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Substitution Therapy. A New Problem of Biomedical Ethics and Medical Law

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Summary

Substitution maintenance therapy can be judged from different perspectives focused on its medical, legal, social, economic and ethical aspects. A subject that attracts special attention is the ethical side of substitution therapy. In the opinion of the opponents of substitution maintenance therapy, there are several key ethical problems that make this therapy immoral. From our point of view, it is unethical to refuse a patient this kind of help (substitution therapy). Substitution therapy for opioid dependence should be seen as the most ethical and humane of all methods. The absence of substitution therapy in the Russian Federation puts Russian patients in an awkward position.

Key Words: Substitution Therapy; biomedical ethics; medical law.

Every year a wide range of new medical problems become the object of ethical evaluation. The reasons for this are: the invention of fundamentally new research methods, therapies and technologies, as well as ongoing changes in social morality. Still, the problems of transplantology, genetics, reproduction, cloning and manipulation with stem cells, moral problems connected with "The End of Life" (old people's homes and death by lethal injection), abortion, ethical aspects of psychiatry and of providing help to people living with HIV/AIDS remain pressing questions for biomedical ethics [7, 26].

In the context of biomedical and legal problems within the field of psychiatry, the main topics are: confidentiality, the stigmatization and decriminalization of patients, and the provision of patients' rights. Narcology, which has come close to being an essential part of psychiatry, has never – unlike psychiatry – been given serious consideration from the viewpoint of biomedical ethics, up to and including the present time. This may be because it has been linked with the status of people having problems with alcohol and drugs, who were not treated as real patients. For example, for many experts a drug-addicted person was not on the same level as a person with schizophrenia. As a result, critical ethical and legal problems of narcology in the context of biomedical ethics were avoided and were not taken into account. (This is especially true of Russian narcology.) There were attempts to ignore operating standards in the ethics of psychiatry and lawful criteria in the sphere of narcology.

As a result, in Russian narcology there were (and continue to be) repressive non-medical strategies practised in the sphere of providing help to patients, which are hard to compare with anything that can be found in psychiatric strategies. The most striking example of that is the mandatory therapy for drug- and alcohol-addicted people in the conditions applied in administering treatment in labour camps; this has been practised for years and still receives wide support. In fact, patients were sent there not to receive treatment, but "for correction and for deliverance from a bad habit, and from a parasitic and immoral way of life". Officials responsible for Russian narcology, as well as narcology experts, put forward the idea that "drug-addicted people should not receive relief from the withdrawal syndrome, because that might decrease their social dangerousness". In this way the tactic of "torture for edification" was confessed. It was suggested that drug addiction should be viewed as a mental disorder of psychotic type, which would make it possible to hospitalize

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a narcological patient against his/her own will, according to the 29th article of the Law of the Russian Federation "About Psychiatric Help..." [29].

Being under the pressure of society and remedial organizations that cancelled the practice of mandatory treatment more than ten years ago, the area covered by ethical problems in the field of modern Russian narcology has been greatly enlarged after the problem of opioid addiction appeared. There are several critical problems involving biomedical ethics and medical law in this sphere now:

1) The problem of implementing the principle of "informed consent";
2) The existence of the principle of "straight away refusal of psychoactive substance (PAS) usage" as the condition for giving a patient the right to enter treatment and rehabilitation programmes (as well as the problem of providing ARV treatment to HIV IDUs);
3) The existence of the principle of "paying for anonymity" in administering therapy for narcological diseases;
4) The problems that arise from using scientifically unjustified methods (for example, stereotoxic operations on a brain [33], "birch therapy" [31], methods based on forming a mythological mode of thinking and instilling irrational fear (for example, with the help of what is known as 'coding');
5) Neomoralistic approaches;
6) Bans on the use of substitution maintenance therapy [13, 22]. This is last of the problems we have listed here, but it is actually present in all of them, so it is worth making the effort to analyse all these ethical problems in Russian narcology.

The problem of the principle of "informed consent" is that a patient who continues to be addicted to alcohol or drugs during treatment does not get all the information that he/she urgently needs to be able to take deliberate decisions about the choice of the therapy, or can only get this information in a strained way. First of all, this relates to the practice of 'coding', when 'informed consent' is based on providing a patient with false information about the essential mechanisms that come into play in applying this method. A patient is told that "a substance that blocks opioid receptors will be given", or "the activity of the brain will be changed, and that will lead to a lowering of the craving for a substance", or that "a coding of a dosage" will be performed, or "a subconscious form of an illness will be demolished". In cases like these, 'informed consent' is implemented when a patient signs a document where it is stated that the person who is signing agrees that in the case of a voluntary breach of a treatment regimen, when a dose of alcohol (or a drug) is taken, the person's health could be damaged, or a lethal outcome might be caused. Scientists ground this method on its psychotherapeutic effect – the new attitudes a patient forms because of his/her fear of taking a psychoactive substance. In reality, that patient's health is in no danger, while the practical result is that an expert knowingly misleads a patient. According to ethical principles, and because of its unscientific character, this method is prohibited by the World Narcological Community [18].

One of the basic principles regulating Russian narcology is the principle of "straight away refusal of psychoactive substance (PAS) usage" . As a matter of fact, a person's wish to fulfill this condition determines the amount of help that a person can get from official medicine, and is a crucial factor in deciding whether a patient will be able to get into a hospital or be included in rehabilitation programmes. This condition is an independent refusal by the patient, before treatment is prescribed, to take psychoactive substances. However, the ethical question arises of whether a person can be expected to get rid of a pathological craving for psychoactive substances before treatment starts. It can be supposed that the existence of such a condition is based on the position of narcology experts who see a PAS-craving symptom as a " bad habit" or "moral defect", which could be got rid of by simply by making an effort of the will. Could this, perhaps, turn out to be a way that is used by these doctors to exclude "unpromising patients" from the therapy if they have no motivation or only a weak motivation for entering treatment? A paradox arises here: if someone could independently get rid of a pathological craving for psychoactive substances, what role could a doctor play? No other medical profession makes such severe demands on its patients. For example, if the demand was made on a person with schizophrenia to get rid of a state of delirium "through his/her own will-power" before hospitalization, that would be considered a bad joke, at best.

Russian narcology demands a patient's "straight away refusal of psychoactive substance (PAS) usage" without taking into account the existence of another principle – the step-by-step lowering of the dose and graduated admission to a remission schedule. This conspicuous lack of understanding may have as its most immediate effect a patient's refusal to admit traditional narcological help or his/her independent decision to regulate these questions by gradually reducing the dose of a drug or looking for a drug substitute. In the case of opioid addiction, the role of a substitute is very often played by alcohol or illegal 'street' drugs, which are less addictive. It can be said that the principle of "straight away refusal of psychoactive substance (PAS) usage" contradicts ethical rules, which require a doctor "to help all patients without making any distinctions between them".

HIV-positive active IDUs face the same problem. These people are not allowed ARV therapy because they break hospital rules (by continuing to take PAS). This leads to the outcome that the number of patients who are able to get ARV therapy on the basis of the principle of refusal is very low. In addition, this practice lowers

patients' compliance with HIV therapy and boosts the spread of the HIV epidemic.

Another ethical problem that arises in Russian narcology is the problem of "paying for anonymity". According to the existing rules, a person addicted to alcohol or drugs who would like to receive treatment anonymously, without any narcological registration, has to pay for the therapy. The same therapy could, after all, be provided to that person for free in the case of a refusal of anonymity. So, the question of biomedical ethics is how the anonymity of therapy can be correlated with payment for that therapy.

Undoubtedly, beyond the limits of bioethical norms and medical rights, it must be recognized that, currently, narcological treatment sometimes takes the form of inflicting physical pain (activating a pain syndrome) on a patient. In any case, the "birching therapy" proposed by scientists from Novosibirsk working at the Research Institute of Hygiene and the Research Institute for Therapy (Russian Academy of Medical Science) is based on these principles. It includes "series of birchings on the buttocks, from 5 to 60 birchings during one treatment session" [31]. The authors of the method say that "this progressive method" leads to the "activation of endorphin receptors as the result of the sensation of pain and leads to a rise in the production of endorphins after the birching".

One of the most critical and controversial ethical problems is the issue of the ban on substitution maintenance therapy in the Federation. Substitution therapy consists of the prescription to patients with opioid dependence of fixed doses of medications that are opioid agonists (analogues of drugs from the same pharmacological group). These prescriptions should be made out in the hospital under medical control and should be based on a patient's mental condition. The goals of such a treatment are: normalization of the mental (narcological) condition of a patient; the blocking of a pathological craving for drugs, on the basis of aetiology and pathogenetics; lowering the likelihood of overdosing and lethal outcome; reducing the chances of taking illegal 'street drugs' or absolutely stopping the taking of illegal drugs; lowering the criminal activity of a patient, connected with his/her need to get money to buy drugs; preventing the spread of HIV by increasing compliance with therapy [17, 19-21]. The factors that regulate the choice of patients who can join substitution therapy programmes are: repeated lack of success in applying opioid treatment, concomitant pathology (first of all, HIV-infection), age over 18-21, apart from the requirement of voluntary and informed consent. The most often used medicines in substitution therapy are buprenorphine and methadone.

Substitution maintenance therapy can be judged from different perspectives focused on its medical, legal, social, economic and ethical aspects. The foundation for the medical aspect is the scientific basis of this approach, as has been stated in many scientific studies [2, 4-6, 11, 12, 14, 23, 24, 28, 32]. The legal aspect of the therapy has several problems: the regulation of substitution therapy procedures, the correspondence of norms which, on one hand, regulate the circulation of drugs, and, on the other, regulate treatment provision. In Russia the problem of incongruence of legislation led to confrontation within the Russian Narcological Society and the Federal Drug Control Service. The social aspect of the invention and the existence of substitute therapy is based on the concept of safety/risks for society, as well as on the concept of its benefits/advisability. The social aspect may be linked with the economic aspect, which views this therapy as profitable, once the costs of participating in the programme are compared with the costs of participating in traditional treatment measures (in a permanent establishment, in a hospital, or in a rehabilitation centre), as well as the costs of keeping someone in prison, considering the criminal behaviour often connected with taking drugs. [3, 10].

A subject that attracts special attention is the ethical side of substitution therapy. This subject is often the main factor that accounts for the existence of a ban on this method. It is the argument that is used most often by its opponents (according to social research, 20% of the respondents and 25% of the narcologists interviewed protest against substitution therapy on the grounds that it is "immoral") [7, 13, 15, 22]. The essence of the problem is what should be considered ethical and what should be considered immoral. In the opinion of the opponents of substitution maintenance therapy [7], there are several key ethical problems that make this therapy immoral. Firstly, this requires an ethical evaluation of the "refusal of drug addiction treatment, because the addiction continues". Secondly, there is another ethical question: "Is it correct to offer a person a drug that is new to him/her, which might induce that person to refuse other drugs and so become less dangerous to society?" Thirdly, its opponents say that "The ideology of harm reduction programmes (including substitution therapy) take up "a more respectful attitude to drug users than that adopted by any other medical approach".

It should be mentioned that many arguments against substitution therapy are based on an incorrect idea about the method's essence. Thus, the treatment of drug addiction with a view to making a person completely stop taking drugs, while his/her health undergoes a definitive improvement, is not the main aim of substitution therapy. People who support substitution therapy see the idea of a complete refusal to take PAS, for most patients with opioid addiction, as being impossible to achieve (as has been proved by many studies, and in line with common sense). Opioid addiction is proclaimed to be a chronic disease, so the goal is to help patients stop taking all PAS, or at least, to reduce the frequency and the amount of taking PAS, or to refuse the intravenous usage of PAS. So, there is an attempt to attain two goals – a minimum one and a maximum one. If the latter goal is impossible to achieve, then an attempt can still be made to achieve the former. Therefore, the argument that describes the

substitution therapy usage as unethical (entailing a refusal to allow drug addiction treatment, on the grounds that the disease will continue) is unfounded, because substitution therapy does not imply a total or definitive refusal of any other form of drug. It can be related to the group of palliative therapies. In some cases, what a patient is offered is a way forward to a step-by-step (rather than an immediate) refusal of opioids; that means providing 'treatment' in the authentic sense of the term. From our point of view, it is unethical to refuse a patient this kind of help (substitution therapy). According to one definition [7], a common demand made by biomedical ethics is that all patients should be helped without making any differences between them; the principle of imposing a refusal of PAS usage, as required in Russian Narcology, is, in fact, almost impossible to apply, because the nature of the illness itself is incompatible with that principle. A patient who is given no chance to enter a substitution therapy programme, because doctors cannot provide it, is, in practice, deprived of the opportunity to receive any kind of treatment (apart from a regime prescribed to block the withdrawal syndrome, so as to improve the "quality of life"). It seems paradoxical that opponents of the substitution therapy say that it is unethical because "patients who enter substitution therapy programmes continue, in fact, to have dependence problems, and the doctor who treats them does not give them any other treatment, which he could give when he treats drug addiction". To agree with such a position means to blame all palliative therapy and to say that it should be evaluated from the ethical point of view. (It might be better to say "unethical"!).

It is also a doubtful argument to say that substitution therapy is unethical only because it is incorrect "to offer a person a drug that is new to him/her, which might induce that person to refuse other drugs and so become less dangerous to society". The substitution of a drug whose use belonged to a criminal setting with a legal medicine (even if this medicine contains a PAS), is only one of the many goals of the therapy. There are also humane goals, such as those of improving a patient's "quality of life", and reducing the risk of overdosing, suicidal behaviour and lethal outcomes; these are, in fact, the most important points, and they should be taken into account by a doctor who prescribes a substitution therapy. These goals cannot be judged as immoral from the viewpoint of biomedical ethics.

It would be astonishing to conclude that the substitution therapy approach is unethical, because of the adoption of "a more respectful attitude to drug users than that adopted by any other medical approach".

A major question arises here: who could possibly consider a surplus of medical humanism (if that is possible in general) to be immoral? Moreover, it is not at all clear, either, why doctors applying other methodologies do not respect their patients so much (I am referring to the view taken by opponents of substitution therapy). Could it be that the problem lies not only in the attitude to patients who have narcological (dependence) problems, which could be considered to be the standard (if one listens to these opponents), but also in traditional attitudes to patients in all the various spheres of medicine?

It is known that more than one million patients currently participate in substitution maintenance therapy programmes in all parts of the world. The number of such patients has grown from 73,400 in 1993 to 450,000 in 2004 in the European Union [8, 9, 25, 27, 30]. So, over a period of 11 years, access to the programmes has grown more than 6 times. The models available for substitution maintenance therapy evolve in the course of time. One of the reasons for the spread of buprenorphine programmes in world narcology is not disappointment over methadone projects, but an attempt to escape the need to 'bind' a patient to the hospital, and to make everyday visits to a doctor unnecessary [14]. Another modern trend is that of widening a circle of specialists who are able to prescribe medicines for substitution maintenance therapy. This trend means attracting the doctors of general practice to this problem.

The countries that have been actively introducing these methods in the last few years are China and Iran. The growth in the numbers of patients receiving substitution maintenance therapy ranges between 500% and 1000%, according to the official data of the Health Departments of these countries, who initiated their programmes in 2003. According to the same data it is predicted that the increase in numbers of patients by 2008 will be 350,000 in China and 150,000 in Iran [1].

In most countries located within the former Soviet Union (Lithuania, Latvia, Estonia, Ukraine, Kyrgyzstan, Moldova and Azerbaijan) the number of patients who get an opportunity to receive substitution maintenance therapy is growing. In other countries within the former Soviet Union (Belarus, Georgia, Armenia, Uzbekistan), there is a legal basis for the implementation of such programmes. Pilot projects are now under way in these countries to determine the place and role of substitution maintenance therapy in the narcological treatment system.

Because of the alarming trend for HIV/AIDS to spread, WHO, together with UNODC and UNAIDS, has formulated the official report after a series of researches and analyses on the effectiveness of substitution therapy based on randomized experiments in 2003. In this report substitution maintenance therapy is called one of the most effective ways of treating drug dependence and preventing HIV/AIDS. Methadone and buprenorphine were included in the WHO's "List of Basic Medicines", which includes "medicines that are needed to provide minimal health care standards in all the countries..." and that should be made "available every time, in adequate amounts and at an adequate price, which society itself can support" in 2005.

As is known, substitution therapy is prohibited in the Russian Federation ("it is prohibited to treat drug dependence with PASs included in list II") and, for that

reason, it is not applied. By contrast, in most countries of the former Soviet Union there is a legislative basis that gives the opportunity to use substitution therapy. These laws appeared after the fall of the Soviet Union, in response to the need to overcome high levels of drug addiction, the low effectiveness of traditional treatment methods, and the widespread presence of HIV/AIDS among IDU's.

Substitution maintenance therapy programmes are included in the system of narcological help provided to people with opioid dependence as an additional measure. These programmes did not lead to the closing of any other programmes in any of these countries. Still, discussions continue on the topics: 'How often should they be used?; 'For how long can a patient participate in these programmes?'; 'What doses should be made available?'. Discussions about the ethical side of substitution therapy ended long ago.

The absence of substitution therapy in the Russian Federation puts Russian patients in an awkward position. They cannot receive all the help they would receive if they were in any other country. It should be also considered as unethical that the dominant rule of the "straight away refusal of psychoactive substance (PAS) usage" discriminates 70% of patients who cannot receive any form of professional, scientifically based help (such as substitution therapy).

Substitution therapy for opioid dependence should be seen as the most ethical and humane of all methods. The current ban on this kind of therapy should be seen as a violation of the norms of biomedical ethics and medical law.

Therefore, in evaluating the substitution supporting therapy as a question intrinsic to narcology while respecting the rules and basic principles of biomedical ethics: independence, justice, the principle "do not hurt", it can be concluded that, from the viewpoint of biomedical ethics, the analysis and evaluation of real narcological theory and practice should not be avoided. In this connection, it should be noted that, while narcology is part of psychiatry, it does, in fact, promotes other principles and ethical rules that are based on ambivalent attitudes to a narcological patient (i.e., one with alcohol or drug dependence). And this attitude differs from the attitude taken towards a patient with schizophrenia, neurosis, or mental backwardness. All the points mentioned here make it clear how important it is to activate the discussion in the medical sphere and so get to the point of working out new norms of biomedical ethics and medical law in response to the peculiarities of the current situation in narcology.

The existence of "special ethical conditions" in Russian narcology and the existence of special attitudes to drug-addicted people can be explained because of the appearance of the "neomoralistic" approach (to quote a term proposed by Meilachs [16]) that is specific to the 'post-perestroika' period in the Russian Federation. Many authors characterize the situation in the sphere of attitudes to drug-users (including patients) as a state of moral panic that has led to the appearance of neomoralism. As P. Meilachs says, the central moral dividing line in neomoralism was the dividing line that regulated relations in the public sphere. So this dividing line determines "what is permitted in a public sphere and what is not. The main strategy of neomoralists is to protect this public sphere".

In conclusion, it can be said that the special attitude of the medical community to the problems of narcology (especially drug addiction) is caused by the official strategy of enforcing what are thought to be 'civilized standards', while suppressing the strategy of biomedical ethics based on concepts of humanism, justice and the welfare of patients. This should become a subject of discussion and analysis among medical professionals.

References

1. AHMADI J. (2002): Buprenorphine Maintenance Treatment for Iranian patients with opioid dependency. *Addict Disord Their Treat*. 1 25-27.
2. BALL J. A., ROSS A. (1991): The effectiveness of methadone maintenance treatment. Springer-Verlag, New York, N.Y.
3. BARNETT P. G., HUI S. S. (2000): The cost-effectiveness of methadone maintenance. *Mt Sinai J Med*. 67:(5-6) 365-374.
4. BYRNE A., NEWMAN R. (1999): Methadone - myths and mystery. *Heroin Crisis*. Bookman Press, Melbourne. pp. 141-150.
5. DALE A., JONES S. S. (1992): The Methadone Experience: The Consumer View. The Centre for Research, London.
6. DOLE V. P., NYSWANDER M. A. (1965): Medical treatment for diacetylmorphine (heroin) addiction. *JAMA*. 193:(8) 646-650.
7. ELSHANSKI S. (2003): Ethical and psychological problems of programs of harm reduction. *J Narcology*. 2 36-51.
8. EMCDDA (2002): Annual report on the state of the drugs problem in the European Union and Norway. http://www.annualreport.emcdda.eu.int.
9. EMCDDA (2003): Legal aspects of substitution treatment. An insight into nine EU countries. http://www.emcdda.europa.eu/publications.
10. ERICKSON P. J. (2001): Drugs, violence and public health: What does the harm reduction approach have to offer. Fraser Institute, Vancouver.
11. GIBSON D. R., FLYNN N. M., MCCARTHY J. J. (1999): Effectiveness of methadone treatment in reducing HIV risk behaviour and HIV seroconversion among injecting drug users. *AIDS*. 13 1807-1818.
12. GUNNE L. M., GRONBADH L. (1981): The Swedish methadone maintenance program: a controlled study. *Drug Alcohol Dep*. 7 249-256.

13. KRASNOV V. N., IVANETS N. N., DMITRIEVA T. B., KONONETS A. S., TIGANOV A. S. (2005): Memorandum "Say no to methadone programs in Russia" (Use of methadone cannot be considered treatment). *Medical Newspaper*. March.
14. LOWENSTEIN W., GOURARIER L., COPPEL A., LEBEAU S., HEFEZ S. (1995): La methadone et les produits de substitution. Suivi du toxicomane par le medicine generaliste. Doin, Paris.
15. LUKIANOV V. Effectiveness of harm reduction. http://www.narkotiki.ru/ecolumn_5346.html.
16. MEILAKHS P. (2003): Danger of moral panic on drugs. *Credo-News*. 1 20-27.
17. MENDELEVICH V. (2003) Substitution treatment as a base for treating resistant drug addiction. Paper presented at the International Conference, Kazan.
18. MENDELEVICH V. (2004): Paradox of principal of Russian narcology. *Russian Psychiatric Journal*. 6 24-29.
19. MENDELEVICH V. (2004) Substitution therapy and legalization of drugs: misunderstanding. Paper presented at the International Conference, Kazan.
20. MENDELEVICH V. (2005): Medical and public arguments in discussion on substitution treatment. *Narcology*. 3 68-72.
21. MENDELEVICH V., MENDELEVICH B. (2004) Substitution treatment. Paper presented at the International Conference, Kazan.
22. NADEZHDIN A. (2001): About "substitution treatment". *J Narcology*. 5 66-71.
23. NEWMAN R. G. (1994): What's so special about methadone maintenance? *Drug Alcohol Rev*. 10 225-232.
24. NEWMAN R. G., WHITEHILL W. B. (1979): Double-blind comparison of methadone and placebo maintenance treatments of narcotic addicts in Hong Kong. *Lancet*. 2:(8141) 485-488.
25. OKRUHLICA L., TIMULAKOVA K., MIHALEKOVA A., KLEMPOVA D. (2000): Methadone Maintenance Treatment in Slovakia. *Euro-Methwork*. 18 11-12.
26. PELIPAS V. (1998): Ethical problems of practical narcology. *J Narcology*. 1 75-94.
27. PROCHASKA J. O., DICLEMENTE C. C., NORCROSS J. C. (1992): In search of how people change. Applications to addictive behaviours. *Am J Psychol*. 47:(9) 1102-1114.
28. RENNER J. A. J. (1984): Methadone maintenance: past, present and future. *Adv Alcohol Subst Abuse*. 3:(75-90).
29. RUSSIAN GOUVERNEMENT (1993): Federal Law on Psychiatric care. 238.
30. SOLBERG U., BURKHART G., NILSON M. (2002): An overview of oiate substitution treatment in the European Union and Norway. *Int J Drug Policy*. 13 477-484.
31. SPERANSKI S., CHUKHROVA M. (2004). Paper presented at the International Conference, Kazan.
32. WARD J., HALL W., MATTICK R. P. (1999): Role of maintenance treatment in opioid dependence. *Lancet*. 353 221-226.
33. ZAVIALOVA N. (2000) Clinical peculiarity of neurostereotaxic operation on drug addicts. Paper presented at the Conference of Russian Psychiatric Association, Moscow.

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