Sundhedsstyrelsen
National Board of Health

PRESCRIPTION OF INJECTABLE HEROIN FOR DRUG USERS

2008

Prescription of injectable heroin for drug users

URL: http//www.sst.dk

Key words: Heroin, drug users

Language: English

Translation from Danish to English: Joergen Engraff

Category: Report

Format: Pdf

Version: 1,0

Version date: 20071022

ISBN (electronic version): 978-87-7676-658-0

English version published by National Board of Health, Denmark, March 2008

This report should be referred as follows:
Prescription of injectable heroin for drug users
National Board of Health, Denmark, March 2008

The report is an English translation of the report:
Ordination af injicerbar heroin til stofmisbrugere,
Sundhedsstyrelsen, 22. oktober 2007

For further information please contact:

National Board of Health
Islands Brygge 67
DK-2300 Copenhagen
Denmark
Phone +45 72 22 74 00
E-mail:sst@sst.dk

Foreword

In its letter dated 1 May 2007 the Ministry of the Interior and Health requested the National Board of Health to provide a comprehensive medical report on existing knowledge about prescription of heroin for drug users.

The aim of this report is to assess the extent to which there is a foundation for grounds to supplement existing substitution treatment using methadone and buprenorphine with an offer of substitution treatment with injectable heroin for selected groups.

For the purpose of preparation of the present report the National Board of Health has established a group of experts consisting of Adviser Peter Ege, Senior Consultant in Social Medicine, Professor Morten Grønbæk and Research Assistant Anders Blædel Gottlieb from the National Institute of Public Health, Head of Centre Mads Uffe Pedersen from the Centre for Alcohol and Drug Research, President of the Danish Society for Addictive Medicine Thomas Fuglsang, Senior Consultant MD, and Christian Hvidt, Senior Consultant MD, from the City of Copenhagen Social Services.

For use in connection with the report Professor Morten Grønbæk and Research Assistant Anders Blædel Gottlieb from the National Institute of Public Health at the University of Southern Denmark have conducted a systematic review of existing research literature on medical prescription of heroin for specifically vulnerable drug users.

Supervision, National Board of Health, 22 October 2007

Anne Mette Dons
Head of Department,
Senior Consultant MD

Helle Petersen
Project Manager,
Senior Medical Officer

Contents

1 Summary

In the view of the National Board of Health existing evidence on medical prescription of injectable heroin for drug users that do not benefit from regular methadone treatment, shows that there are reasons to supplement existing substitution treatment using buprenorphine and oral methadone with injectable heroin and/or injectable methadone (in combination with oral methadone) as a second-line treatment. Evidence from the Dutch and German trials supports this view. Evidence from the Spanish and Swiss trials points in a similar direction but the quality of this evidence does not permit such a conclusion. Preliminary experience from the ongoing British RIOTT trial with injectable heroin/methadone versus optimised oral methadone treatment indicates that optimised oral methadone substitution treatment should be offered to the great majority of opioid dependent drug users and that treatment with injectable heroin and/or injectable methadone should be reserved for the relatively few opioid dependent individuals who in spite of optimised oral methadone substitution treatment do not benefit from this treatment.

In brief the National Board of Health concludes as follows:

- Existing evidence on medical prescription of heroin for drug users who do not benefit from first-line treatment with regular methadone, shows that there may be reason to *supplement* existing substitution treatment using oral methadone with injectable heroin and/or injectable methadone (in combination with oral methadone) as *second-line treatment*

- That treatment with injectable heroin combined with oral methadone should be offered as highly specialised intensive treatment for the relatively few patients who in spite of long term substitution treatment with methadone and/or buprenorphine do not benefit from this treatment (continued massive intravenous use of prescribed or illegal substances and having or being threatened by serious health complications as a consequence thereof)

- The target group for treatment with injectable heroin are the specifically vulnerable drug users who in spite of treatment with oral methadone continue to have almost daily intravenous opioid abuse, who are physically and mentally very vulnerable and who have a high incidence of illegal activity. The group who thus has not benefited from treatment with oral methadone is estimated at 600 persons corresponding to about 10 per cent of individuals in methadone treatment. It is not known how many of these actually want to and/or are able to receive treatment with injectable heroin. It is estimated by the National Board of Health that the actual target group will be 300 to 400 individuals. A further qualification of the estimate with regard to the size of the target group would require a review of a fairly representative group who do not benefit from oral buprenorphine or methadone

- The functional capacity of the most severely vulnerable drug users under treatment who constitute 2 to 3 per cent of the individuals in methadone treatment, the so-called ”hard to treat”, are functionally impaired because of severe medical, psychiatric and social problems to such an extent that they cannot be expected to comply with the basic requirements related to treatment with medically prescribed heroin

- The most severely vulnerable drug users outside the treatment system, the so-called ”hard to reach”, are not directly a target group for treatment with injectable heroin

- Heroin treatment will only have very little influence on the overall drug abuse situation

- Treatment with injectable heroin will not right away reduce the number of drug related deaths in Denmark. It is worth noting, however, that if an offer of heroin treatment can attract and retain individuals who either have not benefited from the treatment offered so far or who are currently not in treatment, mortality in this target group may be reduced

- Treatment with intravenously administered heroin is more expensive, more complex and more risky and therefore it will always be a second-line treatment

- Treatment with injectable heroin is a resource demanding and specialised health care service which must comply with a defined protocolled monitoring. This fact must be considered in connection with implementation in a Danish context where at present substitution treatment of opioid dependence is based in the social services

- It is problematic not to secure the quality of first-line treatment before focusing on second-line. Experiences from abroad indicate that priority should be given *both* to securing the quality of oral buprenorphine and methadone maintenance treatment for the greater part of opioid dependent individuals *and to the launching* of treatment with injectable heroin to a relatively small group of opioid dependent individuals who do not benefit from optimised treatment with buprenorphine and oral methadone.

2 Background

There is an estimated number of 27,000 drug users in Denmark, and of this group about 20,000 are opioid users (heroin users). About 1,000 of the latter are characterised as specifically vulnerable drug users. It is this group of specifically vulnerable drug users who have constituted the target group for considerations on treatment with medically prescribed heroin.

The specifically vulnerable drug users are not a clearly delimited group. There is much movement into and out of the group and in addition the concept "specifically vulnerable drug users" is a relative concept both with regard to present situation and with regard to individual history.

The National Board of Health has described this area on former occasions:

- In 1998 the National Board of Health produced a memorandum on the Swiss heroin trial. Against the background of the Swiss trial the National Board of Health estimated that it was not possible to establish that heroin treatment was superior to other substitution treatment.

- In 2001 the Government established an expert group who considered "initiatives for the specifically vulnerable drug users". The majority of the expert group found that there were still large and unexploited opportunities for improvement of existing treatment services including social and psychosocial support both in substance-free treatment and in methadone treatment.

- In 2002 the National Board of Health conducted an evaluation of the Dutch trials with medical prescription of heroin for drug users undertaken in 2002. Against this background the National Board of Health estimated that heroin treatment had a positive effect in relation to the selected target group. The overall conclusion was, however, that priority should be given to optimising the existing treatment system rather than to the launching of trials with the administration of heroin as part of drug abuse treatment.

- In 2005 the Government entered into an agreement with the parties involved in the political agreement on the social spending reserve for 2006 in the area of drugs. Against this background injectable methadone was introduced as a treatment opportunity for opioid dependent drug users in July 2006. On the basis of medical judgment this treatment may be used for patients who in spite of long term substitution treatment and psychosocial support continue to have massive intravenous use of prescribed and illegal opioids and who at the same time are threatened by serious health complications as a consequence of this. The immediate aim of the treatment is to prevent a worsening of the patient's health condition and in the longer term to achieve improvement of quality of life both socially and with regard to health. This treatment involves ongoing reporting to the National Board of Health with a view to evaluation of the treatment provided. So far the National Board of Health has only received very few reports.
  The National Board of Health recently inquired the municipalities whether this treatment opportunity has been taken into use or not. So far the Na-

tional Board of Health has received 3 reports regarding three instances of treatment as part of the monitoring system. Furthermore one municipality has answered our inquiry and stated that this municipality had no drug users in treatment with injectable methadone.

Research indicates that in many cases drug dependency may develop into a chronic disease that has characteristics in common with other chronic diseases such as type 2 diabetes and hypertension. Treatment offered to heroin abusers must be based on the best available scientific evidence on the effect of the treatment and must be influenced neither by prejudices nor by ideology.

For use in connection with this report focus has been on the countries who have introduced heroin prescription. Germany and Spain have introduced a trial scheme whereas the United Kingdom, Holland and Switzerland have introduced this treatment on a permanent basis.

Professor Morten Grønbæk, the National Institute of Public Health at the University of Southern Denmark, has undertaken a systematic review of existing research literature on medical prescription of heroin for specifically vulnerable drug users.

In the present report the National Board of Health will consider whether there is sufficient knowledge on the medical prescription of heroin to specifically vulnerable drug users to qualify a decision on the launching of treatment with injectable heroin as a supplement to the substitution treatment with buprenorphine and oral methadone which is the preferred treatment in Denmark at present.

Following the Dutch heroin trial a comprehensive German trial has been conducted as well as a more restricted trial in Spain for which reason the Danish Government has found it appropriate to undertake a renewed overall assessment. The National Board of Health is still waiting for the final results of the ongoing trial in the UK which will not be available until 2008.

Focus in the present report will be on the feasibility of the treatment and the effect of heroin prescription. The effectiveness of heroin prescription will be assessed at an individual level whereas effectiveness at the social level, e.g. cost effectiveness and cost-benefit analyses will only be briefly mentioned.

3 Answers to questions put by the Ministry of the Interior and Health

Are the specifically vulnerable drug users with severely reduced physical and mental capacity involved in the trial/the programme?

It is estimated that there is a group of about 1,000 individuals who may be characterised as specifically vulnerable drug users. The group of specifically vulnerable drug users consists both of opioid dependent drug users who are not in treatment (the so-called ”hard to reach”) and opioid dependent drug users who do not function well in treatment (the so-called ”hard to treat”).

About 6,000 individuals are in substitution treatment with oral methadone or buprenorphine in Denmark.

The functional capacity of the most severely vulnerable drug users in treatment, who constitute 2 to 3 per cent of the individuals in methadone treatment, is so poor because of severe medical and psychiatric e.g. psychotic and social problems that they cannot be expected to comply with the basic requirements related to treatment with medically prescribed heroin.

This group of the most severely vulnerable drug users with greatly reduced functional capacity and with mental diseases do not form part of the British, the Swiss, the Dutch, the German and the Spanish heroin trials.

Specifically vulnerable drug users who constitute 10 per cent of the individuals in methadone treatment and who have many years of abuse and mental and somatic disorders are part of the trials abroad. But it should be noted that drug users with severe mental (psychotic) problems and chaotic behaviour cannot comply with the requirements related to visiting a treatment institution several times daily and staff supervising injectable medication. If these drug users are defined as the ”most severely vulnerable” drug users, the most severely vulnerable drug users do not form part of the foreign trials. Indication for heroin treatment is not primarily the degree of vulnerability but lack of benefit from normal substitution treatment.

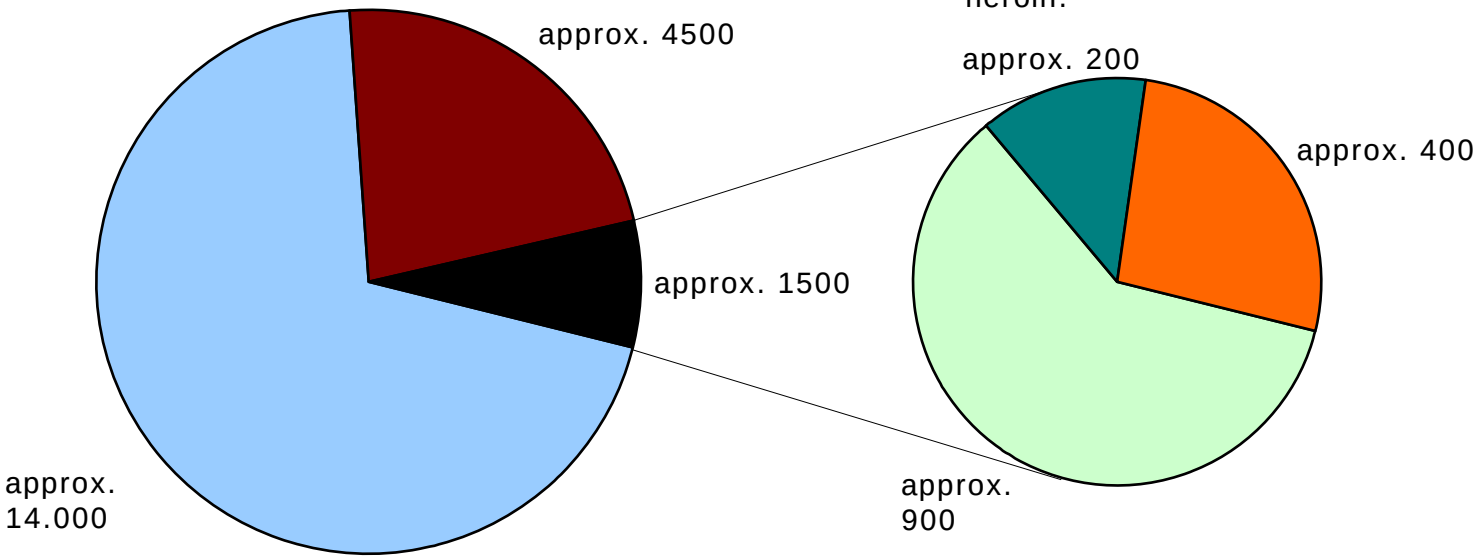
In many international studies it is seen that about 25 per cent of individuals in traditional (standard) oral methadone treatment do not benefit from treatment as assessed on the basis of among other things unchanged use of heroin, unchanged other abuse (benzodiazepines, cocaine, alcohol) and risk behaviour.

It has not been possible to decide prior to enrolment for oral methadone treatment who would and who would not benefit from this treatment. This is only seen in the course of treatment.

The table below is an estimate of the number of opioid dependent drug users in Denmark and the proportion of this group who are in substitution treatment with buprenorphine or methadone and an estimate of the number that may possibly benefit from treatment with injectable heroin

Estimate of the overall number of opioid dependent drug users – about 20,000 - and the relative proportions of this group who do and do not benefit from current substitution treatment.

Estimate of the number of opioid dependent drug users – about 1,500 – who do not benefit from current oral substitution treatment and the proportion hereof – about 400 individuals – who would constitute the target group for injectable heroin.



- Not in substitution treatment: a) not yet felt any need for treatment, b) have been in treatment but do not want to/are not able to receive treatment or c) drug-free treatment following phasing out of substitution treatment
- Benefit from current oral substitution treatment
- Do not benefit from current oral substitution treatment
- Not a target group for injectable heroin because of massive multiple drug abuse of non-opioids or not wanting treatment with injectable heroin
- Cannot take part in treatment with injectable heroin due to severe mental, somatic or social problems
- Target group for treatment with injectable heroin

To what extent may it be assumed that positive results can be attributed to intensified psychosocial initiatives rather than heroin as such?

In this connection information is requested on how the content and the quality of the psychosocial initiatives are defined? As well as the extent to which there is an unequivocal definition of the terms standard and intensified psychosocial treatment respectively?

Generally psychosocial treatment refers to the professional social care aspect of drug abuse treatment which typically comprises supportive, advisory or psychotherapeutic interviews both in relation to the drug abuse and in relation to social problems. In a holistically oriented treatment environment psychosocial treatment will be linked to pharmaceutical and other medical treatment. The overall aims of the treatment for drug abuse are reduction of illegal abuse and risk behaviour, improvement of mental and somatic health functions, improvement of social conditions (e.g. housing, work), reduction of crime and reduction of problems at community level (e.g. spread of abuse related infections, accidents, disorderly conduct, crime etc).

The literature review gives more reason to assume that the positive results are linked to intensified psychosocial care than to assume that the documented effect of heroin supported treatment is an expression of the pharmacological effects of heroin. Thus it is not *solely* the pharmacological effect of heroin in itself *but also to a high degree* the structured, intensive and specialised treatment, of which the administration of heroin forms a part, that plays a role. Heroin makes it possible to provide considerably extended treatment and care where the patient is seen at least twice a day 7 days a week throughout the year and has contact with professional health care persons who can immediately assess and take action in relation to various problems with regard to abuse, physical and mental health, social issues etc. which specifically vulnerable drug users may show signs of.

The National Board of Health estimates that comprehensive health care and social care in such an intensive form cannot be provided for this target group without a concurrent offer of injectable heroin.

The content and the quality of psychosocial initiatives are not similar across the trials described in the literature review. In the trials described there is thus no unequivocal understanding of standard and intensified psychosocial treatment respectively. The consequences of this with regard to the interpretation of the trial results are not significant as the results point in the same direction.

Is there a further description of the content of health and social care respectively, and in what way is this integrated in the interdisciplinary treatment provision?

The clinical picture seen in cases of drug abuse is often complex and treatment is multidisciplinary and comprises health care as well as social care. The health care part comprises both a medical assessment/examination of the abuse problems and an examination of any concurrent somatic and mental conditions in connection with the actual medical treatment of abuse. In addition general preventive and advisory health care services will also be provided e.g. in relation to hepatitis and HIV. Social care includes various supportive and advisory interviews, e.g. concerning housing, livelihood and various care services. The medical/health care treatment is often an integrated part of the overall treatment and care services for drug users.

The group of opioid dependent drug users is characterised by a very high incidence of mental disease, poor somatic condition, social problems including low educational level and little affiliation to the labour market, a high incidence of crime, poor social network etc. It is well documented that the treatment outcome often depends on services that supplement methadone. The best treatment results are achieved when several professional services (health care, social care and psychotherapeutic care) are provided targeting the various problems that the drug user presents. In other words the best results are achieved when holistic and individually differentiated treatment and care are provided.

Drug abuse treatment also differs both with regard to content and organisation depending on the overall aim of treatment. Thus a treatment aim may be that the drug user becomes drug free or the aim may be short or long term possibly life-long substitution treatment. The aim of substitution treatment in the first instance is not to achieve total abstinence ,but to stabilize the drug user pharmacologically, socially and mentally.

In earlier heroin trials (UK and Switzerland) there is no further description of the content of health care services (health care understood as pharmaceutical and medical care) and social care including psychosocial care and its integration in the interdisciplinary treatment and care services.

In the later heroin trials (Holland, Spain and Germany) psychosocial care is part of an organised treatment environment within which both health care and social care are provided. Health care services were provided on an individual basis along with psychosocial care and have not been further described in these trials. In the Dutch trial the content of social care is not further described, in the Spanish trial social care is described briefly and in the German trial social care is described in detail. Thus it may be concluded that the trials are not wholly similar as concerns psychosocial care but there is no doubt that psychosocial care plays an important role in all the trials.

Has any comparison been made with a control group who have solely received methadone treatment? If so: Has this control group – apart from heroin – received exactly the same treatment with regard to economic resources, staff, psychosocial care, physical environment etc?

In the Dutch and the German trials comparisons have been made with a control group who have received methadone and the same psychosocial care as the group receiving heroin.

Have known sources of error (regression towards the mean etc) as well as the bias known from experience to influence any trial/new initiative that is the object of public attention, gets increased resources and has especially dedicated staff etc. been taken into account in connection with the calculation of results?

In the Dutch and the German trials known sources of error have been taken into account. But in the communication of trial results no account has been taken of the general fact that most probably the effect of treatment will be smaller in later daily practice than in a scientific trial.

What is on average the number out of a group of 1,000 drug users whose condition is better/ unchanged or worse when receiving heroin compared to drug users who have been given ordinary substitution treatment (methadone and buprenorphine)?

In the Dutch trial on average 240 out of 1,000 drug users have managed better in heroin supported treatment. This figure has been calculated by subtracting the proportion who benefited from methadone treatment (29 percent) from the proportion who benefited from heroin treatment (53 per cent).

In the German trial on average 120 out of 1,000 drug users have managed better in heroin supported treatment than in methadone treatment. This figure has been calculated by subtracting the proportion who benefited from methadone treatment (45 per cent) from the proportion who benefited from heroin treatment (57 per cent).

Can it be concluded by a comparison of results to what extent heroin prescription alone or heroin prescription in combination with methadone treatment gives the best results?

No, this has not been studied.

Methadone has a relatively long duration of action and need only be administered once every 24 hours. Heroin has a relatively short duration of action, and in the case of treatment solely with heroin administration will be required 3 to 4 times every 24 hours. Treatment with injectable heroin is complex and risky. And in addition there will always be a risk of diversion to the illegal market. Therefore it is estimated that self-administration of injectable heroin outside the treatment institution as part of a so-called 'take-away' scheme is not justifiable. In order to secure sufficient opioid coverage with pharmacological substitution during 24 hours, treatment with injectable heroin is administered on the actual treatment premises at least twice every day which covers 12 to 16 hours, and this is supplemented with oral methadone for self-administration in order to cover the remaining part of the 24 hours.

It would seem unrealistic to imagine a form of treatment with the exclusive use of injectable heroin both because of the resources required for a highly specialised health care service to be open 24 hours, but also because the patients in that case would have to visit the treatment premises to receive treatment 3 to 4 times a day.

Both in the Swiss, the Dutch and the German heroin trials heroin was combined with methadone. None of the heroin trials described have used heroin in a take-away scheme. In the case of need for take-away medication for instance in connection with holidays etc., it has been necessary to change medication to oral methadone.

But it may be concluded from the results of the trials described that for some of the patients who took part in the trials, heroin prescription in combination with methadone treatment (a nightly dose) is superior to traditional substitution treatment.

To what extent has there been independent critical assessment of the results by external/international parties?

The Dutch, the British and the Swiss heroin trials have been subjected to independent critical assessment by international/external parties. As part of the ongoing enquiry by the National Board of Health on medically prescribed heroin a literature review has been made in which also the Spanish and the German heroin trials have been subjected to such external assessment.

Are there factors that make it difficult or impossible to transfer results to a Danish environment, for instance differences between the countries with regard to the social function of drug users, drug taking habits and doses and the degree of treatment coverage?

In the view of the National Board of Health one cannot be quite certain that heroin treatment in Denmark will yield the same results as in Switzerland, Holland and Germany. On the other hand there are great similarities between the three countries mentioned with regard to socio-economic conditions, treatment services and the drug environment. The countries mentioned have fairly well-established treatment institutions, and substitution treatment primarily with methadone is the dominant treatment method. The degree of treatment coverage is probably somewhat greater in Holland than in Denmark, but possible differences in treatment coverage are of fairly minor importance because in all the countries there is the opportunity to receive substitution treatment for individuals who meet criteria corresponding to the criteria fixed in Denmark.

In all 4 countries heroin users have a profile of high age and they are marginalised and socially excluded. Drug using habits vary greatly in Holland compared to the other countries in so far as the majority of the drug users consume heroin by smoking or sniffing. But at the same time the Dutch studies show that heroin smokers had the same benefits from heroin treatment as the smaller group who took heroin intravenously. It seems, however, that the methadone doses used in Denmark are larger than the doses used in Holland and maybe also somewhat larger than the doses used in Germany and Switzerland, and it cannot be excluded that this may have influenced the poorer treatment results, especially in Holland, in the control group that received methadone. It is well documented that an individually adjusted and sufficient, possibly large, methadone dose is positively linked to favourable treatment results.

By way of conclusion it should be noted, however, that based on the similarities between the countries mentioned, the treatment services of these countries and the respective heroin abusing populations, it is to be expected that the rather similar experiences that have been made in these countries with heroin treatment can be transferred to Denmark.

As an argument against heroin prescription it has on former occasions been mentioned –by among others the majority of the group of experts who in 2002 rejected this treatment option – that there is a big unexploited potential for improvement of existing treatment services. Does the National Board of Health consider that at present the existing treatment services are extended quantitatively and qualitatively to such a degree that the argument mentioned no longer carries any weight?

Though there has been a certain quantitative and qualitative development of treatment services since 2002, there are still very big unexploited possibilities for improvement of existing treatment services.

In order to secure the best possible treatment and continuity of treatment for drug users in the same way as for other chronic conditions/diseases with a need for long term and possibly continuing care, there is a need for extension of multidisciplinary, cross-sectoral cooperation involving a further description of the division of tasks between the different sectors.

Treatment of drug abuse in Denmark is generally characterised by a lack of standardised and evidence based professional procedures with regard to both health care aspects and social care aspects of treatment, and there is a lack of quality assurance. Neither is there any consensus regarding treatment targets. Previously the aim of treatment was “cure” meaning a drug-free condition. But for a great part of drug users, drug dependency is a long term, possibly chronic, condition characterised by frequent relapse. Drug abuse treatment should be seen as a long term and at times continuing form of treatment, the effect of which depends on the degree of retention in treatment. Therefore the effect of treatment should be assessed during treatment in relation to multiple drug abuse, improved somatic and mental health, improved social capacity, reduction of crime and reduction of problems at community level.

So far there have been great differences in the quality and content of drug abuse treatment. The coming National Board of Health guideline on medical treatment of drug users in substitution treatment which is planned for publication at the end of 2007, is aimed at securing uniform quality of the most significant core medical services. In the long term the guideline may constitute a basis for the required quality assurance of health care aspects of substitution treatment and guide the municipalities with regard to organisation of treatment.

There is also a need for an overall monitoring of treatment involving the establishing of clinical databases that will provide a needed and necessary basis for reporting selected indicators and thus quality assurance of services provided.

An extension of the treatment system does not preclude the launching of new initiatives and trials aimed at patient groups who have not benefited from the treatment they have received so far.

An argument against heroin prescription used on former occasions – by among others the majority of the members of a group of experts who rejected this treatment option in 2002 - is that from a medical point of view it would be irrational to use heroin for treatment rather than other accessible pharmaceuticals. Since then it has been made possible to prescribe injectable methadone. Are there differences between the group of drug addicts who already at present may be offered prescription of injectable methadone and the group who, if this decision is taken, would be offered prescription of heroin? From a health care perspective what would be the comparative advantages and disadvantages of prescribing heroin instead of injectable methadone?

Generally speaking the target group for injectable methadone is the same as the target group for injectable heroin. It is not possible to predict who will benefit from treatment with injectable methadone and injectable heroin respectively. Experiences from foreign trials show that most patients prefer treatment with injectable heroin. A number of patients who receive treatment with injectable methadone indicate that they would prefer heroin treatment, and treatment with heroin can probably attract and retain a number of individuals who do not consider injectable methadone as an attractive alternative to oral methadone treatment.

From a medical perspective it is more appropriate to use a preparation that can be taken orally and which have a long duration of action rather than to use a preparation that has to be taken intravenously or that must be smoked/sniffed and which in addition has a shorter duration of action. The grounds for use of both injectable heroin and injectable methadone as substitution preparations, therefore, are not only medical but have to do with harm reduction in a social and a criminal perspective.

Treatment with injectable heroin is more expensive not primarily because the preparation in itself is more expensive but because the necessary control measures require more staff resources. The short duration of effect requires several patient visits per day and requires that the institution that administers treatment has longer opening hours. Therefore substitution treatment with heroin will always be the treatment of second choice which will only be used in the cases where treatment with oral methadone or injectable methadone has proved hopeless.

Because of the longer duration of the effect of methadone, treatment with injectable methadone is easier to organise than treatment with injectable heroin and need only be given once a day whereas injectable heroin must be given at least twice per day. Treatment with injectable methadone is cheaper, partly because the preparation is cheaper and partly because administration is less resource demanding. Moreover there are no complications involved in changing between injectable methadone and orally administered methadone. Injectable methadone may lead to tissue irritation and may damage the veins used. Maybe for this reason treatment with injectable methadone is not considered attractive by intravenous heroin abusers. Heroin causes very little tissue irritation and is more suitable for intravenous administration than methadone.

The risk of unintended events (overdoses etc.) is more significant in connection with heroin treatment than with methadone treatment. It should be noted, though, that neither in Switzerland, Holland nor Germany have there been any fatal events in connection with supervised administration of heroin, but in all trials there have been cases of overdoses.

Both forms of treatment can only be provided by specially trained health care staff in a specially intensive treatment environment that will be able to provide treatment of acute life threatening conditions arisen in connection with the administration of medicine.

An argument against heroin prescription used on former occasions – by among others the majority of the members of a group of experts who rejected this treatment option in 2002 – is that over time it is to be expected that it will be difficult to maintain the delimitation of the group that is to be offered heroin treatment. In the view of the National Board of Health to what extent will it be possible to delimit the group in question and then maintain this delimitation?

In 2002 the majority of the members of the expert group found that over time great difficulties were to be expected concerning maintaining the delimitation of the group and thus the number of drug users that are to be offered prescription of heroin.

Heroin treatment is to be reserved for individuals who do not benefit from the treatment of first choice in the form of treatment with buprenorphine or oral methadone. Treatment with injectable heroin thus is to be reserved for individuals who in spite of long term substitution treatment with buprenorphine or methadone and psychosocial support continue to have intravenous use of prescribed or illegal opioids and who suffer from or are threatened by serious health or social complications for this reason.

Against the background of the most recent experiences from Switzerland and our own experiences with injectable methadone, the National Board of Health considers that it is possible to establish an arbitrary delimitation of the relevant group. The prescription of injectable heroin for drug users is to be restricted to a special group of doctors.

The National Board of Health cannot assess in advance whether it will be problematic to maintain this delimitation, but monitoring of treatment corresponding to the monitoring of treatment with injectable methadone will answer this question and at the same time make it possible to adjust treatment services.

An argument against heroin prescription used on former occasions – by among others the majority of the members of a group of experts who rejected this treatment option in 2002 – is that the introduction of heroin prescription will contribute to a confusion of messages communicated in connection with initiatives to prevent drug abuse not least in relation to young people. Does the National Board of Health consider that the introduction of this treatment option will involve a risk of such confusion?

This does not seem probable. Against the background of experiences from Switzerland there has been a registration and calculation of the prevalence and the rate of incidence of heroin abuse. The rate of incidence peaked in 1990 and has since dropped markedly.

In the view of the National Board of Health, may heroin prescription be expected to reduce the number of drug related deaths in Denmark and, if so, how much? Could there be a risk of deaths caused by the consumption of medically prescribed heroin?

In the view of the National Board of Health an immediate reduction of the number of drug related deaths in Denmark is not to be expected. Both the Dutch and the German trials showed the same mortality in the group receiving heroin treatment and in the control group. It may be mentioned, however, that if an offer of heroin treatment can attract and retain individuals who either have not benefited from treatment received so far or who are not at the moment receiving treatment, mortality in this target group may be reduced. The effect on overall mortality will, however, be marginal. Against the background of these trials and the Swiss experiences there is no reason to expect deaths in connection with the consumption of heroin, but as already mentioned there is an increased frequency of unintended events.

What is the estimated yearly gross cost of heroin treatment of a drug abuser?

The Dutch quote a cost per patient per year of € 16,000 and the Germans have calculated a cost of € 18,000. These costs pertain to trial circumstances, but depending on how treatment is organised a yearly cost of DKK 100,000 to 150,000 per year per patient is to be expected.

In the view of the National Board of Health, does the overall yearly gross expenditure bear comparison with the expected outcome of treatment – seen in isolation and seen in relation to the possible use of similar resources in the area of drug abuse, e.g. with a view to extending the degree of treatment coverage, improvement of treatment with the usual substitution substances (methadone and buprenorphine) and strengthening of the psychosocial care which is to accompany substitution treatment?

In the view of the National Board of Health it is difficult to transfer the above mentioned results to a Danish environment. The National Board of Health cannot determine whether the added cost of launching treatment with injectable heroin bears comparison with expected treatment results. Thus it will be a political decision whether treatment with injectable heroin as a supplement to existing substitution treatment with buprenorphine and methadone is to be introduced in Denmark.

The conclusion reached in a cost-utility analysis of the Dutch heroin trials is that methadone plus heroin is less costly to society than traditional methadone treatment. Treatment with heroin was linked to somewhat increased quality of life (assessed through Quality Adjusted Life Years per patient per year) compared to methadone treatment. The higher treatment costs were more than compensated for through reduced costs of prosecution and reduced crime related costs. Net gain from treatment was € 12,793 per year per patient. In the German trial the effect is smaller, but in the second intermediate report on the trial it is stated that both types of treatment (i.e. methadone plus heroin and methadone alone) is cost-effective because of increased quality of life (assessed through Quality Adjusted Life Years per patient per year). The cost of heroin treatment was € 18,000 per patient per year and € 6,100 for methadone treatment. In the group receiving heroin savings were found in the field of crime related costs of € 6,000 whereas in the group receiving methadone there were increased costs of € 2,300. Thus heroin treatment was somewhat more expensive than methadone treatment, but on the other hand it was more effective – greater effect on health, greater reduction of illegal abuse.

Is there a need to launch a Danish clinically controlled trial of treatment with injectable heroin or would it be possible, against the background of international experience, to launch treatment with injectable heroin in accordance with the guidelines for treatment with injectable methadone?

In the view of the National Board of Health there is no need to launch a controlled trial of treatment with injectable heroin, partly because considerable trials have already been carried out in a European environment and partly because injectable heroin is a well-known substance. Implementation of treatment with injectable heroin as a treatment of second choice in Denmark should comply with a protocol involving the possibility of overall monitoring and adjustment of treatment activity.