



WORKSHOP REPORT

How to scale-up and implement opioid substitution treatment based on the experiences of selected EU Member States

Vilnius, Lithuania

22-23 May 2012

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Introduction and objectives

Both drug-free treatment and opioid substitution therapy (OST) are available in all EU Member States, Croatia, Turkey and Norway. OST, combined with psychosocial interventions, is considered to be the most effective treatment option for opioid dependence. In comparison with detoxification or no treatment at all, both methadone and high dose buprenorphine treatments show better rates of retention in treatment and

significantly better outcomes for drug use, criminal activity, risk behaviours and HIV-transmission, overdoses and overall mortality.¹

The WHO Guidelines for the Psychosocially Assisted Pharmacological Treatment of Opioid Dependence recommend that OST with methadone or buprenorphine be used in preference to detoxification for most patients, that methadone be used in preference to buprenorphine, and that both methadone substitution therapy and detoxification services be made widely available, including prisons.

In the 12 countries that joined the EU more recently, the number of OST clients nearly tripled between 2003 and 2009. Proportionally, the expansion of OST in these countries over this period was highest in Estonia, Bulgaria and Latvia. Overall, it is estimated that about half of the European Union's problem opioid users have access to OST. However, in Eastern Europe, countries with the largest number of IDUs and the worst HIV epidemics still have the poorest coverage levels.

As of June 2011, 143 national drug dependence treatment guidelines from 30 countries in Europe were collected and made available on the EMCDDA's Best Practice portal. 57 of the national guidelines from 24 countries contained recommendations on OST, however in just over a third of these the 2 key WHO recommendations were reflected.

In September 2011, Member States in the European Region adopted the European Action Plan for HIV/AIDS 2012-2015 and have committed to reducing the number of new infections acquired through injecting drug use by 50%. Guidance and political commitment have yet to be translated into action and provision of OST is a key intervention in this effort in urgent need of scaling up.

The overall objective of workshop organized by the WHO Regional Office for Europe and Vilnius Centre for Addictive Disorders on May 22-23, 2012 in Vilnius, Lithuania was to identify and share best practices, experiences and challenges regarding OST implementation and scaling up in a number of EU Member States (including Lithuania, Latvia, Estonia, Portugal, Bulgaria, Romania and Poland) which have recently translated available global guidance into national guidance, and to assess the impact of the guidance development process on OST scaling up (see workshop agenda in Annex 1).

Specific objectives of the workshop were to:

- 1. Present and discuss the evidence for harm reduction and drug dependence treatment, specifically OST;
- 2. Map the current situation and progress made over the past years regarding provision of OST in the participating countries and discuss experiences, challenges and best practices;
- 3. Develop and discuss country 'case studies' on the implementation and scaling up of OST;
- 4. Present and discuss the available international and national guidance for the treatment of opioid dependence and OST;
- 5. Present and discuss the key findings from the WHO Collaborative Study on Substitution Treatment for Opioid Dependence and HIV/AIDS that involved European sites in Lithuania, Poland and Ukraine;

¹ WHO. (2009). *Guidelines for the psychosocially assisted pharmacological treatment of opioid dependence*. Geneva: World Health Organization.

- 6. Discuss the experiences with and the impact of the development of national guidance on implementation and scaling up of OST;
- 7. Discuss the need for the development of a practical guidance toolkit on 'how to implement and scale up OST', which would draw on the international guidelines but would be more practical;
- 8. Discuss the way forward to scale-up OST and expand HIV prevention services for IDUs in line with the European Action Plan for HIV/AIDS 2012-2015 by application of lessons learnt and best practices presented.

The **expected outcome of the workshop** was a comprehensive overview of best practices, experiences, challenges and available guidelines regarding scaling-up and implementing OST in the participating countries, to serve as baseline information for the development of practical written guidance on how to scale-up and implement OST.

Participants of the workshop included: experts from 7 EU Member States, including Lithuania, Latvia, Estonia, Portugal, Bulgaria, Romania and Poland (representatives of the Ministries of Health and National Drug Centres as well as civil society representatives); international experts; representatives from partner organizations, including EMCDDA, ECDC, Council of Europe Pompidou Group; representatives from the Executive Agency for Health and Consumers and the WHO Regional Office for Europe (see participant list in Annex 2).

Martin Donoghoe (WHO Europe), Cinthia Menel Lemos (Executive Agency for Health and Consumers), and Emilis Subata (Vilnius Centre for Addictive Disorders) welcomed the participants.

In his opening speech, Martin Donoghoe underlined that HIV epidemic begins to get under control in many parts of the world. Unfortunately, this is not the case for much of Europe and it is therefore very important to scale up and implement effective interventions for HIV prevention in the region.

To set that stage for country case study presentations and subsequent discussions and elaborations, the workshop began with general regional level presentations that offered a 'broader picture' and provided strategic figures related to drug and infectious diseases epidemiology as well as service provision in Europe.

Setting the stage

Cinthia Menel Lemos (Executive Agency for Health and Consumers) presented an overview of the European Health Programme (see participant presentations in Annex 3). She provided background information on the Executive Agency for Health and Consumers, which implements the EU Health Programme and is a funding agency that launch tenders. It is particularly important for the Agency to widely disseminate knowledge and best practices, and to demonstrate the impact of funded projects. In this respect, when developing a regional level practical guidance toolkit on "how to implement and scale up OST", it would be important to keep in mind the question of how to assess/evaluate the toolkit's impact once it has been put in place.

Furthermore, Cinthia elaborated on the Second Action Plan (2009-2013) for combating HIV/AIDS in the EU and the neighbourhood countries, which priorities prevention that is based on evidence and robust surveillance

systems; on meaningful behavioural data to ensure that the key factors behind the epidemic are adequately addressed; and is linked to voluntary and counselled testing for HIV, universal access to treatment, care and support. Most important priority groups are men who have sex with men (MSM), injecting drug users (IDU), and migrants from high prevalence countries. Geographically, Eastern Europe and neighbourhood countries are priority regions for HIV prevention activities, which should aim to become sustainable over time.

In order to help achieve the second objective of the European Union Drugs Strategy (2000-2004), namely to attain a substantial reduction over five years of the incidence of drug-related health damage (such as HIV, hepatitis B and C and tuberculosis) and the number of drug-related deaths, Council Recommendation 2003/488/EC were adopted in June 2003. This Recommendation encourages Member States to set as a public health objective the prevention of drug dependence and the reduction of related risks. It also envisages measures to reduce substantially the incidence of drug-related health damage, including *inter alia*: providing comprehensive substitution treatment; access for drug abusers in prison to services similar to those provided in the community (continuity of care); promoting prevention and screening of HIV, hepatitis B and C, tuberculosis and sexually transmitted infections; provision of appropriate access to the distribution of condoms, needles and syringes and to exchange centres; and provision of emergency management of overdoses.

Cinthia also outlined the specific on-going HIV/AIDS and drug prevention projects that are funded by the Agency as part of the 2008-2013 Health Programme. These include funding to WHO Europe for scaling-up access to high-quality harm reduction, treatment and care for injecting drug; Mental health and HIV/AIDS project focusing on the new EU countries; Correlation II; SRAP project focusing on addiction prevention within Roma and Sinti communities; Health Promotion for Young Prisoners (HPYP) project; a project for Improving Access to HIV/TB testing for marginalised groups (Imp.Ac.T); a project to empower civil society and public health system to fight TB epidemic among vulnerable groups (TUBIDU); HIV and co-infections prevention strategies in Europe project to help guide the future of HIV prevention in Europe; as well as funding for several conferences. Cinthia finished her presentation by telling participants about the new Health for Growth Programme (2014-2020), that has four general objectives and that is currently under discussion with the European Council and Parliament.

Emilis Subata (Vilnius Centre for Addictive Disorders) (see participant presentations in Annex 3) presented the outline of the workshop agenda and provided an overview of the workshop's objectives, making a special emphasis on the need for the development of regional level practical guidance toolkit on "how to implement and scale up OST" as informed by the documented country cases studies, experiences and views of country representatives, experts and observers. Emilis reminded that countries were sent a format for country case study presentation and suggested that this format can be further expanded, if needed, to capture the complexities of national situations and to provide further insights. Emilis also informed that representatives from Bulgaria could not attend the meeting, but they have kindly shared their country presentation with the organizers of the event.

In his presentation, **Martin Donoghoe** (WHO Europe) (see participant presentations in Annex 3) provided an overview of the HIV infection among people who inject drugs (PWID) in Europe, focusing primarily on quantitative data and providing figures to frame the subsequent discussions at the workshop. This data

confirms that since 2001 there has been a 2.5 fold increase in the total number of HIV infections reported in Europe. Eastern Europe and Central Asia are particularly affected, with about 1.5 mln estimated to be living with HIV and the HIV epidemic continuing to grow at an alarming and accelerating pace. However, treatment is not keeping pace with HIV infections, and treatment coverage is less than 25% of all people who are in need of treatment. Thus, in Eastern Europe and Central Asia the number of people dying from AIDS-related causes has increased more than 10-fold between 2001 and 2010. While the European region (as defined by WHO) show no evidence of the HIV epidemic stabilizing in the region as a whole, disaggregating this overall data by subregions (defined by WHO as West, Centre, and East) reveals further, major insights into the dynamics of the HIV epidemic. The ECDC and WHO data suggests that in 2010 the East had a far higher rate of reported HIV than either the West or Centre; injecting drug use is contributing to the epidemic in the East to a much greater extent (43%) than either West or Centre; the temporal trends also show that the epidemic is increasing at a dramatic rate in the East whilst the adjusted rate for West and EU/EEA shows some stabilization. It is important to note that many newly diagnosed cases of HIV in the Centre and East are of unknown mode of transmission. This maybe for various reasons, including people being afraid of reporting their risk behaviours, but also because people may engage in multiple risk behaviours. Furthermore, the recent increases in heterosexual HIV in the East seem to be likely associated with sexual transmission from IDUs. AIDS diagnoses continue to increase in the East at an alarming pace. Injecting drug use remains an important route of transmission in some "new" EU countries (Estonia, Latvia and Lithuania in the East, Poland in the Centre), although in EU/EEA rates are lower than in the East and IDUs contributed only 4% of cases reported in 2010.

Dagmar Hedrich (EMCDDA) (see participant presentations in Annex 3) spoke about trends in access and availability of OST in EU, Norway, Croatia and Turkey. With about 1.3 mln problem drug users (mainly heroin) in Europe and at least 1.1. mln Europeans undergoing drug treatment every year, over half of patients receive OST. This brings the estimated coverage rate for OST in the EU to around 50%. 72% of clients on OST in EU-30 receive methadone. The coverage of opioid substitution treatment varies significantly between countries, however, with some countries reporting less than 10 % of their estimated number of problem opioid users undergoing such treatment and others, mainly in Western Europe, reporting more than 50 %. In particular, the number of treatments in Eastern Europe remains low compared to the rest of Europe (the 12 post 2004 MS represent only 5% of the total of substitution treatment, while representing 20% of the population and reporting often relatively large opioid problems).

Importantly, until 1993, only about 73,000 patients were on OST in EU. Substantial scaling up of OST began in the 1990s and this process was driven by the HIV epidemic among PWID. It was impossible to achieve high coverage rates by limiting OST provision to specialized treatment centres only, and scaling up became possible through the involvement of GPs. The involvement of general practitioners has played a major role in France, the Czech Republic, Germany, Austria and the United Kingdom in facilitating access, improving geographical coverage, reducing waiting times and thereby improving the availability and coverage of substitution treatment. Waiting time is of particular relevance as well, and if the waiting time is very long, then some people from the waiting list may die by the time they would be offered OST.

As far as prison setting was concerned, Dagmar pointed out that drugs were a major factor in imprisonment in EU. On the one hand, a substantial percentage of inmates are convicted for drug-related offences. On the other

hand, the prevalence of drug use is very high in prisons, reaching up to 48% in males, and ranging between 30% and 60% in females. Furthermore, newly released prisoners face an acute risk of drug-related death during the first two weeks after release. In this regard, both availability of OST in prisons and continuity of treatment are of vital importance. Disruption of continuity of treatment, especially due to brief periods of imprisonment, was also found to be associated with very significant increases in HCV incidence. Yet, EU (+3) data demonstrates a delayed adoption of OST in the prison setting (about 7-8 years gap after OST introduction in the community), with coverage still being very low and 6 countries having no OST available in their prisons. Only 19 of 30 European countries allow inmates to start OST in prison, and only 8 countries provide prion OST at a scale comparable to the community. Thus, while ingredients such as integration of service provision, referrals and partnerships, stakeholder support and optimal use of existing infrastructure can all be considered as important ingredients of success, as Dagmar highlighted, "If we don't address the situation in prisons, then we have a handicap in achieving good impact." It is also important to note that following a period of expansion and a focus on quantity, more attention now needed to address standards and quality.

Then, Martin Donoghoe (WHO Europe) (this preliminary data is not included in participant presentations in Annex 3) took the floor and spoke about PWID's access to services in Europe. He opened his presentation with background information on European Action Plan for HIV/AIDS 2012-2015 as a framework for urgent action, the four strategic directions of the Action Plan, priority actions and their relevance to drug dependence, prevention of HIV among PWID, ensuring affordable and quality pharmacological treatment of opioid dependence and reducing barriers to accessing services. Martin also emphasized that in the context of concentrated HIV epidemic it is vital to focus on most at risk populations, and it is important to note that broad mass media campaigns designed for general populations may not have a serious impact on the epidemics driven by shared use of unsterile drug injecting equipment. In this regard, priority actions 1.2.1, 1.2.2 and 1.2.4 of the European Action Plan for HIV/AIDS 2012-2015 including those relating to needle and syringe programmes, opioid substitution therapy and the provision of antiretroviral therapy to drug injectors. The coverage targets for these three interventions are set in the Action Plan (and WHO/UNODC/UNAIDS technical guide) as follows:

- More than 60% of people who inject drugs are regularly reached by needle and syringe programmes (200 syringes per IDU);
- More than 40% of opioid-dependent people are receiving OST;
- More than 75% of HIV-positive injecting drug users for whom ART is indicated are receiving it.

WHO Europe has started to collect data measuring progress towards the achievement of these targets and Martin presented these data for the first time at this workshop. First, data confirm that IDU related HIV is a significant problem in Estonia, Latvia, Lithuania, Poland and Portugal (with all these countries represented at the workshop) where more than 35% of all HIV infections reported in 2010 were transmitted through injecting drug use. Second, while many EU countries provide OST coverage above 40%, most countries represented at the workshop provide OST coverage below 15%. Third, in many of these countries where percentage of IDU on OST is low, there is also a high percentage of IDU among total reported HIV infections. Fourth, many EU countries appear to have failed to reach a coverage of 200 syringes per IDU per year, with many of the

countries represented at the workshop having significant HIV transmission among drug injectors and falling way below that target.

In response to Martin's presentation, two important comments were made. First, in some European countries there was a significant increase in injecting use of stimulants, and it would be important to keep this in mind, as OST would not be indicated for this population. Second, colleagues from Switzerland noted that while HIV argument when advocating of OST is generally very helpful, for countries where HIV is no longer driven by IDU this argument is of little relevance and it is hard to begin actively using other arguments once the audience becomes particularly sensitive only to the HIV argument. In this regard, participants of the discussion agreed that it would be important to use simultaneously all available arguments in support of OST (e.g., reductions in HCV rates, OD and criminality etc) in advocacy efforts, with different arguments having different weight in different contexts and settings.

Finally, **Emilis Subata** (Vilnius Centre for Addictive Disorders) (see participant presentations in Annex 3) gave an overview of existing international guidance on how to implement and scale-up OST and the need for the development of regional level guidance. He also pointed out that before 2000 there were almost no studies in less-resourced countries and various cultural settings, but the 2008 WHO collaborative study on OST included Lithuania and Poland (as far as countries participating in this workshop are concerned). In 2009, WHO published *Guidelines for the Psychosocially Assisted Pharmacological Treatment of Opioid Dependence*. When producing this document, WHO paid particular attention to the procedures of developing guidelines. Standard methods for the synthesis of evidence and grading recommendations were used. When there was a lack of evidence, professional consensus was sought.

Furthermore, Emilis noted that 143 national drug dependence treatment guidelines from 30 countries were collected by EMCDDA Best practice portal. Out of these, 57 guidelines from 24 countries contained recommendations for OST and 18 guidelines published after 2009. Importantly, OST guidelines had highest proportion of references to RCT and Cochrane library (especially UK and Germany). Most guidelines specify the dosage at the beginning of treatment; most agree on the need of direct supervision of dispensing in the initial phases of treatment and specify conditions on which take-away doses can be given; most agree that OST should be offered to pregnant women, with the preference of methadone, though evidence suggest that buprenorphine is also beneficial; guidelines concur that psychosocial support should be routinely offered; and, finally, there is a general convergence of national guidelines with WHO Guidelines.

However, for a country to have well written guidelines, does not automatically mean that quality services are implemented in all OST sites and that there is good access to services and coverage of OST. This is because *only valid implementation of guidelines makes real difference*, and it can often happen that guidelines are not well-implemented. This may be due to various reasons, such as barriers from social, organizational, economic point of view, opposing reaction from professionals and patients, and resistance that may be triggered by changes and innovation. However, there are also valuable experiences of successful guidelines implementation that were documented in various countries, including assessing the implementation of guidelines through a set of indicators for quality assurance (Denmark) or developing special instruments assessing "the implementability" of guidelines (Netherlands); engaging key professionals in the promotion of change through associations of professionals (Finland, Germany, Slovenia); providing continuous learning through inclusion of OST guidelines

in training curricula of psychiatrists and in post-graduate training courses (Baltic States); producing a range of "how to" guides to help with the implementation of guidance at local level and developing a "shared learning database" with ideas and tips for successful guidelines implementation (UK).

Summarizing some of the reasons for underdevelopment of OST programmes in new EU countries (including Bulgaria, Romania, Poland, Estonia, Latvia and Lithuania), Emilis emphasized overall low priority for dependence treatment; unwillingness of health care administrators and/or professionals, e.g. psychiatrists, to be involved with injecting drug users; political/ideological arguments about legitimacy and effectiveness of non-abstinence orientated and harm reduction programs; and low quality of existing OST with limited effectiveness.

While there are general WHO Guidelines in place and many countries have introduced their own national ones, these guidelines often tend to focus on *clinical* issues (such as dosage, eligibility criteria etc.). Thus, there is a need for a different type of guidelines dealing with *practical* issues and focusing on "how to" questions and provide tools for addressing common challenges to scaling up and implementing quality OST programmes. The target group for this practical guidance would be policy makers on the national, regional and local levels as well as administrators of health care institutions, leaders of OST programmes. It is expected that this guidance will contain documented inputs on how countries scaled up and implemented OST and dealt with challenges. This will be achieved by following continuous steps of practical actions by health policy makers and programme leaders in overcoming obstacles for implementation and scaling-up of OST and by incorporating "case studies", "best practices" and "success stories" from EU countries, particularly the ones shared at this workshop. Ultimately, this guidance would encourage countries to apply other countries' successful experience and to replicate these successes in their local contexts and settings.

Summary of initial discussion related to the need for practical guideline

The discussion that followed these introductory presentations provided some key insights and helped to raise further questions:

- When developing these practical guidelines, it would be important to document the main reasons for low scale and quality of OST and to explain why these obstacles have not been addressed so far. This would also help WHO and other technical agencies to provide key enabling ingredients to enable countries to scale up the coverage and improve the quality. In the past, there were several projects that produced guidelines but they did not necessarily resulted in a major change in terms of scale-up of services:
- There is clearly no need for another clinical guideline, but there are things which practitioners do not find in the existing guidelines. What is needed therefore is *operational*, *practical guideline*.
- We may also consider calling this document a "toolkit" that contains specific tools to address a range of problems, using a "if I have this problem how do I solve it?" approach;
- Guidelines should be focused on issues specific to the European region;

- It would be important for the practical guidelines to focus *inter alia* on financial aspects of multisectoral mechanisms. For example, in Romania, several ministries are involved in OST implementation, with some responsible for guideline adoption, others for service delivery, and others for funding. Yet, there is a lack of clarity in terms of distribution of funding for different sets of activities and how to mainstream this funding to achieve higher scale and quality of OST. Multisectoral collaboration between different actors in the field is important;
- There is a definite need to involve OST programme clients as well as representatives of civil society organizations representing affected communities in the process of guideline development (and validation). Social workers can also make an important contribution in this process;
- Including decision-makers and policy-makers in the target group for this guideline was a good decision;
- Some EU countries have already achieved high coverage and can provide OST to everyone in need. For
 these countries, guidelines should also address the concerns of politicians (that emerge as the
 countries achieve adequate scale-up) related to, for instance, leakages of OST medications to black
 markets;
- When guidelines are developed in collaboration with other countries, it may be easy to get support within the country. However, for the regional guidelines to be relevant to individual countries, they need to take into consideration, whenever possible, national legislations and political contexts;
- It is hoped that new practical guidelines would be helpful in terms of building/strengthening the social service component; better calculating the costs of services; better planning the services and being able to demonstrate the expected outcome of scale-up to service funders;
- Substantial scale-up of OST services is hardly possible without involving GPs, and it would be important to address this issue in the practical guidelines;
- While being of regional/general nature, the practical guideline need to "put the fundamentals down";
- It is essential to involve actual countries and local experts in the process of guideline development, to help foster the sense of country ownership;
- Once the guidelines are developed, it might be appropriate to consider the inclusion the issues of OST scale up and implementation in Biannual collaborative agreements between the WHO and national governments;
- Involving patients in various aspects of OST (planning, implementation, evaluation etc) is recognized as important. Patients are also key stakeholders in OST advocacy. In this regard, it might appropriate to include questions of "how to empower patients" and "how to set up successful patient literacy programmes" in the guidelines;
- Global investment framework for HIV/AIDS is important in terms of supporting OST, and this may need to be reflected in the guideline.

Country presentations

Participating countries were requested to make presentations and to share their experiences in implementation and scaling-up of OST programmes. For the preparation of country case studies, participants were sent a general content format that covered 15 areas ranging from basic epidemiological information on HIV and IDU prevalence and dynamics to risk management measures in OST for staff, patients and site.

Romania

Mihai Corciova (see participant presentations in Annex 3) pointed out that one of the recent highlights in drug use patterns in the country is the rise in the use of "legal highs" or "ethno-botanical plants," and many service providers don't have a good idea on how to deal with this type of clients. As far as problem drug use is concerned, Bucharest alone has about 18 thousand estimated PDUs. Self-declared drug use in Romanian prisons is about 7.6%. The Romanian network of medical, psychological and social care includes three main state ministries/agencies and non-governmental organizations, including private services providers. 51.7% of 2163 people admitted to treatment in 2010 were opiate users. 359 patients were receiving OST (methadone/ buprenorphine/ suboxone/ naltrexone). NSPs were largely supported by donors. However, as funding from major donors was discontinued, many NSPs had to close down. Two OST guidelines were approved in Romania in 2009 and 2010 for both community and prison settings. In prison setting, OST first started as a pilot program in June 2008 in one Penitentiary Hospital. During this phase, protocols were developed, tested, formally approved and implemented. Training was provided for security, medical, educational staff but also for peereducators. OST programme was then expanded and is now available in 3 hospital prisons and in 7 prisons. Since 2008, 65 inmates were included in OST, with the majority of clients continuing the treatment they had started in their communities, prior to incarceration. Also, as Mihai noted, when introducing OST in the country, it was politically more convenient to refer to OST as "harm reduction" intervention rather than "treatment". However, as the case with NSPs makes it clear, the overreliance on donor funding for PWID services can cause severe disruptions of services /service discontinuation, when major donors withdraw their support.

Poland

Kamila Gryn, in her presentation on OST in Poland (see participant presentations in Annex 3), suggested that the estimated number of people with opioid dependence is close to 15,000 in this country. Nearly 30% of all patients admitted to treatment in 2008 were heroin (including "kompot" also known as "Polish heroin") users. By 2011, the total number of clients of methadone treatment programme has reached 2,200 people. While the number of IDUs seem to be decreasing and the number of OST patients has been slowly increasing, the OST

coverage rate in Poland is still very low at about 15%. Currently, there are 25 sites offering OST across 18 cities in 14 regions, with 2 regions having no OST yet and Gdansk having got first OST center last year only. There are also 7 OST programmes in prison setting.



Map 1. Current availability and geographical coverage of OST in Poland

The are a number of problems facing OST problems in Poland, including strong [op]position of drug-free oriented centres (80 inpatient drug-free centres in the country); limited knowledge about biological nature of drug addiction; common belief among practitioners/psychiatrists that abstinance is the most important therapeutic goal; inadequate financing of drug dependence treatment, with 75% of state funding going to less effective inpatient drug-free oriented centers; strong opposition on local levels, where rehabilitation and drug-free programs have strong influence on politicians; limited interest from psychiatrists and other physicians to get involved in addiction field. As Kamila highlighted, many GPs seem to have never heard about OST, even some psychiatrists have very limited knowledge about OST.

Quality of OST programmes is mainly ensured through licensing and mandatory training courses for staff, and individual treatment plans. The latter, however, are formally developed for only 20 percent of all clients, with another 60 percent also having individual treatment plans that are not fomally documented in writing. There is a range of services and expertise (e.g., psychiatric expertise, social support, counselling etc.) that are in place at OSTcenters, although most of them are only partially available.

Despite numerous challenges, the way of thinking is changing in Poland, both among specialists and politicians – they cannot easily dismiss OST anymore. One of the lessons learnt is that it is very helpful to engage and collaborate with various groups, including people in the government and MoH, as their support is important.

Lithuania

Loreta Stoniene, presenting Lithuanian national case study on implementation and scaling-up OST (see participant presentations in Annex 3), emphasized that a recently completed UNODC regional project entitled "HIV/AIDS prevention and care among injecting drug users and in prison settings" had positive impact in terms of scaling up OST programmes in the Baltics. Although the project has ended at the times of financial crisis, all the newly established sites continue to operate through national funding.

With estimated 5,458 PDUs, HIV infection in Lithuania is mainly transmitted through shared use of unsterile drug injecting equipment. While access to HIV testing and counselling by PWID remains very limited, HIV prevalence among PWID is estimated at the level of 8%. OST was introduced in Lithuania in 1995 and is now available in 12 out of 60 municipalities. As of 2010, there were 712 clients enrolled in OST programmes in the country.

To help achieve higher coverage and better quality, fully equipped mobile clinics/buses became operational since 2010. During the lifespan of UNODC project, 8 new OST sites were established in Lithuania through the "seed money" mechanism, with sites receiving funds for technical needs, such as renovation of premises, purchase of equipment, ensuring security at sites etc. National clinical guidelines were developed by Lithuanian Psychiatric Association, reviewed by Vilnius and Kaunas universities and Ministry of Health, and published in 2010. Furthermore, 18 hour training curriculum was developed and approved by Vilnius University Medical Faculty for Department of Post-Graduate Physician Training (2007).

Table 1. OST availability and coverage in Lithuania

Indicator	2006	2010
OST sites	12	21
OST coverage	6.5 %	13.1 %
OST in police custody centres	No	Yes
OST in prisons	No	Preparations cancelled

In accordance with adopted guidelines, OST clients in Lithuania are referred for HIV, HCV and TB testing and counselling. OST programme is subject to both internal and external monitoring and evaluation, with the latest

MoH audit inspection (2011) having identified many gaps in provision of OST and recommending to improve legal framework for OST.

OST programmes in Lithuania introduced a set of quality indicators and are also providing case management to increase compliance. Each case manager supervises and coordinates multidisciplinary services for 30 patients, and individual treatment/support plan is designed for each OST patient from the beginning of the treatment. Self-help groups also operate in the country. Lithuanian MoH has also issued a number of regulations aimed at improving control of opioid medications and reducing the diversion of opioid medications to the black market.

As far as prisons and pre-trial detention centres are concerned, these institutions are supervised by different state agencies, and OST is available only in Police custody centres. With police authorities willing to allow arrestees to continue their OST, cooperation with law enforcement sector was further enhanced through signing of a tripartite interagency collaboration agreement, whereby the agreement was reached to refer drug users arrested by police at Roma settlement to drug treatment (mostly OST). It was noted that three months after the initiation of implementation of this agreement, the rates of petty crime in the area populated by Roma decreased by 70 percent.

Although current political environment around the introduction of OST in prisons is rather unfavourable, there are some glimpses of hope as one OST client, who was imprisoned for 40 days and who was denied access to OST during his incarceration, has recently went to court and is now suing authorities.

Finally, while advocacy activities in Lithuania have been very limited, one recent project documented an unexpectedly large number of media representatives ignoring the subject of OST and avoiding discussions and/or meetings on the OST-related issues. The exact reasons for this unwillingness of Lithuania media to get involved in OST advocacy have not been firmly established yet.

Portugal

Graça Vilar began her presentation (see participant presentations in Annex 3) by providing an overview of the geographical coverage of OST, which is now available in 45 outpatient units throughout the country. In 2011, 38,292 patients received drug treatment, with 26,351 patients receiving OST. Of all patients on OST in 2011, 78% were on methadone and 22% received buprenorphine. The coverage level is estimated at 69%. When a new public outpatient unit is created in the country, OST is one of the therapeutic interventions available from the start. OST is also available in some harm reduction low-threshold programmes, which on average serve about 1,500 patients per month.

OST is also available in prisons for both initiation and continuation of treatment. Overall, 505 inmates are enrolled in OST programme, with the majority receiving methadone (29 inmates on buprenorphine).

Monitoring and evaluation of OST programmes in performed at a national level, and indicators such as coverage, # of programmes, # patients enrolled, type of OST provided, waiting time, and abstinence from illicit

street drugs are being used. There is also Integrated Multidisciplinary Information System in place, which is designed to prevent 'doctor shopping' by the patient. When receiving OST, clients can continue using other services, and for those excluded from the programme there is a possibility to get enrolled at a different site as an alternative option.

Portugal doesn't have formal national guidelines for OST provision, but there are informal guidelines which are followed widely. The lack of formal OST guidelines cannot be explained purely by technical reasons, as there is some resistance from psychiatric profession, who fear that guidelines can restrict their autonomy and put them under control. Furthermore, some psychoanalytically-minded and trained psychiatrists are not interested to get engaged with the OST issues.

Some of the threats to OST services include closure of sites/services and limited access of patients to specialist counseling in the contexts of on-going austerity measures. Antiretroviral rationing is another barrier. However, existing threats also present opportunities for harmonizing multiple services in one place, for negotiating ART prices, and for greater involvement of people who use drugs in service design, implementation, monitoring and evaluation.

This presentation was followed by the second presentation by Portuguese colleagues. José Queiroz (see participant presentations in Annex 3) began his talk by presenting some background data on HIV epidemic among IDUs in Portugal, where HIV prevalence rates among drug injectors are among the highest in Western Europe. However, the year 2010 seems to have been a turning point, with decrease in HIV prevalence observed now. According to a recent report of EMCDDA (2011), methadone has been made available in Portugal since 1977, buprenorphine since 1999 and recently also the buprenorphine/naloxone combination. Decree Law 183/2001 Article 44.1 and Decree Law 15/93 Article 15.1–3 stipulate that methadone treatment can be initiated by treatment centres whereas buprenorphine treatment can be initiated by any medical doctor, specialised medical doctors and treatment centres.

New harm reduction/low-threshold programmes operate on the basis of agreement/protocol with local authorities and service providers, and a medical doctor's cooperation is needed for low threshold services to be set-up. One of the significant characteristics of OST in Portugal is a very low threshold of for entry into OST, as initial dose of 30mg methadone can be given to a client by a nurse at low-threshold facilities during his/her first visit based on the informed consent of the client and without formal assessment and diagnosis by a physician. This allows for immediate involvement/ integration of a client into the programme and leads to repeated contacts with professionals, as almost all clients come back. Some harm reduction programmes are mobile which helps to reach larger numbers of clients.

Estonia

Aljona Kurbatova (see participant presentations in Annex 3) emphasized that Estonia is still one of the leading countries in Europe in terms of spread of injecting drug use, HIV, MDR-TB and high rates of overdose deaths. There is also a significant problem of co-morbidities among drug injectors. Over the past 12 years, that country

has witnessed a dramatic increase in HIV prevalence, but the number of newly diagnosed HIV infections has been decreasing over the past several years and is now stabilized. The latest estimated size of the IDU population in Estonia was calculated back in 2004, suggesting that there were 13,801 IDUs living in the country. However, while the cohort of IDUs seems to be aging, there is growing evidence that points to the rise in injecting use of amphetamines. The drug market is constantly changing in Estonia (so the health specialists find themselves in a position of 'chasing the change') and according to the HIV prevalence study conducted among IDUs in the city of Narva in 2010, 71% of the respondents said that their main drug was amphetamine.

Until 2003, OST was provided only by few health care institutions. Initial scale-up of OST began with financial support from the Global Fund in 2004. However, with the withdrawal of the GF funding from the country, OST services continued to operate through mechanism of transition to national funding (national and local municipality level). In 2010, with the financial support from the UNODC, first integrated OST/ARV treatment programme was launched in Tallinn. Due to high demand, the number of treatment slots rapidly increased from the originally planned 15 to 35. Further increase in capacity is planned for 2012-2013.

Until 2012 availability of OST was geographically limited to Tallinn and North-East of Estonia (cities of Narva, Jõhvi, Sillamäe and Kiviõli). Starting from 2012, OST is also available in the city of Tartu. Altogether, there are 10 OST sites in the country. OST is also available in prisons (since 2009) and 2 pre-trial detention centres (since 2010). When initially there was no methadone in detention centres, the prison authorities were suggesting that there was no need for OST scale up in prisons, because by the time inmates get to prison they are already detoxed. Now that they have OST in pre-trial detention centres, the number of clients on OST in prisons also increased. As of 2011, 1141 patients were receiving OST in community setting; 217 patients received OST in prisons, and 257 – in pre-trial detention centres/ police custody facilities.

Integration of OST with other services has improved in recent years, although there is still more room for improvement. OST is available in all TB hospitals; integrated OST/ARV/TB treatment programmes are currently available in Tallinn and Kohtla-Järve. Since 2012 additional funds are allocated to an OST site in Narva to provide special services to mothers with young children who need special attention/support, including baby care and arranging legal documents for children (birth certificates etc.).

First opioid OST guidelines were developed in Estonia by Estonian Society of Psychiatrists in 2007 and also endorsed by the National Institute for Health Development (NIHD). The work on a new OST clinical protocol is in currently in progress (as the current guidelines were found to be often 'too ideological/rhetorical' and 'less practical'. Importantly, all treatment guidelines have a status of recommendation and are not adopted by a legal act. This in some way is helpful, because it provides for greater flexibility and there is no need to adopt a new legal act every time the standards/guidelines need to be changed.

OST programmes use case management approach, albeit without a dedicated case management stuff. Multidisciplinary teams include a psychiatrist, a psychologist, a nurse and a social worker, and some teams have GPs as well. OST can only be provided by licensed health care facilities.

Some of the key problems and challenges in OST scaling-up and implementation in Estonia include: low coverage, but due to the lack of the latest estimate of opioid users the need for scale-up is evident but unclear

in geographic terms (waiting list only in Tallinn while some other sites may have empty slots); critical shortage of medical staff, especially psychiatrists due to migration to countries with higher salaries; health care providers are reluctant to start OST and prefer to deal with less problematic patients; some health care professionals do not consider OST (and harm reduction) as "real treatment"; patient perspective is missing; GPs are not yet allowed to prescribe OST. However, the significantly reduced number of psychiatrists in Estonia due to migration is also an opportunity for making broader involvement of GPs in OST a reality.

Latvia

Finally, Speaking about pharmacotherapy of drug dependence in Latvia, Astrida Stirna (see participant presentations in Annex 3) suggested that with a total population of about 2 mln people, Latvia had only one methadone ST programme in one centre until 2009. Buprenorphine (paid by clients) was available in the country since 2003. Although by 2010 ten sites providing long-term methadone pharmacotherapy were operational in the country (the scale-up was supported through external funding from UNODC), Latvia has the lowest number of OST clients among all other EU countries. As of the end of 2010, 193 clients were enrolled in methadone pharmacotherapy throughout the country, of whom 120 were receiving OST in the capital city of Riga.

Following the adoption of Cabinet of Ministers' regulation in January 2012, OST has been introduced in prison setting very recently, in April 2012.

The Association of Latvian Addiction Specialists has developed new Clinical Protocol of long-term methadone pharmacotherapy, which is now being considered for approval by the National Health Service. Existing OST programmes use a multidisciplinary approach and have been evaluated twice, in 2007 and 2011.

German experience with OST and implementation and scaling-up of OST in prison settings

In conclusion of "country presentation" component of the workshop, Professor Dr. Heino Stöver, Fachhochschule Frankfurt am Main University of Applied Sciences, presented two thoroughly researched and highly comprehensive presentations on implementation and scaling-up of OST. Referring to a wide range of sources, including historical data and international studies, Dr. Stöver presented a case study of OST in Germany, and spoke about the provision OST in the context of prison settings. In his first presentation, Dr. Stöver discussed the findings of his analysis of national substitution register in Germany, the IMPROVE study, and outlined the emerging issues in OST provision in Germany. His second presentation contained data from a number of studies on drug use and OST in prisons, with special focus on the recent developments in Germany and the UK. Dr. Stöver's two presentations are provided in full in Annex 3 to this report.

Group work on how to implement and scale-up OST in an EU country and recommendations for the development of regional-level guidance

For this group work assignment, country teams were given four questions to discuss and to prepare a plenary feedback. The results of this exercise are summarized in a table below.

Table 2. Country teams' group work and discussions on OST scale-up and implementation

COUNTRY	WHAT DO YOU THINK ARE THE MAIN OBSTACLES IN YOUR COUNTRY TO IMPLEMENTING AND SCALING-UP OST?	WHAT DO YOU THINK IS THE ADDED VALUE OF THE NEW PRACTICAL GUIDANCE TOOLKIT FOR IMPLEMENTING AND SCALING-UP OST IN YOUR COUNTRY?	WHICH TOPICS/ISSUES RELATED TO IMPLEMENTATION AND SCALING-UP OF OST DO YOU THINK SHOULD BE ADDED TO OR DELETED FROM THE DRAFT GUIDANCE TOOLKIT?	DO YOU HAVE ANY OTHER SPECIFIC RECOMMENDATIO NS FOR THE FURTHER DEVELOPMENT OF THE GUIDANCE TOOLKIT?
ESTONIA	- OST is not listed in any legal act as essential public health service; - OST is considered "dirty medicine"/ "not real treatment" by some health care workers, and many medical professionals do not take it seriously; - Poor reputation of OST; - addiction is not considered as chronic disease by general public; - OST has to be provided by psychiatrists, but there are not enough of them to ensure scale-up or even maintain current coverage; - Exact need for scale-up is unclear [because of a lack of up-to-date estimates of the population of opioid users for various geographic areas]	- Helps to identify best practice and possible models of delivery most suitable to the specific country (a la carte menu of possible solutions from which to select); - Guidance on how to promote/demonstrate the necessity for scale-up; - Guidance on the recommended composition of service (pharmacological, psychosocial etc, ratios of specialist per patient); - Guidance on the quality improvement (including patient literacy)	- Under individualized treatment and/or monitoring of outcome include recommendations/models for follow-up (at least during short period of time directly after discharge); - Under OST in prisons also describe interventions to ensure continuity of care and to reduce overdose/drug related death risk after release; consider issues such as provision of training to prison guards; - Under cooperation with law enforcement include best practice models of the OST delivery in detention centers and training of police force; - Under treatment compliance include patient literacy	- The content of relevant chapters (treatment compliance etc) to be discussed/consulte d with representatives of the patient organisations; - Provide for incountry reviews of draft guidance toolkit

COUNTRY	WHAT DO YOU THINK ARE THE MAIN OBSTACLES IN YOUR	WHAT DO YOU THINK IS THE ADDED VALUE OF THE NEW PRACTICAL	WHICH TOPICS/ISSUES RELATED TO IMPLEMENTATION AND	DO YOU HAVE ANY OTHER SPECIFIC RECOMMENDATIO
	COUNTRY TO	GUIDANCE TOOLKIT FOR	SCALING-UP OF OST DO	NS FOR THE
	IMPLEMENTING AND	IMPLEMENTING AND	YOU THINK SHOULD BE	FURTHER
	SCALING-UP OST?	SCALING-UP OST IN YOUR	ADDED TO OR DELETED	DEVELOPMENT OF
		COUNTRY?	FROM THE DRAFT	THE GUIDANCE
1077/10	Last of main stream	Cuidenes teallitis costul	GUIDANCE TOOLKIT?	TOOLKIT?
LATVIA	- Lack of mainstream	- Guidance toolkit is useful	- Draft guidance toolkit is	- Elaborate specific international
	funding for OST and one	to convince politicians and	professionally prepared and covers all essential	mechanism which
	unified budget/funding	civil servants in		
	source: some funding	responsible ministries	issues.	(as EU directive)
	comes from the Ministry	about the need for OST		should ensure
	of Health; another part	programmes, and helps		country response
	comes from the Ministry	practitioners to		for guidelines and
	of Justice and Ministry of	understand and		toolkit
	Interior, as well as from	implement OST;		implementation;
	municipal budget;	- Guidance contains		- Consider
	- Existing funding does	practical information for		mentioning the issue of OST
	not cover all the needs of	specialists on how to		
	existing OST programmes,	organise OST and collaborate with involved		provision and
	and does not provide			scale-up in long term collaboration
	means for starting new	institutions		
	OST sites; - Different attitudes to			agreements between WHO and
	OST from politicians,			national
	municipalities and			
	professionals			governments (MoH)
LITHUANIA	- Lack of political support	- Will uniform OST	- Advocacy in national and	- Distribute
LITHOANIA	(PM) and	services in different	community levels;	updated document
	misunderstanding about	institutions;	- Mention the issue of	for comments to
	evidence-based	- Will help to improve	implementation of	the national
	treatment methods;	quality of OST services;	financial principle	networks of OST
	- Government officials do	- Will help to unify	"finances follow the	sites.
	not express explicit	implementation of	patient";	sites.
	support to OST because	national guidelines;	- Describe experiences	
	they are afraid of losing	- Will be used as advocacy	from other countries on	
	political support;	instrument for policy	how GPs can be involved	
	- A fear of political	makers.	in prescribing OST.	
	scandals (as OST	makers.	in prescribing 031.	
	supporters can be			
	'accused of' legalisation/			
	liberalization of drugs);			
	- Controversial opinions			
	about OST influence			
	decisions of municipality			
	authorities, and may also			
	additionities, and may also			

COUNTRY	WHAT DO YOU THINK ARE THE MAIN OBSTACLES IN YOUR COUNTRY TO IMPLEMENTING AND SCALING-UP OST?	WHAT DO YOU THINK IS THE ADDED VALUE OF THE NEW PRACTICAL GUIDANCE TOOLKIT FOR IMPLEMENTING AND SCALING-UP OST IN YOUR COUNTRY?	WHICH TOPICS/ISSUES RELATED TO IMPLEMENTATION AND SCALING-UP OF OST DO YOU THINK SHOULD BE ADDED TO OR DELETED FROM THE DRAFT GUIDANCE TOOLKIT?	DO YOU HAVE ANY OTHER SPECIFIC RECOMMENDATIO NS FOR THE FURTHER DEVELOPMENT OF THE GUIDANCE TOOLKIT?
	exert influence on the formation of opinion of a wider public; - Stigmatization from medical staff / administrators; - Strong opposition from some NGOs and catholic authorities			
POLAND	- Strong position of drug- free oriented centers (80 inpatient drug-free centres); - Low knowledge about biological nature of drug addiction and biological treatment; - Belief that abstinence is the most important/main therapeutic goal; - Inadequate financing of drug addiction treatment - 75% of state funding goes to inpatient drug- free oriented centers; - Strong opposition on local level, where rehabilitation, drug-free programs have strong influence on politicians; - Little interests from psychiatrists and therapists to deal with clients with drug dependence	- In Poland there are only legal regulations (legal frame for OST) but there are no medical standards on OST; - This general guidance toolkit can be adapted to the specific conditions of the country in which they are used; - The guidance will also contribute to improving the quality of treatment; - The guidance will show the ways how to solve problems	- The guidance needs to cover issues related to cooperation of OST programmes with the National Health Found (institution covering the costs of OST) and local level government	- It would be good to cover some aspects related to medical standards for OST provision
PORTUGAL	- Implementation/scale- up of OST is often dependent on the	The new toolkit could serve as a Quality Standard/Reference	- Reinforce the ethical dimension of the OST by adding a special chapter	- 'How to do monitoring and continuous follow-

COUNTRY	WHAT DO YOU THINK ARE THE MAIN OBSTACLES IN YOUR COUNTRY TO IMPLEMENTING AND SCALING-UP OST?	WHAT DO YOU THINK IS THE ADDED VALUE OF THE NEW PRACTICAL GUIDANCE TOOLKIT FOR IMPLEMENTING AND SCALING-UP OST IN YOUR COUNTRY?	WHICH TOPICS/ISSUES RELATED TO IMPLEMENTATION AND SCALING-UP OF OST DO YOU THINK SHOULD BE ADDED TO OR DELETED FROM THE DRAFT	DO YOU HAVE ANY OTHER SPECIFIC RECOMMENDATIO NS FOR THE FURTHER DEVELOPMENT OF THE GUIDANCE TOOLKIT?
	position/ 'will' of the medical doctors and their believes and perceptions regarding various treatment methods; - Poor data collection, analysis and dissemination to show the successes of OST programme as well as best practices; - Absence of formal national clinical OST guidelines	produced by a global actor (WHO). It could be used by national stakeholders and advocates of OST to gain support for OST programmes, to convince people, and to mitigate potential political, institutional and corporative conflicts.	on the ethics of OST; - The toolkit could also cover topics related to the formation of clients' councils/ associations (for example, similar to the ones functioning in the Netherlands) and establishing the institution of Clients' Ombudsman	up', and in this context address the issue of establishing a regular dialogue with the main key actors at the national level
ROMANIA	- Financial issues: different financial mechanism of the key stakeholders with limited place for coordination/ collaboration; no access to public funds by NGO's and privates OST service providers; - Professionals issues: lack of interest/motivation of professionals working in this area; OST medications considered as "dirty medicine"; low awareness related to the benefits of OST (also in general population); - Confusing legislation & which is also not harmonised between various stakeholders	- If the toolkit is concrete/specific and very pragmatic in terms of its content, it might help to resolve the existing resistances from the national authorities	- Additional content may include "How and what to finance"; "What and how to monitor"	- The content should be very practical, pragmatic; - "how to" language might be a bit too general, and 'soft'. Better to use "it is recommended" language (and provide specific references to evidence base), which may sound 'stronger' in terms of encouraging countries to follow the recommendations; - Consider 'representatives of donor agencies' as a target group for

COUNTRY	WHAT DO YOU THINK	WHAT DO YOU THINK IS	WHICH TOPICS/ISSUES	DO YOU HAVE ANY
	ARE THE MAIN	THE ADDED VALUE OF	RELATED TO	OTHER SPECIFIC
	OBSTACLES IN YOUR	THE NEW PRACTICAL	IMPLEMENTATION AND	RECOMMENDATIO
	COUNTRY TO	GUIDANCE TOOLKIT FOR	SCALING-UP OF OST DO	NS FOR THE
	IMPLEMENTING AND	IMPLEMENTING AND	YOU THINK SHOULD BE	FURTHER
	SCALING-UP OST?	SCALING-UP OST IN YOUR	ADDED TO OR DELETED	DEVELOPMENT OF
		COUNTRY?	FROM THE DRAFT	THE GUIDANCE
			GUIDANCE TOOLKIT?	TOOLKIT?
				the toolkit (in
				addition to other
				target groups that
				were already
				identified)

In the course of discussions of these group work presentations prepared and presented by the representatives of respective countries, participants of the workshop provided some further comments and insights, including:

- It might be possible to formulate some further guidance related to the principle that "funding ideally should go after the patient";
- As far as OST advocacy is concerned, one of the recommendations could be related to engage with individuals who have influence on policy issues/ 'champions';
- It might be worthwhile to include some explicit statement in the guidelines concerning very poor evidence base in support of drug-free treatment (rather than just reiterating that OST is more effective than drug-free treatment), including that drug free treatment is not particularly helpful in terms of preventing drug-related infectious diseases;
- When discussing financial aspects in the guidelines, it might be appropriate to talk about the lack of funding/reductions in available funding due to economic crisis;
- The question of who pays for OST services is very important, as it is directly related to the issue of "ownership";
- It is important to have formal procedures for OST patients to voice their concerns/complaints about the service, if they are not happy with it something that need to be reflected in the guidelines;
- As far as lack of access to OST in prison settings is concerned, cases of patients suing authorities in the court are very important and this might be reflected in the guidelines as well;
- It would be useful to reflect on resource allocation issue in the guideline e.g., how many doctors are needed to manage a certain amount of OST clients etc.

Closure of the meeting

The meeting was closed by thanking all of the participants of the workshop for the very fruitful collaboration and for sharing their data and insights that will be valuable for the development of the next version of the

guidelines/toolkit. Given the unanimous agreement on the unmet need for the 'practical' guidelines/ toolkit, it was agreed that Dr. Emilis Subata will circulate the next draft of the guidelines/toolkit by the end of June 2012. Participants also reiterated that it would be important to share the next version of the guidelines/toolkit with patient groups, civil society forums and associations and to engage them in the process of guidelines/toolkit development and finalization.