Expanding Access to Opioid Substitution Therapy for Injecting Drug Users in Eastern Europe and Central Asia

IAS Yalta Scientific Leadership Summit
17 – 18 October 2008

Table of Contents

Executive Summary:

The International AIDS Society (IAS) convened a scientific leadership summit of senior narcologists, psychiatrists and infectious disease specialists from 7 countries across Eastern Europe and Central Asia (EECA), from 17-18 October 2008, in Yalta, Ukraine. The purpose of the summit was to mobilize action on expanding access to opioid substitution therapy (OST) for injecting drug users (IDU). The meeting was co-chaired by Michel Kazatchkine, the Executive Director of the Global Fund (GFATM) and IAS Governing Council member, and Craig McClure IAS Executive Director. The primary objectives of the meeting were to review the current state of HIV among IDUs in the region, the body of evidence supporting the use of OST and country experiences with this intervention. In addition, the significant challenges and opportunities for expanding access to OST were discussed.

Five major recommendations emerged from the discussion:

Urge health professionals and researchers throughout the world to support colleagues in the region to work together to overcome the barriers to expanding access to opioid substitution therapy. Activities to overcome barriers should include –

1. Urgent adaption of global normative guidelines on HIV prevention, including opioid substitution therapy, among injecting drug users to the regional context to support effective national policy development in EECA;

2. Expansion of language-relevant information dissemination on harm reduction and opioid substitution therapy to the scientific, public health and clinical community in Eastern Europe and Central Asia.

3. Removal of legal and regulatory barriers to expanding harm reduction programmes including opioid substitution therapy, and support for a paradigm shift from criminal justice to a public health approach to addressing opioid dependency;

4. Development of campaigns that educate the general public, policy makers, law enforcement, the media and community stakeholders about harm reduction and opioid substitution therapy; fight stigma and promote the rights of people who use drugs

5. Review of policies and delivery systems to allow expansion of access to opioid substitution therapy through practicing clinicians, HIV treatment centers and family doctors.

IAS follow up to the Yalta Summit will include providing ongoing support to regional networks of health professionals on OST and HIV; production and dissemination of Russian language technical documents on OST; engaging international processes on drug policy including the Commission on Narcotic Drugs in Vienna; and development of an advocacy initiative to leverage the AIDS 2010 conference in Vienna. The IAS offered free membership to all regional participants at the Yalta Summit as a first step towards ongoing engagement and building of a regional reference group for future advocacy.

1. Introduction

The International AIDS Society (IAS) convened a scientific leadership summit of senior narcologists, psychiatrists and infectious disease specialists from 7 countries across Eastern Europe and Central Asia (EECA), from 17-18 October 2008, in Yalta, Ukraine.[1] The purpose of the summit was to mobilize action on expanding access to opioid substitution therapy (OST) for injecting drug users (IDU). The meeting was co-chaired by Michel Kazatchkine, the Executive Director of the Global Fund (GFATM) and IAS Governing Council member, and Craig McClure IAS Executive Director. The primary objectives of the meeting were to:

- discuss the state of the HIV epidemic among IDU
- review the body of evidence supporting use of OST
- map availability, country experiences and challenges in scaling up OST
- discuss priority actions moving forward, and explore opportunities for expanding access to OST for people who inject drugs
- develop and publish a statement on IAS's position on expanding access to OST for injecting drug users in Eastern Europe and Central Asia

In his opening remarks, Michel Kazatchkine acknowledged the leading role of the GFATM in funding harm reduction programmes across EECA. He expressed concern that despite opioid substitution therapy being one of best studied, most effective interventions, with compelling, abundant evidence supporting its use[2] [in treatment of opioid dependence and with regards HIV prevention, treatment and care], the number of methadone and buprenorphine programmes in the region have remained stable or have increased very slowly since in-country introduction. *'There is something wrong with the perpetual pilot status on what is one of the best documented interventions in HIV/AIDS' Michel Kazatchkine, October 2008, IAS Yalta Summit.*

Michel Kazatchkine further called on participants, whose experience, knowledge and expertise focuses on HIV and on treatment of drug dependence, to come together with strong commitment to science and support scale up of OST; recognize drug related issues as a health problem; recognize harm reduction with all its components as an essential element of a comprehensive response to HIV/AIDS; and advocate for decreased regulation of methadone and buprenorphine given that excessive reliance on drug enforcement is a barrier to scaling up.

Craig McClure noted that HIV has exposed the ugly underbelly of our societies around the world with the impact deepened by extreme poverty, social exclusion and marginalization of vulnerable groups including women and girls, homosexuals, sex workers, migrants, prisoners and injecting drug users. In many countries, development of effective policies and implementation of evidence-based interventions is undermined by politically or morally motivated beliefs, attitudes and practices while people continue to die of HIV that can be prevented, and illness related to opioid dependence that can be treated. He added that 'one of the great lessons of the HIV epidemic is that the involvement of affected communities and the respect and promotion of the human rights of all peoples is a fundamental principle required to achieve good public health'.

2. State of the Epidemic - A Public Health Emergency

The first session of the meeting focused on presenting the status of the IDU and HIV epidemics in EECA. There was general recognition that the world is facing a global epidemic of injecting drug use. It is estimated that there are 16 million injecting drug users in 148 countries worldwide, out of whom over 3.7

[1] 25 delegates from Russian Federation, Ukraine, Belarus, Kazakhstan, Kyrgyzstan, Georgia, and Uzbekistan. Invited participants from Lithuania and Tajikistan were unable to participate due to unforeseen circumstances at the last minute.

[2] Wodak A and McLeod L**.** The role of harm reduction in controlling HIV among injecting drug users. *AIDS* 2008; 22 (suppl 2):S81–S92.

million are in EECA.[3] While in other parts of the world there is a general shift towards injecting amphetamine and slight increase in opioids, in EECA and Asia regions, opioids remain the drug of choice. Globally 3 million IDUs are living with HIV, accounting for ten percent of infections worldwide and 30% of new infections outside sub-Saharan Africa. While in most regions of the world HIV prevalence is stable or declining, in EECA the epidemic is still expanding rapidly. Studies show that over time, the proportion of IDUs living with HIV may peak due to changes in HIV testing strategies, and more importantly because of the reporting of a sustained increase in heterosexual transmission related directly or indirectly to IDU. 2008 UNAIDS report shows that overall 62% of the HIV epidemic in this region is attributable to injecting drug use, although the proportion may rise up to 80% or higher in heavily affected countries like the Russian Federation; over 35% of HIV positive women were infected through sharing of contaminated injecting equipment; and another 50% of women living with HIV were infected via unprotected sex with an infected IDU.[4]

The dual epidemics of HIV and IDU pose a public health emergency, associated with physical, mental and social harm. This is compounded by morbidity and mortality created by other public health consequences of injecting drug use including blood-borne viral infections like hepatitis B and C, tuberculosis and other infectious diseases, sexually transmitted diseases, negative impacts on reproductive health, mental health disorders, increased crime and social dysfunction. Discussions that followed showed clearly that the public health emergency due to IDU and HIV will continue to unravel for several years, and yet programs in most countries remain too small to contain the HIV epidemic, while international standards of care for people who use drugs are also not universally applied.

3. Review of Evidence Supporting Use of OST [5]

Research and scientific advances over the past 20 years have shown that drug addiction is not a crime, but a serious relapsing and remitting chronic disease that results from the prolonged effects of drugs on the brain. The development of the disease is a result of complex interaction between repeated exposure to drugs, biological, social and environmental factors, and permanent neurological changes on motivation pathways in the brain.[6]

Gundo Weiler, WHO Ukraine, presented an overview of the evidence for effectiveness of opioid substitution in treatment of drug dependence, and evidence in support of substitution treatment in the context of Universal Access. He added that in July 2005, following a rigorous review process, the WHO Expert Committee on the Use of Essential Drugs consisting of experienced scientists and clinicians from all regions of the world added methadone and buprenorphine to its Model List of Essential Medicines.[7] Participants were reminded that weak evidence indicates that other modalities of treatment including abstinence programmes, antagonist treatment and detoxification, and rehabilitation can also have some benefits, however, while they may result in complete abstinence; they do not work for the majority of IDUs. WHO and UNODC representatives at the meeting also stressed that detention or forced labour are NOT forms of treatment, but are clear inhumane violations of the rights of people who use drugs.

The discussion acknowledged that while OST is not a panacea, there is good evidence showing that regular use of opioid agonist maintenance treatment with methadone or buprenorphine results in significant reductions in mortality, HIV, drug use and crime; compared to detoxification alone. A multi-country collaborative study conducted by WHO to compare outcomes of treatment in different parts of the world

[3] Mathers B.M. et al. Global epidemiology of injecting drug use and HIV among people who inject drugs: a systematic review. The Lancet (online edition) September 24, 2008.
[4] UNAIDS. 2008 Report on the Global AIDS Epidemic. July 2008.
[5] Power point presentation made by Gundo Weiler, WHO Ukraine, can be found on the IAS website at www.iasociety.org
[6] UNODC and WHO. Principles of Drug Dependence Treatment. March 2008. http://www.who.int/substance_abuse/publications/principles_drug_dependence_treatment.pdf (December 2, 2008).
[7] WHO Model List of Essential Medicines, 15th list March 2007. http://www.who.int/medicines/publications/EssMedList15.pdf (December 1, 2008).

found very similar outcomes in different settings including with regards to reduction in heroin use; retention in treatment and reduction in injecting risk behaviour[8].

Summary of research findings that support body of evidence on OST:[9]

- reduction of overall rates of death
- reduction of risk of overdose
- increased retention in drug treatment programmes
- reduction in heroin use in patients; reduction or cessation of illicit drug use
- reduction of risk of transmission of blood-borne infections
- substantial reduction of involvement in criminal activity
- improvement in psychological and physical health
- improvement in re-integration into the workforce and education system
- improvement in social functioning
- reduction in complications for pregnant women and their unborn children who are in OST programmes in comparison with those who are not in treatment
- cost-effectiveness and net financial savings: with 4 to 7 fold savings in reduced drug-related crime, criminal justice costs and theft alone. May exceed 12 fold if healthcare costs included
- no evidence for overall increased drug use in community

Dr. Weiler reiterated that substitution maintenance therapy is a core component of the Universal Access package. Opioid agonist maintenance treatment reduces HIV sero-conversion rates and also improves adherence to ART. Weiler expressed concern that active IDUs are often excluded from treatment or receive treatment late, and yet can achieve good adherence and can have low resistance rates with OST. He emphasized that OST, however, is part of a package of harm reduction services delivered through multiple channels including community outreach, health and social services, and prison settings.[10] He outlined the essential elements of harm reduction including information, education, counselling; HIV testing and counselling; drug dependence treatment, including opioid substitution; needle and syringe programmes (NSP); condom promotion and STI diagnosis and treatment; HIV treatment and care, including ART; hepatitis B vaccination and treatment of viral hepatitis.

OST in the context of Universal Access:[11]

- reduce sero-conversion and HIV prevalence
- reduce risk of HIV transmission and infection
- reduce both the proportion of drug users who inject, and the frequency of injection
- slow long-term progression of HIV disease
- increase adherence to antiretroviral therapy
- promote right to highest attainable standard of health
- provide opportunities for enhancing contact with / and increase access to health and social support systems – without OST, IDUs are more likely to get tested late and receive care late

[8] Lawrinson P et al. Key Findings from the WHO collaborative study on substitution therapy for opioid dependence and HIV/AIDS. *Addiction* 2008; 103(9): 1484-1492.
[9] WHO/UNODC/UNAIDS. Substitution maintenance therapy in the management of opioid dependence and HIV/AIDS prevention. Position Paper. 2004. (accessed September 2008).
[10] From a human rights and public health perspective: "Prisoners and detainees have a right to the protection of their physical and mental health of the same quality and standard as is afforded to those who are not imprisoned or detained." Adopted by United Nations General Assembly resolution 37/194 of 18 (Dec. 1982).
[11] WHO. Effectiveness of Drug Dependence Treatment in Prevention of HIV Among Injecting Drug Users. Evidence for action technical papers. 2005. (accessed September 2008).

4. Mapping availability OST

To provide meeting participants with current information on the state of OST in EECA, IAS engaged the Eurasian Harm Reduction Network to conduct a mapping of policy, regulation, introduction and availability of methadone and buprenorphine across the region.[12] Oleg Aizberg from the Department of Psychiatry and Narcology, Belarus Graduate School of Medicine, Minsk, conducted standardized interviews with key informants from selected countries. The report reflects the November 2008 status of OST across selected countries in EECA.

Summary of findings[13]

In 1995, substitution therapy was introduced in Lithuania, the first country of the former Soviet Union to do so. It has since been introduced in many countries in the region including Ukraine, Kyrgyzstan, Georgia and Belarus. Despite overwhelming evidence, OST is still illegal in Russia and is yet to be introduced in Kazakhstan, Tajikistan and Turkmenistan. The mapping exercise echoed the concerns expressed by participants around low patient coverage levels across all countries in EECA. The country with the highest coverage, Ukraine, reaches less than 5% of injection drug users who need opioid substitution treatment. While progress has been made, OST programmes have remained largely as perpetual pilots, with numbers in treatment stable or increasing very slowly. Kyrgyzstan is the only former Soviet Union country where OST operates in the prison system.

The discussion emphasized the need to bring all OST programmes to scale, and called on the GFATM to create accountability mechanisms that require countries to scale up for example through performance based funding, the technical review panel, grant monitoring and evaluation, programme funding guidelines and support to country coordinating mechanisms. Zurab Sikharulidze suggested that from the start, Global Fund agreements should limit length of pilot projects and special procedures of scaling up developed as early as possible in order to avoid permanent pilot status and the emergence of barriers to scale-up. Michel Kazatchkine reminded participants that while the Global Fund advocates for priority actions against AIDS, TB and Malaria, a strong and unique principle is to respond to nationally defined priorities and plans.

Aizberg noted that regulation of OST in all the countries surveyed is accomplished by health ministry directives. The survey found that buprenorphine is significantly more expensive than methadone in a number of countries, including Ukraine and Lithuania. Despite widespread fears of diversion of methadone, to date there have been only occasional reports of incidents of methadone selling on the black market[14]; he added, however, that Georgia is alone in facing high levels of popularity of illegal buprenorphine. This could be explained in part by the demand created by out-of-pocket payments of US$100 per month for patients receiving government-subsidized treatment. Participants also observed that in many countries, methadone is transported by armed guards to prevent diversion onto the black market; and as a result this drives up costs and undermines cost-effectiveness of programmes.

[12] International AIDS Society and Eurasian Harm Reduction Network. Opioid Substitution Therapy in Eastern Europe and Central Asia. Lead consultant Oleg Aizberg; reviewed by Raminta Stuikyte and Emilis Subata. December 2008.
[13] Power point presentation made by Oleg Aizberg can be found on the IAS website at www.iasociety.org
[14] The meeting was told of a report of a nurse caught selling small doses of methadone in Kyrgyzstan.

Availability of OST In Selected EECA Countries[15]

Country	Year Introduced	On OST '08	Estimated IDUs**
Lithuania	1995	410 in 14 Centers	8,500
Kyrgyzstan	2002	735 in 7 Centers	44,398
Georgia	2005	455 in 3 Centers	12,420
Belarus	2007	50 in 1 Center	45,842
Ukraine	2004	1956 in 38 Centers	400,000
Uzbekistan	2006	140 in 1 Center	40,000
Kazakhstan	Planned 2008		
Tajikistan	Planned 2009		
Russian Federation	Opioid substitution therapy is illegal in Russia		

***Source: IHRD; Harm Reduction Developments, 2008*

5. Country experiences and challenges in scaling up OST

Stigma against drug dependence is very high.
Many participants noted that across several countries, stigma against people who use drugs and those who work with them is very high. McClure reminded the meeting that stigma is also very high in other regions, and has contributed to regressive policy on harm reduction including a 20 year ban on needle exchange in the US, and ongoing battles with the Canadian government to protect gains in securing key strategies including supervised injecting sites.

Participants also felt that there is general lack of media and public support for OST in EECA. Unfriendly journalists and public opinion mean that isolated instances of abuse can undermine and jeopardize an entire programme. Many believed that some civil society organizations and PLHIV do not support OST. HIV and IDU community involvement in advocacy for OST is generally limited, and there is an urgent need for more community champions and expanded community leadership. The group proposed development of national campaigns to challenge stereotypes on drug users, highlighting how they are treated and help de-stigmatize drug dependence.

Standard of Care in the Region
Qualifying criteria for entry into treatment and standards of care vary widely across the region. Policies such as those requiring the involvement of multiple specialists to authorize initiation of treatment or those forbidding take home doses of medication[16]; distance to treatment centres and health system constraints including shortage of drug dependency treatment professionals, further undermine efforts to reach greater numbers of IDUs. In addition, there is inadequate provision of psychiatric and social services to support OST programme clients.

[15] International AIDS Society and Eurasian Harm Reduction Network. Opioid Substitution Therapy in Eastern Europe and Central Asia. Lead consultant – Oleg Aizberg; reviewed by Raminta Stuikyte and Emilis Subata. December 2008.
[16] However, in Lithuania patients are allowed to take up to six days' doses of methadone for treatment at home; while in Kyrgyzstan, methadone doses are dispensed for home use over weekends and holidays

Range of qualifying criteria for OST programmes in selected countries:

Belarus and Kyrgyzstan	Georgia
- patient over 18 years old - two or more unsuccessful attempts at treatment - regular injected opioid use; more than two years history of opioid use - HIV positive or diagnosed with AIDS are treated with top priority	- age 25 or older - at least one treatment attempt - total opioid use three years; at least one year intravenous - HIV positive patients are treated with top priority

Vladmir Mendelevich, Professor Psychiatry Kazan University, emphasized that the situation is especially worrying in the Russian Federation. The abstinence-based treatment paradigm prevails among drug dependency treatment facilities. Prevailing treatment protocols are at variance with the principles of evidence-based medicine and drug dependency treatment specialists, patients and the public are ill-informed about OST.

Many participants were surprised to hear that there is ongoing clinical research in Russia conducted by Levon Isakulyan, testing the use of the opioid receptor agonist-antagonist nalbuphine in the treatment of opioid dependence. Nicholas Clark, WHO Geneva, cautioned that WHO was not aware of the ongoing trials, and would not recommend treatment that does not meet the standard of effectiveness demonstrated by methadone or buprenorphine in treatment of opioid dependence. He further added that nalbuphine has not been tested as part of a comprehensive harm reduction package for HIV prevention, care and treatment. The discussion that followed concluded while it is not the drug of choice, nalbuphine trials may create an entry point for use of OST in Russia. Participants suggested that WHO should urgently monitor the ongoing clinical trials in order to provide normative guidance on the use of nalbuphine in treatment of opioid dependence and in the context of universal access.

Knowledge and awareness

There is a poor level of awareness among specialists, law-enforcement authorities and the general public on the evidence and scientific rationale for OST in the treatment of drug dependence; and its critical role in HIV and other injecting-related public health problems. Aizberg noted that while methadone and buprenorphine have been tested in several clinical trials, there are very few publications in the Russian language; a broader number of providers and policy makers are therefore not able to access information contained in these publications to influence development of evidence-based policy and treatment strategies.

Sergey Dvoryak, Director Ukrainian Institute on Public Health Policy, observed that in many countries of EECA, drug dependence treatment is the domain of narcologists and psychiatrists; while on the other hand, HIV prevention, treatment and care is managed by infectious disease and public health experts. Many in the group expressed the need for a review of regulatory mandates in order to expand training and licensing, allowing experts in HIV treatment, infectious disease, public health, family doctors and general practitioners to prescribe and treat opioid dependence with OST.

> *"There is not enough information on [OST] in Belarus. Ministry of Health had the idea that OST is a secret therapy and we are not supposed to talk about it and it led to more and more myths appearing in the media." Oleg Aizberg*

Oleg Mustafin noted that while OST is completely legal in Uzbekistan, legislation forbids advertising of narcotic drugs hence creating difficulties in information dissemination about OST programmes as this process could be considered as a form of advertising.

Political Leadership, burdensome regulations and law enforcement

There is generally insufficient political leadership on OST across the region. Irina Grishaeva acknowledged that where it has worked, as in the case of the President of Ukraine and parliament in Uzbekistan, political support at higher levels (parliament, president, ministries of health, law enforcement and security) has been critical in the introduction of OST programmes in EECA. However, participants feared that turnover in political leadership may threaten the programme if new officials or politicians are not brought on board. On the other hand, lack of political will and fear of public opposition to OST creates deeply entrenched barriers to the introduction of OST and / or fuels irrational arguments against the expansion of pilot programmes to national scale.

Participants discussed experiences on how law enforcement, burdensome regulations and harsh criminal justice strategies undermine HIV prevention efforts and interfere with IDUs' retention in treatment and their ability to access opioid substitution therapy programmes. Pavel Skala, International AIDS Alliance Ukraine, highlighted strategies employed by his programme in engaging law enforcement. High-level advocacy, political support and leadership have been critical in creating the necessary enabling environment for introduction of OST. This was achieved also through continuous information and education conferences for key stakeholders including policy makers and critical line ministries; visits to countries with model programmes, and dissemination of tailored literature on OST.

Participants discussed how there could be potential backlash resulting from diversion of methadone and buprenorphine and instances of negative press coverage of OST. Some countries also face corruption and demand for bribes amongst law enforcement; and harassment of clients by police. This is compounded by complications in the paperwork required for methadone procurement and importation and may lead to delays in issuing of licenses for treatment centres. Participants feared that corruption may undermine political support and development of national policy towards OST.

The main conclusion from the discussion was that OST introduction needs broad participation of civil society and different government institutions. International organizations like WHO, GF, UNODC, UNAIDS and IAS also play a significant role in that process. Further, it was stressed that it is not enough to mobilize one-off high-level political support for the introduction of OST; sustained political engagement and support is also needed to succeed in scaling up national programmes.

International Drug Policy

Fabienne Hariga, HIV/AIDS expert UNODC, recognized that there is a lack of awareness at country level of international conventions and UNGASS[17] supportive of OST. Myths abound at national level resulting in the creation of legal and regulatory barriers against OST. In the Russian Federation, the *Law on Narcotics and Psychotropic Substances* of 1998 prohibits OST; and while OST is legal in Kazakhstan, the interior ministry is continuously denied permission to import methadone.

Drug control conventions and harm reduction

- [18]The Single Convention of 1961 specifies that the "Parties shall give special attention to and take all practicable measures for the prevention of abuse of drugs and for the early identification, treatment, education, after-care, rehabilitation and social reintegration of the persons involved". Article 38 of the Convention, states that *medical care of drug abusers may include all the tools required to treat the adverse health consequences of substance abuse*

[17] UNGASS. Political Declaration and Declaration on the Guiding Principles of Drug Demand Reduction. 1998. http://www.alde.eu/fileadmin/images/Photo_Library/2008/080306-Towards_a_drug-free_world-ALDE_meeting/Political_Declaration_UNGASS.pdf (accessed December 2008).

[18] International Narcotics Control Board (INCB), established by the 1961 Convention and independent of Governments and the UN, is composed of thirteen (13) members who serve in their personal capacity and are elected by the United Nations Economic and Social Council (ECOSOC) (3 from a list of candidates nominated by WHO and 10 from a list nominated by Governments). It is the monitoring body for the implementation of the international drug control conventions.

- [19]The 1988 UN Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances (article 14 paragraph 4) indicates that "parties to the Convention shall adopt appropriate measures aimed at eliminating or reducing illicit demand for narcotic drugs and psychotropic substances, *with a view to reducing human suffering…which includes interventions to counteract the social and health consequences of drug abuse*".

Hariga stressed that the International Narcotics Control Board (INCB) supports harm reduction, as outlined in the INCB Report1993: "The Board … acknowledges certain aspects of harm reduction as a tertiary prevention strategy for demand reduction programmes"; and in the INCB Report 2000: "Harm reduction programmes can play a part in comprehensive demand reduction strategies but should not be carried out at the expense of other important activities to reduce the demand for illicit drugs, for example drug abuse prevention activities"; and that "Harm reduction should constitute one element of a larger, more comprehensive strategy to reduce the demand for illicit drugs"; INCB Report 2003: "The ultimate aim of the Conventions is to reduce harm" (Article 218); The implementation of drug substitution or maintenance treatment as one of the forms of medical treatment of drug addicts "does not constitute any breach of treaty provisions, whatever substance may be used for such treatment in line with established sound national medical practice."[20]

Participants indicated that more technical support from UNODC was needed to advise law enforcement ministries and drug control committees on drug policy including drug quotas, procurement and reporting to INCB.

Normative Guidelines; Assessment and Monitoring[21]

Mendelevich noted that there is a lack of trust in scientific evidence generated from outside EECA. Alexandr Goliusov stressed that in Russia key experts in narcology and psychiatry, consider methadone and buprenorphine as 'substitutes of one narcotic drug for another', but not as a treatment strategy for opioid dependence. Konstantin Lezhentsev added that in many countries of the region, a serious disconnect exists between the evidence-based discourse of the scientific community and the perception of opioid substitution therapy among policy makers, law enforcement authorities, the medical community and the general public. Evidence on the use of OST is poorly translated into national legislation; policies, official ministry of health directives, rulings or guidelines – and as a result normative guidelines developed at the global level are rarely put into practice in EECA.

Irina Grishaeva further noted that scale-up of national programmes is hampered by the lack of research defining and estimating denominator populations of injecting drug users, and lack of investment in defining adequate levels of coverage with OST required to curb or reverse HIV epidemics among IDUs. Country programmes are grappling with target setting, measuring and tracking indicators of progress, and development of operations research that can generate national evidence on the effectiveness of local programmes. Studies show that with low availability of OST, NSPs alone do not have substantial impact on HIV prevalence. Countries that have successfully controlled HIV epidemics have reached substantial OST coverage rates among IDUs.

6. Recommendations for action and opportunities for expanding access to OST

The Summit was divided into two groups to explore strategies and opportunities for expanding access to OST, examine priorities for action and discuss steps moving forward. Group discussions were built around 3 broad issues – research and evidence; normative work; and advocacy for scale-up – informed by cross-

[19] United Nations. UN Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances. 1988. http://www.unodc.org/pdf/convention_1988_en.pdf (accessed December 2008).
[20] International Narcotics Control Board (Annual Reports). http://www.incb.org/incb/annual_report.html (accessed December 2008).
[21] Donoghoe M.C. et al. Setting targets for universal access to HIV prevention, treatment and care for injecting drug users (IDUs): Towards consensus and improved guidance. *International Journal of Drug Policy*, April 2008.

cutting themes of human rights, public health and the context of universal access to comprehensive HIV prevention, treatment and care by 2010.

a. Research and Evidence

Many participants stressed that evidence from international studies had limited credibility in influencing leading scientists and policy makers within the region. It was pointed out that while this is usually sufficient for application in the development of normative and operational guidelines; national studies would be extremely valuable in engaging parliamentarians, strengthening involvement of local communities of people who use drugs and in expanding continuous physician education and mentoring of general practitioners. It was agreed that there is therefore rationale for strategic research aimed at developing trust in evidence and informing local normative guidance.

- **Generate national and regional evidence** through multi-country collaborative research. There was general consensus that there was no need for more clinical trials on OST. It was recognized that this research would be duplicative on a scientifically proven intervention. The aim of the multi-country collaborative research, however, would be to provide regionally generated scientific evidence to influence policy makers.

- **Disseminate scientific evidence**: Participants expressed concern regarding the low level of dissemination of scientific evidence across EECA. They observed that there was need for more training, dissemination of information in regional languages, including Russian, and development of initiatives that turn science into action. Translational scientific materials for dissemination to medical community and initiatives to enhance application of evidence-based medicine on OST were also identified as priorities.

- **Build national research platforms on OST and HIV:** Participants recognized the challenge of moving the issue of OST in the face of lack of trust in the information and the substantial number of publications that form the body of evidence supporting use of OST. Vladmir Mendelevich proposed the establishment of national research platforms on OST. The purpose of these platforms would be to bring together key stakeholders including the ministry of health; law enforcement; drug policy experts; working groups of experts in addiction therapy from opposing sides [in support of and against OST]; HIV/TB and infectious disease experts; and representatives of people who use drugs.

  The OST research platform would have four broad aims – a) generate a healthy dialogue on evidence on OST, ensuring access to strategic information by relevant authorities and build trust in available evidence; b) stimulate research needed in building the essential body of evidence based on regional and national data; this may entail repeat of studies already proved elsewhere, review of effectiveness of existing programmes or collaborating in multi-country research to expand access to data; c) provide a mechanism for contributing to development and review of evidence-based national legislation, policy and normative guidelines; and d) support advocacy efforts on expanding access to OST

- **Operations research:** The group as a whole felt that given the diversity of approaches to implementation of OST programmes across the region, there was an urgent need to conduct and institutionalize operations research to examine effectiveness of different delivery models, cost effectiveness, and how OST is integrated with HIV, TB, and other health and social services. Operations research would also generate data for cross-country comparison, highlight factors that influence scale-up; examine linkages to other public health concerns created by injecting drug use and HIV, and build a body of knowledge for regional exchange of lessons learned.

- **Social research:** Sergey Dvoryak highlighted the need for more social research to understand the impact of social-cultural and political context on the outcomes of OST programmes; and to understand why there is low uptake of scientific research and evidence generated; understand barriers to OST, solutions, and environmental factors.

b. Normative work on OST in EECA

Participants acknowledged the ongoing support provided by normative agencies including WHO, UNODC and UNAIDS. However, the group as a whole felt that more support was needed from WHO and UNODC in raising visibility of technical challenges countries in EECA are facing in introducing and scaling up OST, and also for specific technical support and translation of normative guidelines into national laws, regulations and policies. Nicholas Clark, WHO expert, cautioned that plans for scaling up national OST programmes should also take into account key issues including dosage, selection of patients, services provided on site, management of procurement and supply chain, mitigating overdose and diversion of methadone and buprenorphine, and long-term sustainability of programmes.

- **Identified issues include –**

- methodology to estimate and track populations of injecting drug users, and trends in evolution of drug use including proportion who use heroin, amphetamines, cocaine, etc.
- research to estimate demand for methadone and buprenorphine; and OST coverage necessary to curb and begin to reverse the HIV epidemic amongst IDUs and impact public health
- target setting for universal access
- technical support to translate WHO protocols, evidence and scientific data into specific equivalent national regulation and treatment guidelines
- technical support to scale up pilot OST programmes into national level programmes
- standardized tools and technical support to increase documentation of OST effectiveness; comparative analysis of results across countries; and case studies of best practice;
- coverage – to take into account contextual factors and benefits; what should be the indicators of the quality of the programmes;
- technical support to review and develop regional criteria for initiating OST; relax OST eligibility requirements and expanding patient access
- monitoring work with legislators / law enforcement; trends in public opinion; etc.
- training modules and tools to improve physician education; and make OST available through general practitioners and HIV treatment programmes
- technical support and capacity building on procurement; supply management; negotiating costs of buprenorphine; monitoring, tracking and reporting on use methadone and buprenorphine to INCB
- guidance and technical support on coordination and integration of OST and HIV programmes.

c. Advocacy for scale-up

In a discussion on strategy on the second day, Zurab Sikharulidze informed participants there was not significant support of OST in Georgia from the international agencies, adding that advocacy may produce some clear results. Sikharulidze reminded the meeting that the government was supportive of OST, but had been running pilot OST programmes that have only grown by 5% over the past 2 years. Participants believed that with pressure and continued funding from the Global Fund, the government would be more willing to consider scaling up. Advocacy tools may include official letters, position papers, legal mechanisms, etc. The group called for greater support in strengthening national and regional advocacy, with concrete recommendations in the following areas –

- "snowball" the Yalta Summit into ever-increasing circles of meetings involving more health care professionals, but also the media, community stakeholders, parliamentarians and law enforcement
- establish an advisory / technical group on IDU and HIV in EECA [also coordinating with the international agencies], whose role will primarily focus on galvanizing attention [on national, regional and international agendas] to the state of HIV and IDU epidemics in EECA, and mobilize a massive effort to address the challenges to expanding access to OST and harm reduction services; while also seeking to encourage regional and international advocacy from all stakeholders including governments, global health institutions, HIV and IDU civil society, people who use drugs, people living with HIV, human rights groups, scientists and health professionals.

- support development of leadership and champions: who would work on a long-term basis with high levels of government; journalists to influence the media; people who use drugs and their families; HIV organizations; medical community and professional societies; etc.
- information dissemination in appropriate regional languages; development of websites with different information resources (libraries, scientific publication and articles, news from OST sites) and networking forums for drug users; policy and drug law enforcement authorities; *publication of a new scientific journal about OST in Russian for medical community*; etc.
- promote delivery of OST and harm reduction services in prisons and detention centers; while there was a feeling among some of the participants that efforts should first focus on "law abiding" citizens, participants were reminded that the human rights framework and UNODC policy considers access for people in correctional facilities and detention centers of equal priority.
- advocate for OST through G8 mechanisms
- leverage CND and UNGASS on Drug Policy; and Shanghai Cooperation Organization[22]
- support development of EECA regional conference or learning network of specialists (narcologists) and other experts supporting use of OST;
- articulate strong human rights, public health, medical ethical principles/ rationale, drawing from existing drug treatment programmes and contrasted against criminal justice strategy.
- support process of documenting case studies; human interest stories; complaints of patients and parents for redress; document and disseminate positive outcomes from OST programmes for example reduction in criminal activity, etc.
- support public campaigns, community outreach and mass media activities to raise awareness, de-stigmatize drug use and educate public about OST
- support site visits to model programmes by policy makers and encourage high-level inter-governmental exchange as a possible strategy of changing attitudes toward injection drug use and OST as an evidence-based intervention[23].
- support facilitating of self-help and mutual support group of OST patients and their relatives; mobilize and educate patients as experts and speakers

7. Conclusion

The Yalta Summit was part of IAS' effort to strengthen regional networks of health professionals; enhance implementation of evidence-based HIV policy and programmes, address major region-specific policy challenges as well as promote rights of most-at-risk communities. The timing recognized the need to build on momentum generated at The Eastern Europe and Central Asian AIDS Conference (EECAAC - May 2008, Moscow) and AIDS 2008 (August 2008, Mexico) towards expanding access to OST for IDU. The Yalta Summit therefore brought together scientific leaders in EECA to act as catalysts in development of a large-scale advocacy effort and a series of activities that can generate pressure to move the issue within the region and internationally. Participants welcomed AIDS 2010 in Vienna not only as critical year that will mark the universal access goal; but also as a major entry point for intensified advocacy over the next 18 months of planning, with the view to using the platform of the International AIDS Conference for presenting new research and challenging accountability. The Yalta Summit was an important step in setting up an advocacy network of public health and medical experts in the region to advocate for expanding OST programmes (and introduce them where not available) across the region. It helped to build a sense of community amongst leading scientists and professionals working on the issue, and generate momentum for greater action against the challenges and status quo of programmes across the region. The IAS offered free membership to all regional participants at the Yalta Summit as a first step towards ongoing engagement and building of a regional reference group of health professionals and researchers for future advocacy.

[22] The Shanghai Cooperation Organisation. SCO. http://www.sectsco.org/home.asp?LanguageID=2 (accessed December 2008).
[23] Qian H, Schumacher J.E, Chen H.T, Ruan Y. Injection drug use and HIV/AIDS in China: Review of current situation, prevention and policy implications. *Harm Reduction Journal* 2006; 3:4.

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