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Long term substitution treatment (maintenance treatment) of opioid dependent persons

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Introduction

Health Political Background

Methadone substitution treatment in Germany is introduced in 1988 in the framework of a scientific pilot study in North Rhine Westphalia. In 1992 a legal basis for substitution treatment of opioid dependent patients with an additional severe psychiatric or somatic co-morbidity is built within the adaptation of the “Betäubungsmittelgesetz”. In 2002 the “guidelines for substitution assisted treatment of opioid dependents” of the General Medical Council from 2002 widen the indication of substitution treatment significantly. These guidelines also state, that substitution treatment has to be provided as a comprehensive therapeutic approach which includes besides an exhaustive medical anamnesis also psychosocial measures as well as a constant evaluation of process and results of the treatment.
Recent statistics show that by now a broad offer of substitution treatment exists. From 1 June 2002 to 31 December 2003 113000 substitution treatments have been recorded as being started of which around 56000 have been recorded as ongoing treatments by 1 December 2003. 70 % of these records concern methadone followed by levomethadone (16.1 %), buprenorphine (12.3 %), dihydrocodeine (1.4 %) and codeine (0.2 %). According to the regional Medical Councils around 8000 medical doctors in Germany have acquired the mandatory qualifications in addiction treatment and, thus, are allowed to carry out substitution treatment. Around 2300 of these medical doctors are treating substitution treatment clients in December 2003.
A new development and the subject of a great deal of controversy is the establishment of heroine assisted treatment. In 2002 in Germany a model project started which investigates the effectiveness of heroin assisted treatment in relation to methadone substitution treatment.

Scientific Background

ICD 10 describes dependence on substances as a cluster of behavioural, cognitive, and physiological phenomena that develop after repeated substance use. Typically there exists a strong desire to take the drug, difficulties in controlling its use, persistence in its use despite harmful consequences, a higher priority given to drug use than to other activities and obligations, increased tolerance, and sometimes a physical withdrawal state. The development and maintenance of dependence is based on a very complex process, which includes physiological, cognitive-emotional and social aspects. The cause of dependence can be described as a combination of biological, psychological and social factors taking into account specific characteristics of the drugs, of the individual and of the social environment. The development of dependence is never caused by one factor exclusively but by a multi-factorial complex of contributing factors. Recent theories state that addiction specific learning as well as addiction-related systems like the mesolymbic system plays an important role. Longer term consumption of heroine leads to medical and social complications. Intravenous drug use

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can result in the transmission of infectious diseases (mainly hepatitis B and C and HIV) and embolism in case of bad solution of heroine. The compulsion to get heroine can result in social problems, because purchasing of heroine is illegal and often criminal acts are necessary to finance heroine use.
There are several estimates of the number of problematic opiate users in Germany. Based on treatment data, police data and drug related death data of 2003 the number of problematic opiate users is estimated to be between 92000 and 182000 which means 1.7 to 3.4 persons per 1000 inhabitants in the age range 15 to 64 years.
Substitution treatment (treatment of opioid-dependent persons using substitution substances) is one part of addiction treatment. Its goals are harm reduction and the stabilisation of opioid dependent persons. Integration of opioid-dependent persons in a treatment-setting, reduction of consumption of psychoactive substances, reduction of risk behaviour (primarily related to infectious diseases), decrease of mortality and improvements concerning the social, psychic and physic situation are seen as a success of substitution treatment as maintenance therapy.

Research Questions

This HTA report focuses primarily on the following four research questions:

1. Which evidence based indicators to evaluate the medical effectiveness and benefit of long term substitution treatment (maintenance therapy) with methadone, levomethadone, buprenorphine, and diacetylmorphine (heroine) do exist?
2. Which medical effectiveness and benefit does long term substitution treatment (maintenance therapy) have?
3. Which effectiveness does long term substitution treatment (maintenance therapy) in relation to abstinence oriented treatment have?
4. Which cost-benefit relation does long term substitution treatment (maintenance therapy) have?

Results and Discussion

Studies concerning the effectiveness of long term substitution (for this study long term substitution is defined as duration of substitution of at least one year) are mainly comparative studies between different forms of treatment and longitudinal studies under natural conditions. The evaluation of the results of these kinds of studies is hampered by selection bias and bias due to dropout.
Despite these serious restrictions in most studies focusing on substitution treatment the reduction of consumption of illegal opioids, reduction of risk behaviour and of criminal behaviour can be seen as an empirically proven medical / social success of substitution treatment. The significant reduction of mortality is the most valid indicator for success of substitution treatment. Concerning the improvement of life and health situation the results of the studies are contradictory. Only the reduction of the incidence of HIV can be seen as proven.
The comparison between abstinence oriented treatment and substitution treatment is very problematic. Since the studies show that both kind of treatment have their achievements but also their failures it would make much more sense to ask which kinds of treatment for which kind of opioid dependent persons during which stage of the addiction career is more promising. The retention rate is one indicator that is relevant concerning this aspect. The results show that the retention rate of substitution treatment is

higher than the retention rate of abstinence oriented treatment. One conclusion from this fact could be that substitution treatment is more promising than abstinence oriented treatment for clients with serious drug problems in a first phase. For the validation of this conclusion further studies are needed which do not see abstinence oriented treatment and substitution treatment as competitors but as complementary, looking into differentiated effectiveness for different sub-groups of clients.
Concerning economic evaluation of substitution treatment the results are very inhomogeneous, since different parameters for effects and costs are used and different alternatives are compared. Cost-Effectiveness should be investigated taking into account all important factors of cost reduction. There is a need for studies that include the individual health benefit as well as potentials for cost reduction on the level of society. Regarding economical aspects substitution treatment is efficient in avoiding secondary illnesses (infections) and decreasing criminality.
From the perspective of medical ethics substitution treatment as well as medical prescription of heroin are in principle acceptable. The appropriateness and the ethical tenability should be evaluated on the basis of established medical ethic principles - like the interest of the patient – taking into account the specific situation of the client.

Conclusions / Recommendations

Despite serious methodological restrictions the medical / social success of substitution treatment can be seen as empirically proven on the basis of the studies available. Also from economical and ethical perspective substitution treatment can be seen as an acceptable and reasonable method of treatment. Based on these results it can be recommended that substitution treatment should be available in principle for all opioid dependent persons. The decision whether substitution treatment or another treatment (e. g. abstinence oriented treatment) is more promising has to take into account the individual situation of the client. Unfortunately just a few studies focusing on possibilities to combine substitution treatment with abstinence oriented approaches (seeing them as complementary) exist, which could provide an empirical basis for this decision. Some results deliver arguments that substitution treatment is more promising than abstinence oriented treatment for clients with serious drug problems in a first phase. For the validation of this conclusion further studies are needed which do not see abstinence oriented treatment and substitution treatment as competitors but as complementary, looking into differentiated effectiveness for different sub-groups of clients. This approach would be in line with the opinion of many experts who claim that substitution treatment and abstinence-oriented treatment should be integrated and complementary parts of the treatment process in addiction treatment.

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