

*WHO Regional technical consultation on monitoring progress and supporting capacity building to validate dual elimination of mother-to-child transmission of HIV and congenital syphilis*

**REPORT**

17-18 December 2015  
Astana, Kazakhstan



**World Health  
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## ABSTRACT

Globally the commitment to eliminate mother-to-child transmission of HIV and congenital syphilis has been strengthening. In June 2011, a Global Plan towards the Elimination of New HIV Infections Among Children and Keeping Their Mothers Alive was launched, led by UNAIDS, co-convened by the World Health Organization and UNICEF and in collaboration with an additional 25 agencies. Given the types of interventions necessary to prevent the mother-to-child transmission of HIV and syphilis in pregnancy, a dual approach towards eliminating the infections in infants.

In 2012, a technical consultation aimed to reach consensus on the criteria and processes that should be used to validating country achievements towards the elimination of mother to child transmission of HIV and syphilis. Following this consultation, the "Global Guidance on Criteria and Process for Validation of Elimination of Mother-to-Child Transmission (EMTCT) of HIV and Syphilis" was issued.

To continue progress and endorse the validation framework for EMTCT of HIV and syphilis in Europe and Central Asia, the WHO in partnership with UNAIDS, UNFPA, UNICEF, and key partners convened a technical consultation on EMTCT of HIV and syphilis in December 2015. The meeting took place in Astana, Kazakhstan on December 17 and 18, 2015 and aimed to review progress towards elimination validation, share experiences within the Region and obtain feedback on the validation tools from Member States.

The presentations, discussions and key recommendations and conclusions from the consultation are presented in this report.

### Keywords

AIDS  
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## List of abbreviations and acronyms

AIDS	Acquired immunodeficiency syndrome
ANC	Antenatal care
ARV	Antiretroviral
CBO	Community based organizations
CDC	[United States] Centre for Disease Control
CS	Congenital syphilis
DFA-TP	Direct fluorescent antibody staining of <i>Treponema pallidum</i>
ECDC	European Centre for Disease Control
EMTCT	Elimination of mother-to-child transmission
GARPR	Global AIDS Response Progress Reporting
HIV	Human immunodeficiency virus
HBsAg	Hepatitis B surface antigen
IgM	Immunoglobulin M
MDG	Millennium Development Goal
MOH	Ministry of Health
MPR	Microprecipitation reaction
MTCT	Mother to child transmission
NAAT	Nucleic acid amplification test
NGO	Non-government organization
PCR	Polymerase chain reaction
PEP	Post-exposure prophylaxis
PLHIV	People living with HIV
PWID	People who inject drugs
SOP	Standard operating procedures
Rh	Rhesus factor
RPR	Rapid plasma reagin
STI	Sexually transmitted infection
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNFPA	United Nations Population Fund
UNICEF	United Nations International Children's Emergency Fund
VDRL	Venereal disease research laboratory
WHO	World Health Organization

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## Background

Globally the commitment to eliminate mother-to-child transmission (EMTCT) of HIV and congenital syphilis (CS) has been strengthening. In June 2011<sup>12</sup> a Global Plan towards the Elimination of New HIV Infections Among Children and Keeping Their Mothers Alive was launched by a coalition of partners and led by UNAIDS. An interagency task team on EMTCT, co-convened by WHO and UNICEF and comprised of 25 organizations aligned its structure to support countries towards achieving their EMTCT goals as well as support the achievement of the related millennium development goals (MDGs), including MDG 4 (reduce child mortality), MDG 5 (improve maternal health) and MDG 6 (reduce the spread of HIV).

In the context of actions needed to achieve MDGs 4, 5 and 6, the global initiative for elimination of CS<sup>3</sup> was launched in 2007, and in 2012 the epidemiologic, economic and health systems benefits of investing in the elimination of CS<sup>4</sup> were outlined. Given the types of interventions necessary to prevent the mother-to-child transmission of HIV and syphilis in pregnancy, a dual approach towards achieving accelerated control of both HIV and syphilis prevention was recommended. A consolidated and integrated approach through the maternal and child health care systems would lead towards the dual elimination of both HIV and congenital syphilis infections in infants.

In 2012, WHO, UNAIDS, UNFPA, and UNICEF jointly conducted a series of country visits to assess progress in the prevention of mother-to-child transmission (MTCT) of HIV and syphilis. This was followed by a technical consultation that aimed to reach consensus on the criteria and processes that should be used for validating country achievements towards the EMTCT of HIV and/or syphilis. Following this consultation, the “*Global Guidance on Criteria and Process for Validation of Elimination of Mother-to-Child Transmission (EMTCT) of HIV and Syphilis*”<sup>5</sup> was issued.

In September 2014, a follow-up Global Consultation on the EMTCT validation process took place in Geneva giving further stimulus and providing tools for elimination validation. These tools were successfully piloted in the European Region in December 2014.

The EMTCT response in Europe and Central Asia are unique in a number of important ways, including: high levels of antenatal care service delivery, high testing rates for HIV and syphilis, the highest antiretroviral (ARV) coverage for pregnant women of all the WHO Regions and a strong programme commitment. This has already led to several countries in the Region being close to meeting the criteria for validation.

However, there are also important challenges facing the Region. This includes a high proportion of infections among pregnant women residing in key populations and vulnerable groups (e.g. drug users and partners of drug users, sex workers and migrants) and stigma and human rights issues. Commodity stock-outs and high prices continue to exist and some countries face a challenging transition from Global Fund to state financing. Two countries in

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<sup>1</sup> Eliminate new HIV infections in children is a core element of strategic direction 1 of the WHO Global Health Sector Strategy on HIV/AIDS 2011-2015 [http://whqlibdoc.who.int/publications/2011/9789241501651\\_eng.pdf](http://whqlibdoc.who.int/publications/2011/9789241501651_eng.pdf)

<sup>2</sup> Vertical transmission of HIV eliminated, and AIDS-related maternal mortality reduced by half by 2015 is a strategic goal of the UNAIDS Strategy 2011-2015 <http://www.unaids.org/en/aboutunaids/unaidstrategygoalsby2015/>

<sup>3</sup> <http://www.who.int/reproductivehealth/publications/rtis/9789241595858/en/index.html>

<sup>4</sup> [http://apps.who.int/iris/bitstream/10665/75480/1/9789241504348\\_eng.pdf](http://apps.who.int/iris/bitstream/10665/75480/1/9789241504348_eng.pdf)

<sup>5</sup> Global guidance on criteria and processes for validation: elimination of mother-to-child transmission (EMTCT) of HIV and syphilis. 2014 <http://www.who.int/hiv/pub/emtct-validation-guidance/en/>

the Region, the Russian Federation and Ukraine, have the highest numbers of pregnant women with HIV and reported MTCT cases. While progress in both these countries has been impressive, success in achieving elimination in the Region rests in a large measure on the ongoing commitment and success of the programmes in these two countries.

To continue progress and endorse the validation framework for EMTCT of HIV and syphilis in Europe and Central Asia, the WHO in partnership with UNAIDS, UNFPA, UNICEF, and key partners convened a technical consultation on EMTCT of HIV and syphilis in December 2015. The meeting took place in Astana, Kazakhstan on December 17 and 18, 2015.

The objectives and the expectations of the consultation included:

- To review progress towards elimination validation in European and central Asian countries.
- To present the validation experience accumulated so far in the Region and discuss challenges and ways of problem solving issues.
- To get feedback on the validation tools and input for adjustment if relevant.
- To discuss the role and potential of validation processes to impact on the quality of services, data, systems strengthening, collaboration and accountability.
- To develop an EMTCT implementation plan and associated timelines to ensure coordination and accountability.

The meeting participants included:

- National counterparts, including managers of the national HIV/AIDS programmes, STI programmes, experts in PMTCT and civil society organizations involved in provision of services for PLHIV.
- International experts in epidemiology, HIV, PMTCT, STIs and public health.
- Representatives of the WHO Headquarters, WHO Regional Office for Europe and WHO country offices.
- Major partner organizations, including UNAIDS, UNICEF, UNFPA, the WHO Collaborating Centres, The Global Fund, CDC, ECDC, civil society organizations.

Approximately 90 individuals from 27 countries<sup>6</sup> participated in the consultation. This report summarises the proceedings, key points and main conclusions from the meeting.

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<sup>6</sup> Armenia, Azerbaijan, Belarus, Bulgaria, Croatia, Denmark, Georgia, Germany, Greece, Estonia, Kazakhstan, Kyrgyzstan, Latvia, Lithuania, Moldova, Netherlands, Poland, Romania, Russian Federation, Serbia, Slovakia, Sweden, Tajikistan, Turkmenistan, UK, Ukraine, Uzbekistan

## Proceedings

### Opening session

#### *Welcome remarks*

**Shaffiq Essejee (WHO Headquarters), Marina Semenchko (UNAIDS RST), Alexandr Kossukhin (UNFPA), Tetyana Tarasova (UNICEF), Deborah von Zinkernagel (UNAIDS Headquarters)**

**Marina Semenchko** thanked all participants for their attendance at the meeting and proving their input into the development of the EMTCT guidelines and tools. Progress towards PMTCT of HIV and syphilis has been impressive though the future lies in the elimination of vertical transmission. Dr Semenchko noted the meeting was designed to be practical, and requested that all countries that were interested or ready to validate identify their issues or challenges. She wished all participants a productive meeting.

**Shaffiq Essejee** thanked the meeting organisers for the invitation and honour of representing the WHO Headquarters. Dr Essejee noted that the European Region was a clear leader for countries around the world on how to manage PMTCT of HIV and syphilis. He noted that strategically the WHO was now discussing how the programme could be expanded to other diseases, including hepatitis B. He was looking forward to hearing about the experiences of countries in the Region and to use lessons learned in other parts of the world.

**Deborah von Zinkernagel** identified UNAIDS great interest in the EMTCT agenda. She identified a number of leading countries (e.g. Belarus and Bulgaria) in the Region and acknowledged there are many other countries that are similarly close to initiating validation. Dr Zinkernagel identified the key question for the meeting as: How can EMTCT be achieved in a way that respects the human rights of women and children? She noted that UNAIDS saw the elimination target as possible and thanked all countries for their work in this area.

**Alexandr Kossukhin** noted that impressive results had been achieved in the PMTCT and MDG's 5 and 6. He noted it is now time to confirm these achievements and ensure their sustainability. The UNFPA has been contributing to this process through two strategies: the first focused on caring for women living with HIV, and the second to prevent transmission for women exposed to the virus from high risk populations who have an unplanned pregnancy. He wished all participants a successful meeting.

**Tetyana Tarasova** acknowledged the evolution of the prevention agenda over the past 15 years, when initial discussions were about a reduction of transmission, to today when discussion focused on the EMTCT of HIV and syphilis. UNICEF has championed a four part program: the PMTCT of HIV, paediatric HIV treatment and care, prevention of HIV among adolescents and young people and protection, and care and support for children affected by HIV and AIDS. Dr Tarasova drew attention to high risk populations who are not attending healthcare institutions: an issue which must be addressed to decrease the case rates of HIV and CS.



## *Introduction to the meeting and scene setting*

**Lali Khotenashvili, WHO Regional Office for Europe**

**Lali Khotenashvili** noted that the WHO European Region has achieved the lowest numbers of MTCT HIV and congenital syphilis in the world. The Region has a lot to be proud of including the highest levels of estimated ART coverage for PMTCT, the highest testing coverage of pregnant women and the highest rate of early infant diagnosis. The data presented from GARPR shows the Russian Federation has as many HIV cases as the rest of the Region combined, followed by Ukraine. Ukraine has highest rate of HIV MTCT cases per 100 000 live births followed by the Russian Federation. Central Europe has the lowest number of cases, followed by the Western and then Eastern Europe. The data shows CS was a big concern in the 1990s though there was a progressive reduction in the number of cases until 2006. Since that time progress has plateaued leading to questions about how possible it is for the incidence to continue to be reduced.

HIV testing in pregnant women remains a very sensitive issue, and there is a wide variety of testing frequencies that are carried out in the Region. Frequently the national testing policies do not match the epidemiological context and are therefore not well justified. In number countries there is no universal testing policy, though some countries test up to four times during pregnancy.

Dr Khotenashvili told participants monitoring and evaluation is central to the validation process. Validation will focus on impact and process indicators with specific targets for each. The data reported through GARPR is more complete for HIV than for CS. There continue to be significant issues still with the case definition for CS. It must be harmonised across the Region to align with the WHO standard. This harmonization will have a significant impact on the results for the CS indicators. While there many strong programs for PMTCT in Europe and Central Asia there are some issues that exist that will be discussed during the meeting. These include:

- The reliability of data
- The strength of existing laboratory services
- Heterogeneity in the case definition for CS
- Differences between countries in the degree of coverage of ANC services.

Subsequent to the meeting in April, a number of modifications were made to the validation process. Countries requested a simplification of the validation process, and removal of the Regional Committee which was thought to add too much bureaucracy.

Dr Khotenashvili reviewed the outcomes for the meeting and reminded participants to think about the implications more broadly of validation, particularly its ability to strengthen the national health system and influence quality of health care service delivery.

# **Plenary Session 1: Regional perspectives on processes and tools for the validation of the EMTCT of HIV and congenital syphilis: Reminding validation processes and criteria**

## *The global landscape of PMTCT of HIV and syphilis and progress towards elimination*

**Dr Shaffiq Essejee, WHO Headquarters**

Dr Essejee presented a global perspective on the EMTCT of HIV and syphilis. The campaign was developed in 2013, and prior to this there was no established criterion for elimination of MTCT of HIV and CS as a public health threat. Historically, the MTCT programme has followed a trajectory from control (a reduction in the incidence, prevalence, morbidity to a level that is locally acceptable) to elimination (a reduction to zero in a geographical area) and will eventually move to eradication (a permanent reduction to zero worldwide).

Dr Essejee reviewed the impact and process indicators for EMTCT and described the additional validation requirements which focus on time, geography, laboratory services, monitoring and evaluation and human rights. Countries that cannot meet the targets for validation can undertake a pre-validation process which focuses more on the case rate indicator and requires the country has a defined plan about how they will reach the elimination targets.

A number of important global challenges persist, including poor maternal ARV retention in breastfeeding women, when there is more than a doubling of transmission. There is also a lack of family planning services to enable women to prevent unintended pregnancies. The elimination of CS has also been neglected in some parts of the world.

Future efforts globally should focus on getting treatment initiation and retention for women. Bioline has recently introduced a dual rapid test for HIV and CS, and there is now a global focus on a “triple elimination agenda” for HIV, CS and hepatitis B.

## *Discussing validation tools*

### **The data quality tool**

**Ulrich Laukamm-Josten (WHO consultant), Yuri Kobyshcha (WHO consultant)**

Dr Kobyshcha stressed the need to have an effective monitoring and evaluation system to identify systematic errors in the delivery of HIV and syphilis care. Data must be quality assured, which requires it is accurate, reliable, complete, sensitive, timely, confidential, be precise and have integrity. During the validation missions that have already been undertaken confidentiality and concerns about its protection played a significant role in the quality of data systems and data linkage systems.

During validation the data verification process begins with the review of documentation, including guidelines, plans, monitoring and evaluation documents, regulations, case definitions, and documentation on the relationship between different settings. The efficacy and comprehensiveness of the system is evaluated over a period of one to three years.

Mr Laukamm-Josten identified a number of aspects to data quality that are reviewed during validation, including:

- The quality with which results are recorded and documented
- An assessment of the kinds of tools used
- The presence of patient histories
- Reporting forms
- Standard operating procedures
- Sources of potential error.

Challenges that had been encountered included:

- Double counting of women due to repeat testing or the woman attending multiple facilities.
- Obtaining denominators for the total number of women tested in a given period.
- Some women were tested though were not told of their result (which is critical).
- A lack of follow up or ability to assess retention.
- A concern that the data presented was not representative of country wide results.
- A lack of nationally standardised case definitions.

While it is not compulsory for countries to collect data for the additional GARPR indicators (3.3, 3.7, 3.8, 3.9, 3.10, 3.11) it was noted that they were helpful in the assessment process.

Dr Laukamm-Josten emphasised the need to bring attention to reporting stillbirth cases as they are often left out of national STI control and prevention programs. It was also emphasised that the MTCT of HIV and syphilis are proxies for a failure in the health system.

During the discussion that followed the presentations several participants noted the importance of addressing small numbers' issues in low prevalence countries. Some countries stated a single case of transmission can significantly skew the results. Participants asked WHO to envisage addressing this issue in the global validation guidance that is currently under revision.

## **Laboratory assessment tool**

### **Dr Magnus Unemo (WHO Collaborating Centre for Gonorrhoea and other Sexually Transmitted Diseases)**

Dr Unemo participated in the laboratory assessment missions to Moldova, Bulgaria and Belarus. Prior to the mission, a review of the country report and other relevant documents (e.g. policies, SOPs, guidelines, standards, reports from recent evaluations) is undertaken. The mission proper includes a snapshot of indicative laboratories in the country. Interviews and observational visits are conducted, as well as a review of the transportation and storage procedures, the sampling processes and reporting chain. Normally the mission visits the national reference laboratory and a number of lower level laboratories. A review of this information is synthesised in the form of a detailed report and disseminated to representatives and the Ministry of Health.

The laboratory focused goals for the EMTCT of HIV were to ensure:

- Laboratories were performing tests with accuracy >99%.
- Screening is sufficiently sensitive with an appropriate confirmatory test and processes to identify women who are HIV positive.
- Timely access of diagnosis and treatment monitoring and early infant diagnosis.
- Appropriate quality assurance processes were in place and being used.
- Reporting systems are accurate and well-constructed.

The laboratory focused goals for the EMTCT of syphilis were to ensure:

- Laboratories are performing tests with >95% accuracy with an appropriate confirmatory test and an alternative test for discordant or inconclusive results.
- Screening is sufficiently sensitive, including for stillborn infants.
- Screening is available at all levels of healthcare service delivery.
- There is an understanding of the levels of stockouts, aiming for a rate of less than 4%.

A number of issues were identified during the missions that had been conducted thus far, which centred on the:

- Completeness of documents and questionnaires prior to the mission.
- Completeness of descriptions of the national lab networks, roles and responsibilities of the different levels of the healthcare system.
- Roles and responsibilities of the national reference laboratory.
- Implementation of national guidelines and standards.
- Large numbers of HIV and syphilis test formats, assays and algorithms, many of which were not validated.
- Different levels of quality assurance in different settings.
- Suboptimal sensitivity of the syphilis tests and a lack of assays for definitive diagnosis of MTCT of syphilis.
- High frequency of testing to compensate for a lack of individual test sensitivity.
- Documentation, recording and reporting of test results, the linkage of results to the patient record and the ability to identify pregnant women.
- Variability in the case definition for CS.

Dr Unemo noted that while many of the professionals in the country were aware of these challenges and limitations they lacked the resources to make changes. A benefit of being involved in validation is that it enables policy makers and programme managers to present a stronger case to the Ministry of Health to obtain additional resourcing. He encouraged countries not to think of the process as punitive but rather to identify challenges and opportunities.

After the presentation discussion focused on the microbiological evidence that is required to prove stillbirth due to CS. The only definitive way to prove this is to undertake an autopsy and PCR test.

## **Human rights and community engagement tool**

**Marina Semenchko (UNAIDS RST)**

Dr Semenchko presented the Human Rights and Community Engagement Tool. It involves ten items:

1. No criminalization for vertical transmission
2. No compulsory testing and treatment
3. No mandatory or forced abortion, contraception or sterilization
4. Informed consent
5. Confidentiality
6. Availability, accessibility and the quality of services
7. Equality and non-discrimination
8. Community involvement and accountability
9. Combating gender-based violence
10. Access to the justice system, reparation and compensation for harm.

These factors are assessed through two methods: Document analysis and interview questionnaires. The document analysis reviews country reports, different overviews of the healthcare and human rights systems, and reports from international organizations. The interviews involve meeting with professionals working in health and engaging in discussions about what happens in the country. The experts in this process are nominated individuals from civil society and legal backgrounds.

**Hovhannes Madoyan (Real World, Real People, Armenia)** noted that the most frequently observed human right's violations included a breach of confidentiality, the refusal to provide health care services, the delivery of healthcare services in a manner that violates human dignity and poor quality service provision. It was also noted that clients often refuse to complain due to a fear their HIV status will be disclosed and a lack of trust that rights could be protected. NGOs and civil society organizations are a resource and have the ability to support PLHIV who have these concerns and this should be leveraged in HIV programming.

The human rights tool generated a significant amount of discussion. Some country representatives acknowledged the importance of the tool and they noted that there can be a large discrepancy between what is legislated and what is enforced or occurs in countries. This should be considered during the assessment process.

Some countries expressed concern about the human rights assessment. They felt human rights assessments left country's vulnerable to negative sentiments that may be expressed by NGOs. It was reiterated that human rights are critical to the sustainability of EMTCT programs, and it is important to get an alternative picture from the NGO sector, though it is not the case that answers on all 10 items need be completely positive to pass the assessment.

Some countries suggested it would be helpful to have some tools to assist with the collection of data. An example was a reference sheet for each indicator about what to collect, and how.

Some countries noted conflicts between the rights of the foetus and the rights of the mother. An issue that has arisen is what to do when the mother refuses treatment. It was noted there was no internationally accepted response to this issue.

Participants also asked countries who had undertaken pre-validation who they used as the international expert for the human rights assessment. This decision was really context dependent. In Moldova the questionnaire was shared with number of regional NGOs. Bulgaria used a human rights lawyer as an expert, though initiated the process with a roundtable meeting with NGOs. In Belarus, the human rights specialist was a colleague of the mission. Many country representatives felt that the human rights tool was too complicated and requested WHO to consider simplification of this tool.

## **Plenary session 2: Validation experience accumulated in the Region**

### ***Sharing validation experience accumulated in the region: Pre-validation missions to Bulgaria and Belarus, country report preparation in Moldova*** **Lali Khotenashvili (WHO Regional Office for Europe)**

Lali Khotenashvili described the pre-validation missions which had been conducted. The WHO Regional Office for Europe coordinated the group of international experts in laboratory services, data and human rights to undertake the country missions. The mission members also included including representatives of WHO Collaborative Centres and regional, subregional, national civil society organizations, representatives of the WHO, UNAIDS, UNICEF and UNFPA regional and country offices. Prior to the mission, the country prepared and submitted country validation reports and documentation that was reviewed by the members of the mission. The missions occurred over a week-long period during which time the members worked intensively with the national working group formed by the Ministry of Health. During the mission there were visits and discussions in the capital city and one of the lower performing districts that were chosen by the Ministry of Health. The mission visited health care facilities belonging to primary, secondary and tertiary care including HIV, STI, obstetrics/gynaecology, reproductive health, family planning, laboratory settings. Along with that mission visited and discussed with NGOs, CBOs, civil society settings, youth organizations, international donor and partner organizations.

After the mission has been conducted, a debriefing process occurs where mission members shared the preliminary findings and the recommendations with the Ministry of Health officials as well as technical and civil society experts who were involved in the mission. In Turkmenistan, this took the form of a roundtable discussion with more than 100 people. A feedback report is also produced and shared with the country with detailed recommendations to address the challenges that were identified. At the time of the meeting five representatives of 11 countries in the European Region had expressed an interest in applying for validation.

### ***Panel discussion***

#### **Tonka Varleva (Bulgaria), Elena Petrova (Bulgaria)**

Dr Varleva and Dr Petrova spoke about the Bulgarian experience of EMTCT validation. In Bulgaria the National Validation Committee was responsible for filling out the country validation report and all relevant documentation with support from a number of experts from epidemiology and the national reference laboratory. The Human Rights Tool was completed by specialist lawyers and the NGO sector. The final report was prepared by the Ministry of Health under their regular budget.

The preparation for the report and the mission was challenging as it required issues within the country in a novel way. The preparatory process, mission proper and debriefing session with experts regarding national PMTCT and congenital syphilis prevention issues were particularly useful. The mission helped identify a number challenges and ways of resolving them in an evidence based way. The recommendations helped to strengthen the systems responsible for eliminating MTCT of HIV and syphilis as well as having a broader effect on strengthening the country's health system overall.

### **Oleg Pankratov (Belarus), O. Paduta (Belarus)**

Belarus described the experience of EMTCT validation as very constructive and it highlighted many positive healthcare delivery practices. They viewed validation as an opportunity to obtain an objective, external vision of the way HIV and syphilis services were delivered and receive international assistance from a panel of experts. This enabled the country to assess how well it was harmonised with global trends.

The process led to a standardization of what data was collected in the primary healthcare setting. It was suggested that it would be useful for future missions to issue Standardised Operating Procedures with clear descriptions about what data and information should be collected and for what period.

The management of CS was discussed, including the case definition and patient management.

### **Mircea Betiu (Moldova)**

Dr Betiu discussed the challenges associated with writing the country report for Moldova. The National Validation Team in Moldova was comprised of three STI specialists, three HIV specialists, one individual from family medicine and one individual from the Commission on Reproductive Health. Some challenges were encountered when writing the report including the discovery that the data for HIV for last year will not allow Moldova to apply also for validation for HIV. Therefore the country made a decision to only apply for validation of the elimination of congenital syphilis.

In Moldova, syphilis and HIV interventions are delivered across a wide range of settings including ANC, reproductive health, STIs, obstetrics, gynaecology and postnatal care. The views of each of these areas needed to be reflected in the country report, which presented some logistical difficulties. The country also struggled with discrepancies in the case definition for CS because it differs on the basis of its use in clinical and epidemiological contexts.

The country has a well-established system for data collection. During the mission additional information was requested and though it had been collected it was difficult to extract. They also discovered that data for CS was aggregated and not available as case-level data.

Getting people from different agencies to work in a collaborative manner was a challenge. This wasn't anticipated and workshops were conducted to encourage collaboration between services and the NGO sector. Despite the challenges incurred preparing the country report, overall it was a very positive and productive experience. It helped to inspect CS control and prevention efforts from a variety of perspectives and it promoted collaboration and partnership among the different sectors that were involved.

## **Plenary session 3 & 4: Working Groups' Session**

Table 1. A summary of the conclusions of the Working Groups' session regarding EMTCT of HIV and syphilis and the assistance required.

Group	Country	Intention to validate for HIV	Intention to validate for syphilis	Explanation of choice and assistance requested	Next steps to achieve validation
<b>Group A</b>	Slovakia	Yes, in 2016	Yes, in 2016	<ul style="list-style-type: none"> <li>No MTCT of HIV and few syphilis cases. There are problems with data for process indicators 1 and 2. Assistance is required from WHO Regional Office, who could send an official statement to encourage cooperation between specialists.</li> </ul>	<ul style="list-style-type: none"> <li>Inform the national Ministries of Health of the procedure for EMTCT validation.</li> <li>Prepare the documentation.</li> <li>Collect the needed (and available) data.</li> <li>Contact the WHO Regional Office to initiate the validation process.</li> <li>Invite WHO for a mission.</li> <li>Improve the focus on STIs among countries where the response is thought to be insufficient.</li> <li>Identify regional solutions to tackle HIV and syphilis among migrants.</li> <li>Overall, all countries have difficulties with data for testing coverage for pregnant women and require assistance.</li> </ul>
	Moldova	Yes, in 2017	Yes, in 2016	<ul style="list-style-type: none"> <li>The country has good data availability.</li> </ul>	
	Ukraine	Unsure	No	<ul style="list-style-type: none"> <li>The country needs support to implement the WHO testing and treatment guidelines. There are challenges with the standards, including an absence of a strategy for STI prevention.</li> <li>Instability in the domestic political situation presents ongoing difficulties.</li> </ul>	
	Croatia	Yes, in 2017	Yes, in 2017	<ul style="list-style-type: none"> <li>For syphilis the diagnostic standards need strengthening as does universal testing for pregnant women. Currently the policy for syphilis sits within the program for STIs and HIV testing occurs when there are medical indications.</li> </ul>	
	Poland	Yes, in 2016	Unsure	<ul style="list-style-type: none"> <li>All pregnant women are tested for HIV. STI clinics and testing requires revitalization (including improved coordination between STI clinics, gynaecologists and the Ministry of Health). There is insufficient data for the validation of syphilis.</li> </ul>	
<b>Group B</b>	Romania	Mission planned for next year	Mission planned for next year	<ul style="list-style-type: none"> <li>No foreseeable issues reported.</li> </ul>	<ul style="list-style-type: none"> <li>Assistance with a small surveillance project on the proportion of stillbirths related to CS and how many of these women were screened.</li> <li>Assistance is required to garner the political will to update and implement new treatment protocols for syphilis and the introduction of rapid testing.</li> </ul>
	Serbia	Yes, currently ready	Yes though not currently prepared	<ul style="list-style-type: none"> <li>Currently the legal framework only includes screening for HIV. Screening for syphilis only occurs in high risk populations.</li> <li>There are problems with the data for the screening and treatment coverage indicators.</li> <li>Clinical guidelines need to include syphilis screening, though there are financial restrictions.</li> <li>There is heterogeneity in the case definition of stillbirth due to CS.</li> <li>There are issues with obtaining data from private healthcare providers.</li> </ul>	
	Belarus	Undertook pre-validation mission in 2015, ready for complete mission	Undertook pre-validation mission in 2015, ready for complete mission	<ul style="list-style-type: none"> <li>99.4% receive antenatal testing though testing takes a long time. There needs to be rapid testing to shorten the time to treatment.</li> <li>There is high treatment coverage among pregnant women though PWIDs do not attend ANC services.</li> <li>While there is a good rate of syphilis screening the test is non-treponemal and not up to date.</li> <li>Syphilis treatment should be changed to the penicillin standard and treatment in the primary healthcare setting.</li> </ul>	



				<ul style="list-style-type: none"> <li>Data on stillbirth due to CS isn't collected, so general stillbirth data is reported. A mechanism should be developed to test for stillbirth due to CS.</li> </ul>	
	Georgia	Yes, ready for pre-validation	Yes, ready for pre-validation	<ul style="list-style-type: none"> <li>ANC coverage is 88%: 12% do not attend and 1% deliver at home. There are one or two cases a year MTCT of HIV where women were infected after screening.</li> <li>Treatment is free, and the country has moved to Option B+. Very few women do not want to receive screening or ANC services.</li> <li>To improve coverage of ANC there must be more education and help with practical problems like transportation for those living in remote areas.</li> <li>There are issues with syphilis treatment: chronic cases need more sophisticated treatments. The national treatment guidelines are not adequate.</li> <li>Data on stillbirth due to CS isn't collected, so general stillbirth data is reported instead. A mechanism should be developed to test for stillbirth due to CS.</li> </ul>	<ul style="list-style-type: none"> <li>Prepare to undertake pre-validation process.</li> </ul>
	Estonia	Yes, ready for pre-validation	Yes, ready for pre-validation	<ul style="list-style-type: none"> <li>There is very good treatment coverage, which is free. However PWIDs are unaware of their rights and need NGO assistance with linkage, services and education.</li> <li>It is believed there is good testing and treatment coverage though it is difficult to prove because of poor quality epidemiological data.</li> </ul>	<ul style="list-style-type: none"> <li>Requires assistance to create political will to change legislation to mandate the collection of data from ANC services.</li> </ul>
	Netherlands	Yes, ready for validation	Yes, ready for validation		<ul style="list-style-type: none"> <li>Undertake a survey of the number of undocumented migrants.</li> <li>Better understand the reasons women refuse to screen for HIV.</li> </ul>
	Denmark	Yes, ready for validation	Yes, ready for validation		<ul style="list-style-type: none"> <li>Address human rights issues for undocumented migrants who have no rights to access ANC services.</li> </ul>
	Latvia	Not reported	Not reported	<ul style="list-style-type: none"> <li>ANC coverage is high (80% within 12 weeks and 95% over the course of pregnancy). If no testing has occurred or their status is unknown the woman receives a rapid test at birth and the infant receives PEP.</li> <li>Some women LHIV believe ARVs are harmful or unnecessary resulting in approximately 4-5 cases of MTCT of HIV/year. This points to the need for more education, social support and transport assistance.</li> </ul>	<ul style="list-style-type: none"> <li>Assistance with developing the procedure for PEP.</li> <li>Improve gaps in the uptake of treatment.</li> </ul>
<b>Group C</b>	Armenia	Yes, currently organising.	Not reported.	<ul style="list-style-type: none"> <li>There are difficulties obtaining the denominators for some indicators.</li> <li>There is sufficient data according to the monitoring and evaluation system and adequate laboratory facilities.</li> </ul>	<ul style="list-style-type: none"> <li>Conduct the WHO validation missions with interested countries.</li> <li>Sent a letter to the Ministry of Health about the WHO EMTCT meeting.</li> <li>Some countries require clarification about the calculation of the denominators for the indicators (i.e. who is included and what is the timeframe).</li> <li>There were questions about the</li> </ul>
	Uzbekistan	Yes, in 2016.	Yes, in 2016.	<ul style="list-style-type: none"> <li>A review of the case definition and diagnostic criteria for CS should be undertaken.</li> <li>The appropriate regulatory documents exist.</li> </ul>	
	Turkmenistan	Not reported	Yes, in 2016.	<ul style="list-style-type: none"> <li>There are plans to create a Working Group at the Ministry of Health to progress validation.</li> <li>Conduct an analysis of the human rights context in the country.</li> </ul>	

	Lithuania	Yes, in 2016.	Yes, in 2016.	<ul style="list-style-type: none"> <li>There are many cases of transmission that occur when women do not attend birthing centres and are diagnosed after giving birth. Due to this, some cases of transmission are believed to be inevitable.</li> </ul>	<ul style="list-style-type: none"> <li>reliability of the existing data.</li> <li>Some countries wished to compare how other health systems were calculating their own indicator data.</li> <li>Some countries wish to undertake an analysis of the human rights situation relevant to PMTCT and what methods can be employed to assess this.</li> </ul>
	Russia	To be coordinated.	To be coordinated.	<ul style="list-style-type: none"> <li>There were concerns about the legal framework surrounding women who refused treatment and the correct way to manage the issue.</li> </ul>	
<b>Group D</b>	Azerbaijan	Yes, date to be confirmed.	Yes, date to be confirmed.	<ul style="list-style-type: none"> <li>Improve the countries knowledge of their epidemics by conducting a situational analysis.</li> <li>Optimise the monitoring and evaluation systems to enable harmonization with the validation tools.</li> <li>Increase commitment within countries, including financing, management, quality assurance and the efficiency and effectiveness of the supply system.</li> <li>Improve the regulatory framework to enhance cross-sectoral and interdisciplinary cooperation to strengthen public health. This should not just be the domain of the Ministry of Health.</li> <li>Improve compliance with existing national legislation.</li> <li>Ensure strategies are all harmonised so there are no conflicts between different strategies and legal frameworks.</li> </ul>	<ul style="list-style-type: none"> <li>Increased advocacy support and linkage with financial donors.</li> <li>Introduce rapid testing by non-medical staff (particularly NGOs).</li> <li>Conduct in-country missions to review progress of the EMTCT programs.</li> <li>Provide expert technical assistance to requesting countries, particularly around legislation, testing and treatment.</li> <li>Review and adapt the regulatory frameworks in line with the latest WHO recommendations.</li> <li>Strengthen in-country capacity for prevention, testing and treatment of HIV and syphilis.</li> </ul>
	Kazakhstan	Yes, 2016	Yes, date to be confirmed.		
	Kyrgyzstan	Yes, 2017	Yes, 2017		
	Poland	Yes, 2016	Yes, date to be confirmed		
	Tajikistan	Potentially 2017, to be confirmed	Yes, date to be confirmed.		

After the Working Group presentations there was a discussion about patient confidentiality. It was acknowledged that it was good that countries were concerned about patient confidentiality, though in some cases, concerns about confidentiality were becoming disproportionate and creating issues with monitoring and evaluation. It was thought that a regional statement from WHO on the confidentiality could be useful to help appropriately manage these concerns.

Countries identified that it was challenging to access migrant populations as a target group for the EMTCT of HIV and CS. Migration has led to localised epidemics and individuals in these localities do not always have access to ART. Migrants are not accepted by the place of residence, nor the place where they are working and consequently lack access to services. This is a major issue in the Region and must be resolved.

## **Plenary Session 5: Improving reporting of the EMTCT of HIV and CS**

### *Indicators to validate EMTCT of HIV and CS: Introductory notes*

**Shaffiq Essejee (WHO Headquarters)**

Shaffiq Essejee reviewed the details of the EMTCT indicators in greater detail. A summary of the indicators is presented below in Table 2.

**Table 2.** A summary of indicators for the EMTCT of HIV and CS presented by Shaffiq Essejee<sup>7</sup>

	Elimination	
	HIV	Syphilis
<b>Impact indicators</b>	MTCT < 2% (Or< 5% if breastfeeding)	No MTCT rate
	Case rate ≤ 50 per 100 000 live births	Case rate ≤ 50 per 100 000 live births
<b>Process indicators</b>	ANC1 ≥ 95%	ANC1 coverage ≥ 95%
	Testing coverage ≥ 95%	Testing coverage ≥ 95
	ART coverage ≥90%	Treatment coverage >95%

After a brief description of the EMTCT indicators there was a discussion about data collection for the indicators as well as HIV and syphilis programming more broadly. Discussion centred on how to calculate:

- The denominator for the process indicators. This is derived from national prevalence statistics or fertility rates (depending on the indicator), and may be an approximation because many countries lack precise figures.
- ANC coverage.
- The coverage of HIV and syphilis testing among pregnant women.
- Treatment coverage of pregnant women living with HIV or syphilis.

Some participants (particularly those from smaller countries) wished to average their EMTCT statistics over a longer period of time (e.g. two years) rather than to inspect the figures over a single year. The data in these countries was easily skewed due to their small population size.

<sup>7</sup>Full details on the indicators can be obtained in the World Health Organization’s Consolidated Strategic Information Guidelines <http://who.int/hiv/pub/guidelines/strategic-information-guidelines/en/>

Discussion also focused on HIV and syphilis cases among migrant workers and undocumented migrants. It was acknowledged by the meeting organisers that each country faces its own peculiarities in trends for EMTCT data. However countries were also reminded that the point of validation was to improve the quality of healthcare services. When the validation of EMTCT was assessed the peculiarities will be assessed contextually though countries should be improving the services delivered to these women.

### *Panel discussion*

- Could country lacking data on HIV and syphilis testing and treatment coverage for pregnant women still prove the elimination and if “Yes” – how?
- Could validation be done via desk review without country missions, If YES, what could be criteria

**Facilitator: Saulius Chaplinskas (Lithuania). Panellists: Susan Cowan (Denmark); Anna Marzec-Boguslawska (Poland), Jan Mikas (Slovakia), Tatjana Nemec Blazic & Jelena Barbaric (Croatia), Daniela Simic (Serbia)**

**Susan Cowan (Denmark)** referred to the question regarding whether countries could apply to validate without complete data. She was unsure, and felt that it is important to have a complete dataset. In Denmark, they felt the surveillance system was operating well though when testing was scaled up a significant increase in diagnoses ensued. The increase in diagnoses was greater than what they had expected and they were random in their distribution and demographic profile. Dr Cowan supported the idea of validation via a desk review under special circumstances, the most important of which was willingness for countries to be self-critical and honest about the situation in their country.

**Anna Marzec-Boguslawska (Poland)** felt the first question presented a number of problems. Taking the specific case of Poland, the country is missing a lot of data at the national level. Doctors are under significant time pressures and find it difficult to report on the conditions under surveillance. Current data suggests in Poland there are one or two cases of MTCT of HIV annually, though without complete data it isn't possible to know if this situation is representative. Syphilis presents a more complex picture.

In response to the second question, Ms Marzec-Boguslawska felt it was possible to validate via desk review. She noted that in many cases countries will still require a site visit. She also noted that there are significant benefits to be garnered through having a delegation of experienced international experts visiting the country to review the PMTCT program. It assists in comprehensively assessing the situation and provides important input for strengthening the country's program.

**Jan Mikas (Slovakia)** stated the quality of data in Slovakia is good. There have been two confirmed cases of CS in the past five years, and the country has considering undertaking EMTCT validation. However the country lacks data for the process indicators. To rectify this situation they will have to develop new processes around data collection in collaboration with the Slovak Society of Gynaecology and Obstetrics, the Slovak Paediatric Society and the Slovak Society of Dermatovenerology. Close collaboration with the WHO European Regional Office will be instrumental in making this goal possible.

In response to the first question Dr Mikas felt it was possible to validate in the absence of complete data though only under specific circumstances. If the incidence and number of cases is low, the country has a good surveillance system with high quality of data and a well-functioning healthcare then it may be possible. Dr Mikas also felt it was possible to validate via desk review if the country had achieved all relevant indicators.

**Tatjana Nemeth -Blazic (Croatia)** noted that the Croatian HIV prevention program for the period 2011-2015 finished in 2015. A new, revised program for the next period 2016-2020 is in the preparatory phase (draft version) and is currently in the process of being adopted. No specific program exists for syphilis as it is part of the broader STI strategy. There are very low rates of syphilis and in recent years, no cases of CS. Most cases of HIV transmission exist among MSM and the MTCT of HIV is very rare (one case of transmission occurs every three to five years).

The country faces some challenges collecting data for validation for HIV and syphilis. The reason is because according to current regulations, based on the epidemiological data on HIV/AIDS and syphilis, pregnant women are not mandatorily (routinely) tested for syphilis in Croatia. Therefore, data on HIV and syphilis testing among pregnant women are not collected at national level. Pregnant women are not tested for HIV and syphilis unless there is a medical or epidemiological (heightened risk) indication. Also, currently, no national guidelines exist for the diagnosis of syphilis and there's room for improvement. The syphilis-focused process indicators are therefore problematic. While there are routine mechanisms established for impact indicators an issue similar to other countries is encountered with some of the process indicators.

Regarding the first question, Dr Nemeth-Blazic stated it would be possible to validate through the development of some additional data collection strategies within the country. A temporary sentinel surveillance system could be established for one to two years to collect data on HIV and syphilis testing of pregnant women. Regarding data on syphilis testing, it is possible to collect data on testing of pregnant women in transfusion institutions in Croatia in collaboration with the Croatian Institute of Transfusion Medicine because in practice all or majority of pregnant women aside for HBsAg and Rh factor testing are also tested for syphilis. This could be established through the transfusion institutes within the country, which have existing data collection systems.

Dr Nemeth-Blazic thought it would be possible to validate via a desk review process.

**Danijela Simic (Serbia)** discussed the low prevalence of HIV, and low incidence of syphilis predominantly among males collected from different source of data while only a few MTCT and CS cases have been registered in the last decade in Serbia. Syphilis prevalence data is collected using bio-behavioural surveys among defined most at risk populations. The prevalence among sex workers is approximately 4%, among people who inject drugs 1% (only among males), among men having sex with men 1.5% and among young Roma is 1% (only among males). Serbia has a very well established prevention program for MTCT of HIV where the focus is on transmission for women living with HIV who are undiagnosed. There are a number of barriers to validation in Serbia, most of which relate to the process indicators. These include the need to further investigate the proportion of stillbirths that are due to CS. There is high coverage with ANC services (>95%).

Dr Simic thought it would be possible to validate via a desk review process.

The discussion that followed the panel presentation centred on migrant workers. There was a concern that migrant workers were travelling from with low to higher prevalence areas and acquiring HIV at some point during the journey. This contention was refuted by some in the room. All countries acknowledged that migrant workers are very hard to reach, and stressed the ongoing need to focus on this group to tackle the transmission of HIV and syphilis.

## **Plenary session 6: Improving the laboratory diagnosis of syphilis and HIV**

**Co-chairs: Gvantsa Gasviani (Georgia), Ludmila Derevyanko (Ukraine)**

*Major challenges regarding HIV and syphilis laboratory diagnosis.*

*Common issues in lab diagnosis of congenital syphilis in Eastern Europe, differences with other settings and the reasons for a pragmatic use of the Laboratory Assessment Tool*

**Dr Magnus Unemo (WHO Collaborating Centre for Gonorrhoea and other Sexually Transmitted Diseases)**

**Professor Unemo** presented on the diagnosis of MTCT of syphilis (including CS). He reiterated that in the laboratory standards, a definitive diagnosis of syphilis requires the demonstration of treponema padillium in a clinical specimen by dark field microscopy, DFA-TP, validated NAAT or an equivalent method. However these assays are not widely available. The widely accepted tests which are currently being used include RPR, VDRL and MPR, with the latter being more common in Eastern Europe.

Ideally, screening should use the traditional serologic screening algorithm which uses a non-treponemal (quantitative) test in conjunction with a confirmatory treponemal test. The reverse sequence uses a treponemal test initially with a non-treponemal (ideally quantitative) test for confirmation. The confirmation of a negative result should use a secondary, non-treponemal test.

It is important to consider a number of points when using the traditional screening algorithm. These include: minimising the rate of false positives in low prevalence settings; the potential to miss early primary and latent infections; a higher rate of biological false positives; the prozone reaction can cause false negatives; and there is the need to use the treponemal test with high sensitivity. The reverse sequence is automated though more costly for the high throughput initial screening stage. It detects both primary and latent infection more effectively though it may identify old and treated infections (which can be problematic in high prevalence settings).

The case definition for CS was presented. The global surveillance case definition for congenital syphilis is defined as:

- A stillbirth, live birth, or foetal loss at >20 weeks of gestation or >500 grams to a syphilis seropositive mother without adequate syphilis treatment; OR
- A stillbirth, live birth, or child aged <2 years with microbiological evidence of syphilis infection.<sup>89</sup>

Professor Unemo identified a number of challenges affecting the European Region when diagnosing syphilis. These included:

- Heterogeneity of the case definitions for CS.
- Numerous syphilis test formats, assays and diagnostic algorithms, with many being inappropriately validated.
- The suboptimal sensitivity of the MPR test, which is currently widely used as screening test.
- A lack of tests used to detect IgM.
- Widely different use of quality assurance processes in divergent setting (which has implications for quality controls).

### *Panel discussion*

- *Case definition of congenital syphilis – perspectives from Moldova*
- *Laboratory diagnosis of congenital syphilis in:*
  - *Bulgaria*
  - *Russian Federation*
  - *Belarus*

**Mircea Betiu (Moldova)** stated that in Moldova two CS case definitions currently exist: One for clinical diagnosis and another for surveillance. There are attempts to harmonise the definitions though it is challenging. There are also difficulties in coordinating case definitions across specialist and primary care settings. These challenges have been discussed with the WHO in the context of validation. Using the available data and using these definitions, the country could still validate (there were no cases in 2014, and two a year in 2013 and 2012).

**Elena Petrova (Bulgaria)** reported it had been collecting epidemiological data on HIV and CS since 1990. The country conducted a study to screen pregnant women for syphilis. Most of the participants were Roma women (70%), and the vast majority of diagnoses were made during pregnancy or at birth. 40% of participants were from Bulgaria. Women were not diagnosed earlier in their pregnancy due to a lack of prenatal screening and treatment, especially among the Roma community who frequently don't access treatment.

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<sup>8</sup> Microbiological evidence of congenital syphilis includes any one of the following:

- demonstration by dark field microscopy or fluorescent antibody detection of *T. pallidum* in the umbilical cord, the placenta, a nasal discharge or skin lesion material;
- detection of *T. pallidum*-specific IgM;
- infant with a positive non-treponemal serology titre >= fourfold above that of the mother.

<sup>9</sup> World Health Organization (2014). Global guidance on criteria and processes for validation: elimination of mother-to-child transmission (EMTCT) of HIV and syphilis. Geneva, Switzerland: World Health Organization.

**Margarita Rakhmatulina (Russian Federation)** stated that in Russia the standards around CS case management and diagnosis is managed by the country's professional associations. Ideally, women will be tested in the ANC setting though some are tested later in hospital as a last resort. Approximately 1/3 of women are diagnosed during the first trimester, with another half of women diagnosed in the second trimester.

The Wasserman Test is still used in the country despite recommendations to use other tests. It is hoped this will change in 2016.

Children born from seropositive mothers though not diagnosed with CS prior to birth are observed at three months and a year (via laboratory testing and clinical symptoms) irrespective of whether they received prophylactic treatment. In some cases, the assessment is also carried out at six and nine months.

Questions arose subsequent to the presentation about the proportion of children born to seropositive mothers that showed clinical symptoms. Approximately two thirds of the children had clinical manifestations. The country currently doesn't have data on stillbirths due to CS.

**Oleg Pankratov (Belarus)** stated that in Belarus, 8% of the detected syphilis cases were among pregnant women. Though the national rate of syphilis is decreasing, the proportion of the cases that are in women appears to be increasing. In the most recent years there have been no registrations.

In the past 15 years, there have been 52 cases of stillbirth due to CS though this hasn't been recorded using official statistics. The country has developed a workaround for managing the recording of CS statistics though it is unclear at this stage if this will be acceptable for validation.

Over time, Belarus has found that syphilis positive mothers are a very difficult group to treat because these women are members of very socially marginalised groups. In spite of free, unrestricted access to syphilis testing and treatment services, this group of women is not sufficiently targeted in national programs.

## **Plenary Session 6: Ways forward**

*Discussion on the ways forward:*

- *Drafting regional validation plan: list of countries considering validation and defining preliminary timeframe.*
- *Suggesting how to simplify validation procedures.*
- *Defining major actions for acceleration of elimination of MTCT of HIV and congenital syphilis.*



Discussion was planned as a panel discussion but soon after it developed into a very active general one involving all participants

As short introduction to the discussion on way forward was a summary notes prepared by **Silviu Ciobanu (WHO Moldova)** who acted as the main facilitator for the working group session. He summarised the working groups' suggested next steps towards achieving validation. The subsequent general discussion led to a number of important conclusions.

The main overall message was for WHO to simplify the overall validation process to eliminate cumbersome procedures and the large number and volume of materials to be submitted. Further key messages included the following:

1. A number of countries were early participators in the validation of EMTCT of HIV and syphilis. Moldova was central to the piloting of the process, and Bulgaria and Belarus have all been engaged in pre-validation.
2. The validation process for the EMTCT of HIV and syphilis is an exercise in quality improvement of the national public health response to these diseases. Reports from participating countries confirm this was their experience of the validation process: Countries felt their participation overall was positive and they found it useful to benchmark their country's performance on the EMTCT relative to international standards.
3. This pre-validation mission or "validation readiness assessment mission" as it was called in some countries helps countries approach undertake the validation process in a stepwise manner. This was perceived as more acceptable or achievable by both countries and the international experts as countries can benefit from the expertise of the experts reviewing the country's situation, and comprehensively providing insights about achievements, challenges and the best ways these challenges might be addressed. If the country meets the requirements for validation this may be granted. However, in the case the country does not meet the requirements this approach circumvents any issues with negative ramifications (e.g. blame or punishment) in the event the requirements are not met.
4. All countries that have undertaken pre-validation found it very beneficial. The national working group compiled by the MOH accompanied the mission and were actively involved in all the work that was undertaken. The mission helped national colleagues to look at the issues from different and novel perspectives and benchmark themselves against internationally agreed norms and standards. The missions therefore both strengthened the national programs and were a capacity development exercise for those within countries.
5. Countries requested more specifics about the logistical aspects of validation, particularly around what was involved and how much time and resources were required.
6. While acknowledging very positive impact of the in-country validation missions, feedback also showed that number countries felt there should be other methods offered for undertaking validation. There was strong support for the possibility of a desk review (without an in country mission) though it was suggested this should be dependent on each country's specific situation. Countries that wished to validate via desk review should first have established good surveillance and data linkage systems and have a low prevalence rate. The WHO was requested to consider these alternative validation options when revising the global validation guidance document and define clear criteria as to when each particular option could be permissible.

7. Final feedback was sought from participants on the three validation tools (the data quality assessment, laboratory assessment and the human rights tools).

The Data Quality Assessment Tool:

- The data quality assessment reviews the accuracy, reliability, completeness, sensitivity, timeliness, confidentiality, integrity and precision of the data.
- Appropriate systematic data collection processes must exist and the database must be quality assured, though this may create additional burdens on clinicians and must be approached pragmatically.

The Laboratory Assessment Tool:

- A number of laboratory quality challenges regarding were identified in the pre-validation missions. These included issues with the completeness of documentation and descriptions of the laboratory networks, implementation of the national laboratory standards, quality assurance processes, use of non-validated assays and algorithms for HIV and syphilis and data linkage of patients' results.
- Laboratory diagnosis of syphilis and congenital syphilis requires strengthening in a number of countries.

The Human Rights Tool:

- The assessment of human rights and community engagement was considered an important though sensitive issue and generated considerable discussion. The discussion focused on country-specific human rights challenges and some were concerned about on discrepancies between government and civil society's perspectives on human rights issues. It was stressed that human rights should be viewed as a central tenet of the public health response to HIV and syphilis which was critical to the long-term sustainability of EMTCT.
  - Some countries expressed a concern that while there was a strong legislative framework to protect human rights issues around the EMTCT of HIV and syphilis, this legislation was not enforced.
  - Countries requested a further simplification of the human rights and community engagement tool.
  - They also requested a clearer definition of the human rights that should be met by each country. Participants emphasised the need to clarify that the human rights issues that were to be met were related to the EMTCT of HIV and syphilis, and not human rights issues more broadly.
  - Countries were encouraged to engage civil society and human rights lawyers when undertaking the human rights and community engagement assessment. This engagement has occurred in previous missions: in one mission a lawyer was part of visiting party and in another a local lawyer was invited to join the mission to compare and choose the best approach to ensuring human rights.
5. Not all countries are submitting data on the EMTCT of HIV and syphilis on a regular basis: some of the data reported to GARPR is a decade old, and syphilis data in particular is underreported. A number of additional data related issues are seen across the Region, including poor reliability emanating from the inadequacies with established laboratory services, poor reporting and weak monitoring and evaluation systems.

6. The preparation of the country validation report was challenging for some countries logistically and administratively as it requires specialists and input from different sectors and settings. The outline of country report given in the global guidance document was also challenged: countries asked WHO to simplify the report as there are a number of non-critical sections including country geography, the description of the health system, financing and supply chains.
7. There is a need to move from term “congenital syphilis” towards term “mother to child transmission of syphilis”.
8. Heterogeneity in the case definition for congenital syphilis continues to be an issue in the Region. Not all countries follow WHO case definition. Harmonization of case definition across the region is of high importance to allow inter-country comparisons. Some countries also face conflicting case definitions developed for clinical management versus those for surveillance purposes. In number countries the lack of awareness of the national case definition has led to an over or underreporting of cases of congenital syphilis. Stillbirths due to syphilis may be underreported in the Region as some countries are not routinely undertaking autopsies to identify the cause of death.
9. Feedback was sought on whether countries should be able to validate if data were unavailable for key process indicators (such as testing and treatment coverage of pregnant women). Many participants were sceptical though suggested that in some circumstances it may be possible if countries were aware of what gaps in the data exist and efforts were made to improve these limitations.
10. Numerous countries strongly emphasised the need to revitalise the national focus on sexually transmitted infections. The WHO was requested to provide high level advocacy and technical assistance to countries to strengthen STI control and prevention programs.
11. The WHO was asked to accelerate the development and publication of updated STI case management guidelines.

At the close of the meeting 18 countries (Slovakia, Moldova, Croatia, Poland, Romania, Serbia, Belarus, Georgia, Estonia, Netherlands, Denmark, Armenia, Uzbekistan, Lithuania, Azerbaijan, Kazakhstan, Kyrgyzstan and Tajikistan) expressed an interest in undertaking validation for the EMTCT of HIV, with 13 countries (Slovakia, Poland, Romania, Serbia, Belarus, Georgia, Estonia, Netherlands, Denmark, Armenia, Uzbekistan, Lithuania and Kazakhstan) prepared to undertake the process in 2016 and four (Moldova, Croatia, Kyrgyzstan and Tajikistan) in 2017. Seventeen countries (Slovakia, Moldova, Croatia, Romania, Serbia, Belarus, Georgia, Estonia, Netherlands, Denmark, Uzbekistan, Turkmenistan, Lithuania, Azerbaijan, Kazakhstan, Kyrgyzstan and Tajikistan) expressed an interest in validating the EMTCT of syphilis, and 11 of these (Slovakia, Moldova, Romania, Belarus, Georgia, Estonia, Netherlands, Denmark, Uzbekistan, Turkmenistan and Lithuania) were interested in doing so in 2016 and two (Croatia and Kyrgyzstan) in 2017. Many countries wished to initiate the process with the pre-validation rather than the complete validation process.

## Recommendations

1. Participants reiterated the relevance of the global elimination targets for the Region and reissued their support for the regional elimination goals and targets.
2. Participants also emphasised the relevance of the global validation tools for the Region and supported their use in the region. Specific support was given to the data quality, laboratory diagnosis and the human rights and community engagement tools.
3. Participants interested in participating in the validation (or pre-validation) process should inform the national Ministries of Health of the process and requirements for validation.
4. Countries interested in participating in the validation (or pre-validation) process should formally apply by sending letter to the WHO Regional Office for Europe to register their interest.
5. The WHO was asked to reissue previous statements relating to patient confidentiality during HIV testing and diagnosis.
6. Countries should consider reviewing national processes to ensure a balance exists between safeguarding patient confidentiality though ensuring that this will not lead to such a level of secrecy that the information can be shared with health care staff involved in patient treatment and care.
7. Countries should continue to refine their data collection, reporting and monitoring and evaluation systems, address gaps in the system and continue to strengthen surveillance. Specific issues warranting attention include improving data around hard-to-reach populations of pregnant women.
8. Countries are encouraged to improve testing and treatment coverage data and ensure the availability of data for the process-focused EMTCT indicators.
9. Countries should continue to increase the data reported to GARPR, including data around ANC coverage.
10. The WHO Regional Office will support interested countries to review and update relevant HIV and syphilis strategies and policies. This support will extend to reviewing the testing strategies and algorithms for HIV and syphilis diagnosis to ensure they comply with WHO guidelines. The strategies adopted should possess sufficient sensitivity and specificity, with appropriate confirmatory tests and be accompanied by strong quality assurance and reporting systems.
11. Countries wishing to participate in the validation process should review and harmonise their congenital syphilis case definition to align with the WHO's case definition.
12. Relevant countries should continue to review the human rights context and service provision for undocumented migrants to ensure they are able to be screened and treated for HIV and syphilis.
13. Some countries identified a need to carry out small scale research projects to gain better insights into hard to reach populations, particularly women who are not presenting at ANC services prior to giving birth.
14. Relevant countries should undertake small scale studies to investigate the proportion of stillbirths that are attributable to congenital syphilis if autopsies are not routinely conducted on stillborn fetuses.
15. Countries should continue to address gaps in treatment uptake and retention amongst pregnant women.
16. Countries should review case management and clinical guidelines for the treatment of syphilis to ensure treatment efficacy and avoid under/over-treating the condition in pregnant women and infants.

The WHO was requested to:

1. Simplify the validation process.
2. Reflect in the revised global validation guidance that it is at the discretion of the Region whether or not to have a Regional Validation Committee.
3. Review several methodological options for validation via desk review. The country mission is an important part of the validation process and for many countries of the WHO European Region it is the most appropriate option. However, some countries could be validated via desk review. It would be very helpful if the revised guidance presents a range of options, including validation via desk review, with or without a country mission. Clear criteria should be presented about when each option was permissible.
4. The HIV and syphilis testing of pregnant women is not universal in a number of countries in the Region, particularly those in Central and Western Europe. If countries lack testing and/or treatment coverage data of pregnant women, is it possible that the country could still validate? If this is considered possible, the guidance document should present ways this could be undertaken.
5. Review and simplify the country validation report. Feedback suggested the outline of suggested content given in in the global guidance looks too intensive. Countries requested the content be critically reviewed with an eye to the absolute necessity of the content. The sections on geography, the description of health systems, financing and supply chains may potentially be removed.
6. Critically review indicators listed as other program indicators in Annex 1
7. Give explanation for calculation of impact indicators, particularly around the reported numbers vs estimation data.
8. Better define human rights requirements to be met by countries. The guidelines should be clear that broad human rights issues are not being assessed, rather those specifically relating to the EMTCT of HIV and syphilis.
9. Provide suggestions on the most optimal membership to comprise the country's mission team (based on the Cuban experience).
10. Provide online and phone communication prior to the mission to make the mission proper shorter and more cost effective.
11. Reinforce the importance of confidentiality as part of the "5 C's" when undertaking HIV testing services.
12. Reinforce advocacy for promoting the STI agenda at the international and national level. This should emphasize the need to ensure sustainability of national STI programs, an update of national guidance documents and the ongoing need for capacity building.
13. Accelerate the development and publication of the updated global STI case management guidelines.

## Conclusion

To date there has been great success in tackling MTCT of HIV and syphilis in the WHO European Region. The Region has witnessed some of the most impressive improvements in EMTCT of HIV and syphilis in the world, with a very high level of estimated ANC coverage, the highest rate of infant diagnosis and very high testing coverage of pregnant women.

Countries can now consolidate these gains by confirming the results and ensuring their sustainability through the process of elimination validation. Regional developments suggest the high interest of countries to apply for the elimination validation. It is believed that the elimination validation processes will contribute to the strengthening of health systems, promotion of integration and collaboration and sustainability of HIV MTCT and Syphilis control and prevention programs.

## Closing remarks

**Lali Khotenashvili (WHO Regional Office for Europe)** wished to emphasise a number of important points at the closure of the meeting. She stressed the importance of improving the legislative environment and highlighted Moldova's experience around syphilis, still births and abortion. She noted these HIV and syphilis are not exclusively medical problems: They are also embedded within a human rights context.

She warned countries that returning to their data and examining its validity and reliability may lead to a change in the incidence rates. Nevertheless it is critical that countries consider the quality of data and the need to improve it. This is a key pillar of the validation process. The meeting highlighted a number of data issues including the complete absence of data for some indicators (particularly the process indicators) though some solutions had been identified during the meeting. Irrespective of the solution it is important surveillance needs are balanced with the capacity of clinicians to collect the data. As a first priority, countries should re-examine their case definitions for CS to ensure it aligns with the WHO standard.

She also highlighted some future directions for countries attending the meeting, including:

- To examine the ways that multidisciplinary teams can respond to the MTCT of HIV and syphilis.
- To move towards using the terminology around the EMTCT of HIV and syphilis (as opposed to congenital syphilis).
- To examine the community setting as a key site where interventions may be rolled out.
- To revisit their national guidelines and policies for testing to ensure they harmonise with the WHO and other key international organizations.
- To renew the focus on STIs.
- The importance of timeliness in data provision via the GARPR tool, particularly for ANC data.

The WHO acknowledged countries need for assistance with specific issues. This includes assisting with capacity building around diagnostics, control and prevention for both HIV and syphilis, as well as technical assistance with improving the quality of laboratory services.

**Deborah Von Zinkleman (UNAIDS)** noted the depth and quality of the discussion undertaken at the meeting, and promised to relay information obtained from this meeting back to UNAIDS. She stressed the importance of respecting human rights in the EMTCT of HIV and syphilis and pointed out that good public health and human right are in fact synonymous. She noted contribution of ARVs to the EMTCT of HIV, which has been an absolute game changer. She stressed the need of countries to critically review their national programs, with a view to understanding the gaps in testing and services and developing an appropriate strategy to target them.

**Shaffiq Essejee (WHO Headquarters)** encouraged countries to begin thinking about viral hepatitis as the next set of conditions for elimination. He appreciated the amazing work that was being undertaken in the Region. He stressed the importance of filling in the gaps in monitoring and evaluation, and encouraged countries to return to their data and critically re-examine which subpopulations are being left behind. He thanked organisers for the invitation and all participants for their involvement.

**Alexandr Kossusin (UNFPA)** thanked meeting organisers and participants. He highlighted the importance of all pillars of PMTCT. Mr Kossusin stressed the need to focus on planned pregnancy options and the 5% who were not receiving ANC services.

**Tetyana Tarasova (UNICEF)** also thanked the meeting organisers. She reminded participants of the reality of MTCT of HIV and syphilis: that each case is an actual child. Tatyana wished to stress the importance of the ongoing participation of NGOs, who provide timely access to services and take a social determinants approach to healthcare.

**Saulius Chaplinskis (Lithuania)** identified the importance of country's asking difficult questions and committing to addressing them. In particular, he noted the importance of country's legislation and its enforcement.

A number of individual thanks were offered by Poland, the Union of PLHIV, Armenia, Bulgaria, Uzbekistan, Kazakhstan, Latvia and Kyrgyzstan.

## Appendix 1: The global validation targets for EMTCT of HIV and syphilis

Required indicators for global validation of EMTCT of HIV and/or syphilis	
<b>HIV</b>	
<b>Impact indicators</b>	
Mother-to-child transmission (MTCT) HIV case rate of $\leq 50$ new paediatric HIV infections per 100 000 live births	
MTCT of HIV of $< 5\%$ in breastfeeding populations	
OR	
MTCT of HIV of $< 2\%$ in non-breastfeeding populations	
<b>Process indicators</b>	
Antenatal care (ANC) coverage (at least one visit) of $\geq 95\%$	
Coverage of pregnant women who know their HIV status of $\geq 95\%$	
Antiretroviral (ARV) coverage of HIV-positive pregnant women of $\geq 90\%$	
<b>Congenital syphilis</b>	
<b>Impact indicator</b>	
Incidence of congenital syphilis $\leq 50$ cases per 100 000 live births	
<b>Process indicators</b>	
ANC coverage (at least one visit) of $\geq 95\%$	
Coverage of syphilis testing of pregnant women of $\geq 95\%$	
Treatment of syphilis-seropositive pregnant women $\geq 95\%$	

The qualifying requirements for validation of elimination of MTCT HIV or CS are:

- National EMTCT validation indicators:
  - ***Process indicator targets achieved for 2 years AND***
  - ***Impact indicator targets achieved for 1 or more years.***
- Review of equity considerations, e.g.
  - *Low performance district or high burden area*
  - *Key populations and other vulnerable groups*
- Robust national monitoring and surveillance system
- Basic Human Rights Considerations must be met

The validation process should be initiated by the Ministry of Health, informing the Regional Secretariat of the WHO, who notifies the Regional Validation Committee. In the pre-validation phase, the country prepares a report which is assessed by the Regional Validation Team. This is followed by an in-country assessment of the situation, and finally an evaluation and report on the outcomes of the validation are submitted to Global Validation secretariat through regional Secretariat and Committee. If successful, Global Validation Advisory Committee issues certificate to be signed by the Director General.



The presentation generated many questions about the targets and procedures to be followed by the candidate country.

## Annex 2: Scope and purpose of the Regional Consultation

WORLD HEALTH ORGANIZATION  
REGIONAL OFFICE FOR EUROPE



ORGANISATION MONDIALE DE LA SANTÉ  
BUREAU RÉGIONAL DE L'EUROPE

WELTGESUNDHEITSORGANISATION  
REGIONALBÜRO FÜR EUROPA

ВСЕМИРНАЯ ОРГАНИЗАЦИЯ ЗДРАВООХРАНЕНИЯ  
ЕВРОПЕЙСКОЕ РЕГИОНАЛЬНОЕ БЮРО

### Technical Consultation on monitoring progress and supporting capacity building to validate dual elimination of Mother-to-Child Transmission of HIV and Congenital syphilis in the WHO European Region

/2

Astana, Kazakhstan  
17-18 December 2015

12 August 2015  
Original: English

### Scope and purpose

#### Background

The global community is now firmly committed to eliminating mother-to-child transmission (EMTCT) of HIV and congenital syphilis (CS) as public health problems. These goals are central to the Global Plan towards the Elimination of New HIV Infections Among Children and Keeping Their Mothers Alive and the Joint United Nations Programme on HIV/AIDS (UNAIDS) and the World Health Organization (WHO) global goals to achieve “zero new HIV infections, zero discrimination and zero AIDS-related deaths” by 2030. These goals are also highlighted in the draft WHO health sector strategy on HIV for 2016-2021<sup>10</sup>. There are now clear global, regional and country targets to attain these ambitious goals and an emerging “Validation of Elimination” process.

The countries of Europe and central Asia are unique in a number of important ways, including: high levels of antenatal care, strong laboratory infrastructure, high levels of HIV and syphilis testing, the highest level of all regions of HIV ARV coverage for pregnant women, and strong programme commitment. This has already led to several countries in the region being close to meeting the validation criteria.

However, there are also important barriers and challenges in the region, including: a high proportion of infections among pregnant women in key populations and vulnerable groups (e.g. drug users and partners of drug users, sex workers, migrants), as well as stigma and human rights issues. In addition, there continues to be challenges of commodity stock-outs and high prices and the transition in many countries in the region from Global Fund to state financing. Two countries in the region, the Russian Federation and Ukraine, have the highest numbers of pregnant women with HIV and reported MTCT cases. While progress in both these countries has been impressive, success in achieving elimination in the Region rests in

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<sup>10</sup> UNAIDS. Ambitious treatment targets: Writing the final chapter of the AIDS epidemic. Geneva; 2014. Available online: [http://www.unaids.org/en/media/unaids/contentassets/documents/unaids\\_publication/2014/JC2670\\_UNAIDS\\_Treatment\\_Targets\\_en.pdf](http://www.unaids.org/en/media/unaids/contentassets/documents/unaids_publication/2014/JC2670_UNAIDS_Treatment_Targets_en.pdf)

large measure on the ongoing commitment and success of the programmes in these two countries.

To accelerate progress and endorse the validation framework for EMTCT in Europe and central Asia, the WHO, UNICEF, UNAIDS, UNFPA Regional Offices, along with key partners convened a technical consultation on EMTCT of HIV and CS in the WHO European Region (Astana, Kazakhstan 21-23 April 2015). The consultation reviewed the achievements, barriers and next steps needed for the region and the individual countries; endorsed the regional targets for EMTCT and the elimination validation tools for data monitoring, laboratory and human rights; and committed to working together to share best practices and achieve EMTCT in the region. In line with global targets, key regional targets include achieving:

- low levels of new paediatric HIV and congenital syphilis cases (<50 new cases/100,000 live births);
- low levels of MTCT of HIV (<2% for non-breastfeeding and <5% for breastfeeding women); and
- high levels (>95%) of ANC coverage, HIV and syphilis testing and treatment of pregnant women

The consultation gave a stimulus to validation activities in the region. A number of countries have initiated pre-validation or validation activities and many countries are preparing for validation.

WHO, in collaboration with UNICEF, UNAIDS, and UNFPA, organizes this regional technical consultation to support elimination validation processes and development of related capacities in the WHO European Region

### **Objectives**

1. To review progress towards elimination validation in countries of Europe and central Asia.
2. .
3. To present the validation experience accumulated so far in the Region and discuss challenges and ways of problem solving.
4. To get feedback on validation tools and input for adjustment if relevant.
5. To discuss role and potential of validation processes on quality of services, data, systems strengthening, collaboration and accountability.
6. To develop an EMTCT implementation plan and timelines, to promote coordination and accountability.

### **Expected results/outcomes**

1. A country review of progress on the elimination of mother-to-child transmission of HIV and congenital syphilis.
2. Systematic feedback from stakeholders collated to inform validation tools and processes.
3. An implementation plan to validate elimination of mother to child transmission in countries of Europe and central Asia.

## Participants

- National counterparts, including managers of the national HIV/AIDS programmes, national STI programmes, national experts in PMTCT and civil society organizations involved in provision of services for PLHIV from 15 Eastern European and Central Asian countries (Armenia, Azerbaijan, Belarus, Estonia, Georgia, Kazakhstan, Kyrgyzstan, Latvia, Lithuania, Moldova, Russian Federation, Turkmenistan, Tajikistan, Ukraine, and Uzbekistan) and selected countries of central and western Europe.
- International experts in epidemiology, HIV (PMTCT), STI, and public health.
- Representatives of the WHO Headquarters, WHO Regional Office for Europe, WHO Country Offices, i.e. HIV/AIDS programme country coordinators from Central and Eastern Europe and central Asia
- Major partner organizations, including UNAIDS, UNICEF, UNFPA, WHO Collaborating Centres, The Global Fund, CDC, ECDC, civil society organizations, professional societies, PLHIV.

Estimated number of participants: up to 95

## Venue and dates

Astana, Kazakhstan, 17- 18 December

## Language

English and Russian, with simultaneous translation

## Background documents

- Elimination of mother-to-child transmission (EMTCT) of HIV and syphilis. Global guidance on criteria and processes for validation<sup>11</sup>
- Monitoring and evaluation framework for antiretroviral treatment for pregnant and breastfeeding women living with HIV and their infants<sup>12</sup>
- The global elimination of congenital syphilis: rationale and strategy for action<sup>13</sup>
- Global tools to validate elimination of MTCT of HIV and Congenital Syphilis

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<sup>11</sup>Elimination of mother-to-child transmission (EMTCT) of HIV and syphilis. Global guidance on criteria and processes for validation <http://www.who.int/hiv/pub/emtct-validation-guidance/en/>

<sup>12</sup> Monitoring and evaluation framework for antiretroviral treatment for pregnant and breastfeeding women living with HIV and their infants <http://www.who.int/hiv/mtct/iatt-me-framework/en/>

<sup>13</sup> The global elimination of congenital syphilis: rationale and strategy for action <http://www.who.int/reproductivehealth/publications/rtis/9789241595858/en/>

## Annex 3: Programme for the Regional Consultation



### WHO Regional technical consultation on monitoring progress and supporting capacity building to validate dual elimination of mother-to-child transmission of HIV and congenital syphilis

Astana, 17 – 18 December 2015

Kazzhol Hotel

<b>Thursday, 17 December 2015</b>		
<b>08:30 – 09:00</b>	<b>Registration</b>	
<b>Opening Session</b>		
<b>Co-Chairs: Lali Khotenashvili (WHO), Marina Semenchenko (UNAIDS RST)</b>		
<b>09:00 -09:15</b>	<b>Welcome remarks</b>	<b>Shaffiq Essejee, WHO HQ</b>  <b>Deborah von Zinkernagel, UNAIDS HQ</b>  <b>Alexandr Kossukhin, UNFPA</b> <b>Tatjana Tarasova , UNICEF</b>

09:15-09:40	<b>Introduction to the meeting and setting the scene:</b> <ul style="list-style-type: none"> <li>• Briefing on background and expected outcomes</li> <li>• Short overview of the progress towards elimination of MTCT of HIV and Congenital Syphilis in the WHO European Region.</li> </ul>	Lali Khotenashvili, WHO
<b>Plenary Session 1</b> <b>Regional perspectives on</b> <b>processes and tools for the validation of the elimination of HIV MTCT and Congenital Syphilis</b> <b>Co-chairs: Shaffiq Essejee (WHO), Oleg Pankratov (Belarus)</b>		
09:40-11:00	<b>Global landscape of PMTCT of HIV and Syphilis, progress towards elimination. Reminding elimination validation processes and criteria (20 min)</b>  <b>Discussing validation tools:</b> <ul style="list-style-type: none"> <li>• <b>Data quality tool:</b> <ul style="list-style-type: none"> <li>✓ <i>overview (20 min)</i></li> </ul> </li> <li>✓ <b>Questions and Discussion(30 min)</b> <ul style="list-style-type: none"> <li>✓ <i>What challenges countries might face when assessed by this tool (or when using this tool)</i></li> </ul> </li> </ul>	Shaffiq Essejee , WHO HQ  Ulrich Laukamm-Josten , WHO consultant Yuri Kobyshcha, WHO consultant
11:00-11:30	<b>Coffee break</b>	

## Plenary Session 1 (cont'd)

<b>11:30-12:30</b>	<ul style="list-style-type: none"> <li>• <b>Laboratory assessment tool:</b></li> <li>✓ <i>Overview (20 min)</i></li>   <li style="text-align: center;"><b>Questions and Discussion (40 min)</b></li>   <li>✓ <i>What challenges countries might face when assessed by this tool (or when using this tool)</i></li> </ul>	<b>Magnus Unemo, WHO CC</b>
<b>12:30- 13:30</b>	<p><b>Human rights and community engagement tool</b></p> <ul style="list-style-type: none"> <li>✓ <i>Overview (20 min)</i></li>   <li style="text-align: center;"><b>Questions &amp; Discussion (40 min)</b></li>   <li>✓ <i>Patients' rights and gender equality</i></li>   <li>✓ <i>Human rights and prevention of Mother to child transmission of HIV and Congenital Syphilis – civil society perspectives on barriers and facilitators</i></li>   <li>✓ <i>What challenges countries might face when assessed by this tool (or when using this tool)</i></li> </ul>	<p><b>Marina Semenchenko, UNAIDS RST</b></p> <p><b>Hovhannes Madoyan, Real World, Real People, Armenia</b></p> <p><b>Helena Bilokon, Central Asian women network "Amal"</b></p>
<b>13:30 -14:30</b>	<b>Lunch break</b>	
<p><b>Plenary Session 2</b></p> <p><b>Validation experience accumulated in the region</b></p> <p><b>Co-facilitators: Tonka Varleva (Bulgaria), Mircea Betiu (Moldova)</b></p>		

14:30 -16:00	<p><b>Sharing validation experience accumulated in the region: pre-validation missions to Bulgaria and Belarus, country report preparation in Moldova</b></p> <p><b>Panel discussion. Discussion points:</b></p> <ul style="list-style-type: none"> <li>• <i>What are the major positive outcome and impact of validation processes for country</i></li> <li>• <i>Is there a need to simplify validation processes, if YES , how?</i></li> <li>• <i>Major challenges when preparing country validation report</i></li> </ul> <p style="text-align: center;"><b>Questions &amp; General Discussion</b></p> <ul style="list-style-type: none"> <li>• <i>Is in-country mission necessary for validation</i></li> </ul>	<p><b>Introductory notes: Lali Khotenashvili ,WHO</b></p> <p><b>Panelists:</b></p> <ul style="list-style-type: none"> <li>• <b>Tonka Varleva</b>, Bulgaria</li> <li>• <b>Elena Petrova</b>, Bulgaria</li> <li>• <b>Dmitry Paduta</b> , Belarus</li> <li>• <b>Oleg Pankratov</b> Belarus</li> <li>• <b>Mircea Betiu</b>, Moldova</li> </ul>
16:00-16: 30	<b>Coffee break</b>	
<p><b>Session 3</b>  <b>Working Groups’ Session</b>  <b>Introduction to the Working Groups’ Session: S. Ciobanu (WHO Europe)</b></p>		
16:30-18:00	<p><b>Issues to discuss at the Working group session</b></p> <ol style="list-style-type: none"> <li>1. <i>Each group to suggest 3-5 key actions that should be taken by country to achieve elimination of MTCT of HIV and Congenital Syphilis</i></li> <li>2. <i>Each country to specify: Is country ready to validate elimination of MTCT of HIV and /or Congenital Syphilis:</i> <ul style="list-style-type: none"> <li>✓ <i>If “Yes” – when?</i></li> <li>✓ <i>If “NO”- why not and what assistance from WHO, UNAIDS and other agencies is required to progress towards validation</i></li> </ul> </li> </ol>	<p><b>Participants will split into 5 working groups.</b></p> <p><b>Facilitators:</b> WHO, UNICEF, UNFPA NPOs, WHO Consultants</p>



<b>Friday, 18 December</b>		
<b>Plenary Session 4</b>		
<b>Presenting Working Groups' session outcomes</b>		
<b>Co-chairs: Umutkan Chikmorova (Kyrgyzstan), Margarita Rakhmatulina (Russian Federation)</b>		
<b>09:00 – 10:30</b>	<b>Presentation of the outcomes of Working Groups' session</b>  <b>Questions &amp; Discussion</b>	<b>All working groups</b>
<b>10:30 – 11:00</b>	<b>Coffee break</b>	
<b>Plenary Session 5</b>		
<b>Improving reporting of the elimination of MTCT of HIV and Congenital Syphilis</b>		
<b>Co-facilitators: Tatiana Tarasova (UNICEF), Alexandr Kossukhin (UNFPA)</b>		

11:00-12:30	<p><b>Indicators to validate elimination of MTCT of HIV and Congenital Syphilis: Introductory notes: (10 min)</b></p> <ul style="list-style-type: none"> <li>• <b>Is it challenging for countries to report data on:</b> <ul style="list-style-type: none"> <li>✓ antenatal care coverage</li> <li>✓ HIV and Syphilis testing coverage of pregnant women</li> <li>✓ treatment coverage of HIV pos and Syphilis pos pregnant women</li> </ul> </li> </ul> <p><b>Questions &amp; Answers (15 min)</b></p>	<p>Shaffiq Essejee , WHO HQ</p> <ul style="list-style-type: none"> <li>• <b>Kristi Ruutel</b>, Estonia</li> </ul>
	<p><b>Panel discussion: (50 min)</b></p> <ol style="list-style-type: none"> <li>1. <b>Could country lacking data on HIV and Syphilis testing and treatment coverage for pregnant women still prove the elimination and if “Yes” – how?</b></li> <li>2. <b>Could validation be done via desk review without country missions, If YES, what could be criteria</b></li> </ol>	<p><b>Panelists:</b></p> <ul style="list-style-type: none"> <li>• <b>Susan Cowan</b>, Denmark</li> <li>• <b>Anna Marzec-Boguslawska</b>, Poland</li> <li>• <b>Jan Mikas</b>, Slovakia</li> <li>• <b>Tatjana Nemeth-Blazic</b>, Croatia</li> <li>• <b>Daniela Simic</b>, Serbia</li> </ul>
12:30 – 13:30	Lunch break	
<p><b>Plenary Session 6</b>  <b>Improving Laboratory diagnosis of Syphilis and HIV</b>  <b>Co-chairs: Gvantsa Gasviani (Georgia), Ludmila Derevyanko (Ukraine)</b></p>		
13:30 – 15:00	<p><b>Major challenges re HIV and Syphilis Lab diagnosis observed. Common issues in lab diagnosis of CS in Eastern Europe, differences with other settings and the reasons for a pragmatic use of the Lab assessment tool (20 min)</b></p> <p><b>Sharing experience: (each intervention 7 min)</b></p>	<p>Magnus Unemo, WHO CC, Sweden</p>

	<ul style="list-style-type: none"> <li>• Case definition of Congenital Syphilis – perspectives from Moldova</li> <li>• Laboratory diagnosis of Congenital Syphilis in: <ul style="list-style-type: none"> <li>✓ Bulgaria</li> <li>✓ Russian Federation</li> <li>✓ Belarus</li> </ul> </li> </ul> <p><b>Questions &amp; Discussion (40 min)</b></p>	<p><b>Mircea Betiu</b>, Moldova  <b>Elena Petrova</b>, Bulgaria  <b>Margarita Rakhmatulina</b>, Russian Federation  <b>Oleg Pankratov</b>, Belarus</p>
<b>15:00 – 15:30</b>	<b>Coffee break</b>	
	<p><b>Plenary Session 7</b></p> <p><b>Way forwards</b></p> <p><b>Co-chairs: Lali Khotenashvili (WHO), Marina Semenchenko (UNAIDS)</b></p>	
<b>15:30 – 17:00</b>	<p><b>Discussion on way forward:</b></p> <ul style="list-style-type: none"> <li>• <b>Drafting regional validation plan: list of countries considering validation and defining preliminary timeframe</b></li> <li>• <b>Suggesting how to simplify validation procedures</b></li> <li>• <b>Defining major actions for acceleration of elimination of HIV MTCT and Congenital Syphilis</b></li> </ul>	<b>Panelists TBC</b>
<b>17:00 - 17:30</b>	<b>Closure of the of the meeting</b>	

## **Annex 4: List of participants for the Regional Consultation**

### **Final List of Participants**

#### **Armenia**

Vardan Arzakanyan  
Epidemiologist  
National AIDS Centre

Samvel Grigoryan  
Director of the National AIDS Center  
Yerevan

Trdat Grygoryan  
M&E Officer  
National AIDS Centre  
Yerevan

#### **Azerbaijan**

Tarana Rajabli  
Deputy Director  
Republic Perinatal Center  
Baku

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