



Substitution Maintenance Therapy in Ukraine: Can the Community Respond Effectively to the Challenges of HIV/AIDS?

Introduction

The language of the facts: Ukraine's HIV/AIDS epidemic is the fastest growing in Europe.

Over the last three years the number of officially registered HIV cases in Ukraine has almost doubled.

Every day 48 people are diagnosed with HIV and seven individuals die of AIDS.

After 10 years, injecting drug users (IDUs) and their sexual partners remain the most vulnerable group to HIV.

Modern approaches to HIV prevention among vulnerable groups were not available during these years.

Substitution maintenance therapy (SMT) has been proven to be one of the most efficient tools for HIV prevention among IDUs in many countries. These methods are finally being applied in Ukraine.

The aim of this policy brief is to inform politicians, decision makers, national and international stakeholders, health care professionals, mass media and the general public about substitution maintenance therapy and its implementation in Ukraine from 2004 to 2007.

The briefing contains a concise summary of the achievements and conclusions so far, as well as the challenges, and looks ahead to the further development of this approach in Ukraine.

Why SMT?

In 2001 the World Health Organisation (WHO) identified five key principles of HIV prevention among IDUs, including availability of clean injecting equipment and access to SMT.

SMT can be prescribed to those IDUs who meet the clinical criteria for opioid dependence according to the International Classification of Diseases (ICD-10). Opiates are the most common illegal drugs used in Ukraine.

Substitution maintenance therapy - is a method to treat chronic opiate dependency and prevent the spread of HIV and hepatitis B and C among injecting drug users by prescribing the patient a non-injectable substitute drug (usually methadone or buprenorphine) to be taken on a long-term basis.



Advantages of SMT:

- reduces HIV and hepatitis B and C prevalence rates among IDUs and their partners
- reduces illegal drug use and overdose-related mortality
- improves the physical and mental health of drug dependent patients, and integration in society
- supports adherence to HIV and TB treatment
- reduces crime and undermines the profitability of illegal drug trafficking
- decreases government expenditure on criminal proceedings, imprisonment of IDUs and treatment of diseases resulting from illegal drug use.

SMT and the HIV/AIDS Epidemic

The global HIV transmission rate through injecting drug use is 10 per cent.

In many countries of Western Europe the HIV infection rate has been reduced significantly as a result of large scale-up of SMT programmes.

The situation is critical in Ukraine. The estimated number of IDUs in the country ranges from 325,000 to 425,000. Currently 63 percent of registered HIV cases among adults are related to injecting drug use.

SMT in the World

The implementation of SMT programmes worldwide has more than a forty-year history, starting in the 1960s in the USA, followed by Canada and the UK.

Today methadone or buprenorphine SMT is accessed by almost a million drug dependent people in 60 countries, including 26 countries of the European Union, as well as North and South America, Asia, Australia and New Zealand.

Among post-Soviet countries SMT is implemented in Lithuania, Latvia, Estonia, Moldova, Georgia, Azerbaijan, Uzbekistan, Kyrgyzstan and Ukraine.

In October 2007 the first methadone-based SMT programme was launched in Belarus.

The Traditional Approach to Drug Dependency Treatment in Ukraine

In Ukraine treatment of drug dependency still relies on old Soviet-style methods rather than international standards and the principles of evidence-based medicine. Treatment covers only about 10 percent of those who need it.

The therapeutic approaches of government drug treatment clinics are still guided by protocols issued by the Ministries of Health of the USSR and Soviet Ukraine long before 1991.

Acting in compliance with an outdated treatment philosophy, medical personnel focus on the patient's rapid and complete withdrawal from drugs, which is an unattainable goal for many drug dependent individuals.

State institutions almost never employ cutting-edge approaches to the prevention of risk behaviour among IDUs.



Right to Treatment

Usually drug treatment clinics offer patients detoxification (treatment of acute opiate withdrawal or abstinence syndrome, also known as 'cold turkey'), but its effectiveness is extremely poor: at least 90 percent of patients relapse into drug use in the first six months after detoxification.

The practice of mandatory patient registration which dates back to Soviet times is still prevalent in Ukrainian drug treatment facilities, and every drug user seeking medical help at such a facility will be officially diagnosed with 'drug-addiction'.

This generally leads to negative consequences for patients. For example, they will be automatically registered with the police, and banned from taking certain jobs and from driving.

This mandatory registration system sets up a substantial barrier to health care for IDUs who, fearing stigma and discrimination, try to avoid drug treatment clinics or using social services unless forced to do so.

The right of Ukrainian citizens to treatment is guaranteed by the Constitution. This applies to all Ukrainian citizens, irrespective of the name and nature of disease.

Drug dependency is a chronic condition that needs to be treated in accordance with the standards identified by contemporary science and international best practice.

Constitution of Ukraine

Article 49.

Everyone has the right to health protection, medical care and medical insurance.

...The State creates conditions for effective medical services accessible to all citizens.

Denying access to SMT for drug dependent patients is a violation of lawful right to treatment and health care.

"The illegality of the use of drug substitution such as methadone does not increase the chances of reducing the number of HIV/AIDS. The Commissioner is alarmed by the spread of the virus and sees this as a potential catastrophe for Ukraine... It is the duty of Ukraine to provide treatment, establish rehabilitation and social reintegration services. The HIV/AIDS problem should be addressed urgently".

From the Report by the Commissioner for Human Rights Mr Thomas Hammarberg on his visit to Ukraine 10 – 17 December 2006 (paragraph 196)

SMT and Ukrainian Legislation

An SMT buprenorphine programme was initiated in Ukraine in 2004 with the support of UNDP, in pursuance of a Bill passed by the Ukrainian Parliament following parliamentary hearings on the social and economic problems related to HIV/AIDS and drug abuse. These hearings resulted in a series of recommendations for Ukrainian legislators.

SMT programmes fully comply with the applicable legislation and are implemented pursuant to Item 12 of the National Programme for HIV/AIDS Prevention, Treatment and Support for People Living with HIV/AIDS in 2004– 2008 approved by Decree 264 dated 4 March 2004 issued by the Cabinet of Ministers of Ukraine.

The Government Portal, website of the Cabinet of Ministers of Ukraine, 14 May 2007, <http://www.kmu.gov.ua>

Ukrainian law permits use of substitute medications for medical purposes.

During 2005–2007 the Ministry of Health of Ukraine issued a number of decrees regulating implementation of methadone and buprenorphine-based SMT programmes.



Position of International Organisations

According to the conclusion of the International Narcotics Control Board, the use of SMT does not contradict international drug control conventions.

The above mentioned conventions state that restrictive measures should not impede treatment of drug dependent patients.

Many Governments have opted in favour of drug substitution and maintenance treatment as one of the forms of medical treatment of drug addicts, whereby a drug with similar action to the drug of dependence, but with a lower degree of risks, is prescribed by a medical doctor for a specific treatment aim. Although results are dependent on many factors, its implementation does not constitute any breach of treaty provisions, whatever substance may be used for such treatment in line with established national sound medical practice.

Report of the International Narcotics Control Board for 2003 (2004), INCB, United Nations, paragraph 222

In 2005 the main two drugs used in SMT – methadone and buprenorphine – were added to the WHO Model List of Essential Medicines for use in the treatment of drug dependency.

In 2004 three UN agencies affirmed the importance of substitution treatment as a crucial element of the response to HIV and opiate injection.



The World Health Organization (WHO), the United Nations Office on Drugs and Crime (UNODC) and the Joint United Nations Programme on HIV/AIDS (UNAIDS):

Joint position paper. Substitution maintenance therapy in the management of opioid dependence and HIV/AIDS prevention

Paragraph 23. Substitution maintenance therapy is one of the most effective types of pharmacological therapy of opioid dependence. There is consistent evidence from numerous controlled trials, large longitudinal studies and programme evaluations, that substitution maintenance treatment for opioid dependence is associated with generally substantial reductions in illicit opioid use, criminal activity, deaths due to overdose, and behaviours with a high risk of HIV transmission.

Cost-effectiveness of SMT:

Paragraph 44. According to several conservative estimates, every dollar invested in opioid dependence treatment programmes may yield a return of between \$4 and \$7 in reduced drug-related crime, criminal justice costs and theft alone. When savings related to health care are included, total savings can exceed costs by a ratio of 12:1.



History of SMT in Ukraine

The first pilot SMT projects in Ukraine started in 2004 at drug treatment facilities in Kherson and Kyiv with support from the United Nations Development Programme (UNDP) in Ukraine. These pilots had a limited number of clients.

Buprenorphine was chosen as the substitute drug for project clients because there was no registered methadone formulation in Ukraine at that time. At an early stage of the project, guidelines on administration of buprenorphine were published and doctors were trained in SMT prescription criteria and patient follow-up.

Psychosocial support to project clients was provided by a non-governmental organisation. Patients who were enrolled in the treatment programme suffered from a severe form of opiate dependence: without a job or any legal source of income, they had to engage in criminal activities in order to satisfy their need for drugs, the average daily cost of which added up to about UAH 100.

The pilot SMT programmes were accompanied by an evaluation performed in the framework of a WHO study "Substitution therapy for drug dependent persons and HIV/AIDS".

The first evaluation of the pilot programmes in Ukraine demonstrated that SMT:

- achieved the same results as those reported by evaluators of comparable SMT projects implemented earlier in Western countries
- is a totally safe and technically simple treatment method
- can work in Ukraine, which does not significantly differ from other countries where implementation of SMT has helped contain HIV/AIDS epidemics amongst IDUs.

The achieved outcomes gave a powerful impetus to further scale-up of SMT programmes.

Considering the positive results of the first two pilot projects, the Ministry of Health issued decree 161 dated 13 April 2005 "On implementation of SMT programmes at six government drug treatment clinics in Ukraine".

Outcomes of the first two pilot SMT projects achieved in the first six months (76 patients):

- patient retention rate – 70 percent
- fourfold decrease in illegal opiate use and risk behaviours
- crime rate among project patients dropped to zero.

SMT in Ukraine: Three Years Later

As of April 2008, 756 patients in 23 cities of Ukraine have participated in SMT programmes implemented by the International HIV/AIDS Alliance in Ukraine (Alliance Ukraine) with financial support from the Global Fund to Fight AIDS, Tuberculosis and Malaria (the Global Fund).

Most programme patients have been drug dependent for over 10 years, 60 percent are HIV-positive, the majority are co-infected with hepatitis C, and almost one fifth of them have TB.

One third of the HIV-positive patients are already receiving antiretroviral therapy (ART) and a considerable number of them are being prepared to start this treatment.

The proportion of women in the ART programme is 23 percent, whereas women count for 33 percent of the HIV-positive clients.

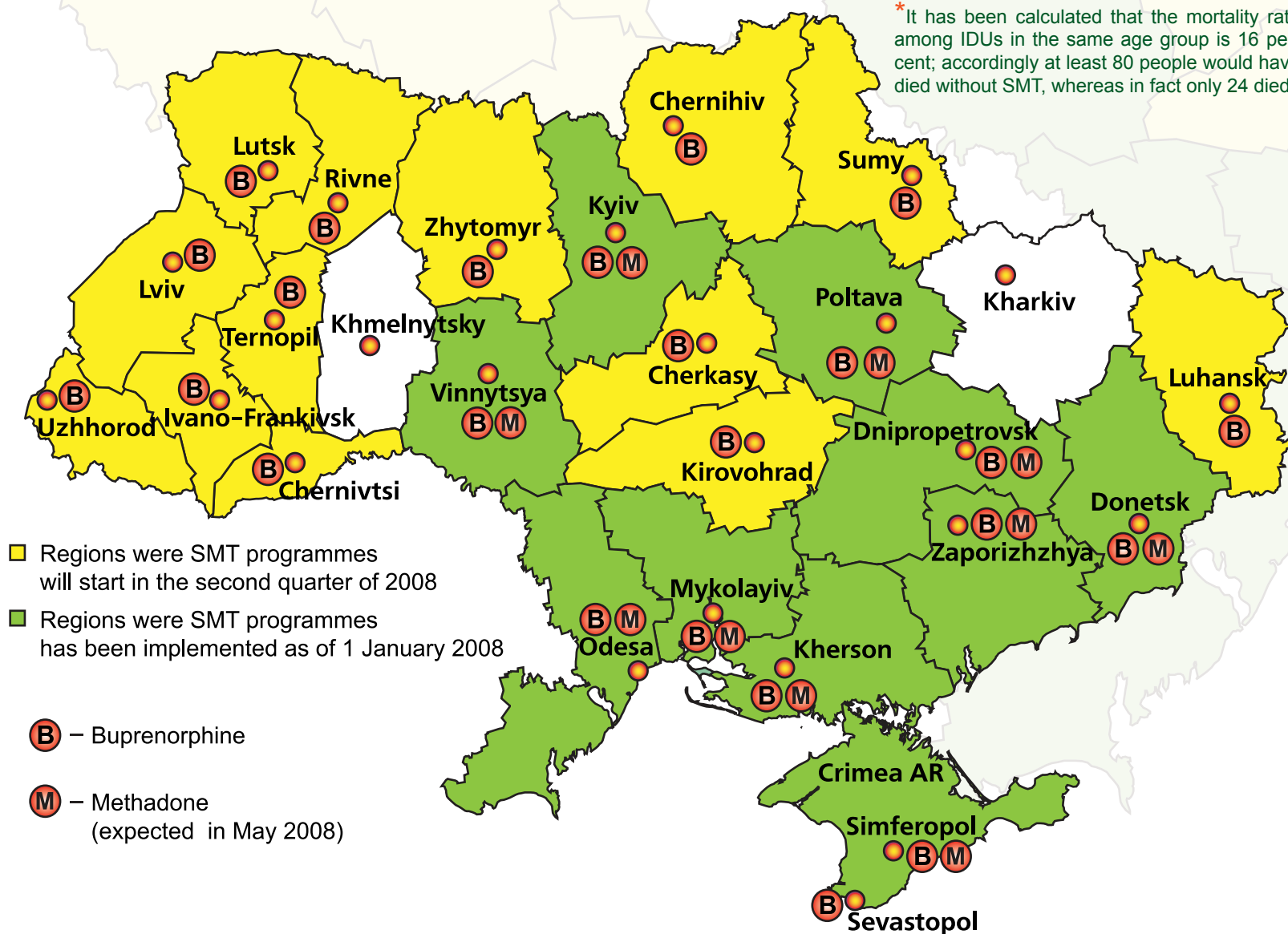
This points to a need to refine and develop treatment services, as well as related outreach services, in order to ensure more tailored service delivery to meet the needs of HIV positive women in the SMT programme.



SMT Programme Successes

- *Illegal opiate use among clients has reduced substantially*
- *risk behaviours have reduced fourfold*
- *over a quarter of clients are receiving life-saving HIV treatment (ART); nearly 20 percent are receiving treatment or follow-up for TB*
- *68 patients have returned to their families, 73 patients have found jobs*
- *56 lives have been saved**
- *because of the SMT programme in 2006–2007 alone, illegal drug traffickers lost about UAH 27 million in illegal profits*
- *medical professionals have observed the effectiveness of the programme, that buprenorphine treatment is safe and efficient, and have developed the skills related to the clinical management of SMT provision*
- *the attitudes of many patients to the programme has changed from distrust to willingness and active participation.*

* It has been calculated that the mortality rate among IDUs in the same age group is 16 percent; accordingly at least 80 people would have died without SMT, whereas in fact only 24 died.





Prospects for SMT Implementation

The SMT programme has received positive feedback from the general public and drug treatment specialists.

Importantly, these pilot SMT programmes have proven to be much more efficient than the traditional 're-formative' approach.

Doctors have learnt that patient behaviour is largely dependent on accurate assessment of the appropriate drug dosage: when the dose is sufficient, the patients are more likely to comply with the treatment regimen.

Psychosocial support of SMT programme clients has also been successful. The involvement of non-medical staff (psychologists, social workers, drug dependency counselors) has been key to this success.

In the framework of the programmes run by the Alliance Ukraine with support from the Global Fund, in early 2008 17 more medical facilities started implementation new buprenorphine-based SMT programmes.

In early April 2008 the first batch of methadone was delivered to Ukraine, allowing 38 medical facilities to start implementing methadone-based programmes for 2220 patients.

150 more HIV positive patients will be enrolled in SMT programmes in Kyiv, Odessa and Mykolayiv within a project supported by the US Agency for International Development (USAID).

It is planned to enrol 300 more patients in integrated methadone-based SMT programmes run in Dnipropetrovsk oblast with support from the William J. Clinton Foundation.

Thus in 2008 coverage is planned for more than 3000 patients with SMT programmes at 54 medical facilities in 23 oblasts of Ukraine.

By July 2009 the number of patients receiving SMT will increase to 6000.

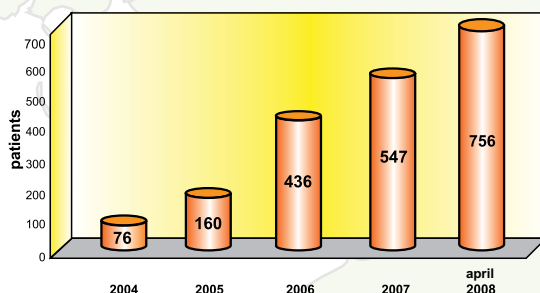
"Substitution therapy has long been recognised as the best international practice to treat drug dependency and prevent HIV transmission amongst injecting drug users due to its medical, social and economic benefits. Why then is it still not implemented in Ukraine?"

M. E. Polishchuk, Head of the Parliamentary Committee of Ukraine on Health, Mother and Child Care, 1 December 2003

Table. Number of patients receiving SMT supported by the Alliance Ukraine, including key characteristics.

Key characteristics	TOTAL
Number of clients	756
including women	173
Average age	35
Average drug history (years)	13,6
Number of clients with HIV, including those on ART	455/155
Number of clients with hepatitis B or C	485
Number of clients with TB	126
Average dose of buprenorphine (mg)	11

Increase in the number of patients from 2004 to 2008





Personal Stories: Patients and Their Parents

Oleg Voynarenko, 29, SMT programme client, Kherson:

"I started using drugs at school. Once I tried homemade opiates, I could never say "no" to them. At first I used them from time to time, but after a year I was taking them every day or even several times per day. However I still thought I could give them up whenever I wanted to. And one day I found myself in a situation when I had to give up: I was offered a good job which required lots of travel. I decided to kick the habit on my own, but on the very first day I started feeling so bad that I had to go to hospital.

That's how my long journey through drug clinics and rehab centres began. Every time I started treatment, I was confident I would never use drugs anymore. And time after time I ended up using again. My family and friends lost hope and were expecting the worst to happen, because my health deteriorated dramatically. I was detained by the police a couple of times, and I thought I was going to go to prison or die soon.

When I applied to a drug treatment clinic again, I was offered substitution therapy. At that time I had no idea what it was. I've only heard some of my friends say that in foreign countries they provide methadone to junkies free of charge, and it just made me envious.

I was offered buprenorphine instead of methadone though. However at that point I didn't care what they gave me, as long as it could keep me from shooting up.

That's how I became a client of the first pilot SMT programme in Ukraine. It didn't take too long to realise that this was the only thing that could help me.

At first it was difficult to readjust. My old life rotated around drugs: find or steal money to buy drugs, find money for tomorrow and so on and so forth. Buprenorphine set me free from this ceaseless merry-go-round.

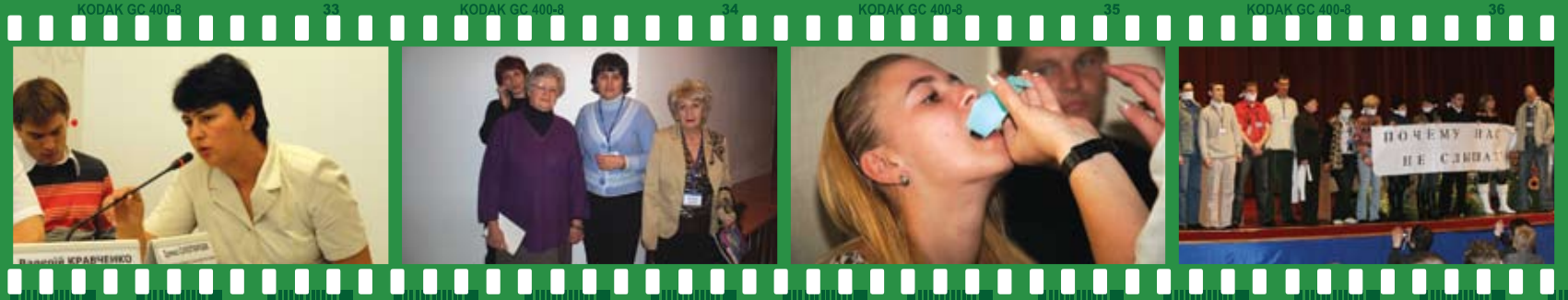
I started to get used to attending my drug clinic regularly to receive my tablets, and I even started thinking about finding a job.

My health improved significantly, I overcame depression as well as I was no longer suffering from pain. I was ready to turn over a new page. I knew there were many drug users in our city who wanted to start SMT but didn't have the chance to join the programme.

So my friends and I decided to set up a community-based drug user organisation which would advocate for our rights and in particular for greater access to SMT. With some support from others we registered the organisation 'Probuzhdennya' ('Awakening'), which has been successfully implementing social projects in Kherson for two years now.

Today, three years on, I am a totally different person: I have a job, I'm studying at university, my family and friends have already forgotten the narcotic nightmare we lived in for so many years.

Whatever people might say, for users like me substitution therapy is the only chance not only to save, but also to change our lives dramatically."



Iryna Sukhoparova, 48, mother of an SMT programme client at the Kyiv city drug treatment clinic:

“My daughter and her husband have been patients of this programme for almost two years. Before they joined the programme, they had been using street drugs for many years, in particular homemade opiates and heroin. They were treated several times at drug clinics and rehab centres, including Christian ones, but it was all in vain.

Only their enrolment in the substitution maintenance therapy programme has enabled them to return to a full and normal life.

Jointly with other parents of the Kyiv-based SMT programme we surveyed 70 patients whose drug history ranged from 10 to 17 years.

They have experienced in full all the negative consequences of this severe disease: they’ve had troubles with the law, some of them have served prison terms, they have many chronic illnesses and a history of troubled relationships with their friends and relatives.

Now they have all rebuilt their relationships with their families, many of them have found jobs, and they are no longer involved in crime as they don’t need to steal money to get another fix.

Among the programme patients there are mothers with one or two children. Their children used to live with their grandparents. Today, thanks to substitution treatment, the parents can bring up their children themselves and take them to kindergarden and school.

They tell me proudly about their children’s success in school and particularly in sports.

Here are just a couple of the most commonly repeated statements by the programme clients who took part in our survey:

- *“My mother never thought it would ever be possible”*
- *“My parents have started to trust me again”*
- *“I’ve come to understand that I love life and that there’s nothing more important for me than my parents and my son.”*

An excerpt from an open letter to Ukrainian President Viktor Yushchenko written by SMT programme clients (4 December 2007):

“... At last we have an opportunity to give up crime, into which we were forced by circumstances, and become active members of society.

While using SMT programme services most of us have managed to quit illegal drugs, find jobs, receive treatment and bear children, availing ourselves of the same opportunities as all other citizens of Ukraine.

However we can show even better results, provided that SMT programmes work in accordance with international best practices, are evidence-based and tailored to the most pressing needs of their clients...”



Methadone and Buprenorphine

Today the most commonly used drugs in SMT programmes worldwide are methadone and buprenorphine. Although each drug has its strengths and weaknesses, four out of five programmes implemented worldwide use methadone.

Methadone

- methadone in Ukraine is 20 times cheaper than buprenorphine, thus allowing treatment of a much higher number of patients. This creates much greater potential for a substantial impact on the HIV/AIDS epidemic among IDUs in Ukraine

- under Ukrainian conditions, methadone requires accurate and flexible dosing by a doctor, along with the patient's strict compliance with the doctor's orders (to prevent the risk of possible overdose, especially in the initiation phase). Effective methadone delivery needs dosing guidelines that are made on the basis of individual need. Underdosing leads to less favourable outcomes
- it is also available in Ukraine on the black market, where drug users use it intravenously. It therefore has a bad reputation with law enforcement agencies and the general public

Buprenorphine

- buprenorphine has a more favourable reputation than methadone amongst the public and policy makers in Ukraine

- if the dose is appropriate, it may be taken once every two days
- it is a prescription drug officially sold in Ukrainian pharmacies; it is included in the National list of essential medical drugs and products (Decree 400 of the Cabinet of Ministers of Ukraine, dated 29 March 2006)
- it is more difficult and time-consuming for medical staff to control sublingual administration of buprenorphine
- there are no official guidelines in Ukraine on administering buprenorphine to pregnant women dependent on opiates
- the drug is very expensive (today the average monthly cost of this treatment course for one patient adds up to \$170, while the cost of a comparable methadone-based course is only \$8)

Table. SMT Drugs Officially Registered and Authorised in Ukraine

No	Name of drug/ brand name	Year of registration	Drug formulation	Manufacturing company
1	Buprenorphine hydrochloride	1997	Injection solution, ampoules	Kharkiv state-run pharmaceutical company 'People's Health'
2	Buprenorphine/Ednok	2001	Sublingual tablets	Rusan-Pharma Ltd, India
3	Buprenorphine Ethypharm	2007	Sublingual tablets	Ethypharm, France
4	Methadone hydrochloride	2003	Concentrated oral solution	BUFA, the Netherlands
5	Methadone/Methanol	2006	Tablets, oral solution	Pharmascience Inc., Canada
6	Methadone/Methaddict	2007	Tablets	Salutas Pharma GmbH/Hexal AG, Germany
7	Methadone hydrochloride/ Molteni	2007	Oral solution	L. Molteni e C. dei fratelli Alitti - Società di esercizio S.p.a., Italy
8	Methadone hydrochloride/Methadose	2007	Tablets; dispersible tablets	Mallinckrodt Inc., USA



There are benefits and challenges with both therapies. The substantially lower cost of methadone suggests much greater potential for scaling up to national coverage of SMT. On that basis, Alliance Ukraine support the scale up of methadone in particular. Its modest cost and the substantial evidence base demonstrating its effectiveness make it a high priority therapy to address HIV vulnerability and opiate dependency in Ukraine.

Different people respond to methadone and buprenorphine in different ways. To meet these different needs, both drugs should ideally be available to treat opiate dependency and to prevent HIV transmission.

It is therefore recommended not to restrict the choice of medication used in substitution treatment to buprenorphine, but instead the government should do everything in its power to simplify the introduction and scale up of methadone maintenance treatment.

Joint WHO/UNAIDS/UNODC Mission on Opioid Substitution Therapy in Ukraine (November 2004)

SMT and Politics

Because of their excessive propensity to populist rhetoric and disrespect for professional opinion, until recently the majority of Ukrainian politicians held negative opinions of SMT.

A number of times, certain political forces in Ukraine have used their objection to methadone treatment as a political argument against their opponents during parliamentary election campaigns.

Politicians have commonly used moral or ideological arguments that do not have a scientific basis regarding SMT. This has hindered the course of SMT introduction, in particular methadone.

Many policy makers are dedicated to an abstinence-based solution to the problem of opiate dependency. Usually they ignore the fact that the failure rate is too high to promote abstinence-based treatment as a primary response to opiate dependency.

While drug-free programmes should be a necessary part of the opioid dependence treatment system, the role of methadone and buprenorphine SMT should be key.

The implementation of methadone-based programmes still meets considerable opposition from Ukrainian law enforcement agencies (Ministry of Interior, Security Service

of Ukraine) and some community-based organisations and faith groups which promote total abstinence from drugs.

Although the National HIV/AIDS Programme envisages implementation of SMT, political opposition hampers full-scale programme deployment.

The MoH of Ukraine has issued new orders on SMT scale-up but these take time to be actually implemented.

The Narcotics Control Board (NCB), despite being affiliated to the MoH, has for a long time ignored MoH decisions to implement methadone-based SMT programmes and publicly voiced its objections.

At the same time drug users regularly report that drug smugglers are providing methadone powder on the Ukrainian black market.

Here we see an obvious paradox: drug control measures are impeding treatment efforts, but have no effect on illegal drug trafficking.

The MoI and SSU consider the hypothetical risk of government-procured methadone leaking into the black market more dangerous for society than the fast-growing HIV/AIDS epidemic and the increasing number of Ukrainians who are dying without receiving the treatment they so desperately need.



Politicians speak about SMT

Some Ukrainian politicians, particularly those who have relevant medical training and education, are aware of international best practices and the efficiency of SMT and are willing to implement it. Politicians who are medically trained have been more open to a scientific and humane drug treatment policy.

“Substitution therapy is a requisite. Its opponents will say that drug users should be ‘burnt, annihilated, or exterminated’.

Yet this is so unreasonable, one has to be mentally ill to say it. Instead of avoiding the problem we should try and solve it. Substitution therapy has proved to be an efficient method in many countries of the world. We should make use of this experience in Ukraine.”

Andriy Shkil, Ukrainian Member of Parliament, 2004

“Methadone-based therapy indeed reduces the flow of illegal drug trafficking and helps resocialise drug users and reduce their involvement in crime. The most vocal opponents of methadone must be those who either knowingly or intuitively are anxious about the potential decrease in illegal drug profits; that is, drug traffickers and corrupt officials.”

Sergiy Shevchuk, Ukrainian Member of Parliament, March 2005

Despite the diversity in opinions, different political parties in Ukraine have one thing in common: whenever their members served as government ministers they all voiced their support for SMT programme implementation and scale-up.

Timeline: Key Advocacy Facts and Events Related to SMT Implementation in Ukraine

December 2003

A hearing on Ukraine’s response to the HIV/AIDS epidemic and illegal drug use is held at the Ukrainian Parliament. Alliance Ukraine Executive Director Andriy Klepikov emphasises the need for SMT programme implementation in Ukraine.

February 2004

The Ukrainian Parliament passes a resolution to approve recommendations put forth at the parliamentary hearing on Ukraine’s response to the HIV/AIDS epidemic and illegal drug use, including the need for SMT implementation.

April 2004

Ukrainian Prime Minister Viktor Yanukovich signs a new National HIV/AIDS Programme for 2004–2008, which inter alia provides for SMT programme implementation.

March 2005

Methadone and buprenorphine are included in the WHO Essential Drugs List.

April 2005

The Minister of Health issues the first order on implementation of SMT programmes in six cities of Ukraine.

June–July 2005

Ukrainian law enforcement agencies attempt to ban the medical use of methadone in Ukraine, but fail after protests by NGOs and international organisations.

November 2005

On behalf of the Government of Ukraine the Minister of Health signs a cooperation agreement with the William J. Clinton Foundation, which includes a commitment to implement methadone-based SMT programmes in Ukraine.

August 2006

Prime Minister of Ukraine Yuriy Yekhanurov signs Ukraine’s Country Proposal to The Global Fund to Fight AIDS, Tuberculosis and Malaria for the 7th round of funding. The proposal includes a commitment to provide access to SMT for 3000 people by the end of 2007.

December 2006–November 2007

The government of Prime Minister Viktor Yanukovich supports activities aimed at implementing methadone-based SMT programmes by issuing a number of necessary decrees.

For the first time in the history of independent Ukraine, the government earmarks national budget funds to treat 300 patients with SMT.

The Minister of Health of Ukraine signs a series of orders that regulate SMT programme scale-up, including methadone-based projects.



December 2007

The issue of methadone-based SMT programme implementation is for the first time considered at a meeting called by the President of Ukraine.

In response to the results of the meeting on 12 December, the President issues a decree aimed at eliminating existing barriers to SMT programme scale-up.

On 18 December the NCB in consultation with the SBU issues a certificate authorising import of the first batch of methadone to Ukraine to be used in SMT programmes.

“Substitution therapy is no magic bullet. However at this point there’s no better approach for countries with fast-growing AIDS epidemics.”

Dmytro Tabachnyk,
Vice Prime Minister of Ukraine,
4 December 2007

January 2008

An amended version of the Law ‘On narcotic drugs, psychoactive substances and precursors’ comes into force. The new law mentions the concept of drug-related harm reduction as one the key strategies of government drug policy.

The law also cancels the government’s monopoly on the use of narcotic drugs for medical purposes, which opens the door for NGO-based implementation of SMT programmes.

International Cooperation

The Global Fund remains the biggest donor supporting Ukraine’s response to the epidemic: about two thirds of all HIV/AIDS prevention and treatment programmes in the country are funded with Global Fund money, including SMT programmes.

The following international organisations provide financial as well as technical support to SMT programme implementation in Ukraine:

- **US Agency for International Development (USAID)**
- **The Clinton Foundation HIV/AIDS Initiative**
- **World Health Organisation**
- **Joint United Nations Programme on HIV/AIDS (UNAIDS)**
- **United Nations Development Programme (UNDP) in Ukraine**
- **United Nations Office on Drugs and Crime**
- **Open Society Institute/ International Harm Reduction Development Programme**
- **French and Italian Red Cross.**

A joint WHO, UNAIDS and UNODC mission that visited Ukraine in late 2004 recommended providing access to SMT for at least 60000 opiate dependent patients in the near future (that is, to approximately 70 percent of officially registered drug dependent people in Ukraine).

The International Narcotics Control Board (INCB) at the request of the national Narcotics Control Board in February 2007 approved Ukraine’s total demands for methadone (procured for medical purposes) which was estimated at 193 kilograms.

This allows Ukraine to freely import the drug from a country of origin in compliance with the strict rules specified by international drug control conventions.

Challenges to SMT Implementation

The existence of supportive national legislation, as well as a fair number of trained professionals who are willing to share their experience, gives us good reason to believe that in the near future most opiate dependent people in Ukraine will have access to high-quality treatment.

At the same time, despite the progress made and the accumulation of good evidence for the effectiveness of SMT, there are still certain barriers to programme scale-up. These can be divided into two types:



Legal and Logistical Barriers

The procedure for the use of narcotic drugs within medical facilities is regulated by decrees of the Cabinet of Ministers and orders of the MoH of Ukraine. These were created at a time when SMT implementation was not on the government's agenda, so specific issues related to SMT provision were not taken into account. A great number of restrictions hinder large-scale implementation of SMT programmes and may have a negative impact on the efficiency of treatment programmes.

These restrictions include:

1. A ban on the use of low-concentration oral methadone solution administered with the help of a dispenser. This is the most common way to administer methadone to patients worldwide, because medical staff can easily control the process.

2. A ban on distribution of substitute drugs to outpatients for take-home use without medical supervision.

Even stable patients who strictly comply with the treatment regimen and could use the substitute drug at home on their own are deprived of this option.

This overstretches medical facilities and makes life difficult for clients who also go to work and have to travel considerable distances every day to get to the clinic and receive treatment. Patients report feeling as

though they are 'chained to their clinic', unable to go outside their city to study, travel or visit relatives.

3. If a patient is hospitalised at another medical facility which is not licensed to supply narcotic drugs for medical purposes, he or she will have to stop their substitution treatment. As a result many patients have to refuse treatment for other chronic conditions.

4. SMT is not available in detention centres and prisons where large numbers of drug users are in acute need of drug dependency treatment.

5. The number of Ukrainian doctors who have been trained in SMT provision is still insufficient. In addition, health personnel report that directors of drug treatment clinics are still not sufficiently motivated to train their medical staff in SMT provision.

Psychological and Economic Barriers

1. Because of limited government support for SMT programmes, patients and doctors feel insecure and fear that the treatment may be stopped at any point due to lack of funding, delayed supply of the substitute drug, or even prohibition of SMT by the government.

2. It is estimated that currently only 10–15 percent of drug dependent people will seek help at drug treatment facilities. This small proportion points to some of the inadequacies of the current system: the restrictive mandatory patient registration system which forces drug users to disclose their illicit drug use, the discrimination experienced by drug users in those facilities, and the ineffectiveness of the therapeutic methods employed in government drug treatment facilities.

3. Drug treatment professionals have still not accepted the idea of treating drug dependent patients in accordance with harm reduction principles; they have no experience of working in multidisciplinary teams, which as well as doctors include social workers and psychologists.

4. Driven by economics, directors of drug treatment clinics often prefer to work with a set number of in-patients, rather than develop out-patient services. The only quantitative indicator used to evaluate a government clinic's efficiency is a set number of beds that are occupied for a set number of days. A clinic has to achieve this target to be eligible for further government funding. This system acts as an incentive to only provide in-patient services, rather than out-patient or outreach services which are more cost-effective.



5. Because of strict internal policies for medical staff, protecting against the risk of legal liability even in case of minor incompliance with the procedure for handling narcotic drugs for medical purposes, directors of drug treatment clinics are afraid to implement SMT programmes and eventually refuse to do so. This problem is exacerbated by inconsistent and incomplete government regulations.

6. Providing treatment, care and support to people who use drugs has only limited public support. Many Ukrainians think that SMT is too expensive to provide to drug users who have “no one but themselves to blame for their disease” while many people with other chronic illnesses also need treatment and adequate financial support. Public education about the society-wide benefits of treating drug dependency is lacking.

7. Staff of drug treatment clinics are often unwilling to treat drug users humanely, or as people with equal rights to services. This undermines the potential for successful treatment.

8. Finally, some directors of AIDS Centres and TB clinics consider implementation and rollout of SMT programmes to be the sole responsibility of drug treatment clinics. However it has long been proven that integration of SMT services into the work of AIDS and TB clinics significantly improves the effectiveness of substitution maintenance treatment.

Recommendations

- **Competent state bodies, first of all the Ministry of Health of Ukraine and relevant oblast and local services, should lead the implementation and scale-up of existing SMT programmes in order to ensure an adequate and timely response to the HIV/AIDS epidemic.**

- **Replicate good practice in effective SMT implementation and by the end of 2008 provide access to SMT for 6000 opiate dependent patients with a particular focus on enrolment of HIV-positive men and women, because they are the key driving force behind increasing HIV/AIDS incidence in Ukraine.**

Given the experience accumulated thus far and the technical expertise provided by many international organisations, it is valid to say that substitution maintenance therapy can become a powerful strategy to contain the epidemics of HIV/AIDS and hepatitis B and C in Ukraine.

- **Implement all provisions of the National HIV/AIDS Programme relating to SMT rollout. Ensure support for the enforcement of relevant orders of the MoH of Ukraine, including fulfilment of the government’s commitments to the Global Fund.**

- **Review and amend the policies and procedures regulating the use of narcotic drugs within medical facilities in order to remove the existing legal barriers to provision of SMT in accordance with the best international practices.**

- **Actively promote NGO and drug user community participation in SMT programme design, delivery, monitoring and planning of further service improvement.**



Key Messages

- *Treatment and prevention of HIV/AIDS is primarily the responsibility of medical professionals, working with their patients, who make informed decisions about what drugs should be used to treat their patients based on the best evidence.*
- *Law enforcement and regulatory agencies should not impose barriers to or restrictions on SMT programme scale-up. Their role is to fight illegal drug trafficking and to monitor the legal use of narcotic drugs.*
- *SMT providers should rely upon a relevant and updated legal framework that regulates the use of narcotic drugs within medical facilities.*
- *All patients with chronic opiate dependency should have access to SMT regardless of their HIV status.*
- *Social and psychological support to patients on SMT can significantly improve treatment effectiveness.*
- *Ukraine should draw on international best practice and lessons learnt by other countries that have managed to halt the spread of HIV/AIDS among IDUs.*
- *SMT programmes should be funded by the government, not only by international donors.*
- *Scale-up of a methadone-based SMT programme will help to significantly reduce the cost of other prevention and treatment programmes and save money in the national budget.*

Covering 6000 patients with SMT services in 2008-2009 will allow Ukraine to start designing a truly effective response to the challenges of the HIV/AIDS epidemic.

Substitution Maintenance Therapy in Ukraine: Can the Community Respond Effectively to the Challenges of HIV/AIDS?

© International HIV/AIDS Alliance in Ukraine
5 Dymytrova St., building 10A, 03680 Kyiv
Tel.: (+380 44) 4905485
Fax: (+380 44) 4905489
e-mail: office@aid alliance.kiev.ua
<http://www.aid alliance.kiev.ua>

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Authors:
Sergiy Dvoryak (Ukrainian Institute on Public Health Policy)
Pavlo Skala (International HIV/AIDS Alliance in Ukraine)
Design: Andrei Mukhin
Translation from Ukrainian: Dmitriy Vozniyk
Proof-reader: Lily Hyde

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