EVALUATION OF METHADONE MAINTENANCE THERAPY IN THE REPUBLIC OF MOLDOVA

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# Content

Acronyms  
Acknowledgments  
Executive Summary  
1. Background and objectives  
2. Methodology  
3. Challenges and limitations  
4. HIV situation in the Republic of Moldova  
5. Legal context of the implementation OST in the Republic of Moldova  
6. Status of methadone maintenance therapy in health care institutions  
7. Status of methadone maintenance therapy in Penitentiary Institutions of the Penitentiary Department of the Ministry of Justice  
8. Obstacles for the expansion of methadone maintenance therapy  
9. Monitoring and evaluation  
10. Recommendations for the development of MMT in the Republic of Moldova  
References  
Annex 1.
### Acronyms

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Description</th>
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<tbody>
<tr>
<td>AIDS</td>
<td>Acquired Immunodeficiency Syndrome</td>
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<tr>
<td>ARV</td>
<td>Antiretroviral (drug/therapy)</td>
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<td>CMCC</td>
<td>Country Multisectoral Coordination Committee</td>
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<td>CIS</td>
<td>Commonwealth of Independent States</td>
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<tr>
<td>EMCDDA</td>
<td>European Monitoring Centre for Drugs and Drug Addiction</td>
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<td>EU</td>
<td>European Union</td>
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<tr>
<td>FGD</td>
<td>Focus Group Discussion</td>
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<td>GFATM</td>
<td>Global Fund to Fight AIDS, Tuberculosis and Malaria</td>
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<tr>
<td>HBV</td>
<td>Hepatitis B Virus</td>
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<tr>
<td>HCV</td>
<td>Hepatitis C Virus</td>
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<tr>
<td>HIV</td>
<td>Human Immunodeficiency Virus</td>
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<tr>
<td>IDU</td>
<td>Injecting Drug Use / User</td>
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<tr>
<td>INGO</td>
<td>International Non-governmental Organization</td>
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<td>MMT</td>
<td>Methadone Maintenance Treatment</td>
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<tr>
<td>M&amp;E</td>
<td>Monitoring and Evaluation</td>
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<tr>
<td>NGO</td>
<td>Non-governmental organization</td>
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<tr>
<td>OST</td>
<td>Opioid Substitution Therapy</td>
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<tr>
<td>PI</td>
<td>Penitentiary Institution</td>
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<tr>
<td>RND</td>
<td>Republican Narcological Dispensary</td>
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<tr>
<td>STI</td>
<td>Sexually Transmitted Infections</td>
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<tr>
<td>TB</td>
<td>Tuberculosis</td>
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<tr>
<td>UN</td>
<td>United Nations</td>
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<tr>
<td>UNAIDS</td>
<td>Joint United Nations Programme on HIV/AIDS</td>
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<td>UNDP</td>
<td>United Nations Development Programme</td>
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<tr>
<td>UNGASS</td>
<td>United Nations General Assembly Special Session</td>
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<tr>
<td>UNODC</td>
<td>United Nations Office on Drugs and Crime</td>
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<td>WHO</td>
<td>World Health Organization</td>
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Acknowledgments

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Finally, deep gratitude is extended to the IDU, outreach workers who welcomed us with enthusiasm and without hesitation and shared their experiences with us.

Dr. Emilis Subata
July 27, 2007
Executive summary

This mission was contracted by Soros Foundation Moldova. The international consultant was assigned to develop a detailed methodology of assessment and evaluation of methadone substitution pilot projects in the Republic of Moldova; to assess and evaluate the existing substitution therapy programs; to develop the preliminary Assessment and Evaluation Report; to show and share the preliminary Assessment and Evaluation Report’s results to all interested parties/stakeholders during a round table in order to confirm the results and share lessons learned.

International consultant’s work included desk review of available documents and field mission to the Republic of Moldova July 9-13, 2007 (including field trips to Penitentiary Institutions Nr 15 and 18 July 10, 2007 and Balti July 11, 2007). The following institutions were interviewed: a/government ministries/departments/agencies, b/UN agencies, c/INGOs and NGOs, d/Republican Narcological Dispensary, and Narcological Unit at Balti municipal hospital (MMT programmes). Focus group discussions and one to one interviews were conducted with: a/patients of MMT programmes, b/staff working in MMT, and c/outreach workers. In total, international consultant met with 36 representatives of 17 organizations and with 36 beneficiaries from the target group (IDU). Most of the information obtained through the meetings with policymakers, stakeholders, and IDU was of a qualitative nature. However, wherever possible, actual numbers of beneficiaries /IDU/MMT patients were obtained.

Tentative findings and recommendations were presented at the Meeting of the Minister of Health with the main stakeholders of MMT July 11, 2007 and at the roundtable discussion at the Ministry of Health July 13, 2007. Inputs received in these discussions were included in the present report.

Main findings and recommendations are summarized below:

The Republic of Moldova in recent years has developed a clear policy on HIV Prevention and control, reflected by the Law on HIV Prevention (2007) and the National Programme on the Prevention and Control of HIV/AIDS and STI 2006-2010. Both documents include methadone maintenance therapy as an integral component of high importance for HIV prevention in the Republic of Moldova, which should be widely available for IDU in all geographical areas. Nevertheless, the Order of the Ministry of Health since 2003 set narrow indications for MMT, at the same time restricting access of IDU to MMT. 2003-2007 MMT was available only in Republican Narcological Dispensary in Chisinau for a very limited number of IDU. By July 10, 2007 there were only 16 patients in MMT programme in Chisinau and no patients in Balti, where MMT program opened April 2007. Virtually no IDU on ARV therapy were receiving so far MMT. The coordination between health care facilities providing MMT and ARV therapy for PLWHA was on the unsatisfactory level.

Since July 2005 MMT was implemented at the Department of Penitentiary Institutions of the Ministry of Justice of the Republic of Moldova. The Republic of Moldova was the pioneer country to implement MMT in penitentiary institutions as a strategy for HIV/AIDS prevention. By July 10, 2007 there were 20 IDU in 3 penitentiary institutions in the Republic
of Moldova. The staff invested their efforts in expansion of MMT and improvement of the quality of services at penitentiary institutions.

In spite of existing gaps, the country has existing infrastructure of governmental health care facilities. The Government developed a comprehensive policy for the prevention of HIV/AIDS and has raised significant financial resources to combat HIV/AIDS, including by significantly expanding access of IDU to MMT.

To expand MMT and its role in HIV prevention in the Republic of Moldova it is recommended:

- *Legal acts* which regulate MMT, should be thoroughly reviewed by legal and medical experts, and adjusted to be in line with world best practice and human rights of the patients. It is recommended to expand MMT programmes in the governmental health care institutions with capacity building of existing staff;

- National standards/protocols of MMT should be adopted based on existing international practice and in the respect of a comprehensive approach, such as HIV prevention and ARV therapy, TB, Hepatitis B and C, STI prevention and care;

- Successful MMT programmes should be implemented in geographically decentralized way with appropriate control. Psycho-social and legal support should be available in health care institutions and through cooperation with NGOs. Comprehensive approach in providing the whole range of medical services to IDU such as ARV therapy, TB, and STI treatment/care should be promoted in all new and existing MMT programmes;

- Information dissemination about MMT should be improved and developed with the consultation of all main stakeholders; information materials on MMT should be made widely available to IDU, their families and other stakeholders;

- Capacity building of the MMT staff should include development of the training programme based on the lesson learned in the line with international standards. It is important that the ongoing continuous training and support system (including for the staff of penitentiary institutions) should be established;

- A comprehensive monitoring and evaluation plan to monitor the quality of services and treatment outcomes should be established in the country. Monitoring and evaluation activities should be an integral and continuous part of each MMT programme;

- MMT should be expanded in penitentiary institutions by increasing significantly numbers of IDU in existent MMT programmes and by establishing MMT programmes in other penitentiary institutions. The application of the MMT should be individualized, including the possibility to continue MMT for inmates with short-term sentences in penitentiary institutions till their release and referral them to health care institutions after their release.
1. Background and objectives

Opioid substitution therapy (OST) and particularly methadone maintenance therapy (MMT) has been recognized as an effective tool to prevent HIV among injecting drug users (IDU) and to increase the adherence of eligible people with HIV/AIDS to anti-retroviral (ARV) treatment (WHO, UNODC, UNAIDS, 2004; WHO, 1998; WHO, 2005a; WHO, 2006a). Methadone and buprenorphine has proven highly effective in the treatment of opioid dependence and HIV prevention and have been included recently into WHO XIV Edition of the Model List of Essential Medicines (WHO, 2005b).

The latest scientific research data suggest that substance dependence is a chronic brain illness with frequent relapses. Substance dependence nowadays is often compared with other chronic diseases, such as hypertension, diabetes and asthma (McLellan A.T. and al., 2000, UNODC, 2003). There are no particularly “cures” for chronic diseases. Nevertheless, with appropriate long-term therapy and medical care, also the behavior change in patients, it possible to eliminate or reduce symptoms of chronic diseases and reach high quality of life. Opioid substitution therapy in this context is recognized as cost-effective strategy, which allows to achieve high retention rates of IDU in therapeutic programmes (UNODC, 2003).

Opioid substitution therapy (OST) has been widely used to prevent HIV among IDU and improve adherence in ARV therapy in Western Europe. Most of the Western European countries has granted wide access to OST. For instance, in France the coverage with substitution therapy was 58-72% of estimated problem drug users, Ireland 52-61%, Spain 41-49%, Germany 39-49%, the Netherlands 41-46%, and United Kingdom 45%.

The number of drug users among prison inmates is usually higher than in general population. In most of the studies done in European Union, the prevalence of drug use is usually greater than 50%, though this number fluctuates between 22% and 86%. Most of drug users while in prisons reduce their drug use. Nevertheless, in the European Union 10-42% of inmates use illegal drugs regularly in prisons. The prevalence of injecting of drugs in prisons usually is between 15 and 50% (EMCDDA, 2005).

There are also growing number of studies and recommendations that methadone and buprenorphine maintenance treatment should be a part of HIV prevention strategies in prisons as important and highly effective public health intervention (WHO, 2007; WHO, 2005c; Stöver H, Hennebel LC, and Casselman J., 2006, Dolan K et al. 2003). Opioid substitution therapy (OST) with methadone or buprenorphine has been increasingly used in prisons in European Union countries (EMCDDA, 2003, 2005). For instance, in Spain 18% of all inmates, or 82% of opioid dependent persons receive OST (EMCDDA, 2005).

The Republic of Moldova initiated MMT in October 2004 (Ministry of Health and Social Protection, 2006). By July 10, 2007 there were 16 persons in MMT at Republican Narcological Dispensary (RND) and 20 in Penitentiary Institutions. The estimated number of IDU population in the Republic of Moldova was 77 000 – 116 000 with the midpoint of 97 000. With the 22 patients in MMT in 2004 the estimated coverage of IDU by OST was less than 1% (WHO, 2006b).
Therefore, implementation of methadone maintenance therapy programmes in the Republic of Moldova could hardly provide any impact on HIV spread or saving of lives of IDU with HIV by their involvement into ARV therapy. At the same time this is financially possible because the Republic of Moldova has raised substantial financial resources to respond to AIDS epidemic, including those specified to fund methadone programmes.

The objective of this assessment and evaluation of methadone maintenance therapy programmes in the Republic of Moldova was to provide the Government of the Republic of Moldova (namely Ministries of Health and Justice) with evaluation and recommendations on how to scale up the provision of methadone maintenance therapy programmes.

The evaluation looked at what was the status of MMT programmes in the Republic of Moldova. Also the evaluation looked at what were the main obstacles in the expanding of MMT programmes and increasing their role in the reversing of AIDS epidemic in Moldova. The evaluation lead to recommendations that can improve the implementation of methadone programmes in the Republic of Moldova and advise on the necessity of further expansion of the existing methadone maintenance therapy programmes.

2. Methodology

International consultant started the work with a desk review of the documents produced by the UNAIDS, EMCDDA, Government of the Republic of Moldova and other organizations. In addition to meetings in Chisinau, the international consultant undertook a field missions to the Penitentiary Institutions Nr 15 and 18 outside Chisinau July 10, 2007 and also Balti city July 11, 2007. These sites were selected because there were the only sites where methadone maintenance therapy was available in the Republic of Moldova. In addition, Balti is the city, where the majority of IDU reside and there is a high prevalence of registered HIV and IDU cases.

Representatives of the following institutions were interviewed: a/Ministries /departments/agencies; b/UN agencies; c/INGOs and NGOs. Two focus group discussions were conducted with a/IDU and b/outreach workers. One to one interviews were conducted with beneficiaries. A complete schedule of the mission and the list of persons met are attached in annex 1 (see table 1 and 2). The field schedule of the international consultant was established in consultation with Soros Foundation Moldova. In total, the international consultant met with 36 representatives of 17 organizations and with 36 beneficiaries (for details see tables 1 and 2).

Most of the information obtained through the meetings with policymakers, stakeholders, and IDU was of a qualitative nature. However, wherever possible, actual numbers of beneficiaries / IDU / social workers were obtained. Interviews/focus group discussions were semi-structured in nature, allowing the international consultant and/or the respondents also to pursue issues of relevance or of local importance.
Meetings with policymakers and stakeholders offered not only a venue for information gathering but also an opportunity for the international consultant to validate his findings, discuss initial observations, and check whether areas of importance had been overlooked. Before leaving the country, the international consultant presented tentative findings and recommendations at the roundtable discussion at the Ministry of Health July 13, 2007. Inputs received in this meeting were included in the present report. The final report was completed on July 27, 2007.

### Table 2. Number of organizations / representatives interviewed during the field mission in the Republic of Moldova

<table>
<thead>
<tr>
<th>Total (organizations / representatives)</th>
<th>UN agencies, International NGOs</th>
<th>Government officials / medical institutions</th>
<th>Local NGOs</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>4/4 (1 female / 3 male)</td>
<td>9/16 (4 female / 12 male)</td>
<td>4/16 (4 female / 12 male)</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>17/36 (9 female / 27 male)</td>
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### 3. Challenges and Limitations

Overall, the methodological approach was in line with the purposes of this mission. The field visits, while tightly scheduled, allowed the international consultant to interact with many people in a relatively short period of time. It should be recognized, however, that it was not possible for the International Consultant to visit all stakeholders.

Several meetings were attended by a large number of people. This caused some complications in communication and may have affected the scope and the reliability of information provided by the respondents. The international consultant tried to have separate one to one complementary sessions with the respondents when they felt the information provided was somehow biased because of the presence of an audience. This was not always possible and at meetings with beneficiaries at penitentiary institutions the medical staff of penitentiary institutions was present.

Gender, age and geographical distribution of direct beneficiaries, direct recipients and indirect beneficiaries of methadone maintenance therapy program, prevention, care and support projects were not systematically available. Reporting formats of implementing organizations differed.
The legal and policy framework on methadone maintenance therapy programme would deserve a more thorough review by a legal expert. During the short term of the mission, and with no provision for translation costs, the international consultant was able to review only the documents that had been translated in Russian or English.

4. HIV situation in the Republic of Moldova

The Republic’s of Moldova estimated population (except population from Transnistrian region) is 3,391 thousand people. According the Human Development Report 2005, the Republic of Moldova was in the 115th place from 177 countries (Scientific and Practical Centre of Public Health and Health Management, 2006).

The estimated number of IDU population in the Republic of Moldova was 77 000 – 116 000 with the midpoint of 97 000 (WHO, 2006b).

From 1987 to the 1st January 2007, 2527 HIV-positive cases were registered in the Republic of Moldova (right bank) and 873 in the Transnistrian region, the total cumulative number being 3400. 34.4% of cumulative HIV infected people were female and 65.6% were male (National Centre of Scientific and Practical Preventive Medicine, 2006).

As in other countries of the region, the HIV epidemic in the Republic of Moldova is driven mostly by injecting drug use (IDU) – approximately 62% of registered cumulative cases. Republic of Moldova experienced an outbreak of HIV infection in 1997 and 1998, when respectively 404 and 408 new HIV cases were detected. The IDU constituted 87.9%, 84.8% and 85.8% of newly diagnosed HIV cases in the years of 1997, 1998 and 1999.

In recent years, the proportion of IDU among new HIV cases has been steadily decreasing (54.5% in 2003, 50.1% in 2004, 42.8% in 2005, and 38.2% in 2006). There was a constant increase of the incidence of HIV cases contracted through a sexual route. Nevertheless, the number of new HIV cases among IDU in absolute numbers during the last years had a tendency to increase (179 in 2004, 228 in 2005 and 236 in 2006). At the same time the total number of new HIV cases has been steadily and rapidly increasing: 357 in 2004, 533 in 2005 and 618 in 2006 (National Centre of Scientific and Practical Preventive Medicine, 2006).

In the year 2003 there were 27 persons on ARV therapy with 74% probably infected through drug injection. In 2004, there were 82 persons in ARV therapy of whom 60% were probably infected through drug injection. In 2005 there were 109 persons in ARV therapy, out of whom 45% were probably infected through injection of drugs (Ministry of Health and Social Protection, 2006). By July 2007 there were 305 individuals on ARV therapy. The significant part was constituted by IDU, though the exact number of IDU was no known.

5. Legal context of the implementation of OST in the Republic of Moldova

a) The Order of the Ministry of Health on the OST: The Republic of Moldova established MMT program in Republican Narcological Centre in October 2004 (Ministry of Health and Social Protection of the Republic of Moldova, 2006) following the order of Ministry of Health of May 20, 2003 Nr. 159 (Ministry of Health of the Republic of Moldova, 2003). The Order of
the Ministry of Health included HIV/AIDS and hepatitis prevention among IDU and general population as one of the goals of the substitution therapy.

The Order established then following indications for OST (Ministry of Health of the Republic of Moldova, 2003):

- Progression of dependence and a patient has to be 2 years or more on the narcological register;
- Health problems due to the use of injected opioids (hepatitis, sepsis, HIV/AIDS);
- Concomitant diseases (malignant tumours, diabetes, mental disorders, pulmonary TB, etc.);
- Repeated unsuccessful attempts of drug free treatment.

OST was allowed by the Order to be carried out at the Republican Narcological Dispensary.

OST was to be managed through an advisory medical commission.

Annex 1 of the order describes that OST could be provided as a:

- Short or a long-term (longer than 1 month) detoxification (only in in-patient conditions);
- short term maintenance therapy (up to 6 months);
- Long-term maintenance therapy (longer than 6 months).

Annex 1 also includes some clinical recommendations regarding the initial doses of substitution medications (methadone). “The dose is adjusted in the first three days in order to diminish the consequences of ceasing the use of drugs”. In accepted world practice, it usually takes a longer time to titrate a maintenance dose.

Annex 2 indicates necessary measures for control of substitution medications in the health care institutions (record keeping of substitution medication, storage of medication, delivering, and reporting).

Annex 3 is a form of Agreement between the participant and the health care facility for the delivery of substitution therapy. It is required to be signed by a patient and health care institution. In spite, that the patient is supposed to be an adult person, a signature of family member is also required in this form. The Annex 3 also includes detailed description of obligations of patients, who will participate in MMT.

The Order does not indicate, if there is a possibility to take substitution medications home and on what conditions. As the procedures for take-home of medications are not specified, patients do not have a possibility to use medications at home on any conditions. Daily attendance of the clinic interferes with the social integration of patients (jobs, family holidays or weekends, travel, etc.). At the same time the Law on Legal Turnover of Narcotic, Psychotrophic Substances and Precursors (Monitorul Oficial, 1999) allows patients to receive and use at home prescribed substances from the List II for 7 days.

The Order also does not specify the continuation of MMT in other health care institutions. For instance, if a MMT patient is hospitalized for TB, AIDS, sepsis, pneumonia, trauma,
etc., there is a risk that MMT will be discontinued. The absence of this provision does not permit the continuation of MMT in other inpatient medical facilities, if injecting drug use is followed by health complications and concurrent illnesses, such as TB, AIDS, sepsis, pneumonias, traumas, abscesses, etc. Under the Article 15 of Law on Legal Turnover of Narcotic, Psychotropic substances and Precursors (Monitorul Oficial, 1999) the physician in the inpatient institution can prescribe medications, which are on the List II, and OST should be available for continuation.

July 2005 MMT was introduced to Penitentiary Department institutions under the Ministry of Justice of the Republic of Moldova. The OST with methadone was initiated and implemented with the existing Order of the Ministry of Health (2003) as the guiding principle. The Republic of Moldova was the first country in the CIS, which has introduced OST in penitentiary institutions.

b) National Programme on prevention and control of HIV/AIDS and STI 2006-2010. The national strategy to increase the access of IDU to MMT has been clearly defined in the National AIDS programme on prevention and control of HIV/AIDS and STI 2006-2010(2006). The scope of the Strategy IV of the programme “Expanding of HIV/AIDS/STI activities among vulnerable groups which aim at consolidating NGO and state efforts” is to “ensure the access of persons from vulnerable groups to health and social assistance services, counseling and voluntary testing to HIV/AIDS/STI, to information, prevention activities, individual measures of protection and treatment”. The activities include “accomplishing through joint efforts of government institutions (Ministry of Health and Social Protection, Ministry of Justice, Ministry of Education) and NGOs, the implementation of prevention projects, including projects based on “harm reduction” strategy, among contingents and vulnerable groups: injecting drug users; detainees in penitentiary institutions; commercial female sex workers; sexual minorities; unschooled and unemployed youth; migrants, including repatriates; Roma; children and youth with mental disabilities, etc.” The third activity specifically calls upon development of MMT: “Extending the methadone substitution programme, increasing access of substitution therapy in specialized institutions subordinated to the Ministry of Health and Social Protection and in the Penitentiaries” (2006).

c) Law on the Prevention of HIV Infection. The Parliament of the Republic of Moldova February 16, 2007 has adopted the Law on the Prevention of HIV Infection (Monitorul Oficial, 2007a). The article 7 of the law “Prevention of HIV/AIDS among IDU” requires “ministries involved, other central administrative bodies, other decentralized services of public health to develop educative and rehabilitative (medical and social) programmes targeted to decrease illegal drug consumption among IDU, HIV prevention and attracting them to OST on voluntary basis”. The article urges ministries involved, other central administrative bodies, and other decentralized services of public health to make these medical and social programmes fully geographically available across country. The law indicates that MMT should be confidential for patients and should be implemented for patients, who are in agreement with this therapy and meets the selection criteria.

Monitorul Oficial, 2007b) incorporates activity 3.12 “to ensure therapy of alcohol and drug dependence according the existent legislative and normative acts”, where Ministry of Health, Ministry of Social Protection, Family and Child and the Ministry of Interior hold the responsibility for this activity. The activity 3.14 in the Action Plan foresees the “introduction into practice HIV prevention methods among IDU (substitution therapy)” (responsible institution Ministry of Health). Though these activities, as indicated, should be monitored every 6 months, the Action Plan does not have the specific target indicators for these activities. This creates difficulties in monitoring of the activities and to what extent they were implemented. Neither funds allocated for these activities are included in the Action Plan.

6. Status of methadone maintenance therapy in health care institutions

Methadone maintenance programme was introduced in October 2004 in RND. By July 10, 2007 there were 16 patients on maintenance. 15 patients were attending the outpatient department of RND, while 1 patient was in the TB treatment inpatient unit and continued to receive MMT. 6 patients in MMT were HIV positive, 4 with the diagnosis of TB.

The staff of MMT consisted of the physicians-narcologists, nurses, and a psychologist. Patients willing to undergo MMT were referred to inpatient unit of the RND. In approximately 1 week methadone dose was titrated in inpatient conditions. After that patients were referred to continue MMT at the outpatient unit of RND.

Patients attended to consume methadone every day, including weekends and holidays, under the supervision of the nurse. The liquid form of methadone was used, which was prepared from concentrate in the pharmacy. Dosimeter for dispensing of methadone solution was used. There was a separate room for methadone dispensing with the safe for limited methadone supply. Methadone dispensing office was open from 8 till 15 work days and from 9.00 till 9.30 weekend and holidays.

Medical records on methadone dispensed in dispensing room were kept accurate. Patients put their signatures next to each dose dispensed to them.

Since 2004 the pharmacy, which prepared methadone solution, under the request of the staff of RND added a color to methadone solution. The intention was to provide a possibility to identify diverted methadone if it was seized by the law enforcement officers.

There were group meetings for patients every Tuesday morning, facilitated by a psychologist. According the agreement of RND and NGO “Your Choice” psychosocial support and educative sessions were provided by the NGO staff. Only few patients of MMT attended “Your Choice” psychosocial support sessions, which were hosted at the NGO premises. The attendance of the psychosocial groups facilitated by a psychologist and NGO staff were at the responsibility and willingness of patients and were not compulsory to attend.

There were no professional social workers in the staff of RND MMT team. Thus the social needs of MMT patients (lost documents, job training and finding a job, housing, health insurance, problems with the law, etc.) were not assessed. Specific individual multidisciplinary treatment/social reintegration plans with specific time-lines and the
involvement of patients were not developed. The effectiveness of MMT for individual patients was not periodically evaluated.

In the focus group discussion patients have indicated that for some of them daily attendance to RND outpatient department for methadone was difficult. It interfered with finding and maintaining jobs, travel and spending time with family on weekends or during the holidays. When patients had fever, they had also to come for their methadone to RND. Patients indicated that they were too “attached” to MMT. The “attachment” or “too much dependence” on RND was one of the reasons of the negative perception of MMT among IDU and prevented them from entering the MMT program. On the other hand, “attachment” was the reason for tapering down methadone doses and quitting MMT altogether after a few months with subsequent risk of relapses.

There was not a possibility to receive methadone if hospitalization to other health care institutions occurred (except in TB treatment unit, which was next to narcological inpatient unit). Patients indicated that in cases of hospitalizations (for AIDS, pneumonia, traumas), they had to come daily to RND. Neither there was a possibility generally to continue MMT in arrest houses, after MMT patients were detained. Though on the case to case basis RND staff was able to supply methadone into arrest houses, there were no legal acts which regulated the continuation of MMT there.

HIV testing was available free of charge at MMT programmes and was offered for patients approximately twice a year. CD4 counts and viral load were also free of charge. Tests for hepatitis C were not available free of charge, neither treatment for hepatitis C.

Random urine screening for illegal drugs was performed. Positive urine screen tests were followed by discussion with the narcologist. Patients were not discharged from MMT upon positive urine screens.

In the focus group discussion patients indicated that MMT has positively influenced their life. They were able to reduce or to withhold from illegal drug use. Some of them found jobs. They did not have to engage in criminal activities. Most of them indicated that the situation in their families has significantly improved.

Most of the patients indicated that their mental and physical situation has also significantly improved. Nevertheless, some patients indicated that they felt withdrawal symptoms in the morning, and thought they were receiving insufficient maintenance doses. Patients indicated that if they approached a physician for the increase of the dose, sometimes they were denied the increase of the dose. In other cases the physician increased methadone dose, though unwillingly.

In the focus groups discussion patients indicated that the communication between MMT staff and patients were not very good. MMT physician narcologist as her main responsibility indicated position of the Head of the Day care unit. Supervision of the Day care unit was considered as the priority responsibility, while MMT was considered as an “additional workload”.
Patients in the focus group discussion indicated that there were many more IDU, who could benefit and would be willing to enter MMT. As the main obstacle, they indicated the negative attitude of the staff of RND to MMT. According their words the staff often considered MMT as a last resort therapy for the “hopeless” IDU. Inpatient detoxification and abstinence were considered as “superior” therapies than MMT as they aimed for “cure”.

Patients have indicated that the concentration of methadone seemed different for them on several occasions in the past. They were approaching staff on these occasions, when allegedly “weaker” or “diluted” methadone was dispensed. There was no independent control at RND of the concentration of methadone. Therefore, it is impossible verify patients’ complaints.

At Balti municipal hospital MMT programme was opened in April 2007. MMT programme in Balti was staffed by a physician narcologist and a nurse. Methadone supplies and a dosimeter were stored in safe in physician’s office. In April 2007 one patient was referred to start MMT in the RND inpatient unit in Chisinau. After inpatient phase he was transferred to Balti with the maintenance methadone dose of 70 mg. For 2 months patient’s mental and physical status was stable with the maintenance dose of 70 mg. Several weeks before the consultant’s mission, the patient asked a narcologist to decrease methadone dose as he wished to leave the MMT programme. This was followed by opioid overdose in the beginning of July. Patient was brought into the emergency room by the ambulance and patient was hospitalized for detoxification. Another two patients, who applied for MMT in Balti were referred to Chisinau for dose titration in an inpatient unit of the RND. Due to unknown reasons they have not been hospitalized and never started MMT in Balti.

In Balti at the narcological official registry there were officially 841 drug dependent persons, from whom 64% were with opioid dependence. 318 or 37.8% were HIV positive and 15 had AIDS. Nevertheless by July 10, 2007 there were no patients in MMT in Balti after 3 months since the official start of MMT programme in Balti.

During the individual interviews with IDU-clients of harm reduction programs, it was noted that IDU did not know about the new possibility to enter MMT at Balti. The IDU knowledge about MMT was extremely low as IDU did not know the basic goals and principles of MMT.

Both in Chisinau and Balti the printed information on MMT for patients and their family members was almost non existent. RND has printed a brochure “About methadone” (prepared by Holy Catania) in local and Russian languages. Translations from brochure, originally written for US citizens, were not adapted to the local context. In Balti only few copies of the brochure were available.

MMT programmes in health care institutions were funded partly from the funds of RND and partly from GFATM. The funds of the GFATM were not used for the development of MMT as committed by the Government. The indicators of the development of MMT July 10, 2007 were very much behind the plan. At the number of meetings, Governmental bodies, UN organizations and INGOs expressed their deep concern that there was a real risk, that the planned indicators for the MMT will not be reached till 2008. This caused a risk
of exclusion of further funds for the development of MMT from the next GFATM project for the years of 2008-2013.

7. Status of methadone maintenance therapy in Penitentiary Institutions of the Penitentiary Department of the Ministry of Justice

The Republic of Moldova was the first country among CIS countries to introduce OST in penitentiary institutions July 2005.

According to the data of the medical services of the Department of Penitentiary Institutions of the Ministry of Justice 879 or 9.9% of 8 876 inmates were considered as potential drug users in 2005 (Ministry of Health and Social Protection, 2006). At the end of 2005 there were 7 IDU (cumulative number) all males, who have been involved in methadone therapy. At the start of the therapy the daily methadone doses ranged from 30 to 80 mg. Doses were individually selected. Then, gradually doses of methadone were reduced up to 5 mg/day. After methadone was interrupted, the withdrawal treatment was offered for 2-4 days with intravenous infusions, Tramadol, vitamin C and other vitamins, sometimes benzodiazepines. After the typical 6 month course of MMT with dose reduction at the end to zero, patients were considered “cured”. The term of treatment depended on the contract signed with the person wishing to start methadone therapy. Initially the contract term was 6 months (standard for everyone). During the therapy, depending on the patient’s clinical condition, a discussion was held with the patient. It could be suggested to him/her to extend the therapy if necessary; however with the reduction of the daily dose to 5 mg. When a patient wished, the contract was extended (Ministry of Health and Social Affairs, 2006).

July 10, 2007 there was a cumulative number of 44 patients, who participated in MMT in penitentiary system. From that number about ¾ of patients was HIV positive, 1 patient received MMT and ARV. July 10, 2007 there were 20 patients who were in MMT. MMT for IDU in penitentiary system was initiated in the infectious disease ward of the Republican Clinical Hospital “Pruncul”. A physician narcologist was available at the hospital ward for diagnosis of opioid dependence, medication prescription, education and evaluation of the treatment. After the methadone dose was stabilized during a few weeks time, inmates could continue MMT at PI Nr 15 and PI Nr 18 in their medical units as patients or as ordinary inmates outside medical units. The existing infrastructure of medical units was used in the dispensing of methadone (offices for medical procedures), which were additionally equipped with safes for storing of limited methadone supplies.

Heads of medical units in PI 15 and 18 (both were physicians internists), were responsible for the implementation of the MMT in PI. They underwent extensive specific training on OST. Consultations and assistance in the matters, related to MMT, was constantly provided by the chief specialist, a specialist psychiatry and narcology at the Department of Penitentiary Institutions of the Ministry of Justice of the Republic of Moldova.

Many inmates during the interviews admitted that MMT had a positive effect on their health status. E.g. patients at Republican Clinical Hospital “Pruncul” told the interviewers that their CD4 count has considerably improved and that they gained weight. Patients were aware about the positive influence of MMT to their immune system and felt physically improved.
At penitentiary system specific leaflets on MMT were printed and distributed among inmates with positive and realistic information about MMT. Much of information was passed through direct and regular communication between the medical staff and inmates.

Also inmates indicated that participation in MMT programmes has significantly improved their quality of life: patients did not had cravings and did not had to be involved in unlawful activities in order to gain money, to work for other inmates in order get the dose of illegal drugs or to get money from outside the prison. They indicated that MMT, if sufficiently expanded, could significantly reduce the overall problems because of illegal drugs in PI.

Several patients interviewed at PI expressed their willingness to continue maintenance on methadone till the end of their term. After that they were interested to be transferred to the existent health care facilities in Chisinau or Balti. The legal mechanism of transfer was not yet established. There was one inmate so far, who was successfully transferred from PI to MMT at the RND after he was release before his term was over.

As indicated by some inmates and medical staff of PI, the most prevalent problem in MMT was at the end of 6 month course of MMT. At the end of the 6 months contract patients reduced their dose to 5-15 mg/day. As some of inmates indicated, usually when the dose was reduced to 15 mg and less, patients suffered severe opioid withdrawal symptoms, which were present for several weeks. Such patients due to their withdrawal status caused many problems for the medical staff, as their behavior became unpredictable. Patients could go out of balance, they became anxious or even aggressive. Patients, who often had relatively short-term sentences, requested that they could have a possibility to continue methadone maintenance with the adequate doses till the day of the release and than to be transferred to Chisinau or Balti MMT programmes. At the moment of the mission MMT programmes in penitentiary institutions were funded by the GFATM.

8. Obstacles for the expansion of methadone maintenance therapy

In recent years the Republic of Moldova has developed a coordinated policy for HIV/AIDS prevention. This policy is documented at the highest national level by the Law for HIV prevention (Monitorul Oficial, 2007a) and the National Programme on Prevention and Control of HIV/AIDS and STI 2006-2010. The Republic of Moldova in the last two-three years clearly defined MMT by the law and the National programme on HIV/AIDS prevention and control as integrated and substantial part of HIV prevention and social inclusion of IDU and other vulnerable groups. In 2007 it was clear that narrow indications (criteria) for MMT, and other provisions of the Order of the Ministry of Health from 2003 (e.g. interference with social integration) were counterproductive and did not allow to use MMT potential in HIV and other infectious disease prevention in the country. Neither did they correspond to the country policy defined in legislative acts and national programmes.

Some narcologists, nurses, representatives from the the NGO received initial training through the workshop, which was organized in Chisinau by UNODC (2004, 2005) with the translation into Russian language of the training manual (Verster A., Buning E., 2003) Euromethodwork, 2003). Two groups of specialists attended study visits at Vilnius Centre for Addictive Disorders funded by UNODC (2005) and Soros Foundation Moldova (2006).
Nevertheless, there was no systematic continuous medical training at home. Most of the staff in narcological institutions did not develop a positive attitude to MMT, as a therapy approach, easily accessible on outpatient basis to the great numbers of IDU. Inpatient detoxification and abstinence orientated therapy was still largely preferred by the staff. At the same time, follow-up psychosocial treatment/support and relapse prevention programmes were so far extremely limited in the country.

In Moldova there were job positions of narcologists allocated in different geographical areas (narcological service), with many vacant positions. Unfortunately, the existent network of the narcological service in the country so far failed to offer wider range of therapeutic and HIV prevention services for IDU, including psychosocial support and MMT.

The negative impact so far on the access of MMT among IDU and the quality of MMT programmes has been done by the law enforcement agencies. From the words of the medical staff, few years ago law enforcement officers were very much against methadone maintenance programme. They made frequent raids to RND units without notice of the head of the institution, interfered with therapy procedures and, according the words of staff members, treated medical staff as well as patients as “potential drug dealers”. It is worth to notice that National strategy of drug control has not been developed and adopted yet. Due to poor coordination of activities of different sectors (e.g. Ministry of Interior and Ministry of Health), expansion of MMT in the country, ensuring high quality of services and increasing access of IDU to MMT in implementation of the National policy on HIV/AIDS remains problematic.

National clinical protocol on MMT and other therapies for drug dependence has not been developed. The absence of clinical protocols implies the limited use of MMT in other health care facilities in different geographical areas of the country. Absence of clinical protocols also creates difficulties in the ensuring of the quality of MMT.

As there were so far no regulations on how MMT could be provided in other health care facilities, especially for patients who receive ARV therapy, organization and coordination of ARV therapy and MMT was extremely difficult in the Republic of Moldova.

The special attention deserves the negative attitudes on MMT among some of IDU, their family members, medical staff, governmental representatives, and NGOs. During the focus group discussion with IDU they indicated different opinions which were prevalent among IDU community. One of them was that “narcologists deliberately hook IDU on methadone in order to get, eventually, rid from them by means of administering toxic substance”. Another assumption was that “methadone is a toxic substance, so only hopeless drug users enter methadone maintenance programme”. This attitude was reinforced by the fact, that many opioid dependent persons could not enter MMT programme early in their drug taking history, even if they were willing to. If they were to apply for the treatment the first time in their life, the existent criteria required them to wait for at least another two years before they could be eligible for OST. There were prevalent beliefs among IDU community that methadone is highly toxic and the withdrawal from methadone is long and difficult.

On the whole, the official narcological services by patients in the focus groups discussion was considered as not providing “real” therapy and not supportive. IDU indicated that they
had no confidence for official narcological service. MMT was considered as another method of “control” upon IDU, rather than a means of real treatment and support. Some patients believed that if they used illegal drug while being in MMT programme, they would be referred to the police. Most patients tended to avoid applying for treatment to the official narcological service, as the real medical and social help was not available. On the other hand, after applying for official narcological services, IDU were included into the official narcological register, which significantly restricted their possibilities to find or maintain jobs, drive a car, etc. Thus most often IDU chose to treat withdrawal symptoms by “self-therapy” at home with benzodiazepines and other available medicines on their own or with the support of their friends.

IDU, their family members, health workers and NGOs did not have enough objective information of MMT. Russian TV programs were often mentioned as a significant source of negative information about methadone. RND has translated and published a booklet printed in USA “About Methadone” in 2005 in Romanian and Russian. The booklet was not adapted to the local conditions, and it is not clear how well it was accepted by IDU and their families. The international consultant could not spot other printed information materials on MMT in health care institutions and NGOs, which were active in harm reduction. Some of the NGO, which provided social rehabilitation services for drug users, saw MMT rather as a “competing” and “less effective” treatment approach in achieving and maintaining abstinence among IDU, rather as effective means of HIV/AIDS and other infectious disease prevention. During focus group discussions IDU indicated that negative information from TV and internet was much easily available than scientifically based information.

**9. Monitoring and evaluation**

Important component for the sustainability of MMT in the Republic of Moldova is to retrieve on the regular basis data on the impact of MMT on HIV situation in the country and on the benefits for individuals /community.

Therefore, it is important to have the system of ongoing monitoring and evaluation both of the quality and outcome effectiveness of the MMT programmes.

The importance for the development of the ongoing monitoring and evaluation of the quality and treatment outcome of MMT programmes was well recognized in the past years by different UN agencies. In 2003 the World Health Organization has developed the General Protocol (WHO, 2003) on outcome and process evaluation in the framework of WHO Collaborative Study on Substitution Treatment of Opioid Dependence and HIV.

The WHO Collaborative study has been carried out in Central and Eastern Europe (Lithuania, Poland, and Ukraine), South-West Asia (China, Indonesia, and Thailand) and Iran. The WHO Collaborative Study has developed essential instruments for comprehensive process and outcome evaluation, which were translated into the main languages (including Russian) (WHO, 2003).
The process evaluation, as indicated in the Protocol, includes assessment of existing procedures of substitution treatment, HIV prevention services, satisfaction of programme staff as well as satisfaction of patients with services provided, and other indicators. Retention rate of patients in the substitution treatment programme and the average dose of substitution medication are also the important indicators of the quality of the substitution treatment programmes.

The outcome evaluation in the Protocol covers the impact of substitution treatment to general health and wellbeing of the patient, including the improvement of general health, changes in the illegal drug consumption, risk behavior (injecting and sexual), and changes in the quality of life. The Protocol also covers benefits of substitution treatment to the community (reduction of criminal behavior and employment of patients).

The WHO Collaborative Study Protocol (WHO, 2003) and instruments have been already tested in different regions and countries in transition (Central and Eastern Europe and South-East Asia, Iran). They might be considered to be used in the development of the monitoring and evaluation plan in the Republic of Moldova.

Implementation and expansion of MMT programme in the Republic of Moldova as integral part of the government health care services creates a good basis for its sustainability. Ownership of the MMT by the staff of the programmes, NGOs, beneficiaries and increasing cooperation with AIDS/TB programmes enhance sustainability of the programme.

10. Recommendations for development of MMT in the Republic of Moldova

1. Efforts should be made to increase the accessibility to MMT to IDU in the Republic of Moldova in order to increase impact on the prevention of HIV, hepatitis B and C, TB, and STI. It is recommended to expand MMT programmes in the governmental health care institutions with capacity building of existing staff;

2. *Legal acts* which regulate MMT, should be thoroughly reviewed by legal and medical experts, and adjusted to be in line with world best practice and human rights of the patients. At the same time necessary controls and agreements with law enforcement sector should be put in place, including the continuation of MMT in arrest houses;

3. National standards/protocols of MMT should be adopted based on existing international practice and in the respect of a comprehensive approach, such as HIV prevention and ARV therapy, TB, Hepatitis B and C, STI prevention and care;

4. Successful MMT programme should be implemented in geographically decentralized way with appropriate control. Psycho-social and legal support should be available in health care institutions and through cooperation with NGOs. It is recommended to include representatives of the target group (IDU) into the decision making process in MMT programs. Self-help groups should be supported in all areas where MMT programmes will be implemented;
5. Comprehensive approach in providing the whole range of medical services to IDU such as ARV therapy, TB, and STI treatment/care should be promoted in all new and existing MMT programmes. Inclusion of the NGOs in to MMT provision such as social and legal support should be continued in all levels;

6. To avoid misconceptions about MMT, information dissemination strategy should include close consultation with all stakeholders involved in the MMT programme including IDU networks, outreach programmes/networks, professional groups including medical, law enforcement, media etc. Information materials on MMT should be developed and made widely available to IDU, their family members and all other stakeholders;

7. Capacity building of the MMT staff should include development of the training programme based on the lesson learned in the line with international standards. After the MMT starts in other health care institutions, it is important that the ongoing continuous training and support system (including for the staff of penitentiary institutions) should be established;

8. A comprehensive monitoring and evaluation plan to monitor the quality of services and treatment outcomes should be established in the country. Monitoring and evaluation activities should be an integral and continuous part of each MMT programme. Ready available methodologies as recommended by WHO could be considered in the development and implementation of the monitoring and evaluation plan;

9. MMT should be expanded in penitentiary institutions by increasing significantly numbers of IDU in existent MMT programmes and by establishing MMT programmes in other penitentiary institutions. The application of the MMT in penitentiary institutions should be individualized, including the possibility to continue MMT for inmates with short-term sentences in penitentiary institutions till their release with the referral to health care institutions after their release. MMT programmes in penitentiary institutions should be evaluated on regular basis.
References


UNAIDS, 2005. The “Three Ones” in action: where we are and where we go from here. UNAIDS, Geneva.


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<td>RND</td>
<td>Mr. Tudor Vasiliev</td>
<td>Chief physician</td>
<td><a href="mailto:liv@moldova.md">liv@moldova.md</a></td>
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<td>Focus group discussion with MMT patients at RND</td>
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<td>Victor Burinschi</td>
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<td>Soros Foundation Moldova</td>
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<td>Vladimir Taranu</td>
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<td>Meeting at the NGO “Your Choice” with the staff and self-help group (7 persons, 1 female and 6 men)</td>
<td>NGO “Your Choice”</td>
<td>Valerij Antonov</td>
<td>Director</td>
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<td>Meeting at Republican Clinical Hospital “Pruncul” of the Department of Penitentiary Institutions with the staff of MMT and inmates (5 persons, all male). Observation of methadone intake.</td>
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<td>Ina Birucova</td>
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<td>NGO “Youth for The Right to Live”</td>
<td>Aleksandr Stolear</td>
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<td>Presentation of the initial findings of the mission and draft of recommendations in the roundtable discussion in the Ministry of Health</td>
<td>Ministry of Health</td>
<td>Mihai Beregoi</td>
<td>Project Manager, BUMAD Programme</td>
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