing their substitute medication, the majority will need to be maintained on it for a long time. The important thing is that this stability is the precondition for change and that coercive reductions of medication without the agreement of the patient do not work. Just as psychiatrists are not expected to withdraw depressed patients from their antidepressant medication and as physicians do not withdraw their patients from cardiovascular or other life sustaining medications that stabilise the patient and enable them to lead a normal life without struggling through the debilitating effects of an illness, patients on opiate substitution should not be required to withdraw from a medication that improves their quality of life.

3. ABOUT THE EFFECTIVENESS OF SUBSTITUTION TREATMENT

Substitution treatment is effective both for the individual patient and for society in general with regard to the general public, public health and public spending. Scientific evidence shows that substitution treatment reduces criminality, infectious diseases and drug-related deaths and also improves the physical, social and psychological well-being of the patients.

3. ABOUT THE EFFECTIVENESS OF SUBSTITUTION TREATMENT

3a.

What is the effectiveness for the individual?

Whilst most of the evidence on the effectiveness of sub-stitution treatment comes from methadone, there is an increasing body of evidence on the value of other medications, in particular on buprenorphine. Substitution treatment has been shown to improve the patient's physical well-being by helping patients to:

- Stay alive
- Achieve abstinence from illicit drugs, or a reduced, stabilised pattern of drug use
- Move from impure, illicit drugs to pure pharmaceutically-supplied drugs
- Change the route of drug administration, from injecting to a less harmful way such as oral or sublingual administration
- Keep contact with services.

Furthermore, substitution treatment has proven to improve the patient's social well-being by helping patients to:

- Stabilise their drug use as a means of stabilising their lives
- Reduce the need to resort to criminal activity to source and fund their drug supply
- Empower patients to make choices concerning their chosen lifestyles and life goals.

Effectiveness or success of treatment depends not only on the substitution medication given, but also on the context and

3. ABOUT THE EFFECTIVENESS OF SUBSTITUTION TREATMENT

accompanying aspects of treatment. Psychosocial interventions for example can have an important contribution to the success of substitution treatment. Substitution treatment allows people to resolve other issues in life, such as housing, employment and building a social network.

3b.

What is the effectiveness for society?

The costs of drug use arise from:

- The loss of life through overdose and drug-related illness
- Treatment of overdose and other medical consequences of drug use
- The transmission of disease, particularly HIV and hepatitis, mainly through use by injection
- Loss of quality of life for the families of people with an opiate dependence
- Law enforcement and judicial costs
- Criminal activity
- Loss of productivity and workplace accidents

Although these costs are difficult to quantify and few data are available where costs could be quantified, substitution treatment, and in particular methadone treatment has been proved to help to:

- Improve public health, especially reducing the level of drug-related emergencies, hospital admissions, and mortality as well as halting the spread of HIV, hepatitis and other blood-borne viruses
- Reduce the level of criminality associated with the import, manufacture and supply of illicit drugs, and the level of acquisitive crime associated with the funding of drug habits
- Reduce social welfare costs incurred by drug users and their dependents

3. ABOUT THE EFFECTIVENESS OF SUBSTITUTION TREATMENT

3C.

What are the cost-benefits of substitution treatment?

Of particular significance to policy makers in health-care and criminal justice, is the fact that substitution treatment has also shown to be extremely cost-effective. The US Department of Substance Abuse Services (DASA) and the National Institute for Drug Addiction in the USA have estimated the yearly cost of maintaining an opiate addict in New York in 1991 (presented in US dollars and Euros, respectively):

Untreated on the street	\$43.000 - €40.000
In prison	\$43.000 - €40.000
In a residential drug-free programme	\$11.000 - €10.000
In methadone maintenance treatment	\$ 2.400 - € 2.250

Source: International Forum, 1994.

More recently, in 2001, DASA carried out another study in collaboration with the University of Washington on the cost effectiveness and efficacy of substitution treatment with the following findings.

Reduction of:

Property crimes	64%
Overall arrest rates	54%

3. ABOUT THE EFFECTIVENESS OF SUBSTITUTION TREATMENT

Drug offence arrests	63%
Emergency room visits	65%
Medical hospital admissions	59%
Utilisation of major health care services	56%
Psychiatric hospitalisation	55%

Source: DASA, 2001

The rates of change are even higher for those who remain in treatment for longer than a year. Arrest rates are especially likely to be even lower among patients who remain in treatment over the longer term.

More specifically with regard to substitution treatment in Europe, the British National treatment Outcome Research Study (NTORS) found that for every £1 (€1.5) spent on treatment there is a return of more than £3 (€4.5) in terms of savings associated with victim costs due to crime. The increased expenditure of £1.6 million (€2.4 million) for treatment interventions yielded an immediate cost saving of £4.2 million (€6.3 million) in terms of the reduced victim costs of crime, as well as cost savings within the criminal justice system of about £1 million (€1.5 million). The true cost savings to society may be even greater than this (Gossop *et al.*, 1998).

3. ABOUT THE EFFECTIVENESS OF SUBSTITUTION TREATMENT

3d.

Is it a waste of public funds to invest in substitution treatment?

No, it is not. Investing in substitution treatment for opiate dependence that is based on scientific evidence reduces the negative health and social consequences both for the individual and for civil society. Money spent on treatment is returned manifold in cost-savings in the criminal justice system and public health.

In the case of the individual patient and that of social policy the aim of substitution treatment is to reduce harm. As drug addiction is a condition not easy to overcome, it is important to reduce the harm both to society at large and to the individual. Good quality substitution treatment easily available for anybody who needs it can save many other costs in health care, social welfare and the criminal justice system.

For the planning and policy perspective it is important to consider the problem of opiate dependence in a co-ordinated way in order to assess the benefits not only for one field or department, e.g. health, but also in another, e.g. the criminal justice system.

3e.

Why are some people still critical of substitution treatment?

The stigma of drug dependency is still so strong in most places that those who suffer from it must cope with life-long embarrassment, blame, and rejection. In spite of all we know about the biological nature of the condition, there is persistent disapproval of those who have it, and denial of its prevalence and impact. This powerful stigma keeps people from acknowledging their condition and seeking treatment. It even keeps some people from entering the profession of dependency treatment and prevention, and often results in lower pay for those who do (DASA, 2002).

Apparently it is not enough to improve knowledge about the effectiveness of substitution treatment. It is therefore important to understand the psychosocial roots of this resistance. Kreek *et al.* (1996) described two major reasons for this resistance. Our society is dominated by values of work ethic, competition and autonomy. Drug addiction seems to be dictated by values that are diametrically opposed to these: the pursuit of pleasure, passivity and dependence. Drug dependence is therefore perceived more as a vice than as an illness or a problem, leading to refusal to provide care.

This perception is based on several misconceptions, however. The first one is that heroin addicts experience continuing

3. ABOUT THE EFFECTIVENESS OF SUBSTITUTION TREATMENT

pleasure while addicted. Heroin consumption brings pleasure mostly before the user becomes dependent on the drug. Subsequently, the accompanying problems far outweigh the pleasure, but the user is compelled to continue using heroin in order not to suffer from abstinence symptoms.

The second misconception behind the refusal to provide maintenance treatment is the belief that such treatment prolongs the addicts pleasure, that all they do is 'replace one drug with another'. In reality, patients undergoing maintenance treatment are in perfectly normal state of awareness with no euphoria or 'high' and no withdrawal or 'sick' periods.

Another misconception is that patients do not become drug-free, hence no real change in the patient's situation occurs. People with such a view misunderstand the purpose of substitution treatment. The value of opiate substitute treatment is in the acute phase of opiate dependency – at the time when a person is not able to stop using opiates. Substitution medication can enable a dependent drug user to stop, or greatly reduce, the use of illicit opiates. It can also assist in reducing or eliminating injecting drug behaviour.

The development of adequate treatment will require not only a better dissemination of knowledge about the effectiveness of substitution treatment, but also the demystification of the prejudice existing in all sectors of society.

In most countries each drug user has a right to receive

3. ABOUT THE EFFECTIVENESS OF SUBSTITUTION TREATMENT

professional treatment and care according to currently accepted quality standards. Drug users are citizens with equal entitlements, having the same rights and duties as all citizens, independent of whether they are undergoing professional treatment as a result of their addiction.

3. ABOUT THE EFFECTIVENESS OF SUBSTITUTION TREATMENT

3f.

Are there also disadvantages in substitution treatment?

Yes, there are also some negative aspects to substitution treatment. The most important is the fact that in most cases a person has to receive treatment for a long period of time. The long term aspect has negative consequences both for public spending and for the individual patient.

Although substitution treatment is a cheap form of treatment, when calculated over many years the price of treatment adds up.

Another aspect is the fact that a person becomes a long term patient dependent not only on the medication but also dependent on the person who prescribes it. In some cases this dependency can lead to a passive attitude.

Furthermore, the dependency on the medication and the stigma surrounding it will cause difficulties when a patient wants to move from one place to another or simply travel and take along his medication.

Some people experience side effects of the medication. In the case of methadone the most common side effects include: increased transpiration, constipation, and disturbances of sleep, sex drive and concentration. Such undesirable side effects may persist over longer periods of treatment, but mostly there are no

3. ABOUT THE EFFECTIVENESS OF SUBSTITUTION TREATMENT

medical consequences. In total, these side effects affect less than 20% of methadone clients.

Finally, although methadone is prescribed to pregnant women as it improves her health status, the state of the pregnancy, delivery and the development of the foetus, the newborn baby will have to withdraw from the medication at birth.

It is important to note, however, that the long-term need for care, the dependence on the providers, passivity and resignation are all serious problems that can arise, and should be anticipated in caring for people with a severe chronic illness (cardiac, renal, hepatic, oncological, etc). In conclusion, there are some negative aspects of substitution treatment, which go with chronic treatment in general, but they certainly do not outweigh the benefits.

39.

What are the major challenges ahead?

While the efficacy of opiate substitution treatment has been well proven, there are significant challenges ahead:

- Making treatment as cost-effective as possible while maintaining or improving quality of care
- Increasing the availability and variety of treatment services
- Including and ensuring wide participation by (community based generalists) physicians trained in substance abuse to oversee medical care
- Providing additional funding for opiate addiction treatment and co-ordinating these services with other necessary social services and medical care organisations.

4. THE DELIVERY OF SUBSTITUTION TREATMENT

Substitution treatment is delivered in a variety of ways, both in different settings (primary care, specialised centres, pharmacies and in prison) and with varying dosages and duration of treatment, including maintenance and detoxification regimes. Furthermore, prescribing is often accompanied with a variety of psychosocial interventions.

4a.

Is substitution treatment alone enough?

Opiate dependence often has not only adverse effects on the health of patients but also on their social and mental well-being. It is important that substitution treatment is combined with other components which assess and address these other issues. The advantage of substitution treatment is that when patients are maintained on methadone, other problems can be addressed.

Scientific evidence has shown that the effectiveness of substitution treatment is higher when it is provided as a comprehensive treatment. Prescribing medication should therefore not be seen as an isolated intervention. It is important to identify and address other problems such as medical, social, mental health or legal problems.

This does not necessarily mean that patients should be able to address all their problems in one setting. When treatment is provided by general practitioners or small centres with limited staff, the assessment of the concurring problems could be carried out by them and patients can be referred for additional support to the appropriate services in the region.

Many patients are in treatment for many years and will not require additional care every time they come to receive their medication. Although the staff may find this difficult to accept,

4. THE DELIVERY OF SUBSTITUTION TREATMENT

one has to consider that patients with another chronic relapsing conditions, such as hypertension or diabetes, will not be offered counselling or psychotherapy every time they come for a new prescription.

4b.

What is the best setting for substitution treatment?

There is considerable variation across Europe as to who can prescribe substitution treatment for opiate dependence. In countries such as Denmark, Finland, Greece, Italy, Portugal, Spain and Sweden substitution treatment is provided centrally in specialised programmes with little involvement of primary care and General Practitioners (GPs). In Austria, Belgium, France, Germany, Luxembourg, the Netherlands and the UK, on the other hand, substitution treatment is less centralised and both GPs and specialised centres prescribe. The situation will depend on whether addiction treatment is considered a specialised treatment or a primary care task (Farrell *et al*, 1999).

Specialised centres can provide both medical and psychosocial care. Most specialised centres have a multidisciplinary staff, including medical doctors, nurses, psychologists, drug workers, and counsellors. The staff is specialised in opiate dependence and has had specific training and/or background in the subject.

In most countries, GPs who treat people with an opiate dependence have had special training. GPs do not generally have a multidisciplinary staff as they work on their own or in conjunction with other GPs. However, GPs can liaise with other specialists in the field to whom they can refer patients for psychosocial problems. For the dispensing, GPs need to work closely with pharmacists. Providing substitution treatment in

4. THE DELIVERY OF SUBSTITUTION TREATMENT

primary care normalises opiate dependence to the level of any other treatable condition and patients are not separated from others.

Most prescribers of substitution medication want to see their patients daily in the first phase of treatment, in particular during the phase of induction when the proper treatment is stabilised. Some doctors even prefer their patients to be supervised during the first days or weeks of dispensing. Once patients are stabilised it can be argued whether they need to come in daily to pick up their medication or if they can be given take-home doses or prescriptions. In many places, prescribers of opiate substitution treatment work closely with the community pharmacies, where their patients pick up the medication. Pharmacists have an important role in providing relevant information to their clients. They also have the responsibility to screen prescriptions for potential mistakes or interaction with other medications.

Experience shows that it is important that both settings are necessary for delivering treatment effectively. They allow patients to move between programmes with different thresholds and cater for geographical difficulties. Furthermore, what may work well in an urban setting may not work in smaller towns or rural areas. When budgets are extremely limited, prescribing medication without any additional form of treatment or care can still be an effective way of reaching as many people as possible and offering them an important tool for recovery.

4c.

Should substitution treatment be also available in prison?

Yes, it is important that inmates have the same access to health care as in the community. Research has shown that the reduction of injecting and syringe sharing that occurs with methadone maintenance treatment in community settings also occurs in prison (Dolan *et al*, 1996).

In 1998, the Prison and Drugs Conference in Oldenburg presented recommendations for drug services in a prison setting. They recommended that a wide range of drug services should be available to prisoners, including substitution treatment (both detoxification and maintenance). It was also recommended that prison staff need to receive training in drugs and related (health) problems.

A recent article in the French professional media assessed the likelihood of re-incarceration of drug-using inmates in association with receipt (or non-receipt) of maintenance agonist treatment while in gaol. The importance of substitution treatment in prison on essentially the same terms as in the community was stressed. In addition, it was found that inmates who received maintenance treatment while incarcerated had less than half (19% vs.39%) the likelihood of re-incarceration than those who were detoxified only (Levasseur *et al*. *Ann. Med. Interne* 2002. 153 Supple. to no. 3, pp 1514-1519).

4. THE DELIVERY OF SUBSTITUTION TREATMENT

Individuals on maintenance in the community should have the option to continue to be maintained upon entry to prison. This option is important since the discontinuity of methadone maintenance treatment is likely to result in higher levels of risk behaviour (Swiss Methadone Report, 1996).

People receiving substitution treatment in prison must be able to continue with such treatment on release. There is a particularly high risk of overdose and death after release if patients have been abstinent from opiates. Decisions on continuity should be taken in consultation with the treatment programme in which the prisoner participates once outside prison (European Recommendations, 1998).

There are some countries that provide methadone in all prisons nationwide, such as Spain.

4. THE DELIVERY OF SUBSTITUTION TREATMENT

4d.

Is there a best way to provide treatment?

Yes, research evidence shows that substitution treatment is most effective when delivered in an adequate dosage and for a long period.

Substitution treatment is prescribed in many ways: ranging from short- to long-term programmes and from maintenance to detoxification treatment.

Substitution treatment based on **detoxification** has the objective to bring a person from a high dosage to a low dosage or to nothing within a certain time frame, in general over a short period. **Maintenance** treatment on the other hand acknowledges the chronic nature of the condition and has the objective to bring about stability in the life of the person, allowing for a stable dose over a long period of time. The ultimate goal of maintenance treatment can still be to eventually bring about detoxification but only when the patient is ready for this.

The treatment plan will depend on the objectives of the treatment, which are established on the basis of the possibilities available, the needs and wishes of the patient and the professional opinion of the doctor. In general terms, however, it can be stated that the severer the dependence, the higher the dosage, and the focus should be more towards maintenance than to detoxification.

4e.

Is there an optimal dosage?

Substitution treatment prescribes medication and, like all medications, proper dosing is determined through the doctor-patient relationship, taking into account the patient's medical assessment of individual (metabolic) needs and other medical conditions and treatments.

Substitution treatment has been widely evaluated and has generally proved effective in achieving goals such as reducing the consumption of illegal drugs, risk behaviour and crime. For both methadone and buprenorphine, sufficient dosages have shown to be imperative to ensuring positive outcomes (EMCDDA, 2002).

The optimal dose of methadone for an average opiate-dependent person is between 60-120 mg (and of buprenorphine between 8-12 mg).

Dosages below 60 mg are generally not effective as they are not high enough to provide the blocking effect on the brain cells. Attitudes or opinions about methadone dosing that are not based on scientific evidence on effective dosing undermines the potential value of the treatment.

In conclusion, evidence suggests that the severer the dependence, the higher the dosage should be and the longer the treatment should last (Farrell *et al*, 1999).

4. THE DELIVERY OF SUBSTITUTION TREATMENT

However, each patient presents a unique clinical challenge, and there is no way of prescribing a single best methadone dose to achieve a specific blood level as a 'gold standard' for all patients. Clinical signs and patient-reported symptoms of abstinence syndrome, and continuing illicit opioid use, are effective indicators of dose inadequacy. There does not appear to be a maximum daily dose limit when determining what is 'enough' methadone in methadone maintenance treatment (MMT) (Leavitt *et al.*, 2000).

4f.

Is urinalysis a useful therapeutic tool?

Urinalysis is a vital part of the initial medical assessment of the patient (for confirmation that the patient is actually using opiates).

However, it is often used as a form of control over patients to see if they are not continuing to use illegal drugs with their medication. Many professionals question its effectiveness as a contributing factor to the success of treatment. It is argued that the information can also be obtained by asking the patient, which would save a lot of time and money. It goes without saying that this requires a good patient-doctor relationship, which is based on respect and mutual trust. However, it is also argued that a positive urine test should never be the reason for discontinuing treatment as it is evidence of symptoms of the condition the patient is being treated for, i.e. drug dependency.

49.

How to optimise the quality of substitution treatment?

In order to improve the quality of substitution treatment in your area training is an essential tool. You can involve local trainers and they can use the Euromethwork training manual we have developed:

AD Verster and E Buning (2003). Training manual: Key aspects of substitution treatment for opiate dependence.

In you have no access to local trainers you can contact us for advice on international experts: www.euromethwork.org.

Abstinence: refraining from the use of alcohol or other drugs.

Addiction: a chronic, progressive, relapsing disorder characterised by compulsive use of one or more substances that results in physical, psychological, or social harm to the individual and continued use of the substance or substances despite this harm.

Agonist: pharmacological term for the use of a drug that has a similar action to the drug of dependence.

Antagonist: pharmacological term for the use of a drug that blocks the action of another drug.

Craving: physical and psychological need to use the drug of dependence.

Dependence: a psychological and/or physical need for the drug. When the drug is not used the person experiences withdrawal symptoms.

Detoxification: a form of treatment with the objective to bring a person from a high dosage to a low dosage or to nothing within a certain time frame, in general in a short period.

Drug of abuse: any substance that alters the mood, level of perception, or brain function. These substances include prescribed medications, alcohol, solvents, and illegal drugs.

Half life: amount of time it takes before half of the active elements are either eliminated or broken down by the body. Methadone has a half life of 24 to 36 hours allowing for one daily dose as compared with heroin that has a half life of around 6 hours.

Maintenance: a form of treatment that acknowledges the chronic nature of the condition with the objective to bring about stability in the life of the person, allowing for a stable dose over a long period of time.

Psycho-active substance: a chemical with an effect on the central nervous system that alters mood and/or behaviour.

Relapse: the return to substance use after a period of abstinence.

Substitution treatment: medical treatment of opiate addiction with a drug that has a similar action to the drug of dependence (agonist in pharma-cological terms), thereby preventing withdrawal syndromes and craving.

Tolerance: the need for increasing doses of a substance to maintain its effects.

Withdrawal: physical and psychological effects that occur when opiate consumption is significantly decreased or stopped. There is a craving for the drug when one is abstinent, and these symptoms are relieved when the drug is again taken or when a substitution medication such as methadone is taken.

Literature

- Drugs in focus. Key role of substitution in drug treatment. EMCDDA briefing 1, 2002.
- World Health Organisation (WHO) Management of Substance Dependence.
What do people think they know about substance dependence? Myths and facts for policy makers responsible for substance dependence prevention, treatment and support programmes.
- European Methadone Guidelines. Annette Verster & Ernst Buning, 2000.
- UNODC. Investing in Drug Abuse Treatment: A Discussion Paper for Policy Makers, United Nations, New York, 2003 (http://www.unodc.org/odccp/treatment_toolkit.html).

Websites

www.Eurometwork.org
www.Emcdda.org
www.ihra.net
www.Opiateaddictionrx.info
www.Drugscope.org.uk
<http://www1.dshs.wa.gov/DASA/index.htm>
www.AC-company.org

Bill Nelles, The Methadone Alliance, London, UK

Patrick O'Hare, The International Harm Reduction Association, Rome, Italy

Edo Polidori, Servizio per le Tossicodipendenze, Faenza, Italy

Marc Reisinger, EUROPAD, Brussels, Belgium

Gerrit van Santen, Municipal Health Service, Amsterdam, the Netherlands

Marta Torrens, Institute of Psychiatry, Barcelona, Spain

Acknowledgements

We would also like to thank Michael Farrell (UK), Andrej Kastelic (Slovenia), Luis Patricio (Portugal), Andrew Preston (UK), Icro Maremmani (Italy), Robert Newman (USA) and Emilis Subata (Lithuania) for their comments and suggestions on the final draft of this briefing.

This project was funded by the European Commission,
Directorate G Public Health, project: SPC.2002267.

Neither the European Commission nor any person acting
on its behalf is liable for any use made of the information
in this document.

For more information:

EuroMethwork/Q4Q

Vijzelstraat 77 1017 HG Amsterdam The Netherlands

Tel. +31 (0)20 - 330 34 49 Fax +31 (0)20 - 330 34 50

info@q4q.nl www.euromethwork.org

ISBN: 90-77512-01-2