Regional Technical Consultation on the Dissemination of Consolidated Guidelines on the Use of Antiretroviral Drugs for Treating and Preventing HIV Infection in eastern European and central Asian Countries

> **Consultation report** 29–31 October 2013 Istanbul, Turkey





Dissemination of Consolidated Guidelines on the Use of Antiretroviral Drugs for Treating and Preventing HIV Infection in Eastern European and Central Asian countries

Regional Technical Consultation

29-31 October 2013, Istanbul, Turkey

Report

ABSTRACT

In July 2013, the World Health Organization released the "Consolidated Guidelines on the Use of Antiretroviral Drugs for Treating and Preventing HIV Infection" (available online at: http://www.who.int/hiv/pub/guidelines/arv2013/download/en/index.html). In addition to clinical topics, operational recommendations have also been made on different modalities of service delivery as well as programmatic guidelines to assist countries and partners with their decision-making. The new guidelines expand eligibility criteria for antiretroviral therapy and increase the number of people living with HIV who need it under the new criteria.

A regional technical consultation on the dissemination of the consolidated guidelines in 12 eastern Europe and central Asian (EECA) countries was held in Turkey from 29 to 31 October 2013. It addressed the clinical, operational and programmatic aspects of the consolidated guidelines, countries' current policies and their national plans to introduce and implement the new WHO guidelines. The presentations and discussions from the consultation are presented in this report.

> Keywords AIDS ANTIRETROVIRAL AGENTS GUIDELINES HEALTH POLICY HIV INFECTIONS INTERNATIONAL COOPERATION

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List of abbreviations and acronyms

AIDS	Acquired immunodeficiency syndrome
ART	Antiretroviral therapy
ARV	Antiretroviral
AZT	Azidothymidine
CD4	T-lymphocyte cell bearing CD4 receptor
d4T	Stavudine
EECA	Eastern Europe and Central Asia
EFV	Efavirenz
HBV	Hepatitis B virus
HCV	Hepatitis C virus
HIV	Human immunodeficiency virus
MSM	Men who have sex with men
NGO	Nongovernmental organization
NNRTI	Non-nucleoside reverse transcriptase inhibitor
NVP	Nevirapine
OST	Opioid Substitution Therapy
PLHIV	People living with HIV
РМТСТ	Prevention of mother-to-child transmission (of HIV)
PWID	People who inject drugs
ТВ	Tuberculosis
TDF	Tenofovir disoproxil fumarate
UNAIDS	Joint United Nations Programme on HIV/AIDS
VL	Viral Load
WHO	World Health Organization
ХТС	Lamivudine (3TC) or Emtricitabine (FTC)

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Introduction

The WHO regional technical consultation on the dissemination of the 2013 WHO Consolidated Guidelines on the Use of Antiretroviral Drugs for Treating and Preventing HIV Infection in eastern European and central Asian (EECA) countries took place in Istanbul, Turkey, 29-31 October 2013. Martin Donoghoe (World Health Organization (WHO) Regional Office for Europe) welcomed consultation participants on behalf of Regional Director Zsuzsanna Jakab (WHO Regional Office for Europe). He noted that the WHO "Consolidated Guidelines on the Use of Antiretroviral Drugs for Treating and Preventing HIV Infection" – a set of integrated guidelines on the use of antiretroviral (ARV) drugs in adults, children, pregnant women and key populations including people who inject drugs, sex workers and men who have sex with men, and for both HIV treatment and prevention-usher in a new phase in the history of the HIV epidemic in Eastern Europe and Central Asia (EECA). The effects of treatment on the epidemic have been observed on a global level, and the new guidance will help EECA countries begin to achieve benefits that are being seen elsewhere. A representative of the Joint United Nations Programme on HIV/AIDS (UNAIDS) noted the high levels of treatment coverage in other regions of the world and stressed that HIV treatment is no longer a separate component of the response to the epidemic but instead is integrated alongside prevention efforts. Both speakers encouraged meeting participants to engage in the debate and discussion on the new guidelines.

Objectives and expected results of the meeting

The objectives of the three-day regional technical consultation were to:

- 1. present and discuss the consolidated ARV guidelines with national counterparts, civil society stakeholders, United Nations representatives and other technical partners and donors;
- 2. discuss and agree upon plans to introduce, adapt and implement the guidelines, and to address potential barriers;
- discuss the roles of civil society, United Nations agencies, and other technical partners in this process;
- 4. identify the types of assistance that countries are likely to require from WHO; and
- 5. link dissemination of the consolidated guidelines with the current UNAIDS treatment initiative and other relevant global and regional strategies.

The following results were anticipated:

- Participants in the consultation are informed of the context for the WHO 2013 consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection -(http://www.who.int/hiv/pub/guidelines/arv2013/download/en/index.html), including antiretroviral therapy (ART) for adults and children, the management of major co-infections, prevention of mother-to-child transmission (PMTCT), operational and service delivery as well as programmatic guidance in general.
- 2. Priorities for the introduction of the guidelines at the country level are discussed, and country roadmaps for the adaptation and implementation of the guidelines are drafted.
- 3. The consultation identifies ways in which countries are likely to require technical assistance from WHO, UNAIDS and other technical partners in the course of implementing the revised guidelines.

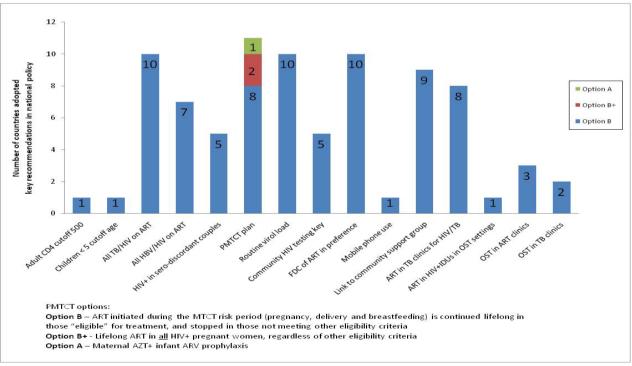
The consultation drew heavily on two key resources assembled beforehand: a summary of current HIV treatment policies for countries in EECA (Annex 1) and a summary of the same countries' anticipated future policies (Annex 2). This information was gathered using a questionnaire. Consultation proceedings were guided by the "Scope and Purpose" statement and meeting programme issued by the WHO Regional Office for Europe (Annexes 3 and 4, respectively). Approximately 80 people attended the consultation (a list of participants appears in Annex 5).

Progress and challenges in scaling up access to HIV treatment

Countries are at very different stages of closing the HIV treatment gap, as reported in the *Global AIDS Response Progress Reporting 2013*.¹ The key question is how the new guidance can help countries close this gap.

It was pointed out that the HIV epidemic in the EECA countries is the fastest growing in the world. Heterosexual transmission is now the main mode of transmission in EECA. However, the proportion of new infections due to injecting drug use remains very high in comparison with other regions. Deaths among people with AIDS are decreasing regionally and globally but are still increasing in the eastern part of the European Region. With regards to PMTCT, low- and middle-income countries in the European Region are doing very well; other regions can learn from Europe in this area. With regards to paediatric cases, the gap between child and adult coverage is increasing globally, with children lagging behind. All EECA countries have national clinical guidelines on HIV treatment developed on the basis of the 2012 WHO European recommendations. A number of regional (2012) and global (2013) recommendations are aligned and many countries have adopted them. There is also a clear indication of a need for further update of current policy. See Fig 1. Current countries' policy on criteria to initiate ART and some key interventions recommended by the 2013 global consolidated guidelines. (See Annex 1 for a more detailed overview of current countries' policy on HIV treatment and care.





* Armenia, Azerbaijan, Belarus, Georgia, Kazakhstan, Kyrgyzstan, Republic of Moldova, Russian Federation, Tajikistan, Ukraine, Uzbekistan

¹ Global AIDS Response Progress Reporting 2013: Construction of core indicators for monitoring the 2011 UN Political Declaration on HIV/AIDS. Geneva, UNAIDS, 2013, http://www.unaids.org/en/media/unaids/contentassets/documents/document/2013/GARPR_2013_guidelines_en.pdf.

Key European challenges to address include the following:

- The HIV epidemic is growing faster than access to ART.
- In spite of a reported increase in heterosexual transmission, HIV-infected people who inject drugs (PWID) in EECA constitute 38% of all cases – the highest percentage globally as compared to other subregions.
- Tuberculosis (TB) is the major co-infection and cause of death in people living with HIV (PLHIV) in EECA.
- Mortality in EECA to increase.

This indicates that national HIV programmes are not very effective. Reasons for this include legislative barriers or political resistance to opioid substation therapy (OST), the irrational use of limited financial resources, and health system issues (vertical programmes oriented towards the general population, with marginalization of key populations coupled with the new challenge of labour migrants in the region). This has implications for how HIV testing, prevention, treatment and care services are organized.

In EECA countries, the treatment gap, i.e. the difference between those on treatment and those who need it but do not receive it, is increasing. There are clear discrepancies between estimated ART coverage, true coverage and the numbers of PLHIV in need of treatment (registered for care and estimated). To improve ART needs assessments and the evaluation of ART coverage, there is a need to set up ART targets for every country and to have better quality estimations of key populations' size and HIV prevalence. There is also a need for well-defined programmatic ART forecasting.

A larger proportion of women than men are on ART in many EECA countries, including the Russian Federation, which s has the greatest number of PLHIV in the region. The greatest challenge in the region is thought to be late presentation for treatment, with notably high levels of people initiating ART with CD4 cell counts already below 200 cells/mm³.

Key issues brought up in this session included prioritization; ART coverage (Fig. 2); epidemiological estimates of PLHIV and their ART needs; the significance of addressing issues faced by people who inject drugs; and the response to barriers to HIV testing, prevention and treatment. The session highlighted the increasing number of people on ART worldwide, widespread willingness and capacity to scale up (in most countries), growing interest in the question of how to sustain funding and a shift towards more nationally-based funding. It was noted that the Russian Federation and Ukraine, with particularly large numbers of PLHIV, account for a considerable proportion of the total PLHIV population in the WHO European Region. Many PLHIV there were infected through unsafe injected drug use. One of the major challenges associated with addressing this situation is that opioid substitution therapy is forbidden in the Russian Federation and only available to a small number of those in need in Ukraine.

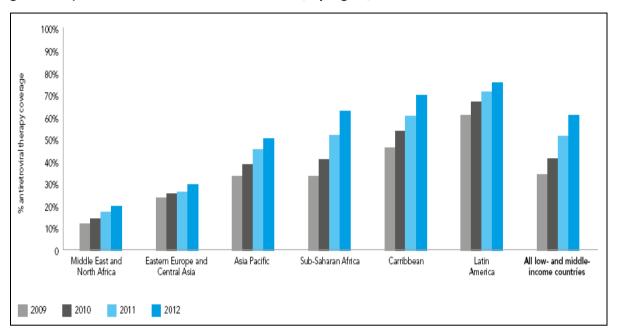


Fig. 2: Percentage of people eligible who are receiving antiretroviral therapy (based on WHO 2010 guidelines) in low- and middle-income countries, by region, 2009-2012

Source: UNAIDS estimates 2012

Session 2

Overview of the Consolidated Guidelines development

The WHO 2013 ConsolidatedGguidelines provide, for the first time, not only clinical guidance along the continuum of care – the "what to do" (such as when to start and what regimens to use), but also operational guidance on how to deliver HIV services (Table 1). There is also new guidance for programme managers in the field as to how to implement the recommendations. The document consolidates guidance across:

- all ages and populations, including adults, pregnant women, adolescents and children (groups covered in separate guidelines in the past), harmonizing ARV regimens and treatment approaches to the extent possible across age groups and populations, as well as addressing specific key populations – people who inject drugs, sex workers and men who have sex with men; and
- the continuum of care from HIV testing and counselling, linkages to care and treatment, general HIV care, and all aspects of ART management.

In addition to new recommendations, it consolidates these with a synthesis of existing recommendations from other guidelines.

The consolidated guidelines were needed for three overarching reasons:

- 1. Advances in science/technology and in vision
 - a. Technologies (including point-of-care, CD4 count and viral load, new drug formulations) b. ART for individual and population benefits
- 2. HIV as a chronic health condition
 - a. Increasing focus on treatment adherence and retention in care
 - b. Chronic care models: decentralization, integration
- 3. Despite scale-up, continuing challenges
 - a. Low ART coverage among children, adolescents and key populations
 - b. Major gaps in quality and in retention along the continuum of care.

The guidelines are global in nature, though EECA countries experiences were taken into account when developing them. The task now is regional adaptation and specifically adaptation to each country in EECA. There are many recommendations to be implemented, implying additional costs. These costs may be limited if the 2010 guidelines are already being fully implemented – though this is not the case in most countries of EECA.

		Operationally relevant	
Clinica O	<i>lly relevant</i> Earlier initiation of ART (CD4 ≤ 500 cells/mm ³)	 Use of fixed-dose combinations as preferred approach 	-
0	Immediate ART for children below 5 years	 Improved patient monitoring to subsetter adherence and detect earlies treatment failure (increased use or 	er
0	ART for all pregnant and breastfeeding women with HIV (Option B/B+) and lifelong ART (Option B+)	 load) Recommend task-shifting, decentralization and integration 	
0	Harmonization of ART across populations (e.g., adults and pregnant women, B/B+) and age groups	 Community-based testing to complement broader HIV testing a counselling 	nd
0	Simplified, fewer, and less toxic first-line regimens (TDF/XTC/EFV)	-	

Discussion

Concern was expressed about the importance of addressing the number of different drugs procured for selected regimens (e.g. a three-drug regimen), particularly in terms of adherence which can be compromised when a treatment regimen is composed of multiple drugs, but also with regards to drug stock-outs. It was noted that fixed-dose regimens would reduce the number of drugs that needed to be procured, simplifying administrative procedures.

Global Fund recipient countries were said to have some advantages in the guideline implementation process due to their large amount of funding. It was suggested that countries without Global Fund support would need to further consider how to prioritize when implementing the guidelines. Implementation may not be able to take place all at once.

Concern was expressed about being more innovative in terms of HIV testing and counselling, and about shifting from a traditionally more cautious approach toward a more "urgent" response. It was thought to be important to set up national testing matrices as a mix of approaches based on national context and epidemiology. Regarding the lack of joint HIV testing and counselling, it was observed that since counselling is time-consuming, a requirement to provide counselling in conjunction with each HIV test may reduce the number of tests administered. This point raised the issue of prioritization.

It was stated that the decision to carry out an HIV test should be taken in collaboration with the patient. Any testing which is not the patient's decision is considered to be mandatory. "Routine testing," for example, should be a routine *offer* of a test and not a test without the patient's explicit consent. Some countries in EECA region reportedly still have policies that the United Nations does not find acceptable, such as mandatory testing of certain populations (e.g. migrants, prisoners and sex workers).

It was proposed that countries need to review their legal frameworks and direct their efforts at key population groups. This should be a multisectoral and decentralized approach involving civil society, general practitioners and primary health care facilities, and should incorporate rapid HIV testing. There was thought to be a need to strengthen referral systems to improve linkages to care.

Challenges such as insufficient linkages to and retention in care, mistrust of the health care system, transport costs and fear about drug stock-outs were attributed to multifactoral issues. The opinion was expressed that HIV testing and counselling needs to be better promoted to people as an asset so that it is not coloured by the fear and stigma still associated with HIV. Another proposed measure for enabling more people to learn their HIV status was to reduce the time lag between the acquisition of initial test results and confirmatory test results so that fewer patients would be lost during the interim period.

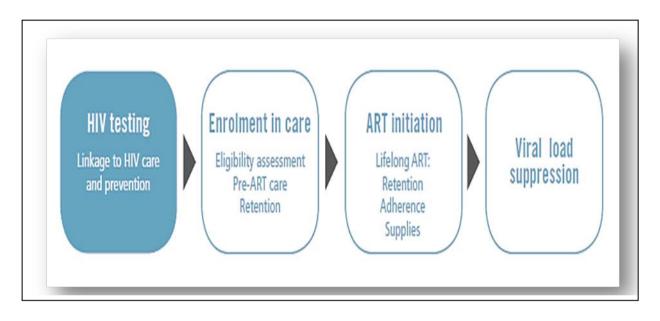
It was observed that WHO HIV testing and counselling recommendations for key populations often do not consider regional and national specificities. In Armenia, for example, 60% of new HIV cases are among labour migrants and 20% are among partners of these migrants. In other words, four-fifths of new cases are outside of traditional key populations. These rural people will not come to clinics for sexually transmitted infections in the capital, nor will they necessarily act on prevention messages. Another issue is the difficulty of maintaining confidentiality in small rural societies.

Willingness to scale up treatment and commitment were clearly expressed in the discussion, as were intentions to shift to state budgets. Coverage and how to calculate was an issue that kept coming up. How to address the needs of people who inject drugs was raised as another vital issue.

Continuum of care

Service delivery should be implemented with a view to strengthening the continuum of care, presented in the WHO 2013 guidelines as HIV treatment and care cascade (Fig. 3).

Fig. 3 The HIV treatment and care cascade



There is substantial attrition as people navigate the steps between testing positive for HIV and initiating ART (see Fig. 3).Global statistics indicate that some 15% to 30% of PLHIV are lost at each step. Coverage of testing remains low as well. Consequently, many people start ART late. Worldwide, one in four people start ART at a CD4 cell count level of less than 100.

Discussion

The discussion began with a question regarding the major barriers to HIV testing and counselling in the countries and the linkages to treatment and care.

It was suggested that an obstacle to retaining patients is the state of shock that people often enter when they learn about having HIV. This response prevents them from absorbing new information, making posttest counselling ineffective.

Drug stock-outs were thought to have an enormous impact on PLHIV. Awareness of possible stock-outs may make some people reluctant to initiate ART because of their fear that they will not be able to continue.

A focus on positive campaigns was proposed with the intention of improving general attitudes by emphasizing that HIV treatment can be very successful.

It was observed that HIV testing often is not linked to HIV care on a global level. Questions were raised about why people drop out of treatment and about what communities might be able to do to improve this situation.

There was a proposal to consider how HIV testing can be promoted, and to further investigate why people are reluctant to undergo testing. It was noted that more efficient methods of promoting testing are needed. This was believed to be a task not only for WHO but for all partners, with civil society involvement being particularly crucial.

Although varying by country, stigma, lack of access, insufficient transportation and lack of confidence in the health care system were thought to be among the reasons people are not retained in HIV treatment. It was also noted that some people do not want to initiate ART because of the anticipated impact of treatment on their lives (e.g., fear of side-effects).

It was suggested that a country-by-country analysis is needed to understand how the HIV treatment and care continuum of care is organized in different settings. There was further emphasis on striving to minimize the loss of patients at different stages of the cascade.

In Kyrgyzstan, it was noted, a number of pilot projects have been launched to increase HIV testing. Nongovernmental organizations (NGOs) are involved in the provision of testing services to key populations, and rapid testing has been introduced at the primary care level. Kyrgyzstan provides what they refer to as a comprehensive package in order to offer testing and diagnosis of HIV.

Stigma and discrimination were identified as key issues, as was the challenge of bringing services closer to the people who need them.

It was pointed out that on page 13 of the new guidelines, key populations are defined in a broader way than in the past (not only most-at-risk populations). Countries can include groups such as labour migrants. This is also in line with the definition of the key populations at higher risk of the European Action Plan for HIV/AIDS 2012-2015. Ethnic minorities and migrants were recognized as very important groups, and it was suggested that social determinants need to be addressed in order to fully meet the challenges facing these groups. Confidentiality issues also need to be kept in mind.

The concern was expressed that the WHO guidelines will not be properly implemented because of limited civil society involvement. WHO developed the guidelines, but the amount of specific information is very limited. Related concerns included the reliance of many countries on Global Fund funding and the need to legalize civil society efforts in some settings.

The final comment was that the new guidelines were created to consolidate all guidelines. WHO expects to progressively update the document. Further, there are specific web-annexes which can be consulted.

Clinical guidance across the continuum of care: ART in adults and adolescents

A summary of the changes in the recommendations of when to start ART in adults was presented (Table 2). In relation to this, the observation was made that it is a national decision whether to take a public health approach or a patient-oriented/individualized approach to ART – both can have the same outcome for patients, but it is not advisable to mix the two approaches.

The view was expressed that while ART as prevention works, it is important to not lose sight of other prevention methods that work equally well. Most HIV transmission occurs before people are put on treatment, particularly during acute infection.

It was suggested that each country needs to understand its own national HIV treatment and care cascade and to understand the weak points in it. The proportion of people who are diagnosed with HIV and are subsequently initiated on treatment was said to be markedly lower in the eastern part of Europe than in the western part. The point was made that this must change if the epidemic is to be curbed.

TARGET POPULATION	2010 ART GUIDELINES	2013 ART GUIDELINES
(ARV-NAIVE)		
HIV+ ASYMPTOMATIC	CD4 ≤350 cells/mm ³	CD4 ≤500 cells/mm ³ (CD4 ≤ 350 cells/mm ³ as a priority)
HIV+ SYMPTOMATIC	WHO clinical stage 3 or 4 regardless of CD4 cell count	No change
PREGNANT AND BREASTFEEDING WOMEN WITH HIV	CD4 ≤350 cells/mm ³ or WHO clinical stage 3 or 4	Regardless of CD4 cell count or WHO clinical stage
HIV/TB CO-INFECTION	Presence of active TB disease, regardless of CD4 cell count	No change
HIV/HEPATITIS B CO-INFECTION	Evidence of chronic active hepatitis B disease, regardless of CD4 cell count	Evidence of <u>severe</u> chronic hepatitis B liver disease, regardless of CD4 cell count
HIV+ PARTNER IN SERODISCORDANT COUPLE	No recommendation established	Regardless of CD4 cell count or WHO clinical stage

The view was expressed that it would be unrealistic to believe that an additional 13 to 14 million people can be initiated on treatment "overnight." Therefore, the WHO 2013 consolidated guidelines suggest that the treatment of people withCD4 cell counts under 350 cells/mm³ should be prioritized ahead of the treatment of people with CD4 cell counts between 350 and 500 cells/mm³.

It was noted that although fixed-dose regimens are highly effective, alternatives are required. At the same time, it is important to act on knowledge about drugs that have been found to have major toxicities. For example d4T (stavudine) is known for its mitochondrial toxicity, and there is a clear recommendation to phase out this drug.

Discussion

The meeting addressed the concern of whether pregnant women should take the antiretroviral drug efavirenz, a practice endorsed in WHO guidelines but not revised by 2013 European AIDS Clinical Society guidelines. The view was expressed that an updated systematic review and meta-analysis, including the Antiretroviral Pregnancy registry do not find efavirenz use during pregnancy to be risky. Although the Guidelines Development Group emphasized that better data on birth defects are needed, it felt confident that potential low risk should be balanced against the programmatic advantages and the clinical benefit of efavirenz in preventing HIV infection in infants and for mother's health, so , it is acceptable to prescribe the drug to pregnant women. Countries' representatives shared their concern regarding the lack of evidence about the impact of EFV on the mental and intellectual development of children who have been exposed to EFV prenatally. This was one of the main arguments against a recommendation for the greater use of EFV during pregnancy. A few participants suggested that further research be undertaken.

The question of what evidence exists to guide decision-making about regimen changes in patients who have achieved virological suppression was considered. It was suggested that preparing patients to switch, including preparing them psychologically, is important, but that such a transition is generally easy to manage in patients whose current regimens have already successfully suppressed their viral load. The key issue, it was noted, is to get people stabilized in care.

The role of the patient in guideline implementation (treatment decisions) was raised and it was noted that health care providers are treating people, not viruses – this means expressing an outlook of "how are you?" rather than "how is your viral load?" The importance of establishing a "secure relationship"' between patient and doctor was emphasized, and it was observed that doing this will likely have implications for retention rates.

The observation was made that many myths exist regarding side-effects, and that it is important to bring evidence to the table in any discussion of side-effects, including side-effects of efavirenz.

It was added that while more ARV combinations are needed, as long as people are achieving viral suppression on effective regimens that are conducive to high adherence, it is not worth it to change therapy without the need . The point was made that health care providers should focus on overcoming some of the key barriers to treatment rather than discussing "one or 15" combinations. The importance of the new guidelines, it was suggested, is in their potential to bring down the unnecessarily high number of HIV-related deaths in EECA countries.

Clinical guidance across the continuum of care: managing common co-infections and co-morbidities

Information about the prevention, screening and management of TB, hepatitis B (HBV) and hepatitis C (HCV) was presented, along with information about the prevention and management of other comorbidities and chronic care for PLHIV (noncommunicable diseases, mental health and drug use disorders).

Tuberculosis

Data from 2009 showed that risk of death within 1st year after diagnosis in TB/HIV population in eastern Europe is 33%. Key problem areas were diagnosis and lack of service integration, with patients only being referred to HIV treatment upon completion of TB treatment – much too late.

The development of the Xpert MTB/RIF assay for the GeneXpert platform was completed in 2009 and is considered an important breakthrough inearly diagnosis of MDR TB. For the first time, a molecular test is simple and robust enough to be introduced in peripheral laboratories (http://whqlibdoc.who.int/publications/2011/9789241501569_eng.pdf).

It was pointed out that the benefits of ART extend beyond the impact on patient health, HIV-related patient survival and HIV prevention. There is also a clear impact on TB incidence. Simultaneous therapy of HIV and TB is recommended and is effective at the individual as well as public health levels. Mortality following infection with TB remains high in PLHIV followed in EECA countries, and multidrug-resistant TB is a particular concern in this part of the world.

Drug use

HIV is associated with injecting drug use in most EECA countries and with recent HIV outbreaks among people who inject drugs in Greece and Romania. It was stressed that people who inject drugs should be put on opioid substitution therapy as part of their HIV treatment, since dealing with drug dependence is a pre-requisite for providing effective health care. The point was made that it is in the interest of the drug user to receive health care, as his or her life is at stake, and also in a country's interest in order to contain the spread of HIV. This view is not reflected in policies across the region with Russia having an explicit prohibition on the use of OST.

Hepatitis B and C

It was noted that while current drugs do not work very well, many new drugs that will be reaching the market in the next few years can potentially revolutionize how HCV is treated. But some of these drugs may be very expensive.

Regarding HIV/HCV co-infection, the observation was made that this condition accelerates HCV-related progression of liver fibrosis and is associated with higher rates of end-stage liver disease and mortality. HIV/HCV co-infected people should initiate ART in accordance with the same general principles guiding antiretroviral treatment for all PLHIV.

As for HIV/HBV co-infection, it was noted that there are higher rates of HBV chronicity among PLHIV, with less spontaneous HBV clearance. HIV/HBV co-infection is associated with accelerated liver fibrosis progression, cirrhosis, hepatocellular carcinoma and higher liver-related mortality, as well as with a decreased response to ARVs. People who are co-infected with HIV/HBV should initiate ART at CD4 cell count levels below 500cells/mm³ unless they already have severe chronic liver disease, in which case they should initiate ART immediately regardless of CD4 level.

Discussion

It was noted that it makes sense to hospitalize patients who are clinically very sick. However, some of the resources spent on expensive inpatient care might be better spent on improving integrated outpatient services. The preferred model of service delivery, it was suggested, is community-based clinics in close physical proximity to patients. A different model is needed to reach people who inject drugs. Civil society groups can play a key role in engaging this population in care.

It was observed that the viral hepatitis community can learn from the HIV experience regarding treatment and drug pricing in particular.

Session 6

Clinical guidance across the continuum of care: ART for pregnant, breastfeeding and non-breastfeeding women

Each region of the world needs to develop its own targets for reducing mother-to-child transmission of HIV.

Rapid changes in the scientific evidence regarding paediatric HIV treatment has led to an equally rapid change in paediatric treatment recommendations in recent years. Countries and patients need to be aware of the differences between Option B and Option B+ for pregnant women (Table 3). Option B means that for women who are not eligible for ART for their own health, consideration can be given to stopping the ARV regimen after the period of mother-to-child transmission risk has ceased. Option B+ means that all pregnant and breastfeeding women infected with HIV should initiate ART as lifelong treatment for programmatic and operational reasons, particularly in generalized epidemics.

Table 3. Evolution of WHO PMTCT and ART Recommendations											
	2001	2004	2006	2010	2013						
РМТСТ	4 weeks AZT; AZT + 3TC, or sd NVP	AZT from 28 weeks + sd NVP	AZT from 28 weeks + sd NVP + AZT/3TC 7 days	<i>Option A:</i> AZT from 14 weeks + sd NVP <i>Option B:</i> triple ARVs	<i>Option B or B+:</i> Moving to ART for all PW/BF						
ART	no recommendation	CD4 <200 cells/mm ³	CD4 <200 cells/mm ³	CD4 ≤350 cells/mm ³	CD4 ≤500 cells/mm ³						
Abbreviations: 3TC = Lamivudine, AZT = Azidothymidine, CD4 = T–lymphocyte cell bearing CD4 receptor, NVP =											

nevirapine, PW/BF = pregnant women and breastfeeding women, sdNVP = Single dose of nevirapine

In summary, there has been a major paradigm shift with a convergence of PMTCT and ART guidance leading towards a simplified, harmonized approach for all adults including pregnant women. All HIV-

positive pregnant and breastfeeding women should start first-line ART (the same regimen for Option B and Option B+). The main focus needs to be on the benefit to the mother's health, the prevention of infant infections and the prevention of partner infections.

Discussion

The point was made that the importance of post-delivery counselling of breastfeeding women must be stressed in order to reduce post-partum HIV transmission during breastfeeding; it was thought that this issue could be better highlighted in the new guidance.

It was observed that one advantage of Option B+ is reduction of HIV transmission during breastfeeding. However, it is not clear what women's attitudes are when they are faced with the prospect of lifelong treatment in spite of feeling healthy. Civil society representatives providing input into the consultation identified a need for greater involvement of pregnant/breastfeeding women in the development of messaging.

Session 7

Clinical guidance across the continuum of care: ART in children

Global paediatric HIV recommendations are in many cases based on evidence from settings with limited access to early infant HIV diagnosis and with high levels of children presenting late with HIV.

When to start treating children

In most countries worldwide, it was noted, early infant HIV diagnosis remains weak and poor. Even when diagnosis takes place, a large drop-off occurs during the treatment and care cascade (see Fig. 3 above), with many children not receiving the treatment they need. There are also technical challenges with regards to delivering the right regimen with the right formulation in relation to the age of the child.

In 2010, the WHO recommendation was to treat all children under the age of one regardless of CD4 cell count or other criteria. In 2013, the new recommendation is to treat all children under the age of five regardless of CD4 count or WHO clinical stage, though priority groups of younger age or severe disease stage have been identified (Table 4).

For children aged five and older, the recommendation is to use the same criteria for ART initiation as for adults and are based on CD4 criteria.

The first-line regimen should be lopinavir/ritonavir for children under the age of three. For children over the age of three, first-line treatment should be harmonized with that of adults.

Viral load monitoring is as important for paediatric patients as it is for adult patients

A few programmatic issues should be taken into consideration:

- It is imperative to identify HIV-infected children through early testing, follow-up and determination of the final infection status of HIV-exposed children. Provider-initiated testing and counselling can be effective in settings where HIV is suspected.
- Health care providers must have access to appropriate paediatric formulations.
- Improvements are needed in training and service delivery for paediatric care and treatment.

• Paediatric HIV treatment must be prioritized to increase coverage and close the treatment gap with adults who have HIV.

Table 4. WHO 2013 (recommendations for starting ART in children
AGE GROUP	2013 RECOMMENDATIONS
< 1 YEAR	Treat all Strong recommendation, evidence of moderate quality
1-5 YEARS	Treat all
	Conditional recommendation, evidence of very low quality
	Priority: children <2 years or WHO stage 3-4 or CD4 count \leq 750 cells/mm ³
	or < 25%
≥5 YEARS	$CD4 \le 500 \text{ cells/mm}^3$
	Conditional recommendation, evidence of very low quality
	CD4 ≤350 cells/mm³ as a priority (as in adults)
	Strong recommendation, evidence of moderate quality

Discussion

Concern was expressed about treating adolescents with antiretroviral regimens that include tenofovir. It was noted that more data including toxicity surveillance is needed to make a final decision on this point.

It was suggested that there are two key obstacles to treating children: limited national manufacturing of drugs and adherence among adolescents. Other meeting participants highlighted challenges around the provision of care to adolescents and noted that better guidance is required to target the specific needs of this group. It was observed that a forthcoming consultation on the elimination of mother-to-child transmission of HIV would be a useful platform for continuing the conversation about these issues.

There was also a discussion about who should be in charge of managing paediatric treatment. It was proposed that adolescents should be considered a separate group. WHO has worked with UNICEF and others on adolescent guidelines to provide more of a direction for adolescent services. Guidance for HIV testing and counselling and care for adolescents living with HIV are available at http://www.who.int/hiv/pub/guidelines/adolescents/en/index.html There was thought to be a need for additional stocktaking regarding what resources are available and what resources are needed in EECA region.

Continuum of care: laboratory monitoring

This session addressed the topics of monitoring the response to ART and the diagnosis of ART failure; monitoring and substitution for ARV drug toxicity; drug interactions; and implementation considerations for key issues such as use of viral load (VL) for patient monitoring.

It was noted that most HIV is eradicated by ART. However, some virus mutates and becomes resistant to it. The dynamics at work in this situation may vary greatly in accordance with which ARV drugs have been used. A particular concern is cross-resistance (the occurrence of viral resistance in the presence of not just a particular drug but also other drugs of the same class).

Another concern is when people stop treatment. This can lead to resistance, leaving fewer future treatment options. It was observed that once ART has been initiated, it should not be interrupted.

Regarding VL monitoring, it was noted that "routine" monitoring should take place six months after the initiation of treatment and then at least every 12 months. Additionally, "targeted" VL monitoring should take place when there are concerns about a non-response or treatment failure (for example in the presence of medical problems, which may or may not be related to treatment adherence and the effects of treatment).

More specifically, VL monitoring can reinforce adherence, provide an early indication of treatment failure, contribute to decision-making about whether to switch to second-line treatment, reduce cross-resistance and inform efforts to decrease HIV transmission via viral load suppression.

In WHO 2013 guidelines the recommended cut-off for viral load of 1,000 copies of the virus per millilitre of blood. Patients whose VL remain higher than this in two consecutive measurements within a three months interval, with adherence support between measurements, are advised to switch to a second-line ART regimen. In situations where VL monitoring is not available, the CD4 cell count should be used. However, in some cases of virological failure the CD4 cell count increases. Thus, the patient appears to be improving but the virus continues to accumulate resistance, with the result that the patient will become increasingly difficult to treat over time.

Another issue raised was the transmission of virus that is resistant to the non-nucleoside reverse transcriptase inhibitor (NNRTI) class of antiretroviral drugs. While this was acknowledged as a concern, it was observed that the threat of NNRTI resistance should not result in provision of reduced treatment. The dilemma is that with more people on ART there can be more resistance, but this is coupled with a reduction in HIV transmission. A central issue in resolving the problem of resistance to ART is that people with early virologic failure need to be identified and their treatment regimens changed accordingly.

For a summary of laboratory monitoring, see Table 5.

Table 5. HIV laboratory monitoring												
Phase of HIV management	HIV diagnosis	Follow-up before ART	ART initiation	Receiving ART	Treatment failure							
Recommended	HIV serology, CD4, TB screening	CD4	CD4	Viral load (CD4)	Viral load (CD4)							
Desirable	HBV, HCV, Cryptococcus antigen, sexually transmitted infections, noncommunicable diseases		Hb for AZT; Cr or glycosuria for TDF; ALT for NVP; BP for TDF	Cr for TDF	HBV (Only if HBV testing was not done at baseline or if the HBV result was negative at baseline)							
Abbreviations: ALT = Alanine aminotransferase, AZT = Azidothymidine, BP = blood pressure, CD4 = T–lymphocyte cell bearing CD4 receptor, Cr = creatinine, Hb = Haemoglobin, HBV = Hepatitis B virus, HCV = Hepatitis C virus, TDF = Tenofovir disoproxil fumarate.												

Discussion

It was observed that if WHO recommends the initiation of VL monitoring in six months after initiation of ART, ministries of health may not allow it earlier, which can be problematic in cases in which a clinician would like to follow a situation more closely. In lower-resource settings, it was thought to be important to know the VL threshold, i.e. below or above 1,000 copies, rather than the specific viral load number. Point-of-care technology that can report this information specifically will be key in more remote settings as it will likely be more affordable than full viral load monitoring.

It was noted that the evidence shows that most patients who initiate ART achieve viral suppression at six months. The six-month mark thus is usually sufficient, but another interval may be considered in some cases. The view was expressed that the best advice when there is limited access to viral load testing is to carry it out at least every six months. Otherwise, having it done one month after ART initiation may be considered, then every three months, if this does not compromise ability to perform VL in other patients.

Operational and service delivery guidance

The major implementation challenges in EECA countries were reported to be low HIV testing levels in key populations, especially in PWID; delayed diagnosis and treatment initiation, and subsequently low retention in care; and low treatment coverage among key populations (although the region has high ART coverage among children).

Guidance for operations and HIV service delivery

A new section in the consolidated guidelines addresses operations and service delivery, including adherence to ART. A simplified, fixed-dose ARV combination once-a-day regimen improves adherence. Other operational considerations to improve adherence are linked to comorbidities, client-related factors, client-provider relations and health systems-related factors. The new guidelines make the following programme-level interventions for improving adherence support:

- minimize out-of-pocket payments;
- use fixed-dose combinations;
- strengthen the drug supply system;
- provide patient counselling, education and peer support;
- provide needle and syringe services and drug dependence treatment for PLHIV who use drugs; and
- provide nutritional support in food insecure settings.

New recommendation at an individual level relates to use of mobile phone text messaging as a simple reminder tool for promoting adherence to ART as part of a package of adherence interventions.

A combination of approaches such as decentralization, integration of services and task-shifting are the key global recommendations in this area of the guidelines, which call for approaches to be adapted to country and subnational settings. The recommendations address five areas:

- <u>Retention across the continuum of care.</u> Barriers to remaining in care include psychosocial factors, structural factors and health care factors. There are no specific recommendations in the guidelines, but multiple interventions are necessary to retain patients in care. Integration of services is considered to work better than non-integration. This includes the co-location of services. Programme monitoring and focused evaluations are needed.
- <u>Service delivery</u>. Decentralization and community support interventions are central recommendations. Besides this, WHO now recommends initiating and managing ART in TB care settings; mother and child health/antenatal care settings in generalized epidemics; and opioid substitution therapy settings with linkages for the continuation of HIV care and treatment.
- <u>Task-shifting</u>, where health care personnel remain insufficient in settings with high burden of HIV.
- Laboratory and diagnostic services.
- <u>Procurement and supply chain management.</u>

Key discussion points

The point was made that priorities need to be determined on a country-by-country basis. National decision-makers need to consider interventions that work in their context with regards to various factors, such as the capacity of health care professionals involved in HIV care. (How much time do they have for each patient?) It was observed that health care decentralization, which can lead to disclosure of a patient's HIV diagnosis without his or her consent, is a challenge in many settings. In some countries, patients who move do not want to be assigned to a new treatment centre because of their concerns about stigma. This issue was said to be related to issues associated with migrant populations in general. A clarification was put forth regarding decentralization: it was said to actually be for those who either cannot access treatment or, if they have moved, cannot return to the centre they would normally attend.

Health professionals' stigmatizing outlook was said to be a major barrier to treatment adherence. Drug stock-outs were also reported to be a problem in EECA countries. In some places, people living with HIV fear that drugs will not be available when they are needed. It was suggested that WHO provide recommendations on what to do if stock-outs occur.

Counselling was thought to be needed, including counselling from those who are not physicians. The observation was made that doctors have little time for counselling. While NGOs are often ready to help fill the gap, it was noted that local models should be developed. Also, clear messages were thought to be needed regarding the safety of generic drugs to address some patients' fears about them.

The observation was made that narcological services need to collaborate with HIV services in EECA countries so to integrate OST for PLHIV receiving HIV care and ART in HIV services and integrate delivery of ART at OST sites, as mentioned in earlier discussion.

With regards to community-based support, there was a concern about how it would be funded. It was pointed out that volunteer peer support programs are one source of support, and an example was given of a program that was very successful at utilizing patients to help their peers.

The point was made that community-based HIV testing and other innovative HIV testing approaches are needed to get people living with HIV into treatment. With United Nations support, saliva HIV testing was introduced in one country. This technology was thought to be useful for delivering HIV testing services to hard-to-reach populations, and key populations are informed about it. Although these tests are still problematic, confirmatory tests can be carried out, making it a potentially effective approach.

In one country with high number of PLHIV, success was reported with delivering ART at the primary care level, particularly with regards to follow-up. Family doctors are involved in monitoring treatment as well as supporting adherence, rather than solely relying on HIV specialist doctors.

Guidance for programme managers

The consolidated guidelines contain many recommendations, and it was observed that countries need to determine which ones to prioritize. Some considerations in this process are:

- 1. Key elements for a transparent and inclusive national adaptation process. This includes involving key stakeholders and ensuring their effective participation, as well as being open about all decision-making criteria.
- 2. "Know your epidemic and know your response". This means taking into account HIV incidence and prevalence, programme and response analysis, equity in access, and contextual issues such as the legal, regulatory and epidemiological situations.
- 3. Key parameters for decision-making, such as ethics, equity and human rights; impact and cost– effectiveness (including modelling); and opportunities and risks.
- 4. Health systems issues including communication, leadership, human resources, drugs and supplies, and health system organization. Some key implementation considerations for specific recommendations include:
 - changing the CD4 cell count threshold for initiating ART in adults and adolescents from 350 to 500 cells/mm³;
 - scaling up viral load testing;
 - moving to lifelong ART for all pregnant women;
 - decentralizing ARV services;
 - expanding treatment criteria for certain populations regardless of CD4 count (e.g., serodiscordant couples, pregnant women, HIV/HBV co-infected people); and
 - phasing out d4T
- 5. The availability of tools for costing and planning (free at <u>www.futuresinstitute.org</u>). Spectrum modules include *AIM (AIDS Impact Model), Goals (Cost and Impact of HIV Intervention)* and *Resource Needs*. Additionally, *OneHealth Tool* provides a single framework for planning, costing, impact analysis, budgeting and financing of strategies for all major diseases and health system components.

The following concrete guidance was proposed for programme managers:

- review elements of the guidance to ensure fair, inclusive and transparent decision-making process at the country level;
- discuss key data needed for evidence-based decisions ;
- examine key parameters for decision making;
- review tools for costing and planning; and
- discuss implementation considerations for key recommendations.

Discussion

National stakeholders participating in the consultation highlighted some of the challenges they faced. A participant from the Russian Federation commented that WHO recommendations are perceived as a gold standard, and there was encouragement to not make programmatic approaches "too radical".

One national stakeholder called attention to the need to address sensitive issues such as access to testing and care for key populations such as prisoners and PWID. It was observed that attempts to integrate services meet with major challenges. Strengthening laboratory capacity was also noted as a major concern.

Other participants commented that decentralization efforts should encompass community-based testing, not merely primary health care settings. Regarding laboratory performance, there was thought to be a need to strengthen quality assurance. It was noted that cost–effectiveness should also be considered in relation to issues such as laboratory equipment. However, because of the small size of some countries of EECA, decentralization is not necessarily an issue for all.

Attention was called to human resource challenges, with shortages of medical experts and staff shortages in rural areas highlighted as particular problems. The ongoing challenge of drug procurement was also noted, with ARV drug stock-outs still said to be occurring.

The opinion was expressed that treatment regimens are not particularly straightforward given that patients often have co-morbidities affecting treatment dosing, e.g. dosing may need to be adjusted for patients on OST.

It was pointed out that while the consolidated guidelines discuss testing for adolescents, there are legal considerations in many countries with regards to parental permission.

The observation was made that if fixed-dose ARV combinations are considerably more expensive than other combinations, this may have a negative impact on efforts to scale up treatment in countries with limited resources allocated to HIV treatment.

Finally, it was noted that the impact on national budgets of decisions such as when to start treatment needs to be considered, and that not all countries are ready to move from initiating treatment at a CD4 level of 350cells/mm³ to the higher threshold of 500cells/mm³. An individualized approach was said to be needed, e.g. in a decision on ART initiation in serodiscordant couples.

With the exception of Turkmenistan, all countries in EECA have networks of people living with HIV, and it was noted that these people should be considered as partners in the HIV response.

The Global Fund's new funding model and strategic investment framework in eastern Europe and central Asia

This presentation from the Global Fund introduced key features of the Global Fund's strategy. These included:

- invest more strategically, focusing on the highest-impact opportunities, including through national strategies;
- replace the "rounds" system with a new funding model, with more predictable and flexible funding and an iterative, dialogue-based application process;
- actively support grant implementation success;
- enhance partnerships to deliver results;
- promote and protect human rights; and
- increase sustainability of programmes and attract additional funding.

The presentation also provided an overview of the Global Fund's new funding model. Countries need to make an investment based on national income level as a percentage of the total grant. The following countries remain eligible for Global Fund support: Armenia, Azerbaijan, Belarus, Bulgaria, Georgia, Kosovo, Kyrgyzstan, Republic of Moldova, Romania, Russian Federation, Tajikistan, Ukraine and Uzbekistan <u>http://www.theglobalfund.org/en/fundingmodel/single/eligibility/</u>.

The presentation additionally highlighted the strategic investment framework for EECA countries, which originates from the general Global Fund Strategy 2012–2016 ("Investing for Impact") and is aligned with Global Fund policies, including the Eligibility Counterpart Financing and Prioritization Policy. The framework is coordinated with and complements partner-aligned disease-specific targets and plans such as the European Action Plan for HIV/AIDS 2012–2015; the new UNAIDS "Treatment 2015" framework; the EECA of PLHIV (ECUO) plan for sustained universal access to ART in the region; and the follow-up of the 2004 Dublin Declaration, 2011 Political Declarations on HIV/AIDS and others.

Global Fund investment priorities in EECA countries should be focused on two complementary pillars:

- Promote and sustain the scale-up of access to antiretroviral treatment, ensuring that the most vulnerable people have access to a continuum of testing, treatment, care and adherence services.
- Promote and enhance access to comprehensive harm reduction, prevention, treatment and care services for people who inject drugs.

It was noted that the above focus should serve as a framework for countries to use and does not exclude groups other than people who inject drugs. For example, strategies should also seek to allocate resources to support and promote activities that address the needs of sex workers and men who have sex with men.

Given different epidemic patterns in the WHO European region , it was proposed that the goal may be to reduce the HIV epidemic to less than 0.5% incidence in key populations (essentially men who have sex with men) and maintain low overall disease burden.

While prioritizing maximum treatment and prevention coverage of key populations, especially in priority geographical areas (including prison systems), a differentiated strategy based on Global Fund eligibility criteria (disease burden and epidemic level) will need to be elaborated for the gradual movement of financial responsibility to countries.

Discussion

There was a query about referring to HIV in EECA region as being driven by unsafe injecting drug use. It was noted that there is an apparent increase in sexual transmission in some countries, but this could also be due to low testing of people who inject drugs. Labour migrants must also be considered when discussing the epidemics and their epidemiology.

It was noted that the Global Fund welcomes responses that are evidence-based and address those key populations that are proven to be at risk of contracting HIV. Country ownership is a central element given that each country is unique. Funding is requested in the context of the national HIV programme. Grant proposal activities should include HIV prevention as well as treatment, in addition to considering how to control multidrug-resistant TB.

Regarding how much co-funding countries need to provide and how it is allocated, it was announced that countries can apply for 100% coverage of a particular activity, for example the provision of methadone. One stipulation is that countries have a vision for moving towards national programmes and sustainable funding.

Interest was expressed in purchasing ARV drugs through Global Fund mechanisms in order to achieve price reductions.

Session 11

Preparation of national action plans on adaptation of the WHO guidelines

During this session, the countries divided into country working groups to further develop national HIV plans based on a template with the key WHO 2013 recommendations (see Fig 4). A summary of country plans for 2014-2015 appears in Annex 2. WHO country office and UNAIDS country office representatives facilitated the discussions.

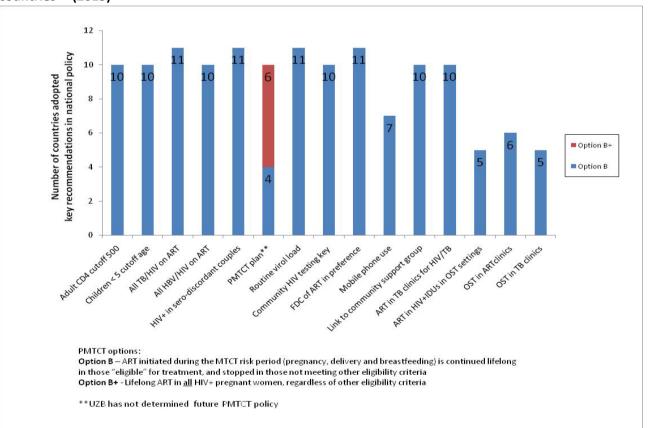


Fig. 4 Anticipated country policies on criteria to initiate ART and other key interventions in 11 EECA countries* (2015)

* Armenia, Azerbaijan, Belarus, Georgia, Kazakhstan, Kyrgyzstan, Republic of Moldova, Russian Federation, Tajikistan, Ukraine, Uzbekistan

Summary: Key interventions to be introduced, timeframe, challenges to overcome and technical assistance requested

Country teams reported back on the top priorities among the new recommendations, as discussed in groups the previous day. It was emphasized that the recommendations in the consolidated guidelines are global in nature and need to be customized for each country, and in some cases for particular regions or even specific hospitals and clinics.

Discussion

The discussion was structured around the key recommendations and key issues in EECA countries:

Increased threshold for initiation of ART (CD4 less or equal to 500 cells/mm³)

The question was raised of whether the new WHO recommendation on when to start treatment would lead to increased funding in EECA countries or whether the result would be non-compliance with the recommendation.

Human resources was reported to be a major challenge for some countries, along with drug procurement. The challenge in the Russian Federation was described as not so much a lack of money but rather a lack of awareness, advocacy and collaboration with decision-makers.

Due to the financial situation, Belarus pointed out a need to explore innovative service delivery approaches such as increasing the role of peers. It was noted that adequate follow-up is severely lacking, with the result that many people who receive HIV-positive test results do not continue on to HIV treatment programmes.

Other consultation participants were concerned about the need to clarify the functional responsibilities of governmental and nongovernmental institutions. There was thought to be a need to increase government readiness to change functional responsibilities and increase capacities in specialized institutions.

Expanding HIV testing to key populations

WHO emphasized that it should be a priority to address the problem of late diagnosis because this impedes the initiation of treatment in people who need it. Meeting participants were asked to consider how availability and accessibility of testing for key populations will be improved.

The observation was made that if more people living with HIV are diagnosed, this creates more work for doctors, raising the question of what incentive doctors have to contribute to efforts to increase HIV testing.

It was reported that Ukraine is not concerned about the new WHO criteria for initiating treatment. The country was said to be ready to treat people and expand testing from state centres to other locations including mobile centres. Decentralization and delegation were thought to have been key in Ukraine. The country has also benefitted from continuous reductions in the cost of ARV drugs.

A meeting participant from Armenia stated that transitioning too quickly to the new treatment initiation criteria could overwhelm the health care system due to resource and infrastructure limitations. Adherence was thought to be a major issue, with some people reportedly stopping their treatment after clinical manifestations of HIV disappear. The Global Fund was said to be the only purchaser of ARV drugs for Armenia, and was said to be reducing its funding. The view was expressed that it would thus be nearly impossible to increase the number of people on treatment.

A meeting participant from the Republic of Moldova shared that when national protocols were revised in 2013, a CD4 cell count threshold of 350 cells/mm³ was left in place, although there are plans to raise the threshold to 500cells/mm³. It was noted that budget constraints need to be taken into account. Late diagnosis is considered to be the main problem in the country. There is interest in expanding HIV testing from solely state providers to NGOs as well.

A meeting participant from Georgia stated that the country has already adopted the recommendation to increase the CD4 threshold for initiating ART from 350 to 500 cells/mm³. Expanding HIV testing was said to be a problem because an existing requirement for identification cards makes some people reluctant to get tested.

It was reported by Kyrgyzstan That late diagnosis is a major problem in the country. National plans were said to call for further decentralization and more extensive NGO involvement. It is also a priority to expand rapid testing and single- (i.e. integrated) care points. The higher CD4 threshold of 500 cells/mm³ may be used as the basis for initiating ART in individual cases, but this will not be the widespread standard.

In Tajikistan, the top priority was said to be increasing coverage of key populations. To expand coverage, the country is reported to be planning to establish testing facilities at so-called "trust centres" which serve people who inject drugs. Rapid HIV testing will be scaled up, in part through the use of mobile services. Other priority groups were reported to be children, particularly those under age 5; serodiscordant couples; and PLHIV who are co-infected with TB or hepatitis. It was reported that ARV drugs are still acquired through the Global Fund in Tajikistan.

Addressing integration of services: HIV/TB and HIV/viral hepatitis

WHO emphasized that one of the major challenges in the region is high incidence of TB, HBV and HCV in PLHIV. Of these diseases, TB is the greatest threat for PLHIV, followed by HCV. It is easier for health care providers to address cases of HBV because HBV responds to treatment with tenofovir, which is part of the ART regimens taken by many PLHIV. Increasing the CD4 counts of people who are co-infected with HIV and viral hepatitis can extend their lives.

Countries were asked to share their plans for the integration of services. Regarding the issue of integrating HIV services with TB and hepatitis services, there was reported to be a lack of collaboration between services coupled with a resistance to collaboration in most countries. The point was made that while some positive examples can be found, many problems with regards to integrated services remain unresolved.

Ukraine has made efforts, for example, to integrate TB experts into AIDS centres. The issue is said to remain a problematic one in Ukraine, and concern was expressed about politicians needing to understand the concept of dual epidemics.

In Kyrgyzstan it was reported that a comprehensive service pilot project exists. The observation was made that many physicians do not realize that there is a need to offer HIV testing for suspected TB patients.

There is also a problem of unlinked patient medical records. Both of these issues contribute to loss to follow-up.

Regarding viral hepatitis, the view was expressed that this is a significant period in the response to hepatitis since not only is there a cure for HCV, but drug prices are expected to fall drastically as new and better drugs become available.

It was noted that in the Russian Federation, an HIV diagnosis triggers a hepatitis test. Hepatitis C treatment is free for people living with HIV, which is not the case for those who are HIV-negative.

A representative from Ukraine reported issues related to the price and monitoring of hepatitis. Patients co-infected with HIV and viral hepatitis need treatment of both infections. It was noted, as when HIV is suppressed in those with co-infection, mortality due to untreated viral hepatitis increases.

The observation was made that no HCV treatment is available in some countries.

A meeting participant from Azerbaijan noted that it is standard practice to test all PLHIV for hepatitis and syphilis. HIV/HCV co-infection figures were said to be as high as 60%. Fibroscan equipment was not available, nor was treatment for HCV, it was reported.

Expansion of access to opioid substitution therapy in Eastern Europe and Central Asia

WHO representative raised concern that in the region where the PWID population is still the most affected by HIV, access to OST is very limited. WHO, UNODC and UNAIDS all support OST as part of a comprehensive package of core interventions for PWID. Concern was also expressed about a need to better address the issue of OST in the specific context of ART adherence and scaling up. The point was emphasized that only a small proportion of those who are diagnosed with HIV go on to receive ART. It was observed that retention in care for PLHIV is a central problem and that patients are regularly lost to follow-up. PWID who are a part of OST programmes have been shown to be able to well adhere to ART and thus reduce mortality.

It was noted that OST and adequate treatment should be joint efforts to achieve successful results. Results of a successful integration of services, supported by the government and financed through TGF in Ukraine were shared.

Prevention of mother-to-child transmission of HIV

Vast majority of the countries have adopted Option B as the PMTCT policy and some of them plan to move to Option B+ in coming years (Table 6)

Table 6. Current and	anticipated PMTCT policy in 11 EECA	countries
Countries	Current PMTCT Policy (2013)	Anticipated PMTCT Policy (2015)
Armenia	B, (2010) National protocol	В
Azerbaijan	B, National protocol	В
Belarus	B+ (2012) National adoption	B+
Georgia	B (2012) National protocol	В
Kazakhstan	B (2011) National protocol	B+ if CD4<500 (2017)
Kyrgyzstan	B (2012) National protocol	B+
Moldova	B (2009) National protocol	B+
Russia	B+ (2013) Nationa protocol	В+
Tajikistan	B (2010) National protocol	B+
Ukraine	A (2007) National protocol	В
Uzbekistan	В	B+??? (not determined)

Regarding ARV drugs for pregnant women living with HIV, it was noted that not offering treatment after a pregnant woman receives an HIV-positive diagnosis contributes to the problem of retention in HIV care and delay in initiation of ART in settings with limited access to CD4 testing. Also, the observation was made that early treatment can support better adherence and increase coverage of ART. Option B was reported to still be the PMTCT standard in the EECA countries.

In Armenia, it was reported, Option B is considered to be optimal as the CD4 count can be adequately measured. A CD4 count of 350 cells/mm³ is still the standard for commencing treatment.

It was noted that Georgia also endorses Option B while recommending against breastfeeding. There were said to be few HIV-positive pregnant women in that country.

In the Russian Federation, the existence of parallel, centralized services was said to inhibit integration. PMTCT services utilize Option B, and new country guidelines have already adopted Option B+. Some pregnant women return for treatment in their next pregnancy, which can also complicate matters if they had started and stopped ART during a previous pregnancy. The Russian Federation was said to be willing to approve Option B+ for all pregnant women. It was noted that there is a shortage of registered ARV drugs for children. Another concern relates to use of efavirenz and tenofovir in children.

It was suggested that strong progress has been made in EECA with regards to pregnant women who have HIV and paediatric HIV treatment uptake.

The observation was made that specific proposals are needed for how to involve NGOs in the response to HIV, and that such proposals were not being discussed sufficiently at the consultation.

Feedback from the civil society organizations and general comments

Civil society representatives noted that regulatory barriers such as mandatory identification requirements constitute an obstacle to implementing ART recommendations. They also called attention to the challenge of providing treatment adherence counselling in specialized care settings.

Another concern emphasized by civil society representatives was discrepancies among multiple databases in settings where PLHIV need to use different health services because of a fragmentation among vertical services.

It was reported that civil society is concerned about the effects of efavirenz during pregnancy.

Civil society representatives called for harmonization of the WHO consolidated guidelines with the guidelines of the European Clinical AIDS Society.

Regarding the challenges associated with retention in HIV care, it was noted that if civil society groups work separately from providers to address this issue, they are unlikely to be successful. There was a call for suggestions from physicians and policy-makers for how collaborative efforts should be structured.

Civil society representatives additionally commented on the lack of access to testing for key populations; lack of access to generic HIV drugs; treatment interruptions; and challenges associated with HIV in prison settings.

Regarding PMTCT, it was noted that civil society groups have an important role to play in reaching women, including women who inject drugs. The point was also made that involving civil society groups may be an effective strategy for improving follow-up among patients co-infected with TB.

Conclusion and next steps

It was concluded that many challenges remain in EECA region in order to improve HIV treatment and access to it. Chief among these was the need to revise policy and practice in order to implement the new WHO recommendations set out in the Consolidated Guidelines on the Use of Antiretroviral Drugs for Treating and Preventing HIV Infection. Coupled with this is a need to prioritize in the introduction and implementation of the recommendations. One key challenge to improve practice is to revise service delivery approaches in EECA countries so as to increase enrolment and retention in services. The integration of some services may facilitate this. There is also an acute need to focus attention on key populations and ensure that groups such as people who inject drugs receive the prevention and treatment they need. Further, there is a need for paediatric antiretroviral formulations.

Given the high prevalence of HIV patients coinfected with hepatitis C, there is a need for cheaper and more accessible drugs for treating it.

The next steps include discussions, at the country level, of the national HIV plans developed at the consultation, the adaptation of national clinical protocols and follow-up technical assistance from WHO and others as requested. This consultation was followed by a meeting on coordinated support for HIV treatment in the WHO European Region.

Current Policy in Oct 2013 (based on pre-workshop questionnaire)	Armenia	Azerbaijan	Belarus	Georgia	Kazakhstan	Kyrgyzstan	Moldova	Russia	Tajikistan	Ukraine	Uzbekistan*
			•		Wh	en to Start	•				
								≤350, <500 for			
Adult/adolescent CD4 cutoff	≤350	≤350	≤350	≤500 (2013)	<350	≤350	≤350	HIV/HBV,or HIV/HCV	≤350	≤350	Not available
Prioritizing ≤ 350 or those sick	< 350	< 350, WHO Stage 3 or 4	< 350	< 350	< 350	< 350	< 350	< 350, WHO Stage 3 or 4	WHO Stage 3 or 4	< 350	< 350
Children < 5 years all	1y and	1y and	1y and	1000	1y and	5y and	1y and	Other (e.g. all children	Based on CD4	< 35	× 330
Pediatric cutoff age	younger	younger	younger	2y and younger	younger	younger	younger	≤ 15)	count	months	Not available
			1	1	CD4 Inde	pendent Cri	teria			Г	
Children > 5 years CD4 ≤ 500	NO	NO	NO	NO	NO	NO	NO	NO	NO	YES	NO
All TB/HIV on ART	YES (2010)	YES (2007)	YES	YES (2010)	YES	YES (2012)	YES (2012)	YES (2013)	YES (2010)	YES (2010)	NO
All HBV/HIV on ART	YES to all (2010)	YES to all (2010)	YES to all	YES to all (2012)	Severe only (2011)	YES to all (2012)	Severe only (2009)	YES to all (2013)	Severe only (2010) Since 01/2010	Yes to all (2010)	Severe only
HIV+ in sero-discordant couples	Conditional (2012)	YES (2010)	YES (2012)	YES (2012)	NO	YES (2012)	NO (2009)	YES (2013)	NO (2010)	NO	NO
PMTCT plan	B, (2010) National	B, National	B+ (2012) National adoption	B (2012) National	B (2011) National	B (2012) National	B (2009) National	B+ (2013) National	B (2010) National	A (2007) National	В
Key populations irrespective of CD4	NO	NO	NO	NO	NO	NO	NO	NO	NO (2010)	NO	Not available
Hep C irrespective of CD4	NO	NO	YES to all	Severe hepatitis	Severe hepatitis	YES to all (2012)	Severe hepatitis	Yes to all	NO	NO	Not available

Annex 1: Current country policies on criteria to initiate ART and other key interventions in 11 EECA countries*, as of October 2013

<u>Current Policy in Oct</u> 2013 (based on pre-											
workshop questionnaire)	Armenia	Azerbaijan	Belarus	Georgia	Kazakhstan	Kyrgyzstan	Moldova	Russia	Tajikistan	Ukraine	Uzbekistan*
		I		I	Wha	t to Start Wi	th	-	I		
TDF+3TC(or FTC)+EFV Adult/adolescent 1st line	YES (2010) FDC not specified	YES (2007) (TDF+3TC) in FDC	YES (2012), FDC not specified	YES (2012)	NO (2011)	YES (2012)	NO (2009)	NO	NO (2010)	NO	YES
TDF+3TC(or FTC)+EFV Pregnant women 1st line	NO	NO	NO	NO	NO (2011)	NO (2012)	NO (2009)	NO (2013)	NO (2010)	NO	NO
Pediatric preferred NRTI	ABC or AZT (2008)	ABC or AZT (2007)	ABC or AZT (2008)	ABC or AZT (2011)	ABC (2011)	ABC (2013)	ABC or AZT (2009)	ABC or AZT	ABC or AZT (2010)	ABC or AZT (on approve)	Not available
LPV/r for NNRTI-exposed <2y	YES (2012)	YES(2010)	NO	YES (2010)	YES (2011)	YES (2013)	NO (2009)	YES (2009)	Yes since 01/2010	YES (on approval)	Not available
LPV/r in children <3y regardless of NNRTI exposure	NO	YES (2012)	YES (2008)	NO (2010)	YES (2011)	YES (2013)	NO (2009)	YES (2009) LPV/r - children > 6 months (2009)	YES (2010)	NO (on approval)	YES
Efavirenz-containing regimens in children > 3y	YES (2008)	YES (2007)	YES	YES (2010)	YES (2011)	YES (2013)	YES (2009)	YES (2009)	YES	YES (on approval)	YES/NO
Children aged 3-10 y	ABC or AZT (2008)	ABC or AZT (2007)	ABC or AZT (2008)	ABC or AZT (2010)	ABC (2011)	ABC (2013)	ABC or AZT (2009)	ABC or AZT or TDF (2009)	AZT or ABC (2010)	ABC or AZT (on approve)	YES
Adolescents (10-19y)	ABC or AZT (2008)	ABC or AZT (2012)	ABC or AZT (2008)	TDF (2010)	AZT (2011)	ABC (2013)	ABC or AZT (2009)	ABC or AZT (2009)	AZT (2010)	Based on Tanner scale (2010)	Not available
Infant prophylaxis	NVP for BF AZT or NVP - non-BF (2010)	AZT for non-BF (2010)	AZT for BF, ART for non- BF (2010)	ART for BF, AZT for non-BF (2012)	ART for all (2011)	ART for BF AZT for non- BF(2012)	AZT only for non-BF (2009)	AZT for 6 weeks for non BF	AZT for BF or non-BF (2010)	AZT -for non-BF (2007)	Not available
Phase out plan for d4T use	YES (2010)	YES (2007)	NOT used since 2010	YES (2008)	NOT used since 2011	YES (2011)	NOT used (2009)	NO	YES (2010)	NO	Not available
Fixed-dose ART combinations in preference	NO to 3 ARVs	YES (2006)	YES (2012)	YES (2012)	YES (2011)	YES (2012)	YES (2009)	YES (2013)	YES (2010)	YES (2010)	Not available

<u>Current Policy in Oct</u> 2013 (based on pre- workshop questionnaire)	Armenia	Azerbaijan	Belarus	Georgia	Kazakhstan	Kyrgyzstan	Moldova	Russia	Tajikistan	Ukraine	Uzbekistan*			
		Recommendations for Monitoring												
Viral load	Routine, 3-6 months (2006)	Routine, 6 months (2012)	Routine, 6 months (2012)	Routine, 4-6 months (2004)	Routine, 6 months (2011)	Routine, 3 months (2012)	Routine, 3 months (2009)	Routine, 2 months (2012)	Routine, 6 months (2010)	Routine, 3- 6 months (2010)	Not available			
Viral load in children	Routine, 3-6 months 06/2006	Routine, 6 months (2012)	Routine 3 months (2008)	Routine, 6 months (2004)	Routine, 3 months (2011)	Routine, 3 months (2012)	Routine, 3 months (2009)	Routine, 3-6 months (2013)	Routine, 6 months (2010)	Routine, 6 months (on approval)	Not available			
Threshold for virologic failure	Adults >200 (2012), Children >1000 (2008)	Adults >200 Children >5000 (2012)	All >200 (2012)	Adults >200, Pregn/child >400 (2012)	Adults/ Pregnant >400 Children >50 (2011)	All > 500 (2012)	All>1000 (2009)	Adults/Pregnant >1000 (2013)	All > 500 (2010)	Adults>50 Children >50 on NNRTI and 1000 on PI(2010)	Not available			
Recommended frequency of CD4 monitoring	Adults/Child 3-6, Preg -3 (2004)	All - 3 months (2007)	Adults -6 , Pregn/child -3 (2008)	Adults/child -4- 6, Preg -3 (2012)	Adults-6, Pregn/child-3 (2011)	All - 3 months (2012)	All - 3 months (2009)	All - 3-6 monthss (2013)	All - 6 months (2010)	Adults - 3, Children - 3-6 (2010)	Not available			

Current Policy in Oct 2013 (based on pre-															
workshop questionnaire)	Armenia	Azerbaijan	Belarus	Georgia	Kazakhstan	Kyrgyzstan	Moldova	Russia	Tajikistan	Ukraine	Uzbekistan*				
	Service Delivery Recommendations														
Provide HIV testing for															
key populations at															
community level with		1/50	VEC	1/50			NEC.			1/50					
linkage to HIV services	NO	YES	YES	YES	NO	YES partially	YES	NO	NO	YES	NO				
Retention in care and adhe	rence support:	1	1	1	ſ	ſ	1		Γ						
FDC of ART in preference	YES	YES	YES	YES	NO	YES	YES	YES	YES	YES	YES				
Use mobile phone sms as	125		120	120		120	125	120	120	123	120				
a reminder tool	YES	NO	NO	NO	NO	YES partially	NO	NO	NO	NO	NO				
Link to community															
support group	YES	YES	YES	YES	YES	YES	YES	NO	YES	YES	NO				
Start ART in TB clinics for															
HIV+ with active TB															
within 8 weeks after start TB treatment	YES	YES	YES	YES	NO	YES	YES	YES	NO	YES	NO				
Start IPT in HIV+ with	115	115	115	TLJ	NO	11.5	115	115	NO	115	NO				
latent TB in HIV clinics	YES	NO	YES	YES	YES	YES	NO	NO	YES	YES	YES				
	120			120	120	120				120	120				
Start ART in HIV+IDUs in															
OST settings	NO	YES	NO	NO	NO	Partially (2 sites)	NO	N/A	NO	NO	NO				
Start and maintain OST in			No (initiation)												
HIV+IDUs in ART clinics	NO	YES	YES (Maintenance)	NO	NO	YES	NO	NO	NO	YES	NO				
Start and maintain OST in															
HIV+ IDUs with active TB															
in TB clinics	NO	NO	YES	NO	NO	NO	NO	NO	NO	YES	NO				
Start and maintain ART in						No (initiation)			NO (initiation)						
HIV+ pregnant women in		NO (initiation)	NO (initiation) Yes			YES			YES						
MCH services	N/A	YES (maintenance)	(maintenance)	NO	N/A	(maintenance)	NO	YES	(maintenance)	NO	NO				
Task-shifting for nurse-		N/A			N/A	N1/A			NI (A	N1/A	NO				
initiated ART	N/A	N/A	N/A	N/A	N/A	N/A	N/A	NO	N/A	N/A	NO				

* Some data are missing as UZB did not submit the policy

questionnaire prior to the consultation. Data showed here are

taken from the national plan that was developped during the

consultation.

Annex 2: Future country policies on criteria to initiate ART and other key interventions in 11 EECA countries (2014 - 2015)

Anticipated Policy in 2014/15 (based on final workshop presentations)	Armenia	Azerbaijan	Belarus	Georgia	Kazakhstan	Kyrgyzstan	Moldova	Russia	Tajikistan	Ukraine	Uzbekistan
				v	/hen to Start					<u> </u>	
Start ART at CD4≤500 regardless of WHO clinical stage	≤500	≤500	≤500 (2017)	≤500	≤500 (2017)	≤500	≤500	≤500 (gradual)	NO	≤500	≤500
Prioritizing ≤ 350 or those sick	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Start ART in children > 5 y at CD4 ≤500 regardless of stage	YES	YES	YES	YES	YES	YES	YES	YES (2017)	YES	YES	YES
		I		CD4 Inc	dependent Criteria	Τ			T	T	
Start ART in all children < 5 years	NO	YES	YES (2015)	YES (2017)	YES	YES	YES	YES	YES	YES	YES
Start ART in all HIV+ with active TB	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Start ART in all HIV+ with hep B	Severe only	YES to all	YES to all	YES to all	YES to all (2017)	YES to all	YES to all	YES to all	YES to all	YES to all	YES to all
Offer ART in all HIV+ sero-discordant couples	YES (indivdually)	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
PMTCT plan	В	В	В+	В	B+ if CD4<500 (2017)	В+	B+	B+	B+	В	B+??? (Not determined)

Anticipated Policy in 2014/15 (based on final workshop presentations)	Armenia	Azerbaijan	Belarus	Georgia	Kazakhstan	Kyrgyzstan	Moldova	Russia	Tajikistan	Ukraine	Uzbekistan
				What to s	tart with						
Adult/adolescent 1st line TDF+3TC(FTC)+EFV in FDC	YES	YES	YES	YES	YES, may be not in FDC	YES	YES	YES	NO	YES	YES
Preferred 1st line ART for pregnant women TDF+3TC(FTC)+EFV in FDC	NO	NO, TDF+XTC+PI	NO, TDF+XTC+LPV/r, AZT+XTC+ LPV/r	YES/NO: TDF+XTC+LPV/r TDF+XTC+EFV	YES	YES	YES	NO (no long term data on EFV safety)	NO	NO	YES
Preferred NRTI for children <3 y ABC +3TC or AZT+3TC	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
1st line ART with LPV/r in children <3y regardless of NNRTI exposure	YES	YES	YES	YES (2014)	YES	YES	YES	YES	YES	YES	YES
1st line ART with EFV in children > 3 years	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
1st line NRTIS for ART in children (3-10 y) ABC+3TC or AZT (TDF)+XTC	YES (individual)	YES	YES	YES AZT(TDF)+XTC	YES ABC+3TC	YES but not TDF	YES	YES	YES ABC+3TC	YES	YES
Policy on Breast feeding practice for HIV-exposed infants	Priority: NOT BF + individual choice	NOT BF	NOT BF	NOT BF	NOT BF	BF + Individual choice	NOT BF	NOT BF	Both, BF and NOT BF	NOT BF	NOT BF
Infant prophylaxis: BF infants of mothers on ART - NVP for 6 weeks Not BF infants - NVP or 2/day AZT 4-6 weeks	BF - NVP 6 w, NOT BF- NVP or AZT-4-6w	NVP or AZT 4-6 weeks	NVP or AZT 4- 6weeks	NVP or AZT 4-6 weeks	NVP or AZT 4- 6weeks	NO	NVP or AZT 4- 6weeks	Under discussion	AZT twice	NVP or AZT-4-6 weeks	NVP or AZT-4-6 weeks
Phase out plan for d4T use	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES

Anticipated Policy in											
<u>2014/15</u> (based on final	Armenia	Azerbaijan	Belarus	Georgia	Kazakhstan	Kyrgyzstan	Moldova	Russia	Tajikistan	Ukraine	Uzbekistan
workshop presentations)	Annenia	Azerbaijan	Delarus	Georgia	Razakiistaii	Ryigyzstan	Wordova	Nussia	Tajikistan	Okraine	Ozbekistan
			Beco	mmondati	ons for Monit	oring					
	1	1	Neco				[[T	1	[
	Widely			Widely	Widely	Widely	Widely	Widely	Widely	Widely	Widely
Viral load	available	Widely available	Widely available	available	available	available	available	available	available	available	available
		1	Servi	ce Delivery	Recommenda	ations				1	
Provide HIV testing for key											
populations at community											
level with linkage to HIV	VEC	VEC	VEC	VEC	VEC	VEC	VEC	VEC	VEC	VEC	NO
services	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	NO
Retention in care and adheren	ce support:			1		1	1		1	1	1
FDC of ART in preference	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Use mobile phone sms as a				-						-	
reminder tool	YES	YES	NO	NO	NO	YES	YES	YES	YES	YES	NO
Link to community support											Under
group	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES	discussion
Start ART in TB clinics for HI+											
wit active TB within 8 weeks											
after start TB treatment	YES	YES	YES	YES	YES	YES	YES	YES	NO	YES	YES
Start IPT in HIV+ with latent											
TB in HIV clinics	YES	YES	YES	YES	YES	YES	YES	NO	YES	YES	YES
Start ART in HIV+IDUs in OST										Under	
settings	NO	YES	YES	NO	NO	YES	NO	YES	YES	discussion	NO
Start and maintain OST in HIV+IDUs in ART clinics	NO	YES	No (initiation) YES (Maintenance)	YES	NO	YES	YES	NO	YES	YES	NO
Start and maintain OST in	NO	TLS	TLS (Maintenance)	TLS	NO	115	11.5	NO	11.5	TLJ	NO
HIV+ IDUs with active TB in											
TB clinics	NO	YES	YES	YES	NO	NO	NO	NO	YES	YES	NO
Start and maintain ART in											
HIV+ pregnant women in		NO (initiation)	NO (initiation)							Under	
MCH services	N/A	YES (maintenance)	Yes (maintenance)	NO	N/A	YES	N/A	YES	YES	discussion	NO
Task-shifting for nurse-											_
initiated ART	N/A	N/A	N/A	N/A	N/A	N/A	N/A	NO	N/A	N/A	NO

Annex 3: Scope and purpose

WORLD HEALTH ORGANIZATION **REGIONAL OFFICE FOR EUROPE**

WELTGESUNDHEITSORGANISATION REGIONALBÜRO FÜR EUROPA



ORGANISATION MONDIALE DE LA SANTÉ BUREAU RÉGIONAL DE L'EUROPE

ВСЕМИРНАЯ ОРГАНИЗАЦИЯ ЗДРАВООХРАНЕНИЯ ЕВРОПЕЙСКОЕ РЕГИОНАЛЬНОЕ БЮРО

WHO Regional Technical Consultation on the dissemination of consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection

Istanbul, Turkey, 29-31 October 2013

14 October 2013 Original: English

Scope and purpose of the meeting

Background

In June 2011 at the United Nations High Level Meeting on AIDS Member States committed to increase access to antiretroviral therapy (ART) so that 15 million people living with HIV (PLHIV) in low and middle-income countries are receiving life-saving treatment by 2015. The European Action Plan on HIV/AIDS 2012-2015¹ commits European Member States to ambitious goals and targets including universal access to treatment by 2015. Although countries in eastern Europe and central Asia (EECA) have made universal access to ART a high priority and indicate progress in scaling up access in recent years, estimated regional treatment coverage is 23% of those in need and remains among the lowest in the world². The population groups most affected by the HIV epidemic represent people who inject drugs and their sexual partners, prisoners, labour migrants, as well as sex workers and men who have sex with men. AIDS-related mortality in EECA between 2004 and 2011 has been increasing³, indicating low coverage of life-saving ART and a need to improve national HIV/AIDS treatment and care programmes.

In July 2013, at the International AIDS Conference in Kuala-Lumpur, the WHO HIV department released the "Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV Infection"⁴ - a set of integrated guidelines on the use of

¹ European Action Plan for HIV/AIDS 2012-2015 <u>http://www.euro.who.int/en/what-we-do/health-</u> topics/communicable-diseases/hivaids/publications/2011/european-action-plan-for-hivaids-20122015

 ² Progress report 2011:Global HIV/AIDS response <u>http://www.who.int/hiv/pub/progress_report2011/en/</u>
 ³ HIV/AIDS Surveillance in Europe 2011 ECDC/WHO:

http://ecdc.europa.eu/en/publications/Publications/Forms/ECDC_DispForm.aspx?ID=1009 ⁴ Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection: http://www.who.int/hiv/pub/guidelines/arv2013/download/en/index.html

antiretrovirals in adults, children, pregnant women and key populations including injecting drug users, sex workers and men having sex with men, and for both HIV treatment and prevention. In addition to clinical topics, operational recommendations have also been made on different modalities of service delivery to optimize programme outcomes as well as programmatic guidelines to assist countries and partners with their decision-making for an equitable and effective response. New guidelines expand eligibility criteria for ART and increase the number of PLHIV who need it under new criteria.

For most of the EECA countries with limited resources and capacity it will be challenging to make programmatic and operational decisions so to fulfil commitment and achieve universal access to ART by 2015. WHO Regional Office for Europe organizes this technical consultation for the national counterparts who are involved in organization and provision on HIV treatment and care cascade in twelve EECA countries (ARM, AZE, BLR, GEO, KAZ, KGZ, MDA, RUS, TKM, TJK, UKR and UZB), and Turkey.

Objectives

- 1. To present and discuss consolidated ARV guidelines with national counterparts, civil society, UN and other technical partners and donors
- 2. To discuss and agree steps in introduction, adaptation and implementation of the guidelines, addressing potential barriers, role of civil society, UN and other technical partners and donors and assistance required from the WHO
- 3. To link dissemination of the consolidated guidelines with the UNAIDS treatment initiative and other relevant global and regional strategies

The regional technical consultation is planned for 3 days with plenary sessions and working groups which would represent country teams.

Expected results

- 1. Participants of the consultation are informed on the context of consolidated ARV guidelines, including ART for adults and children, managing of major co-infections, PMTCT, operational and service delivery as well as programmatic guidance
- 2. Priorities in introduction of the guidelines at country level are discussed and agreed
- 3. Country road maps for adaptation and implementation of the guidelines are drafted
- 4. Technical assistance expected from WHO, UNAIDS and other technical partners in implementation of the revised guidelines is discussed

Participants

- National counterparts, including managers of the National HIV/AIDS Programmes, national clinical experts in HIV/AIDS treatment and care, PMTCT, civil society organizations involved in provision of services for PLHIV from 12 EECA countries (ARM, AZE, BLR, GEO, KAZ, KGZ, MDA, RUS, TKM, TJK, UKR and UZB) and Turkey
- Representatives of the WHO headquarters, WHO Regional Office for Europe, WHO country offices, i.e. HIV/AIDS programmes country coordinators from EECA countries

• Major partner organizations, including UNAIDS, WHO Collaborating Centre on HIV and Viral Hepatitis, UNICEF, The Global Fund, CDC, PEPFAR, and others.

Estimated number of participants: 90

Venue and dates

Dedeman hotel, Yildiz posta Caddesi, 50 Esentepe 3440 Istanbul, Turkey, <u>Istanbul@dedeman.com</u> +90 (212) 337 45 00 29-31 October 2013

Language

English and Russian, with simultaneous translation

Annex 4: Programme



WHO Regional Technical Consultation Dissemination of the 2013 WHO consolidated guidelines on the use of Antiretroviral Drugs for Treating and Preventing HIV infection in Eastern European and Central Asian countries, Istanbul, Turkey, 29-31 October 2013

FINAL PROGRAMME

DAY 1: Tuesd	lay, 29 October 2013	
8:30 - 9:00	Registration	
9.00 - 9:30	Welcome remarks	Martin Donoghoe, WHO Regional Office for Europe
		Naira Sargsyan, UNAIDS Regional Support Team for Europe and Central Asia
		Irina Eramova, WHO Regional Office for Europe
	Introduction of participantsObjectives and expected outcome	
Session 1	Progress and challenges in scaling up access to HIV treatment	Chairs: Ina Karaban, Ministry of Health, Belarus Martin Donoghoe, WHO Regional Office for Europe
9:30 - 11:00	Treatment 2015 Initiative and Strategic Investment Framework	Naira Sargsyan, UNAIDS Regional Support Team for Europe and Central Asia
	• Global Update on HIV Treatment 2013	Marco Vitoria, WHO headquarters
	• Progress and challenges to scaling up access to HIV treatment in EECA countries	Irina Eramova, WHO Regional Office for Europe
	• Progress and challenges to scaling up access to HIV treatment in the Russian Federation	

11:00 - 11:30	 Progress and challenges to scaling up access to HIV treatment in Ukraine Questions and comments from the floor <i>Tea/coffee break</i> 	Oleg G. Yurin, Federal AIDS Center, Russian Federation Tetyana A. Alexandrina, State Service, Ukraine
Session 2	Overview of guidelines development	Chairs: Ina Karaban, Ministry of Health, Belarus Martin Donoghoe, WHO Regional Office for Europe
11:30 – 12:00	 Rationale for the new guidance Guiding principles Process Scope and structure of the guidelines Questions and comments from the floor	Irina Eramova, WHO Regional Office for Europe
Session 3	Continuum of care	Chairs: Ina Karaban, Ministry of Health, Belarus Martin Donoghoe, WHO Regional Office for Europe
12:00 - 12:30	 HIV testing and counseling HIV diagnosis and ARV drugs for HIV prevention Linking people diagnosed with HIV infection to HIV care and treatment 	Marco Vitoria, WHO headquarters
	Clinical guidance across the continuum of care: ART in adults and adolescents	Chairs: Tetyana Alexandrina, State Service, Ukraine Irina Eramova, WHO Regional Office for Europe
12:30 - 13:30	 When to start ART What ART regimens to start with Second- and third-line ART Implementation considerations for key issues (d4T phase out) 	Jens Lundgren, WHO Collaborating Centre on HIV and Viral hepatitis
13:30 - 14:30	Questions and comments from the floor <i>Lunch</i>	

Session 5	Clinical guidance across the continuum of care: Managing common co-infections and co-morbidities	Chairs: Tetyana Alexandrina, State Service, Ukraine Irina Eramova, WHO Regional Office for Europe
14:30 - 15:30	 Prevention, screening and management of common co-infections (TB, Hepatitis B and C) Management of IDU related disorders Questions and comments from the floor 	Jens Lundgren, WHO Collaborating Centre on HIV and Viral hepatitis
Session 6	Clinical guidance across the continuum of care: ART for pregnant, breastfeeding and non-breastfeeding women	Chairs: Aigul Katrenova, Ministry of Health, Kazakhstan Ruslan Malyuta, UNICEF Regional Office for CEE/CIS Countries
15:30 - 16:30	 When to start ART What ART regimens to start with When to switch Infant feeding Implementation considerations for key issues (ART for all pregnant women-Option B+) 	Nathan Shaffer, WHO headquarters
	Questions and comments from the floor	
16:30 – 17:00 Session 7	Tea/Coffee break Clinical guidance across the continuum of care: ART in children	Chairs: Aigul Katrenova, Ministry of Health, Kazakhstan Ruslan Malyuta, UNICEF Regional Office for CEE/CIS Countries
17:00 – 18:00	 When to start ART What ART to start with When to switch 2nd line ART 	Nathan Shaffer, WHO headquarters
	 Implementation considerations for key issues (Introduction of LPV/r) Questions and comments from the floor 	

DAY 2, Wedne	sday, 30 October 2013	
Session 8	Continuum of care: Laboratory monitoring	Chairs: Ainura Kutmanova, Ministry of Health, Kyrgyzstan Charles Vitek, CDC Ukraine
09:00 - 10:00	 Monitoring response to ART and the diagnosis of ART failure Monitoring and substitution for ARV drug toxicity Drug interaction Implementation considerations for key issues (use of VL for patient monitoring) Management of some NCDs in PLHIV Questions and comments from the floor 	Jens Lundgren, WHO Collaborating Centre on HIV and Viral hepatitis
Session 9	Operational and service delivery guidance	Chairs: Ainura Kutmanova, Ministry of Health, Kyrgyzstan Charles Vitek, CDC Ukraine
10:00 - 11:00	 Adherence to ART Retention across the continuum of care Service delivery models (integration and linkage; OST, decentralization) Human resources Laboratory and diagnostic services Procurement and supply management system 	Nathan Shaffer, WHO headquarters
11.00 11.20	Questions and comments from the floor	
11:00 - 11:30	Tea/coffee break	
Session 10	Guidance for program managers	Chairs: Volodimir Zhovtyak, East Europe and Central Asia Union of PLHIV Nicolas Cantau, The Global Fund

11:30 - 13:30	 Process and evidence for decision-making Key parameters for decision-making Opportunities and risk Implementation checklist of key health system issues Monitoring and evaluation of the CG implementation The Global Fund New Funding Model (NFM) and strategic investment framework in EECA region Questions and comments from the floor	Marco Vitoria, WHO headquarters Nicolas Cantau, The Global Fund
13:30 - 14:30	Lunch	
	Preparation of national action plans on Idaptation of the WHO guidelines	Irina Eramova, WHO Regional Office for Europe
14:30 - 14:45	 Guide for group work on action plans – 13 country groups Identify key recommendations to be introduced Discuss potential obstacles for country adaptation and implementation Outline strategies for overcoming the obstacles identified Discuss financial and (or) technical support needs in adaptation of new guidelines 	
14:45 – 16:00	Country group work	Facilitators: HIV coordinators, WHO country offices
16:00 - 16:30	Tea/coffee break	
16:30 – 18:00	Country group work	Facilitators: HIV coordinators, WHO Country Offices

Session 12	Summary: Key interventions to be introduced, time frame, challenges to overcome and technical assistance requested	Facilitators: Vadim V. Pokrovsky, Fedaral AIDS Center, Russian Federation Irina Eramova, WHO Regional Office for Europe
09:00 -11:45	Countries input to the regional agenda	
11:45 – 12:15	Discussion, next steps and conclusion	Facilitator: Martin Donoghoe, WHO Regional Office for Europe
12:15 - 13:00	Lunch	

Annex 5: Participants list

WORLD HEALTH ORGANIZATION **REGIONAL OFFICE FOR EUROPE**

WELTGESUNDHEITSORGANISATION **REGIONALBÜRO FÜR EUROPA**



ORGANISATION MONDIALE DE LA SANTÉ BUREAU RÉGIONAL DE L'EUROPE

ВСЕМИРНАЯ ОРГАНИЗАЦИЯ ЗДРАВООХРАНЕНИЯ **ЕВРОПЕЙСКОЕ РЕГИОНАЛЬНОЕ БЮРО**

WHO Regional Technical Consultation Dissemination of consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection Istanbul, Turkey 29-31 October 2013

21 November 2013 Original: English

Final list of participants

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