



Mission to assess readiness for validation of the elimination of
mother to child transmission of HIV

Latvia, 23-27 May 2016

A report produced

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GLOSSARY

ANC	Antenatal care
CSO	Civil society organizations
EMTCT	Elimination of mother-to-child transmission
EID	Early infant diagnosis
GP	General practitioner
FSW	Female sex workers
HDCD	Hospital for Dermatology and Communicable Diseases
HIV	Human immunodeficiency virus
HPP	HIV prevention points
M & E	Monitoring and evaluation
MSM	Men who have sex with men
MTCT	Mother-to-child transmission
NGOs	Non-governmental organizations
PLHIV	People living with HIV
PMTCT	Prevention of mother-to-child transmission
PWID	People who inject drugs
RDT	Rapid diagnostic test
SOP	Standard operating procedure
STI	Sexually transmitted infections
TGF	The Global Fund to Fight AIDS, Tuberculosis and Malaria
UNAIDS	Joint United Nations Programme on HIV/AIDS
WHO	World Health Organization

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INTRODUCTION AND BACKGROUND

The global community is 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 EMTCT Global Plan and to the UNAIDS 2020 treatment targets and 2030 ending AIDS targets and are highlighted in the WHO health sector strategy on HIV for 2016-2021. There are now clear targets to attain these ambitious goals and an emerging “Validation of Elimination” process.

Responding to country requests, the WHO in collaboration with UNICEF, UNAIDS and UNFPA published a Global guidance offering internationally standardized processes and criteria to validate EMTCT of HIV and congenital syphilis. These processes and criteria need to apply across widely varying epidemiologic and programmatic contexts. A harmonized approach to eliminating mother-to-child transmission (MTCT) of HIV and congenital syphilis is encouraged. However, depending on the progress of national EMTCT efforts, countries may choose to validate the elimination of MTCT of HIV, congenital syphilis, or both.

In September 2011, the WHO European Member States approved the European HIV/AIDS Action Plan 2012-2015 by Resolution 112571 endorsed at the Regional Committee session in Baku on 15 September 2011. The resolution commits Member States to aim for EMTCT of HIV by reducing the rate of MTCT of HIV to $\leq 2\%$ in non-breastfeeding population and $\leq 5\%$ in breastfeeding population. The participants of two regional technical consultations (April 2015 and December 2015, Astana, Kazakhstan) from 18 (about 70 participants) and 27 (about 90 participants) selected countries of central, western and eastern Europe and central Asia respectively representing National HIV/AIDS, STI, PMTCT programs, national and international civil society organizations, people living with HIV and affected communities, international experts, the UN family, major partners including TGF, US CDC, the WHO HQ, Regional and country offices and the WHO Collaborating Centres discussed and reached consensus on the decision that regional goals, targets, criteria and processes for the elimination of MTCT of HIV and CS in the WHO European Region follow Global ones suggested by the Global guidance on criteria and processes for validation of elimination of MTCT of HIV and congenital syphilis¹ except for HIV treatment coverage for pregnant women which in the WHO European region is of $\geq 95\%$ (while Global one is of $\geq 90\%$). This regional goals and targets for validation of elimination of MTCT of HIV and congenital syphilis are as follows:

- a case rate of new paediatric HIV infections due to MTCT ≤ 50 cases per 100,000 live births
- a case rate of congenital syphilis of ≤ 50 cases per 100,000 live births

¹ Global guidance on criteria and processes for validation Elimination of mother-to-child transmission (EMTCT) of HIV and syphilis <http://www.who.int/reproductivehealth/publications/rtis/9789241505888/en/>

- MTCT rate of HIV of <5% in breastfeeding populations **OR** MTCT rate of HIV of <2% in non-breastfeeding populations.
- Antenatal care (ANC) coverage (at least one visit) of $\geq 95\%$
- Coverage of HIV and/or syphilis testing of pregnant women of $\geq 95\%$
- Antiretroviral (ARV) coverage of HIV-positive pregnant women of $\geq 95\%$
- Treatment of syphilis-seropositive pregnant women of $\geq 95\%$

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, highest level of all regions of HIV ARV coverage for pregnant women, and strong programme commitment.

The initiative to eliminate mother-to-child transmission of HIV and congenital syphilis focuses on a harmonized approach to improve health outcomes for mothers and children. The rationale for the elimination of MTCT of HIV and congenital syphilis is that dual elimination will help to improve a broad range of maternal and child health (MCH) outcomes, which aim to reduce child mortality and improve maternal health, reduce the spread of HIV and Syphilis. The similarity of the control interventions necessary to prevent transmission of HIV and syphilis in pregnancy adds to the feasibility of such an integrated approach to the elimination of MTCT of both diseases. Indeed, this integrated approach is necessary to improve the efficiency and quality of MCH services and to offer women more comprehensive primary care services. However, activities in any specific country for dual elimination of MTCT of HIV and congenital syphilis are greatly influenced by differences in HIV and syphilis epidemiology and differences in service delivery models and coverage of health services.

The WHO Regional Office for Europe, in partnership with UNAIDS and also UNICEF, UNFPA and other partners including ECDC and civil society, leads the process for the elimination of MTCT of HIV and CS in the WHO European Region and provides secretariat support.

This is the report of a technical support mission to Latvia in response to the request of the MOH of Latvia to assess country readiness for validation of the elimination of mother to child transmission of HIV.

The major goal and objectives of the mission included the review of the progress achieved in Latvia on the elimination of mother to child transmission of HIV, the assessment of the country readiness for elimination validation and, based on the mission findings, preparing recommendations to accelerate progress towards achieving elimination and elimination validation as appropriate. The Scope and purpose of the mission is attached (see Annex 1).

Method

The validation methodology applied in Latvia followed the globally agreed methodology. The following methods and tools were used:

- The WHO Global guidance on criteria and processes for validation of EMTCT of HIV and syphilis and the global tools². The following tools have been applied:

² <http://www.who.int/reproductivehealth/publications/rtis/9789241505888/en/>

1. *Programmes and services assessment tool*: this tool reviews the programmatic components relevant to the elimination of HIV MTCT.

2. *Data verification and impact assessment tool*: this tool assesses the reliability of the data generated by the country to evaluate achievement of the elimination targets, and to ascertain that the elimination validation impact and coverage targets were achieved.

3. *Laboratory data assessment tool*: this tool verifies the existence of an adequate laboratory network to provide the services needed to achieve and maintain a programme for EMTCT of HIV and to ensure that the results generated by the laboratory network are accurate and reliable.

4. *Human rights, gender equality and community engagement tool*: this tool verifies that EMTCT targets have been achieved in a manner consistent with basic human rights and gender equality considerations, and that communities are meaningfully involved in the planning, delivery, monitoring and evaluation of programmes and services. This includes the engagement of civil society organizations (CSOs) as well as networks of women, young people and other people living with HIV.

- Manuals, reports, protocols, data collection forms, standard operating procedures (SOPs), quality assurance and monitoring documents, laboratory results and recordings were reviewed during all visits.
- Interviews with staff working at the visited institutions and organizations, including civil society organizations were conducted³.
- Feed-back session on the last day was held at the MOH, to which all major stakeholders visited during the mission were invited.

In order to comply with the global requirement that EMTCT of HIV must have been achieved in at least one of the lowest-performing sub-national units, the mission along with capital city of Riga (lowest performing sub-national administrative unit in terms of the highest disease burden) visited also Bauska. Bauska region was identified as possible low performing subnational administrative unit in terms of territorial accessibility, service coverage and equity in health service coverage (9061 inhabitant in the city; 24308 inhabitants in the city with agglomeration area)

The mission team

The validation readiness assessment team was jointly composed by the Regional Validation Secretariat - WHO Europe and WHO CO in Latvia, in partnership with UNAIDS (regional and HQ), UNFPA, ECDC and WHO Collaborating Centres. The composition of the validation team was based on the 4 mentioned above thematic areas to be assessed i.e. Programmatic, Data verification and impact assessment, Laboratory data assessment, Human rights, gender equality and community engagement. The team included regional experts as well as staff members of WHO Europe, UNAIDS RST, WHO CC, a civil society representative, a local lawyer (specialized in human rights) and also a clinician, in response to the special request of the MOH of Latvia. Annex 2 provides an overview of the mission team members.

The mission visited sites of 3 levels of health care provision – central, secondary and primary - and met and discussed with respective major stakeholders there. The list of the sites visited by the mission is given in Annex 3.

Implementation

The mission was implemented during the course of 5 working days in May, 2016. The validation team was divided into 3-4 teams (depending on the mission day) focusing on different areas in accordance

³ The full list of participants of the meetings and sites visited could be found in Annex 4 (the Agenda)

with validation tools and aiming at addressing the planned tasks and at using the time in the most efficient way. Details are given in Annex 4, which illustrates the mission Agenda.

On the first day the full team had a very informative meeting at the MOH, with the national group of experts (the Agenda) who had prepared the country report and also other major national stakeholders, including the leading MOH official in charge of Public health programs and coordination. This meeting provided the opportunity for the validation team to obtain comprehensive information regarding the national context and to ask specific questions or clarifications on the information presented in the country report. Day 2-4 were dedicated to the application of the tools in the various institutions in the capital city as well as in Bauska, which included individual and group discussions, individual and group interviews, observation and review of documents. The data verification component also included review of databases, trace and verification, cross-checking and spot-checking. The entire team was meeting at the end of every working day to share major findings and discuss the main issues of the day. At the end of 4th day, the entire team conducted a joint analysis of the collected information and prepared the presentation and discussion points to be presented and discussed with major stakeholders visited and met during the mission at the debriefing session at the MOH that took place on the last day of the mission.

Day 5 was dedicated to the MOH debriefing session for feedback and discussion with major stakeholders, including high level MOH officials, program-level stakeholders and civil society representatives met during the mission, on the mission findings and recommendations. The mission members highlighted good progress achieved in the country on the prevention of mother to child transmission of HIV, addressed the remaining challenges on the way towards elimination of HIV MTCT in the country and provided recommendations on how to address such challenges in a comprehensive manner and the best possible way, in order to accelerate progress towards EMTCT of HIV and elimination validation in Latvia. After the debriefing session at the MOH, the mission members had a working meeting to discuss the feedback received at the debriefing sessions and the subsequent steps.

RESULTS

Short overview of the health system and the programmatic components related to the MTCT of HIV

Health care services in Latvia are provided by the national, municipal and private health care institutions, both inpatient and outpatient. Health care services financed by the State budget can be received only in those health care institutions which have signed an agreement with the National Health Service.⁴ The process of transformation that took place in last 20 years led to:

- the development of a more centralized system, with state functions consolidated in fewer institutions
- the establishment of one central institution for purchasing health care services (the NHS)
- a health care delivery system with a strong focus on primary care and substantially fewer hospitals

The structure of health care system is given in Table 1.

⁴ Cabinet Regulation No. 1529 (adopted on 17 December, 2013) "The procedures for organising and financing health care"

Table 1 Structure of the health care system

Emergency medical care	
Primary health care	<p>outpatient institutions, outpatient departments of the hospitals or at the patient's residence GP practise (including paediatrician and internist)</p> <ul style="list-style-type: none"> • GP • physician's assistant • certified nurse • midwife • dentist, dentist's assistant; dentistry nurse and hygienist <p>Patient can receive primary health care services by visiting a GP (family doctor), dentist or hygienist on personal initiative or, as part of preventive examination program, upon the request of a GP (family doctor)</p> <p>Home care: Medical care shall be provided at home if patient needs a regular (permanent) outpatient treatment but if due to medical reasons is unable to attend health care institution to receive outpatient care</p>
Secondary health care (inpatient and outpatient)	<p>Outpatient and inpatient care (emergency, acute or planned diagnostics, treatment and rehabilitation) provided by:</p> <ul style="list-style-type: none"> • Multiprofile hospitals: <ul style="list-style-type: none"> on national level – 3 (University Hospitals) on regional level – 7 on local level – 11 • Care Hospitals – 9 • Specialized Hospitals - 12
Tertiary healthcare (inpatient and outpatient)	<p>Tertiary health care is highly specialized one, based on high level novel technologies for complicated health conditions being provided by:</p> <ul style="list-style-type: none"> • Multiprofile hospitals: <ul style="list-style-type: none"> on national level – 3 (University Hospitals) on regional level – 7 on local level – 11 • Care Hospitals – 9 • Specialized Hospitals - 12

The Cabinet Regulation stipulates the measures for the prevention and control of HIV and treatment of people living with HIV (PLHIV), medical and social rehabilitation, the information and education of population on HIV/AIDS issues.⁵

The CDPC) is supervised by the Ministry of Health. CDPC Latvia is the national centre for communicable diseases, including HIV/AIDS surveillance, non-communicable diseases surveillance, M&E, state health statistic, responsible for methodological support, management, coordination and

⁵ Cabinet Regulation No. 628 (adopted 4 November 2003) "Organisational Procedures for Restriction of the Spread of Human Immunodeficiency Virus Infection (HIV) and AIDS and the Treatment of HIV-Infected Persons and AIDS Patients"

supervision at the national level to ensure epidemiological analysis, trends monitoring and to feed in the planning of preventive measures and the evaluation of their effectiveness. According to the Cabinet of Minister's Decree of 3rd April 2012, No 241 the Centre's mission is to implement public health policy in the field of epidemiological safety and disease prevention.

The RAKUS/LIC is the leading national centre providing HIV diagnosis and treatment, outpatient and inpatient services for PLHIV, including treatment for pregnant women and paediatric treatment and care and also prevention and care for HIV exposed newborns. The centre manages the work of the Reference laboratory for all infectious diseases, including the HIV Reference laboratory. The centre gives methodological guidance on the management of PLHIV, post-exposure prophylaxis, advisory help to health care staff and also consultations to populations as needed. Along with that, the RAKUS/LIC provides 24/7 helpline for PLHIV, their relatives and the general population.

Antenatal care (ANC) coverage gradually increased in the country from 92.1% in 2011 to 94.7% in 2015. This proportion reflects 1st ANC visits made before the 12th gestation week, as in Latvia the first antenatal visit should take place before the 12th gestation week. Antenatal care is provided by a multi-disciplinary team including a gynaecologist, a midwife and a GP. Communication between different services involved in antenatal and post-natal care is considered to be good.

The available information suggest that current national regulations offer free services for pregnant women which include not only medical services directly related to the pregnancy, but also those that are not directly related to the pregnancy but pregnant women still might require. The respective details are given below:

- The Medical Treatment Law stipulates that not only Latvian citizens, but also those listed below, have the right to receive **free of charge care for pregnant women and birth assistance** covered the State basic budget and from the funds of the recipient of services, in accordance with the procedures stipulated by the Cabinet:
 - citizens of EU Member States and those of European Economic Area states and Swiss Confederation who reside in Latvia in relation to employment or as self-employed persons, as well as their family members thereof;
 - third-country nationals who have a permanent residence permit in Latvia;
 - refugees and persons who have been granted alternative status;
 - persons detained, arrested and sentenced with deprivation of liberty;
 - spouses of Latvian citizens and Latvian non-citizens who have a temporary residence permit in Latvia
 - asylum seekers, who can receive free emergency medical care, obstetric care, dental care in the acute case, primary health care, psychiatric help and medical assistance for minors (up to 18 years), as well as services in the cases mentioned in the Epidemiological Safety Law and necessary medications for tuberculosis treatment.⁶
- Health care services paid by the State budget are defined by the Cabinet regulation. The health care financing model consists of State compensated treatment (1), Self-paid services by patients (2), Private voluntary insurance (3). Health care is provided by both state and commercial providers. Patients have to cover a "patient's fee" in order to receive health care services. **It is**

⁶ Ibid.

important to emphasize that pregnant women, patients with infectious diseases and children up to 18 years belong to the group exempted by the patient's fee.⁷

It is also important to emphasize that, despite referral from GP is required in order to access the specialists, the referral **is not required to access infectologists (including in case of HIV infection), dentists, oncologists, gynaecologists, psychiatrists, TB specialists, endocrinologists, dermatologists/venereologists, narcologists, ophthalmologists, paediatricians, paediatric surgeons and in case of emergency medical assistance.**⁸

GPs (Family doctors) consultation hours are at least available for 20–25 hours a week depending on the number of patients registered at the GP practice patient list. But mostly GPs consult longer. GP practice has to be open 40 hours per week. GP practise has to have appointment hours - on mornings and evenings, also there are Pre-booked appointments – within 5 working days, and Acute appointments with accessibility on the same day. The health care planning contributes towards strengthening of primary health care and also to increase the role of PCH in the prevention, diagnostics and treatment.

At other times, the patient can receive care from out-of-hours family doctors, 24-hour hospital admission and emergency wards, urgent care wards in health centres, and emergency care teams. However, out-of-hours family doctors are usually available only in urban areas, which might limit access to health care services for people in rural areas; **this issue should be taken into consideration and addressed by the national health care system.**

HIV testing and counselling services are available across the country.⁹

The first case of mother to child transmission (MTCT) of HIV was registered in Latvia in 1999. In total, 66 cases of MTCT were registered between 1999 and 2015. An increase in the number of MTCT cases was reported starting from 2011 with a peak in 2013 (10 cases were reported that year) and a subsequent decrease since then – see Table 2 for more details.

Table 2. New HIV diagnosis in people infected through mother to child transmission¹⁰

Year/transmission	2011	2012	2013	2014	2015
Number of new HIV diagnoses due to MTCT	2	7	10	4	3

Leading national stakeholders believe that the main causes of HIV MTCT in Latvia include the following major issues¹¹:

- Low PMTCT adherence of pregnant women attending ANC
- Late or no ANC attendance by some groups of pregnant women, especially SW and PWID
- Lack of trust in usefulness of PMTCT to prevent MTCT in some population groups
- False feeling of being healthy
- False beliefs that ARVs are harmful for the baby

⁷ Cabinet Regulation No. 1529 (adopted on 17 December, 2013) "The procedures for organising and financing health care"

⁸ Ibid.

⁹ Cabinet Regulation No. 628 (adopted 4 November 2003) "Organisational Procedures for Restriction of the Spread of Human Immunodeficiency Virus Infection (HIV) and AIDS and the Treatment of HIV-Infected Persons and AIDS Patients"

¹⁰ <http://www.spkc.gov.lv/hiv-aids/>

¹¹ ECDC, EMCDDA Mission Report „HIV and hepatitis B and C in Latvia”, 2-4 September 2014”

- Conflicting religious beliefs¹²

Early infant diagnosis (EID) is available in Latvia. The proportion of infants born to HIV-positive women receiving a virological test for HIV within 2 months of birth increased from 68% in 2012 to 82% in 2014. Leading national stakeholders believe that these figures do not reflect the true picture. In reality this proportion might be much higher because of following major issues:

- A number of pregnant woman may choose to deliver abroad (the exact figure is unknown) and infants might get tested there but these cases might not get included in national reporting system.
- It might be the case that RAKUS/LIC does not receive a full feedback report if HIV-positive pregnant women give birth outside Riga biggest maternity hospitals/units.¹³

The National HIV Program is encouraged to put efforts in ensuring that the proportion of infants getting EID is reported at the National Program.

It should be ensured that maternities inform the RAKUS/LIC in a timely manner about babies born to HIV positive mothers, thus preventing disconnection and supporting continuity of testing, treatment and care as needed.

ARV drugs for the prevention of mother-to-child transmission are usually stocked at the RAKUS/LIC - the institution that does procurement of ARV drugs. Other settings/hospitals would need to organise a medical consultation at the RAKUS/LIC and then collect the drugs from there¹⁴. Medications, upon request of the Riga Maternity Hospital (*Rīgas Dzemdību nams*) or other maternity hospital/units, are collected from RAKUS/LIC.

A cabinet regulation stipulates procedures for the reimbursement of expenditures of medical products and devices for out-patient care: Similarly to mothers in the postnatal period, children and PLHIV are exempt from payment, thus ARV drugs for HIV treatment are fully covered by the State budget.¹⁵ However, liquid form of Zidovudine and Nevirapine (NVP) have not been included in the list of reimbursable drugs since in accordance with Cabinet Regulation No. 899 (Adopted 31 October 2006) "Procedures for the Reimbursement of Expenditures for the Acquisition of Medicinal Products and Medicinal Devices Intended for Out-patient Medical Treatment" such request shall be submitted to NHS by the owner of the marketing authorization. Nevertheless, in Latvia liquid form of Zidovudine is provided and supplied by the RAKUS/LIC.¹⁶ However, NVP is not available in liquid form, appropriate for newborns. In accordance with available information, in Riga Maternity Hospital Zidovudine monotherapy is used in newborns since NVP syrup is not available¹⁷. ART for children is started already in the hospital and treatment sufficient drugs sufficient for 4-6 weeks are given to mothers at the time of dismissal. Maternity units place orders; medication is dispensed in the RAKUS/LIC pharmacy shop.

At the same time, according to national "Guidelines on antiretroviral therapy of HIV/AIDS infection" (prepared by NHS and RAKUS/LIC specialists) Zidovudine (AZT) and NVP are recommended for PMTCT.¹⁸ Thus national guidelines follow WHO recommendations but national practice cannot follow

¹² ECDC, EMCDDA Mission Report „HIV and hepatitis B and C in Latvia”, 2-4 September 2014”

¹³ CDC Latvia data

¹⁴ ECDC, EMCDDA Mission Report „HIV and hepatitis B and C in Latvia”, 2-4 September 2014

¹⁵ Cabinet Regulation No. 899 (adopted 31 October 2006) Procedures for the Reimbursement of Expenditures for the Acquisition of Medicinal Products and Medicinal Devices Intended for Out-patient Medical Treatment

¹⁶ NHS information

¹⁷ Riga Maternity Hospital information

¹⁸ NHS data

national guidelines because of unavailability of the necessary drug (NVP syrup) in the country. **It is strongly recommended to ensure the availability of NVP syrup so that the treatment can adhere to national guidelines which follow the WHO recommendations.**

Available data suggest that, starting from 2016, by Cabinet decision, additional financing was allocated for treatment of HIV enabling the MOH to initiate ART in PLHIV not at CD4 count 200 cells/mm³, as it was the case in the country up to 2015, but at CD4 count 350 cells/mm³. While it definitely is an important progress moving from CD4 count 200 cells/mm³ to CD4 count 350 cells/mm³ for the initiation of ART in PLHIV, **the WHO recommends that ART is initiated in all adults living with HIV, regardless of WHO clinical stage and at any CD4 cell count. As a priority, ART should be initiated in all adults with severe or advanced HIV clinical disease (WHO clinical stage 3 or 4) and adults with CD4 count ≤350 cells/mm³¹⁹.**

Data also suggest that country did not move to lifelong treatment for HIV positive pregnant women. Available data (RAKUS/LIC data 2015) on the percentage of HIV positive pregnant women who receive ARV drugs to reduce MTCT, disaggregated by ART regimen, show that in 2015 out of 70 registered HIV positive pregnant women, 20 received ART for about 4 weeks only or even less, due to the late first visit (at 30-35th week of gestation) to the infectologist. 21 pregnant women showed poor treatment compliance, especially those who injected drugs. Out of 62 HIV positive pregnant women who delivered, ARV prophylaxis for the prevention of MTCT was provided to 46 infants only, and only for the first 4 weeks instead of 6 weeks, as it is recommended by the national guidelines that follow WHO recommendations. **It is recommended to consider initiating ART in all pregnant and breastfeeding women living with HIV, regardless of WHO clinical stage and at any CD4 cell count and continuing ART lifelong.²⁰ It is also recommended to follow latest WHO recommendations on infant prophylaxis²¹, namely:**

- Infants born to mothers with HIV who are at high risk of acquiring HIV should receive dual prophylaxis with AZT (twice daily) and NVP (once daily) for the first 6 weeks of life, whether they are breastfed or formula fed.
- Breastfed infants who are at high risk of acquiring HIV, including those first identified as exposed to HIV during the postpartum period, should continue infant prophylaxis for an additional 6 weeks (total of 12 weeks of infant prophylaxis) using either AZT (twice daily) and NVP (once daily) or NVP
- Infants of mothers who are receiving ART and are breastfeeding should receive 6 weeks of infant prophylaxis with daily NVP. If infants are receiving replacement feeding, they should be given 4–6 weeks of infant prophylaxis with daily NVP (or twice-daily AZT).

It is recommended to consider the following with regard to infant feeding²²:

- National or subnational health authorities should decide whether health services will principally counsel and support mothers known to be HIV infected to either breastfeed and receive ARV²³ interventions or avoid all breastfeeding.

¹⁹ Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection Recommendations for a public health approach - Second edition 2016 <http://www.who.int/hiv/pub/arv/arv-2016/en/>

²⁰ Ibid

²¹ Ibid

²² Ibid

²³ All women living with HIV are eligible for initiation of ART regardless of CD4 count

- In settings where national authorities have decided that maternal and child health services will principally promote and support breastfeeding and antiretroviral interventions as the strategy that will most likely give infants born to mothers known to be HIV infected the greatest chance of HIV-free survival, mothers known to be infected with HIV should exclusively breastfeed their infants for the first 6 months of life, introducing appropriate complementary foods thereafter, and continue breastfeeding for the first 12 months of life²⁴ Breastfeeding should then stop only once a nutritionally adequate and safe diet without breast-milk can be provided.

There are also some concerns about some issues listed below:

- Medical services for HIV-positive pregnant women are highly centralized, excluding the involvement of the local Obstetrics & gynaecology in service provision
- Some health care providers at primary level show
 - low awareness about the scale of HIV problems and some reluctance to deal with HIV positive patients
 - stigma towards HIV patients
 - low motivation to carry out quality post-test HIV counselling
- No information about final HIV status of newborns is available for responsible maternity hospital staff
- No separate detailed HIV patients database is kept at the RAKUS/LIC
- The HIV Helpline is ineffective (untrained staff, no answers to calls, no professional advice etc.)

Some other mission findings also suggest that:

- Some vulnerable women might not receive sufficient support during pregnancy. They are reported as being “not adhered” but in many cases it seems they do not receive the necessary information on their condition and ARV treatment.
- Formula feeding for infants born to HIV positive mothers is not provided by the state. A project by the NGO AGIHAS is presently providing free formula, but it will come to end soon.
- After delivery, HIV-positive women might be dismissed with only verbal instructions to take their baby to the GP for registration and to the Infectology Centre, but no concrete referrals, linkages to follow up treatment and care are being provided.
- The mission was not able to verify how many newborn exposed to HIV were taken to the Infectology Centre for the test.
- Some information received by the mission also suggest that about 10% of pregnant women with HIV do not attend ANC – some women experience being refused by health care services, rather than refuse services. They are often drug users and/or SW.
- No counselling services are provided to serodiscordant couples, no prenatal preparation is offered to couples
- Viral Load (VL) tests are frequently not performed due to lack of funds or results are not available at the time of delivery

Staffing related challenges were mentioned by many colleagues met during the mission. It was suggested that some hospitals are understaffed because of the high turnover of medical cadres, as salaries are perceived to be low and young people are not motivated to become doctors.

²⁴ Infants who are HIV infected will benefit from extended breastfeeding and should continue breastfeeding for as long as feasible and desired

It was also suggested that healthcare staff are overloaded by many tasks; they may experience burnout and lose their motivation to support HIV patients.

Confidentiality regarding HIV status looks as a controversial issue: it might represent a barrier to effective services (exposed infants cannot be traced, people who do not attend for confirmatory testing cannot be reminded, etc.); on the other hand, it might become a barrier for the access to services, because PLHIV feel that their privacy is not protected and they fear stigma and discrimination. It is strongly recommended to take into consideration the above mentioned issues regarding confidentiality, to ensure that all forms of HIV testing adhere to the WHO principles of “5Cs” (Consent, Confidentiality, Counselling, Correct test results and Connection (linkage to prevention, treatment and care services)²⁵. Confidentiality: HIV testing services (HTS) must be confidential, meaning that what the HTS provider and the client discuss will not be disclosed to anyone else without the expressed consent of the person being tested. Confidentiality should be respected, but it should not be allowed to reinforce secrecy, stigma or shame. Counsellors should discuss, among other issues, whom the person may wish to inform and how they would like this to be done. Shared confidentiality with a partner or family members – trusted others, and health care providers are highly beneficial²⁶. It should be ensured that these principles are followed in Latvia and keeping confidentiality does not lead to “secrecy”, the staff involved in providing services to PLHIV are informed at the extend needed and PLHIV get all services they need at the scale required.

The collaboration between different settings, primarily ANC, obstetricians/gynaecologists and infectologists is of high importance. The latest developments, including an effective working meeting of 2 leading institutions – the RAKUS/LIC and maternity hospital - and the plan to make final decisions on mechanisms and format of collaboration and coordination look highly important and are strongly encouraged.

The mission was informed by national colleagues about challenges with regard to national HIV treatment guidelines including:

- the additional time that might still be required to get the guidelines endorsed. “New” guidelines were published in 2014 but have not been implemented yet
- the existence of different HIV treatment guidelines in the country, which cause confusion and make it unclear for health care staff what guidelines to follow in the everyday practice.

The existence of National HIV treatment and care guidelines for pregnant women is essential. It should be ensured that there is one set only of National HIV treatment guidelines in the country and that such guidelines are evidence and human rights’ based and follow WHO recommendations. National consensus should be reached on these guidelines among major stakeholders, including professional associations. Guidelines should be endorsed by the MOH. National colleagues might find it useful to consult WHO handbook for guidelines development²⁷ available here http://apps.who.int/iris/bitstream/10665/75146/1/9789241548441_eng.pdf

²⁵ Consolidated guidelines on HIV testing services <http://www.who.int/hiv/pub/guidelines/hiv-testing-services/en/>

²⁶ Ibid

²⁷ WHO handbook for guidelines development http://apps.who.int/iris/bitstream/10665/75146/1/9789241548441_eng.pdf

Overview of HIV/AIDS situation in Latvia

The first HIV case in Latvia was reported in 1987. In total, 6607 cases of HIV infection and 1674 cases of AIDS were registered in the period 1987-2015. Until 1997, new HIV cases were registered rarely but, starting in 1998, the registered number of HIV cases is increased gradually. In the period 2010-2015, the number of new HIV cases in Latvia continued to increase: in 2011 14,4 cases per 100 000 population were reported; in 2013 16,8 and in 2015 19,8 cases respectively. In 2015, 393 new cases of HIV infection and 130 AIDS cases were registered. The highest number of AIDS cases was reached in 2014 with 173 newly registered cases (Tab 3).

Table 3 The number of new HIV/AIDS reported cases and incidence rate in 2011-2015²⁸

Year	2011	2012	2013	2014	2015
Number of new HIV cases	299	339	340	347	393
Incidence per 100 000 population	14.4	16.6	16.8	17.3	19.8
Number of new AIDS cases	114	145	140	173	130
Incidence per 100 000 population	5.5	7.1	6.9	8.6	6.5

HIV cases were registered only among males in the period from 1987 to 1993. The first case of HIV infected female was registered in 1994. Although males are infected with HIV more often than females, since 1994 there has been a gradual increase in the number of HIV-infected females (Table 4).

Table 4 Distribution of HIV cases by gender²⁹

Year/gender	2011	2012	2013	2014	2015
Males	196	218	203	236	264
Females	103	121	137	111	129

Between 2011 and 2015, people aged 30-39 and 18-29 prevailed among the newly reported cases of HIV infection (Table 5)

Table 5. Distribution of new HIV cases by age groups³⁰

Year/age group/cases	2011	2012	2013	2014	2015
0-6	2	7	9	4	3
7-14	0	0	1	0	0
15-17	2	3	0	0	3
18-29	107	99	91	88	111
30-39	118	127	116	128	141
40-49	46	72	83	81	78
50-59	14	20	30	32	43
60+	4	4	10	14	14
Unknown age	6	7	0	0	0
Total	299	339	340	347	393

²⁸ Centre for Disease Prevention and Control of Latvia, State Register of HIV/AIDS cases, 2016.

²⁹ Ibid

³⁰ Ibid

From 1987 to 1993, the transmission mode was only sexual (heterosexual, homosexual). In 1995 the first case of HIV infection associated with injecting drug use was registered and, till 2007 this became the most common mode of HIV transmission. Since 2008 the percentage of cases associated with sexual transmission of HIV (especially heterosexual) increased and the share of HIV infections through drug injection decreased accordingly. In 2015, 150 cases (38%) out of the total new HIV cases were related to heterosexual mode of transmission, while 88 cases (22.4%) occurred because of injecting drug use. There is a very high proportion of new HIV cases (30.3% or 119 individuals in 2015) for which the transmission mode remains unknown (Tab. 6). As it was already mentioned above, the first case of HIV MTCT was registered in Latvia in 1999. Between 1999 and 2015, in total 66 HIV MTCT cases were reregistered – details for 2011-2015 are given in Table 6.

Table 6. Modes of HIV transmission in Latvia in 2011-2015³¹

Year/transmission	2011	2012	2013	2014	2015
Injecting drug use	90	94	77	74	88
Unknown	43	108	101	109	119
Heterosexual	144	112	125	132	150
Homosexual	20	18	27	28	33
Mother-to-child transmission	2	7	10	4	3

HIV infection among pregnant women

Cabinet Regulation No. 611 "Procedures for Ensuring Assistance with Deliveries"³² stipulates that during the first antenatal visit (normally up to 12th week of pregnancy) the HIV test is carried out and should be accompanied by pre- HIV test counselling. HIV testing for a pregnant woman is voluntary and it is provided free of charge in the case women has an individual referral from a GP, doctor-infectologist or gynaecologist. A woman with a reactive HIV rapid test performed at an HIV Prevention Point (HPP) is advised to visit her GP or an infectologist in order to get further laboratory testing. If pregnant women addressing maternity have not been tested during pregnancy or if they have been tested but nevertheless their HIV test results are not available, such pregnant women will be immediately tested in the maternity. In such situations, usually rapid tests are performed.

If pregnant women is tested positive, the specialist will inform and advise them to visit the infectologist at the Riga Eastern Clinical University Hospital (RAKUS/LIC - Infectology Centre), to get recommendations on treatment, care and follow up as appropriate.

According to the data presented by CDPC Latvia and the Medical Birth Register, HIV testing coverage in Latvia in the last 5 years is $\geq 95\%$, thus complying with HIV testing coverage indicators and targets required for MTCT elimination validation³³ (see Table 7). The important issue is to ensure that the number of tests given in the table reflects the number of pregnant women tested and not the number of tests performed.

³¹ Ibid

³² "Procedures for Ensuring Assistance with Deliveries" adopted on 25 July, 2006 <http://likumi.lv/doc.php?id=140695>

³³ Elimination of mother-to-child transmission (EMTCT) of HIV and syphilis Global guidance on criteria and processes for validation <http://www.who.int/reproductivehealth/publications/rtis/9789241505888/en/>

Table 7 Coverage of HIV testing of pregnant women³⁴

Year	The number of deliveries	HIV tests	%
2011	18331	17906	97,7
2012	19401	19039	98,1
2013	20094	19649	97,8
2014	21244	20763	97,7
2015	21496	21127	98,3

In the past five years (2011-2015) 111 new HIV cases in pregnant women have been registered in total. The majority of these women (71 out of 111) were infected through heterosexual HIV transmission, 12 were injecting drug users and, for the remaining 28 women, the mode of HIV transmission remained undetermined/unknown. During the same 5 years (2011-2015) 26 HIV positive children were born to HIV positive mothers in Latvia. The highest number of MTCT cases for these 5 years was in 2012 and 2013 reaching 7 and 10 cases respectively. Since then, the number of MTCT cases shows a decreasing tendency, reaching 3 cases in 2015 – see Table 8. HIV MTCT rate is not available because the year of confirmation and reporting of HIV MTCT cases may differ from the year when the HIV-positive pregnant woman had delivery. Reported case may not refer to the year of birth. As in accordance with national guidelines breastfeeding is not recommended for HIV positive mothers, the HIV MTCT target of <2% for non-breastfeeding population should be reached in Latvia to get elimination validation.

Table 8. Newly registered HIV cases in pregnant women and newborns in the period 2011-2015 (*HIV MTCT rate is not available because the year of confirmation and reporting HIV MTCT cases may differ from the year when the HIV-positive pregnant woman had delivery. Reported case may not refer to the year of birth.)

Year	Number of HIV positive pregnant women who delivered ³⁵	Number of new HIV cases in pregnant women	Number of HIV MTCT cases ³⁶	HIV MTCT Rate*
2011	52	25	2	
2012	48	18	7	
2013	69	32	10	
2014	65	14	4	
2015	62	22	3	

³⁴ CDPC Latvia, Medical Birth Register (MBR), 2016.

³⁵ Medical Birth Register

³⁶ State Register of HIV/AIDS cases

DATA VERIFICATION AND IMPACT ASSESSMENT

This component responded to the following questions:

- 1) is data generated by the country reliable to assess achievement of the EMTCT targets? and*
- 2) has the country achieved the EMTCT targets?*

HIV testing policy and practice in Latvia

According to the Cabinet Regulation No. 628 (adopted 4 November 2003) "Organisational Procedures for Restriction of the Spread of Human Immunodeficiency Virus Infection (HIV) and AIDS and the Treatment of HIV-Infected Persons and AIDS Patients" every individual taking the HIV test shall be provided with pre-test counselling in which the medical practitioner informs her/him about the purposes, procedure, possible results and consequences of the test, as well as modes of HIV transmission and prevention measures and a post-test counselling in which the medical practitioner informs person regarding the test results.

The HIV test results reactive in initial testing have to be confirmed by the National Reference Laboratory (NRL). In case if test was performed at the screening lab the reactive sample is delivered to the NRL for confirmatory test. In case if positive result has been confirmed, the NRL informs the GP or another service provider and simultaneously reports the Centre for Disease Prevention and Control (CDPC) about newly detected HIV case.

There are several levels of laboratory diagnosis in Latvia. Laboratories located at the hospitals, privately owned labs offering state covered laboratory services and National Reference Laboratory. In order to perform state covered laboratory tests, person should have a referral from GP or other specialist (like infectologist, paediatrician) who has contract with National Health Service. The referral form is approved by the Cabinet of Ministries regulation # 265 as of April, 4 2006, annex 79. In order to visit infectologist, one should have referral from GP for the first visit to the infectologist (in order to receive State covered service). If HIV diagnose is confirmed, no referral to access infectologist is needed. Next visits are arranged directly with infectologist.

Every person has an opportunity to visit private laboratory directly to get tested for HIV (with a payment) or visit the HIV prevention points (HPP) to get tested for HIV (rapid test) as well as for HBV, HCV and syphilis (anonymously and free of charge). The network of HPP was created in 1997. At the moment there are 19 HPPs in 16 municipalities across the country. The activities of HPP network are coordinated by CDPC. It provides to the HPPs some goods (syringes, condoms, brochures etc.), methodological support, leadership and education, and municipalities assist with premises; there are also NGOs involved in the functionality of some HPP. The HPPs target groups include drug users, former prison inmates, pregnant women who inject drugs, homeless people, sex workers and their clients, ethnic minorities, men who have sex with men and others. As it was mentioned above, the HPPs perform rapid tests for HIV, HBV, HCV and syphilis.

Overall in 2015, 13 HIV rapid tests were performed in HPPs for pregnant women - two of them were positive. If the person is tested positive he/she is advised to pass ELISA test via different options, one of them could be through GP who have to refer him/her to the screening laboratory In this case the

test is free. Pregnant women and women during the postnatal period up to 42 days are exempted from patient contribution, so visits to GP and other specialists are free.³⁷

There is presently no way to track how many HPP clients went to receive confirmation of their initially positive HIV status (HPP clients are anonymous). According to HPP staff interviewed, many clients do not seek confirmatory testing and therefore many people are “lost” for public health system and do not get officially registered. The exact figure is unknown for local specialists. It suggests that the HIV epidemic development in Latvia is not under strict surveillance control.

Description of the HIV surveillance system in Latvia

Routine HIV surveillance system in Latvia is based on lab results generated in the National Reference Laboratory (NRL) under RAKUS/LIC - Infectology Centre where all blood samples with initially reactive HIV test results are tested. Clinical diagnosis is done by the physician-infectologist of the RAKUS/LIC - Infectology Centre.

The leading institution in HIV surveillance domain is the Latvian Centre for Diseases Prevention and Control (CDPC). The main CDPC responsibilities include provision of technical support to the medical settings, co-ordination, supervision and ensuring proper functioning of the State HIV and AIDS surveillance system (a permanent, dynamic monitoring of the HIV infection epidemic process, analyses of the current epidemiological situation, projecting of the epidemic development, planning of prevention interventions and evaluation of their effectiveness).

HIV/AIDS surveillance and information flow system in Latvia is based on the following basic legislative acts:

- Epidemiological Safety Law declares mandatory notification of every communicable disease including HIV/AIDS;
- Cabinet Regulations No. 7 (adopted on 5th January, 1999) “Procedures for Registration of Infectious Diseases” (<http://likumi.lv/doc.php?id=20667>) requires provision of the written report on detected infectious disease according to the list of reportable diseases to CDPC by any health care provider who diagnosed infectious disease. In case of HIV/AIDS notification should be sent within three working days. The form contains information about gender, age, education, place of residence, sexual orientation, health, possible mode of infection transmission etc. of HIV infected person.
- This Regulation envisages that every primary positive blood sample should be sent to the National Reference Laboratory for confirmation. In case of confirmation the NRL should provide CDPC with a written report. Monthly report about the number of HIV tests performed is also required.
- Cabinet Regulations No. 628 (adopted on 4th November, 2003) “Organizational Procedures for Restriction of the Spread of HIV and AIDS and the Treatment of HIV-Infected Persons and AIDS Patients” (<http://likumi.lv/doc.php?id=80819>) anticipates investigation of every HIV case detected, maintenance of the HIV/AIDS State Register and treatment of HIV-infected persons and AIDS patients.
- Cabinet Regulations (adopted on 4th April, 2006) No. 265 “Record-keeping Procedures for Medical Documents” (<http://likumi.lv/ta/id/132359-medicinisko-dokumentu-lietvedibas-kartiba>)

³⁷ Cabinet Regulation No. 1529 (adopted on 17 December, 2013) "The procedures for organising and financing health care", Article 23.2

approved a) reporting form for confirmed HIV case, b) reporting form for patient with AIDS and c) reporting form for death of HIV-infected person or AIDS patient.

Data sources available in the country

State Electronic Register of HIV/AIDS cases was established in 1997. The registry data include socio-demographic information (including gender, age, and education level), clinical information (including antiretroviral therapy, CD4 count etc) and epidemiological information (for example possible modes of HIV transmission). Health care providers notify the Centre for Disease Prevention and Control of Latvia for every confirmed HIV, AIDS and deaths cases within 3 days, sending filled report – special notification forms about HIV, AIDS and deaths; reporting form for confirmed HIV case; reporting form for patient with AIDS and reporting form for death of HIV-infected person or AIDS patient.

In 2016 the work group was established in order to improve HIV/AIDS register. It is foreseen that at the end of 2016, work group will come-up with amendment for existing regulation containing new improved HIV/AIDS register.

Electronic data monitoring system of HIV prevention point (routine data) services established in 2012. Database on service provision and case monitoring was originally created under UNODC project and currently maintained by CDPC Latvia. Database includes demographic information on clients and visitors (age, gender, nationality, educational level), behavioural data (drug injection habits, sex work experience, prison terms, pregnancy, HIV status), data on drug usage patterns and uptake of offered services (testing on infectious diseases, distribution of syringes and condoms, counselling and motivation, rehabilitation and other treatment options). All data is anonymous – clients are given a code generated by electronic data system. Code and/or system do not contain any sensitive data, like date of birth, name or address. Client may choose whether to use the code when reappearing at HPP or new code will be generated. Each HPP has an access, based on the code, to the data base in order to continuously fill in information about client and his activities (testing, consultations etc). CDPC collects all aggregated data from HPPs. Information can be used solely for statistical and informative purposes.

Medical Birth Register (MBR) was established in 1996. Electronically data has been available since 2000. It is based on the information recorded in the cards issued for newborn by maternity units across the country. Maternity units maintain information in “Newborn Card”, which is obligatory and standardised medical documentation form.

MBR contains information that is essential for epidemiological studies and surveys on perinatal health, including data on all newborn including sex, weight, length, gestational age, Apgar score, as well as the diagnosis of congenital anomalies at birth and the cause of death, wherever appropriate); the mother’s socio-demographic factors (for example age, education level); factors affecting the mother’s health (diseases, complications and health problems during pregnancy) and the delivery (the type of delivery, complications). MBR is obligatory and covers all national data - there are cases just about births in Latvia (no data about residents of Latvia who gave births in other country).

Register of Causes of Death (RCD) was established in 1996. This registry is obligatory and covers all deaths cases in the country. The registry data include personal information (sex, age, birth weight, as well as birth and death data), diagnoses of the causes of death, and other factors related to death.

The information is also retrieved from death certificates for stillbirths. There are data about permanent residents of Latvia who died in Latvia and abroad about whom information (including medical information) is received.

HIV/AIDS data flow

Information about number of HIV tests performed for several (13 in total) categories of tested populations is prepared by HIV testing labs according to the established national standard form³⁸ and presented to the NRL and CDPC on a monthly and annual basis. Population groups categorized for testing among others also include pregnant women. The HPPs also report to CDPC about testing activities (number of rapid tests performed).

Existing system of reporting on a number of tests performed without test results does not allow to measure HIV prevalence in tested populations.

NRL reports data on confirmed HIV cases to the CDPC (National HIV/AIDS Case Register) within 3 working days (National HIV/AIDS Case Register) and to the health care providers who in their turn inform clients about confirmed test results. If HIV /AIDS diagnosis is determined by the health care provider the latter should inform CDPC in a written form by completing the medical documentation in accordance with the laws and regulations regarding the procedures for the infectious diseases registration.

There are some examples of disconnect in data flow between medical facilities at primary level involved in provision of the medical services for mothers and their newborn in the last 2 years and 3 months . One case as an example is shown in Table 9 (data submitted by the CDPC Infectious Diseases Risk Analysis and Prevention Department). All known cases of children born to HIV positive mothers having long time between birth date and HIV testing including confirmatory testing require detailed analysis in order to apply all preventive measures in such children timely enough and to also prevent such cases in the future.

Table 9. Discrepancies between date of birth, HIV testing and notification in relation to HIV MTCT in Latvia

Case	Date of birth	Date of NRL confirmation	Date of notification
1.	28-10-2010	29-02-2016	02-03-2016

RAKUS/LIC reports to the CDPC all AIDS diagnosed cases for inclusion into the National HIV/AIDS Case Register. There is no separate database on HIV patients in the RAKUS/LIC. Preparation for any additional data, analytical reports, and statistical data that is not routinely reported to the National HIV/AIDS Case Register requires time and intensive/huge paper workload for limited staff involved in care to HIV/AIDS patients.

All epidemiological information on HIV is placed on the CDPC web page <http://www.spkc.gov.lv/hiv-aids/>. Due to limited staff capacity no separate HIV Info bulletin is being produced and distributed across the country. It looks like health administration staff outside of capital city has low awareness about HIV situation in the country.

Available data suggests that:

³⁸ Form Nr.HIV-11 , annex 81, Cabinet regulation # 265 as of April 4, 2006

- Routine HIV surveillance system is able to detect the majority of HIV positive pregnant women during the first visit to ANC services
- The HIV surveillance algorithm is based on HIV case reporting with a leading role of the NRL
- HIV test reporting form envisages info on number of tests performed, not the people tested
- National CDPC is an exclusive holder of all epidemiological HIV information in the country, limiting its availability for local health care providers by placing it on the CDPC web site only

Issues of concern:

- The high proportion of cases with unknown mode of HIV transmission (30%)
- Information flow on HIV test results between family doctors and testing providers is fragmented and might lead to the loss of patients for the health system or late presentation for diagnostic and treatment interventions.
- Reported number of tests only does not allow to measure testing coverage of pregnant women as well as HIV prevalence in tested populations
- Lack of in-depth data about pregnant women who belong to risk groups and avoid ANC
- No information about final HIV status of newborns is available for responsible maternity hospital staff
- No HIV patients database at the RAKUS/LIC
- HIV Helpline is not fully effective due limited staffing, lack of well trained staff etc.

Has the country achieved the EMTCT targets?

As it was already mentioned earlier in this report, in order to validate the elimination of MTCT of HIV, the country should achieve the targets and indicators , namely:

- I. Countries should achieve both of following impact targets for validating EMTCT of HIV:**
 - a case rate of new paediatric HIV infections due to MTCT ≤ 50 cases per 100,000 live births
 - MTCT rate of HIV of $< 5\%$ in breastfeeding populations **OR** MTCT rate of HIV of $< 2\%$ in non-breastfeeding populations.
- II. The following process targets also must be attained:**
 - Antenatal care (ANC) coverage (at least one visit) of $\geq 95\%$
 - Coverage of HIV testing of pregnant women of $\geq 95\%$
 - Antiretroviral (ARV) coverage of HIV-positive pregnant women of $\geq 95\%$

Available data suggest that while some validation indicators and targets have been reached (*A case rate of new paediatric HIV infections due to MTCT and Coverage of HIV testing of pregnant women*) or almost reached

(*ANC coverage*), the efforts should continue to achieve also the remaining ones i.e. *MTCT rate of HIV* and *ARV coverage of HIV-positive pregnant women*. Detail discussion and respective recommendations are given below.

Table 10. HIV MTCT elimination validation indicators in Latvia³⁹

	2011	2012	2013	2014	2015	Validation targets
Total number of deliveries	18331	19401	20094	21244	21496	
ANC coverage	92.1%	91.8%	92.7%	93.9%	94.7%	≥95%
HIV testing coverage	97,7	98,1	97,8	97,7	98,3	≥95%
Number of HIV positive babies born	2	7	10	4	3	
Number of HIV positive cases per 100 000 live births	10,9	36,0	49,8	18,8	13,95	≤50 cases per 100,000 live births
The number of HIV positive women who delivered	52	48	69	65	62	
HIV MTCT rate*						<2% in non-breastfeeding populations

***HIV MTCT rate is not available because the year of confirmation and reporting HIV MTCT cases may differ from the year when the HIV-positive pregnant woman had delivery. In this table - data from different data sources.**

A case rate of new paediatric HIV infections due to MTCT: Data suggests that the country reached the target of ≤50 cases per 100,000 live births. It is advisable to take into consideration data for 2013 (when the indicator was too close to critical line) and put all possible efforts to avoid the similar situation in the future.

MTCT rate of HIV: National guidelines suggest formula feeding thus validation target of <2% in non-breastfeeding populations applies to the country. Data to calculate HIV MTCT rate is not available because the year of confirmation and reporting of HIV MTCT cases may differ from the year of birth of HIV pos baby and the year when the HIV-positive pregnant woman had delivery – i.e. the data that are necessary to calculate MTCT transmission rate are not available. **The main recommendations here are as follows:**

- **To ensure the availability of quality data for calculating the rate of HIV transmission from mother to child i.e. to ensure the availability of data on the number of HIV positive children born in any given year and data on the number of HIV positive women who gave birth in the same year**
- **To consider initiating ART in all pregnant and breastfeeding women living with HIV, regardless of WHO clinical stage and at any CD4 cell count and continuing ART lifelong.⁴⁰**
- **It is strongly recommended to follow latest WHO recommendations on infant prophylaxis⁴¹ as current practice of infant prophylaxis followed in Latvia cannot be considered appropriate!**

³⁹ Country validation report; Medical Birth Register; Report regarding antenatal care, abortions and contraception – a state statistical report; Register of Causes of Death;

⁴⁰ Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection Recommendations for a public health approach - Second edition 2016 <http://www.who.int/hiv/pub/arv/arv-2016/en/>

ANC coverage: Available data suggests that ANC coverage shows increasing tendency for last years (2011-2015), reaching 2015 94,7% in 2015 (see Table 10) i.e. it is close to $\geq 95\%$ - the target to be reached for validation. The national colleagues whom mission members talked to believe that in reality the ANC coverage is higher, probably close to 99% as almost all women who deliver in health care settings have been attending ANC . Data suggest that the proportion of deliveries outside of health care system is 1% which means that 99% deliveries takes place in health care settings. National colleagues believe that available data on ANC coverage most likely do not reflect the true picture because of some reporting and communication challenges between different settings including obstetrics/gynaecology, infectious diseases and national CDC. While expert opinion is very important, for validation purposes country would need to submit data proving that ANC coverage in the country is $\geq 95\%$. **Mission recommends reviewing and putting efforts to improve ANC coverage data quality as most likely this target has been reached by the country but data to prove that should become available.**

Coverage of HIV testing of pregnant women: Available national data suggests that HIV testing coverage of pregnant women exceeds the validation target of $\geq 95\%$ - see Table 10. The major concern that mission has with regard to this data is that whether this data reflects number of pregnant women tested or number of tests performed as data mission members were looking at not always clearly suggested that double/multiple testing of pregnant women could be ruled out when calculating this indicator. **Mission recommends ensuring high quality data on HIV testing coverage of pregnant women to avoid any doubts and questions that the country reached this target.**

Antiretroviral (ARV) coverage of HIV-positive pregnant women: Available data suggests that in 2015 there were 70 HIV positive pregnant women registered in the country⁴². All of them were given ARVs for preventing HIV MTCT and the great majority (69 women) were taking ARVs but the duration of medication varied widely and only 37 women has continued treatment for year or more. Here are respective details:

- 1 women didn't receive ART because of lack of adherence
- 20 - had ART for ~4 weeks (for different reasons including late first visit to infectologist (30-35th week), poor adherence)
- 12 patients had ART only during pregnancy, in postnatal period there were no indications for treatment continuation;
- 17 patients had ART during both prenatal and postnatal period;
- 20 patients had ART before pregnancy and during both prenatal and postnatal period

The above data suggests that the country did not move to lifelong ART for pregnant women. **As it was already mentioned above , it is strongly recommended to consider initiating ART in all pregnant and breastfeeding women living with HIV, regardless of WHO clinical stage and at any CD4 cell count and continuing ART lifelong.**

⁴¹ Ibid

⁴² Country report; RAKUS/LIC data, 2015

Laboratory assessment

This component responded to the following questions: **(1) is there an adequate laboratory network to provide appropriate services needed to achieve and maintain a programme for EMTCT of HIV and (2) are the results generated by the laboratory network adequately reliable, sensitive, specific and quality-assured?**

The laboratory assessment consisted of three main steps:

- 1) Assessment of the overall performance of the national laboratory system in supporting diagnosis and appropriate management of HIV;
- 2) Observation of specimen collection, equipment, and HIV testing procedures, including tests and diagnostic algorithms used, in testing facilities; and
- 3) Synthesis of data (observations and interviews) and dissemination of findings.

Main observations regarding laboratory system providing analyses for HIV diagnosis (screening and confirmation)

National HIV laboratory diagnostic network

In Latvia, there are several laboratory levels. There are laboratories at hospitals, which can be the hospital's own public laboratory or a laboratory outsourced to a private laboratory or laboratory network. There are additionally mainly large private laboratories. The laboratories are offering state covered laboratory testing, mainly by referral of samples from general practitioners or attendance of patients. In order to perform state covered laboratory testing, patients should have a referral from a general practitioner or other specialist (like infectologist, paediatrician) who has contract with NHS. Altogether 58 laboratories have agreements with NHS for performing state covered testing (any type of laboratory diagnostic testing, i.e. not only HIV testing).

In general, the HIV diagnostic laboratories are accredited and this is required for reimbursement for performed tests. If there is suspicion about HIV infection or the patient has a referral from general practitioner, infectologist, gynaecologist etc., the laboratory testing is free. During the nine first months of 2015, 23 laboratories performed HIV initial screening testing (25967 tests) that was state covered (9-11601 tests/laboratory). However, 81% of all these tests were performed in only three laboratories (the E. Gulbis, Central and National Medicine Service laboratories). The laboratories ensured sufficient coverage of HIV testing in entire Latvia. The national HIV Reference laboratory is incorporated at the RAKUS/LIC and confirms the HIV screening reactive samples from all additional laboratories (regardless if public or private). Both the public and private HIV screening laboratories are involved in the quality control programme (see below), which is run by the national HIV reference laboratory at RAKUS/LIC, and all laboratories report the number of HIV tests performed to NHS, i.e. in order to obtain reimbursement. The HIV laboratory diagnostic network was highly centralized, however, it appeared appropriately led, supervised and quality assured by the national HIV reference laboratory at RAKUS/LIC, and in general the network appeared well-functioning. The national HIV diagnostic algorithms used for diagnosis in adults and infants (but ideally the HIV DNA/RNA NAAT should be performed within 48 hours) were sensitive and specific and in line with international recommendations. If required for example due to cost savings, the algorithms could even be simplified and still be in line with international recommendations. However, no detailed, evidence-based and implemented national HIV diagnostic guidelines existed.

Additionally, a network of HPPs is active in Latvia since 1997. Currently, it includes 19 HPPs, some involving NGOs, in 16 municipalities across Latvia. At these HPPs, RDTs for HIV (e.g. SD HIV-1/2 3.0, Standard Diagnostics) were used. If HIV test is positive, the individual is informed to attend the RAKUS/LIC for confirmatory testing.

National HIV reference laboratory at RAKUS/LIC

The national reference laboratory functions for nearly all infectious diseases in Latvia were located at the RAKUS/LIC, Riga. The national HIV reference laboratory (nominated by the Ministry of Health) at RAKUS/LIC had been the Latvian reference laboratory for decades. The laboratory had a very central role and also performed the final confirmation of all HIV-screening positive cases in Latvia. The laboratory was extremely well-equipped, organized, and only used internationally well-recognized appropriate diagnostic tests, calibrated pipettes and equipment, and temperature controls. The laboratory also had appropriate standard operating procedures (SOPs) implemented (manufacturer's instructions or developed in strict accordance to manufacturer's instructions), recording form (for test systems, performance of tests, patient-result forms, temperature recording forms etc.), and in general a high level of quality assurance. The laboratory was also accredited according to both ISO15189 and ISO17025 since many years. The national HIV reference laboratory was also involved in international external quality assessment (EQA) schemes for both HIV serological testing and HIV viral load (INSTAND or Lab quality). The results in these EQA schemes were adequate during the last three years. The laboratory was also running the national quality control or proficiency programme for HIV. In this programme, 2-4 sera (2-3 HIV positive per shipment) were distributed 1-2 times per year to all both public and private HIV testing laboratories (also accredited). The reference laboratory also performed some limited validation of HIV tests and checked every new batch of test kits (only standards and one positive sample and one negative sample). Ideally, the national reference laboratory should have an obligation to validate tests (literature search, own in vitro testing or what required) and these results should inform national procurement of HIV diagnostic tests. The reference laboratory also provided training to other HIV testing laboratories.

The laboratory performed primary HIV screening, confirmation of HIV infection in screening-positive patients from the whole country, and follow up of treatment for all HIV-positive individuals in Latvia. In regards to HIV diagnostic tests used, 4th generation tests (detecting both HIV antigen and antibody) were used. Currently, for primary screening Architect HIV AG/Ab Combo test, ABBOTT was used and screening positive samples could be further confirmed using the GenScreen Ultra Ag/Ab ELISA, Bio-Rad and/or the Elecsys® HIV Combi PT 4th Gen – Cobas, Roche. Final confirmation was performed using INNO-LIA® HIV I/II Score, Fujirebio and/or GS HIV-1 Western Blot, Bio-Rad. No expired tests kits or stock outs of test kits were experienced. For HIV screening positive samples submitted from other laboratories, the selection of assays for confirmation was appropriately based on the test used for initial screening. The turnaround times for samples were short, i.e. most assays were run 3-5 times per week. In general, the staff appeared competent in performing and interpreting the results of all the HIV screening and confirmatory tests.

The national HIV reference laboratory was also the only laboratory in Latvia that performed HIV viral load to follow up treatment of PLHIV, EID using the HIV viral load test, and HIV antiretroviral therapy resistance testing (all patients before initiating ARV treatment and when problematic cases e.g. therapy failure; using the ViroSeq HIV-1 Genotyping System, ABBOTT Molecular). Viral load testing was performed in strict accordance to the instructions from the manufacturer, using the internationally well-recognized and validated Roche Cobas TaqMan48 or ABBOTT system. The PCR laboratory was well-

organized, had an effective single-directed work flow, appropriate routines for cleaning, and the work appeared to be performed in an appropriate and quality assured manner by highly competent staff. CD4, CD8 and CD4/CD8 flow-cytometry was also performed at the national HIV reference laboratory.

The electronic recording of all results at the national HIV reference laboratory appeared to be mainly appropriate, including all available information about the patients and their results (with all tests used). Pregnant women as well as newborns to HIV-positive pregnant women (and links in between) could be identified in the laboratory information system.

Regional HIV testing laboratory (Bauska):

In Bauska, a hospital laboratory belonging to the municipality was visited. The laboratory performed few HIV tests (i.e. around 20 per month) and had very few samples from pregnant women. Nevertheless, they used good SOPs (i.e. based on or the actual instructions from the manufacturer), appropriate positive and negative controls, calibrated equipment and pipettes, had appropriate temperature controls and adequate recording of temperatures and results. In general, the staff appeared competent in performing and interpreting the results of the testing. No expired tests kits or stock outs of test kits were experienced. For screening, the 4th generation Access HIV Combo test, Beckman Coulter was used. If screening reactive, confirmation using a RDT (OnSite HIV 1/2 Ab Plus Combo Rapid Test, CTK Biotech) was performed. If confirmed reactive, they were sending the results to the family doctor and asking the family doctor to refer the patient to the Infectology Centre, Riga plus additionally the reactive sample was sent to the NRL at RAKUS/LIC. The NRL reports the results of their further confirmation back to the referring laboratory. The turnaround time for samples was adequate. The laboratory was also for quality assurance involved in the QC programme (see above) run by the National Reference Laboratory at the RAKUS/LIC. Twice per year, they were receiving two samples and their results during last two years were appropriate using both the 4th generation Access HIV Combo test, Beckman Coulter and RDT. Because accreditation is required in Latvia to receive reimbursement for the performed testing, also this laboratory was accredited for performing both the Beckman Coulter tests and the RDT.

Regional HPP (Bauska):

This HPP performed around 22-70 HIV screening tests per year. The SD HIV-1/2 3.0 RDT (Standard Diagnostics) was used. If the RDT was positive, he/she is advised to pass ELISA test through GP who refers him/her to the screening lab (RAKUS/LIC). The HPP doesn't have the follow up if the screening reactive patients ever go for confirmation and, if the patient attended for confirmatory testing, they did not get any results from the confirmation. This is a main problem with using RDTs in Latvia as well as in many other countries. The RDTs used had been obtained from the CDPC. No RDTs were validated before procurement but CDPC tested some (not clear how many) positive and negative clients (not "patients" as harm reduction sites are not medical institutions) before they were distributed. The National HIV Reference Laboratory did not perform any validation and it was said that the Reference Laboratory required money to perform this type of validation.

In general, the head and all staff at all the visited units for sampling of biological specimens and laboratories gave a warm welcome, and all were very interested, supportive, and dedicated to the discussions and to perform a good work. In all visited sampling sites and laboratories, the general observations indicated adequate and safe specimen collection (using safe single-use vacutainer tools and appropriate needles) and subsequent handling, including storage and transport, preparation for testing, performance of testing (using only test systems that were appropriately stored and had not expired) and

recording of results. Furthermore, the equipment was mostly adequate, appropriately calibrated, if needed having UPS as electricity back up, and the work was mainly performed in strict accordance with the instructions from the manufacturer or SOPs, in strict concordance with the manufacturer's instructions.

Human rights, gender equality and community engagement

The following international and regional human rights and gender equality instruments have been signed and ratified:

I. UN

- Convention on the Elimination of all Forms of Discrimination Against Women [CEDAW].
- Convention on the Rights of the Child [CRC].
- Convention on the Rights of Persons with Disabilities [CRPD].

II. Council of Europe

- The Convention for the Protection of Human Rights and Fundamental Freedoms.
- Convention for the protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine.
- European Social Charter (revised).
- Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data.
- European Convention on the Exercise of Children's Rights.
- Council of Europe Convention on preventing and combating violence against women and domestic violence [signed but not ratified].

III. National framework on human rights related to the HIV EMTCT

The general constitutional obligation in public health protection, to be used for control, prevention and treatment of HIV is provided by the Latvian Constitution - Satversme, Art. 111.⁴³ Satversme stipulates equality and prohibition of discrimination⁴⁴, the right to liberty and security of the individual⁴⁵, right to human dignity⁴⁶, and inviolability of private life⁴⁷. The state shall protect the rights of parents and the rights of children. The State shall provide special support to disabled children, children left without parental care or children who have suffered from violence.⁴⁸

The HIV/AIDS issues and the organisation/provision of service delivery, including assistance during pregnancy in general, are regulated by **the Sexual and Reproductive Health Law**.⁴⁹ The Sexual and Reproductive Health Law, Art.11 specifies that:

⁴³ The Constitution of the Republic of Latvia <http://www.saeima.lv/en/legislation/constitution> , Art. 111 states: "The State shall protect human health and guarantee a basic level of medical assistance for everyone"

⁴⁴ Art. 91

⁴⁵ Art. 94

⁴⁶ Art. 95

⁴⁷ Art. 96

⁴⁸ Art. 110

⁴⁹ Sexual and Reproductive Health Law (Seksuālās un reproduktīvās veselības likums) <http://likumi.lv/ta/id/58982-seksualas-un-reproduktivas-veselibas-likums>

- Syphilis prevention, diagnosis, treatment and monitoring shall be carried out by a dermatologist/venereologist.
- The examination, treatment and monitoring of HIV-infected persons and AIDS patients shall be carried out by an infectologist.

Based on the Sexual and Reproductive Health Law, the Cabinet of Ministers adopted a regulation on “Organisational Procedures for Restriction of the Spread of Human Immunodeficiency Virus Infection (HIV) and AIDS and the Treatment of HIV-Infected Persons and AIDS Patients”⁵⁰ and Cabinet Regulation No. 611 "Procedures for Ensuring Assistance with Deliveries" stipulating requirements, in respect to medical assistance to pregnant women.⁵¹

The Epidemiological Safety Law⁵² is a special law regulating epidemiological safety and control/prevention of infectious diseases. Prevention of infectious diseases is part of epidemiological safety measures provided by this law⁵³.

The following legal regulations have been established to support control and prevention of infectious diseases including HIV:

1. Cabinet Regulation No. 413 requires HIV testing in case a person is diagnosed with TB, and TB testing in case a person is diagnosed with HIV, which help early diagnosis of HIV in TB patients and vice versa.
2. Cabinet Regulation No. 774 on procedures for the Determination of Exposed Persons, Initial Medical Examination, Laboratory Examination and Medical Observation⁵⁴. The regulation requires to trace and test HIV exposed persons.
3. Procedures for the Registration of Infectious Diseases”⁵⁵ If an infectious disease is determined or suspected by the health care professional, he/she shall: report about newly detected cases of (HIV/ AIDS to the Centre for Disease Prevention and Control within three working days in writing or electronically, by completing the medical documentation in accordance with the laws and regulations regarding the procedures for the record-keeping of medical and registration documentation of medical treatment institutions⁵⁶.

If an infant is diagnosed with HIV or HIV is suspected, the health care practitioner shall in addition complete the form of urgent notification containing details of the mother and send it to the

⁵⁰ Cabinet Regulation No. 628 (adopted November 4 2003) “Organisational Procedures for Restriction of the Spread of Human Immunodeficiency Virus Infection (HIV) and AIDS and the Treatment of HIV-Infected Persons and AIDS Patients”

⁵¹ Cabinet Regulation No. 611 (adopted 25 July 2006) "Procedures for Ensuring Assistance with Deliveries"<http://likumi.lv/ta/id/140695-dzemdibu-palidzibas-nodrosinasanas-kartiba>

⁵²Epidemiological Safety Law [Epidemioloģiskās drošības likums] <http://likumi.lv/doc.php?id=52951>, the purpose of this Law, as it is stated in Art. 2, “is to regulate epidemiological safety and specify the rights and duties of State authorities, local governments, and natural persons and legal persons in the field of epidemiological safety, as well as to determine liability for the violation of this Law”.

⁵³ Epidemiological Safety Law, Art. 3

⁵⁴ Cabinet of Regulation No. 774 (adopted September 19, 2006) on “*Procedures for the Determination of Exposed Persons, Initial Medical Examination, Laboratory Examination and Medical Observation*”.

⁵⁵ Cabinet Regulation No. 7 (adopted January 5, 1999) on “Procedures for Registration of Infectious Diseases”,

⁵⁶ Cabinet Regulation No. 7 (adopted January 5, 1999) on “Procedures for Registration of Infectious Diseases”, Art. 7.4.

epidemiologist at the Centre for Disease Prevention and Control within three working days. The data will be used for registration of the case and for epidemiological surveillance.⁵⁷

If the microbiology laboratory confirms the HIV infection, the head of the laboratory or his/her authorised personnel shall, within three days, send the notification about the positive HIV test result to the Centre for Disease Control and Prevention.⁵⁸

4. Health care matters in general are regulated by the Medical Treatment Law⁵⁹, but patients' rights are regulated by the Law on the Rights of Patients'.⁶⁰ 5. Organisational and financial matters of state-financed health care are also governed by a Cabinet Regulation⁶¹.

5. The Cabinet Regulation specifies procedures for the reimbursement of expenditures for the Medicinal Products and Medicinal Devices Intended for Out-patient Medical Treatment⁶².

6. The rights and freedoms of the child and the protection framework are provided by the "Protection of the Rights of the Child Law"⁶³.

7. The quality of medical treatment in health care institutions is controlled by the Health Inspectorate⁶⁴.

8. According to Art. 18 (1) of the Law On the Rights of Patients: "A person may use all mechanisms for the protection of rights provided for in laws for the protection of the rights or the interests arising therefrom laid down in this Law, including application to a court in accordance with the procedures laid down in law."⁶⁵

9. According to Art. 18 (3): "For the protection of the rights laid down in this Law or the interests arising therefrom, which are related to medical treatment, a person is entitled to submit a complaint to the Health Inspectorate in accordance with the procedures laid down in laws and regulations for the performance of the necessary activities laid down in laws and regulations, not later than within two years from the date of the infringement of the rights or interests."⁶⁶

10. Detailed HIV/AIDS diagnostic, treatment and prevention measures are described in the guidelines approved by the National Health Service in 2014⁶⁷.

Policies and strategies

The Ministry of Health has elaborated policies and strategies that state objectives and action plans related to HIV/AIDS.

A policy document "Action Plan for 2014-2016 to restrict the spread of HIV infection, hepatitis B and C virus infection, and sexually transmitted diseases"⁶⁸ was drafted, covering a considerable scope of

⁵⁷ Ibid., Art. 7.⁵

⁵⁸ Ibid., Art. 10.³

⁵⁹ Medical Treatment Law (Ārstniecības likums) <http://likumi.lv/doc.php?id=44108>

⁶⁰ Law On the Rights of Patients (Pacientu tiesību likums) <http://likumi.lv/ta/id/203008-pacientu-tiesibu-likums>

⁶¹ Cabinet Regulation adopted on December 17 2013 No. 1529 ""Procedures for the Organisation and Funding of Health Care", <http://likumi.lv/ta/id/263457-veselibas-aprupes-organizesanas-un-finansesanas-kartiba>

⁶² Cabinet Regulation No. 899 (adopted 31 October 2006) Procedures for the Reimbursement of Expenditures for the Acquisition of Medicinal Products and Medicinal Devices Intended for Out-patient Medical Treatment

⁶³ Bērnu tiesību aizsardzības likums, <http://likumi.lv/doc.php?id=49096>

⁶⁴ Medical Treatment Law, Art. 10

⁶⁵ Law On the Rights of Patients, <http://likumi.lv/ta/id/203008-pacientu-tiesibu-likums>

⁶⁶ Ibid.

⁶⁷ Cilvēka imūndeficīta vīrusa (HIV) infekcijas diagnostikas, ārstēšanas un profilakses klīniskās vadlīnijas, <http://www.vmnvd.gov.lv/lv/420-kliniskas-vadlinijas/klinisko-vadliniju-datu-baze/reistras-2014gad/cilvka-immdeficta-vrusa-hiv-infekcijas-diagnostikas-rstanas-un-profilakses-klinisks-vadlinijas>

measures to ensure health care and the prevention of infectious diseases. The draft plan was published for public consultations on March 2014; however, no final document has been adopted by the Cabinet of Ministers yet.

The Public health strategy 2014 – 2020⁶⁹ was adopted by the Cabinet of Ministers on 30 September, 2014.

Barriers identified by the mission

According to the national law, HIV testing and treatment is voluntary. However, there is a Court judgement, where compulsory testing and penalisation of a detainee, refusing HIV test, was justified⁷⁰.

The Law on the Rights of Patients, Art. 15 (3) provides: “The internal rules of procedure of a medical treatment institution and the instructions of the medical practitioner are binding to the patient”.

The doctor has the right to refuse treatment as the Medical Treatment Law, Art. 42 provides: “In cases where the life of a patient is not endangered, but the patient does not observe the specified regimen, does not comply with instructions of the medical practitioners or knowingly harms his/her health and thus directly affects the medical treatment of the specific disease, the doctor has the right to refuse further treatment to the patient.”

On the same grounds, the GP has the right to strike out an adult patient from his/her registry⁷¹. NHS excludes **from paediatric GP** registry persons who have reached 18 years of age. The paediatrician shall inform the person concerned. An adult patient receives further treatment from the GP that is chosen by patient.

Epidemiological Safety Law Section 14. “Rights and Obligations of Health Care Practitioners” stipulates that in cases of infectious diseases (2) except in cases provided for by other laws and regulations, a health care practitioner shall not have the right to refuse to perform an initial medical examination of a patient and to take material for laboratory examination, if he or she has professionally determined that there is cause for suspicion that the patient has become infected with an infectious disease and may spread it.

Legal provisions providing patients’ obligations to comply with doctors’ instructions are contrary to basic rights provided by the Satversme (the Constitution of LV), articles 94 and 96 as well as contrary to Art. 5 of the Convention on Biomedicine. **It should be recommended to provide proper implementation of patients’ rights by amending the Medical Treatment Law.** The Law On the Rights of Patients as well as the Medical Treatment Law provides the basic rights.

During the mission, it was observed that some doctors stated they have the right to refuse treating a patient in the case he/she is not following the doctors’ instructions regarding HIV testing or treatment.

⁶⁸ Veselības ministrijas informatīvie ziņojumi

http://www.vm.gov.lv/lv/nozare/normativie_dokumenti/informativie_zinojumi/?print

⁶⁹ „Sabiedrības veselības pamatnostādnes 2014.-2020.gadam <http://polsis.mk.gov.lv/view.do?id=4965>

⁷⁰ Administratīvā rajona tiesa, Lieta Nr.A420492712, 18.06.2013.

⁷¹ Cabinet Regulation adopted on December 17 2013 No. 1529 ““Procedures for the Organisation and Funding of Health Care”, Article 42.

Informed consent

The Law On the Rights of Patients, Art. 6 (1) stipulates: “Medical treatment is permissible if a patient has given the informed consent thereto. The patient has the right to ask questions and receive answers prior to giving the informed consent.”

Implementation of the provision and insufficiencies in practice have been investigated during the mission. Information provided by clinicians and NGOs revealed the following issues:

- there are cases where informed consent is lacking. Some health care workers felt that it is a doctors’ decision whether to test pregnant women)
- pregnant women are not informed that they have the right to refuse testing or treatment for HIV
- lack of proper information to allow for client’s informed decision regarding HIV testing and/or treatment was reported
- lack of time for proper pre-HIV test information or counselling was reported
- there are no recent documented reports of violation of informed consent of women and adolescents accessing PMTCT and other HIV services
- lack of informative materials on HIV prevention, treatment and indications on the condition of PLHIV for medical professionals, social workers and patients was observed

Patients’ Rights Law, Art. 13, provides for adolescents’ right to freely decide to receive health services/treatment without parental/guardian consent from the age of 14. However, the same law limits adolescents’ right⁷² to freely decide not to receive health services/treatment without parental/guardian consent.

Forced and coerced abortion, contraception and/or sterilization

There is general regulation about pregnancy termination⁷³ General provisions on abortion, contraception and sterilization are provided by the Sexual and Reproductive Health law⁷⁴. According to that law Art. 25 (1), a woman may have an abortion upon request prior the 12th week of the pregnancy. Cabinet Regulations No. 590 are providing procedural regulations on pregnancy termination⁷⁵ The Criminal law sets liability for unauthorised performing of abortion⁷⁶

The use of contraception is a person’s voluntary choice.⁷⁷

No state-compensated contraceptives are available, even for the most vulnerable patient groups. People living with HIV may have difficulties in obtaining and using contraceptives due to financial barriers.

⁷² The Law On the Rights of Patients, Art. 13 (3) If a minor patient (from the age of 14 years) refuses to give his or her consent for medical treatment, but the physician believes that medical treatment is in the interests of this patient, the consent for medical treatment shall be given by the lawful representative of the minor patient

⁷³ Cabinet Regulations No.590 “Organisational Procedures for the Termination of Pregnancy” (<http://likumi.lv/doc.php?id=80585>)

⁷⁴ Sexual and Reproductive Health Law (Seksuālās un reproduktīvās veselības likums) <http://likumi.lv/ta/id/58982-seksualas-un-reproduktivas-veselibas-likums>

⁷⁵ Cabinet Regulations No.590 “Organisational Procedures for the Termination of Pregnancy” (<http://likumi.lv/doc.php?id=80585>)

⁷⁶ The Criminal Law, Section 135 and 136

⁷⁷ Ibid.

Confidentiality and privacy

Main issues reported and observed in relation to people living with HIV:

- poor practices for physical and informational privacy in health care institutions;
- poor knowledge of privacy protection principles;
- no recent documents, reports or surveys on privacy and confidentiality issues in health-care settings.

Recorded examples of lack of privacy protection for people living with HIV:

- code of HIV diagnosis required in prescriptions;
- no information for patients in respect to data protection and/or sharing of data with other health care institutions and professionals;
- provisions allowing disclosure of health care information to unidentified third parties in the service contract with a hospital.

According to the law⁷⁸, a patient has the duty to disclose his/her HIV status to the attending physician. A patient is required to inform his/her attending physician regarding his/her previously provided consents and refusals in relation to medical treatment. Due to lack of data, it is difficult to verify whether and how such provisions are implemented in practice.

Later in 2016 Latvia is going to start operations of the eHealth electronic patients' data base. No proper protection of privacy and confidentiality is provided for HIV patients in the law and Cabinet regulations concerning the application of the eHealth system. According to present plans, each HIV patient is to be registered in the eHealth platform and personal medical data will be stored by NHS, including data provided for the HIV Patients Registry. There is a provision in law allowing patients to prevent access to their data on the eHealth system. However, there is no legal provision allowing adolescents to access and control their health data without parental involvement.

Equality and non-discrimination

The Law On the Rights of Patients, Art. 3 (2) stipulates: "In ensuring the rights of patients, differential treatment based on a person's race, ethnic origin, skin colour, gender, age, disability, state of health, religious, political or other persuasion, national or social origin, property or marital status or other circumstances is prohibited. Differential treatment shall include the direct or indirect discrimination of a person, infringement of a person or an implication to discriminate him or her."

Implementation and practice has been investigated during the mission. It should be stressed that lack of sufficient data has limited the possibility to evaluate the situation. Health care personnel reported that they had observed cases where obstetric care to women with HIV was directly or indirectly refused at some regional hospitals. Medical doctors in regional hospitals advised patients to seek obstetric care in Riga by telling them that it would be the best choice, but the reason for such advice remained unclear.

⁷⁸ The Law On the Rights of Patients, Art. 15 (2) provides:

If the state of health of the patient allows it, he or she has a duty to become actively involved in medical treatment and to provide the attending physician with information within the limits of his or her abilities and knowledge:

- 1) which is necessary for ensuring medical treatment;
- 2) regarding his or her diseases, which may endanger the life or health of other persons;
- 3) regarding previously provided consents and refusals in relation to medical treatment;

NGOs representatives reported some cases where a harassing attitude of medical personnel towards pregnant women with HIV was observed. Reporters believed that those cases were revealing regular attitudes rather than exceptions to usual practice.

NGOs reported cases where discrimination of children due to HIV status of their mothers was observed.

Meetings of the mission revealed poor knowledge of discrimination issues among medical practitioners and social workers.

Availability, accessibility, acceptability and quality of services

There are very limited laws, regulations and/or policies on ensuring availability, accessibility, acceptability and quality of PMTCT services

Limited availability of essential HIV medicines – due to legal and operational barriers in registration (fee, procedures) and inclusion in state compensated list (by request of the producer) is an issue.

The State does not provide state-compensated or subsidised contraceptives and condoms for women/families/couples living with HIV.

Lack of the right to access necessary and quality information related to HIV/AIDS prevention and care was observed.

For HIV patients living in the regions, distance and travel costs to health facilities for HIV diagnostic, treatment, prenatal care, delivery services might create barriers limiting accessibility.

Lack of sufficient data are limiting evaluation of acceptability issues. Data provided to the mission disclosed that HIV patients are reluctant to attend infectologists in the same town (in Jēkabpils, none of the 18 HIV patients is attending the local infectologist). Since there is a high number of cases reporting patients' «non-compliance» to treatments, but no disaggregated data are available on the causes of non-compliance, lack of acceptability of HIV treatment services and other issues negatively affecting patients' participation may be the reasons for poor treatment uptake.

Lack of data on quality has limited the possibility to explore this topic more extensively.

It was observed that there is no common understanding regarding provision of the Medical Treatment Law, Art. 9.1⁷⁹ requiring to provide medical treatment in conformity with clinical guidelines.

State compensated ART is provided according to the «Recommendations on Rational Pharmacotherapy for ART» issued by the NHS. These recommendations are non-compliant with WHO recommendations. A Recommendation is not a legally binding toll, but it is used to limit patients' rights de facto. As it was already discussed earlier in this report, it is recommended that Latvia considers initiating ART in all pregnant and breastfeeding women living with HIV, regardless of WHO clinical stage and at any CD4 cell count and continuing ART lifelong⁸⁰

⁷⁹ Medical Treatment law, Art. 9.1 «Medical treatment shall be performed in conformity with clinical guidelines or by methods used in medical treatment and an evaluation of the safety of use of medicinal products and the effectiveness of the medical treatment, which is performed taking into account medical principles based upon evidence.»

⁸⁰ Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection Recommendations for a public health approach - Second edition 2016 <http://www.who.int/hiv/pub/arv/arv-2016/en>

Other issues related to accessibility of services were reported:

- clients with preliminary positive results for HIV received at the HPP centres are advised to go to GP who have to refer person to the screening laboratory (patient payment) or directly to the laboratory or Latvian Infectology Centre for confirmatory testing (payment according laboratory price list). There is presently no way to track how many HPP clients access the LIC for confirmation of their HIV status. According to HPP staff, many clients do not seek confirmatory testing and do not get registered
- referral by the GP or infectologist is needed in order to get free confirmatory testing
- people with risky behaviours might be referred by their GP to one of the labs for testing. In this case the test is free, but they should pay for post-counselling services. Receiving state-funded services, patients must pay **co-payments**, such as for a GP consultation 1.42 euro and 4.27 euro for infectologist consultation⁸¹

All of the above represent high barriers to testing, treatment and care for vulnerable groups.

Rights of the child

The following issues were observed during the mission and require immediate attention:

- formula for infants born to HIV positive mothers is not provided by the state. A project by the NGO AGIHAS is presently providing free formula, but it will come to end soon
- liquid Nevirapine is not available yet, thus new-borns exposed to HIV are given Zidovudine monotherapy.
- after delivery, HIV-positive women are dismissed with verbal instructions only to take their baby to the GP for registration and to the Infectology Centre after 6 weeks to have him/her tested
- it appeared challenging, if not impossible, to verify how many new-borns exposed to HIV are taken to the LIC for the test. Apparently, 99% of them are tested. In the case this does not occur, it is sometimes very difficult to trace the babies. The duty of a nurse at the LIC should be strengthened to ensure that the proper communication is transmitted to the social worker of the LIC, who shall then try to establish contacts with the family.

Accountability and absence of participation and community engagement

NGOs representatives reported that they are sometimes involved in the implementation of national policies and plans for PMTCT programmes, as well as in the analysis of progress during the preparation of specific reports for the international agencies. Nevertheless, feedback from civil society and the community is not reflected in national PMTCT operational plans and no networks of women living with HIV are present in the country.

Access to justice, remedies and redress

Access to justice, remedies and redress is formally available. However, no data on cases, or individual claims are recorded at the Health Inspectorate, Ombudsmen office and at the State Inspectorate For the Protection of Children's Rights from mothers with HIV.

⁸¹ Cabinet Regulation No. 1529 (adopted on 17 December, 2013) "The procedures for organising and financing health care", Annex 4

One meeting was organized by the State Inspectorate for the Protection of Children's Rights in 2014 to discuss the protection of new-borns exposed to HIV. Suggestions to improve involvement of pregnant women with HIV and to protect sensitive data have been prepared by the Ombudsmen Office in 2015.

RECOMMENDATIONS

1. Ensure that the country moves towards implementing WHO latest recommendations ensuring that ART is initiated in all adults living with HIV, regardless of WHO clinical stage and at any CD4 cell count. The National program should explore feasibility and put efforts aiming at starting treatment as soon as possible after diagnosis. As a priority, ART should be initiated in all adults with severe or advanced HIV clinical disease (WHO clinical stage 3 or 4) and adults with CD4 count ≤ 350 cells/mm³.
2. It is recommended to set feasible national HIV Program targets, define national HIV strategies, actions, package of interventions for the achievement of national goals and targets. The newly developed WHO regional Action Plan on health sector response to HIV that will be submitted for the consideration to the 66th session of the Regional Committee for Europe taking place in Copenhagen in September 2016 could provide guidance when developing national goals, targets and actions.
3. Expand early access of pregnant women to HIV testing services and ensure early linkage to post HIV test services, especially to ART and care for those tested positive.
4. Initiate ART in all pregnant and breastfeeding women living with HIV, regardless of WHO clinical stage and at any CD4 cell count and continue ART lifelong.
5. Follow latest WHO recommendations on infant prophylaxis; ensure availability of WHO recommended ARV drugs as current practice of infant prophylaxis followed in Latvia cannot be considered appropriate. It is recommended that:
 - Infants born to mothers with HIV who are at high risk of acquiring HIV should receive dual prophylaxis with AZT (twice daily) and NVP (once daily) for the first 6 weeks of life, whether they are breastfed or formula fed.
 - Breastfed infants who are at high risk of acquiring HIV, including those first identified as exposed to HIV during the postpartum period, should continue infant prophylaxis for an additional 6 weeks (total of 12 weeks of infant prophylaxis) using either AZT (twice daily) and NVP (once daily) or NVP.
 - Infants of mothers who are receiving ART and are breastfeeding should receive 6 weeks of infant prophylaxis with daily NVP. If infants are receiving replacement feeding, they should be given 4–6 weeks of infant prophylaxis with daily NVP (or twice-daily AZT).
6. It is recommended to consider the following with regard to infant feeding :
 - National or subnational health authorities should decide whether health services will principally counsel and support mothers known to be HIV infected to either breastfeed and receive ARV interventions or avoid all breastfeeding.
 - In settings where national authorities have decided that maternal and child health services will principally promote and support breastfeeding and antiretroviral interventions as the strategy that will most likely give infants born to mothers known to be HIV infected the greatest chance of HIV-free survival, mothers known to be infected with HIV should exclusively breastfeed their infants for the first 6 months of life, introducing appropriate complementary foods thereafter, and continue breastfeeding for the first 12 months of life. Breastfeeding should then stop only once a nutritionally adequate and safe diet without breast-milk can be provided.
7. Ensure availability of updated evidence based guidelines that follow WHO recommendations on treatment and management of HIV positive pregnant women including that in Obstetrics & gynaecology settings and covering delivery approaches; ensure that there is just one set of national HIV treatment guidelines in the country. National consensus should be reached on such guidelines among major stakeholders, including professional associations. Guidelines should be endorsed by

the MOH. Ensure that national practice follows national policies and guidelines. National colleagues might find it useful to consult WHO handbook for guidelines development available here http://apps.who.int/iris/bitstream/10665/75146/1/9789241548441_eng.pdf.

8. Ensure that RAKUS/LIC is informed in a timely manner about all babies born to HIV positive mothers, in order to prevent disconnection and support continuity of testing, treatment, prevention and care as required.
9. Review and put efforts to improve ANC coverage data quality, as this target has most likely been reached by the country but data to prove that should become available. Along with that, put efforts to further improve ANC coverage, paying special attention to pregnant women who use drugs or are SW. Involvement and help of civil society settings might play a crucial role in this task.
10. Ensure high quality data on HIV testing coverage of pregnant women ensuring availability of data allowing to differentiate between number of pregnant women tested and number of tests performed, in order to avoid any doubts and questions concerning achievement of the target of HIV testing coverage in pregnant women.
11. Promote central level purchase and procurement of ARVs.
12. Improve data to allow identification of the mode of HIV transmission. Prevent fragmentation, improve information flow on HIV test results, including between family doctors and testing providers to prevent loss of patients.
13. Since controversial information was received by the mission about the existence of an HIV data base in the RAKUS/LIC, in case such data base does not exist, it should be created.
14. Ensure quality analysis of data collected at the National CDPC, their dissemination, publication and inclusion in the PMTCT Program.
15. Actively involve the Health Inspectorate in monitoring quality of EMTCT services.
16. Optimize collaboration between different settings, primarily ANC, obstetricians/gynaecologists, infectologists, reproductive health and family planning settings.
17. Communication between obstetrician/gynaecologists and infectious diseases specialists should be strengthened and sustainable collaboration ensured through systematic exchange of information, joint activities etc.
18. Elaborate a human resources policy and plan on how to retain health care personnel. Options such as task sharing and task shifting should be considered. An attractive career path for young doctors should also be considered; it might include training opportunities in leading national clinics, maybe also abroad, the opportunity of scientific research in clinical medicine etc.
19. Strengthen knowledge of universal precaution measures in health care settings among health care personnel, including that in relation to providing services to PLHIV. Train healthcare staff on HIV related issues and develop their skills to support vulnerable groups.
20. Increase awareness of HIV in the general population, including knowledge of HIV modes of transmission, prevention measures, supporting early access to HIV services.
21. Promote educational and general awareness campaigns to prevent fear of accessing medical services. Promote awareness of HIV and health seeking behaviours, especially in key populations, by specifically addressing false beliefs such as that of “being healthy”.
22. Provide adequate support and information to pregnant women with HIV on ART, PMTCT, delivery, prevention treatment for the newborn, breastfeeding, etc. Promote awareness among HIV positive pregnant women about ART effectiveness for their health and that of their babies.
23. Produce written materials to be handed to mothers with HIV when they are dismissed from the maternity clinic, so that they have some instructions on how to take good care of their babies’ health.

24. Include municipality social workers in the support network for pregnant women with HIV.
25. Fund NGOs so that they can extend their support services to PLHIV and vulnerable groups.
26. Main recommendations regarding laboratory system providing HIV screening and confirmation services
 - The national HIV diagnostic algorithms used for diagnosis in adults and infants are sensitive and specific. If limited funding, the algorithm for diagnosis in adults could even be simplified and still be in line with international evidence-based recommendations, e.g. from WHO. It is strongly recommended that all HIV-exposed infants have HIV virological testing at 4–6 weeks of age or at the earliest opportunity thereafter in accordance with WHO Recommendations. If funds permit the HIV DNA/RNA NAAT used in EID should also be performed within 48 hours. Detailed understanding of the algorithms and selection of appropriate tests (1st, 2nd and 3rd) is crucial to have them implemented at national, regional and local levels of HIV testing.
 - The national HIV reference laboratory should validate all HIV diagnostic tests (including RDTs) used in the country and/or provide information regarding appropriate manufacturer-independent validations performed by others (e.g. WHO pre-qualification of diagnostics, WHO and other internationally agreed guidelines/recommendations, norms and standards, in scientific publications etc.). This should be an implemented routine and funded component (by state). The national procurement of all HIV tests used in the country should also be informed by these validations and in general performance characteristics should be taken more into account at the procurement (national and/or regional).
 - The implemented quality control programme for HIV testing laboratories should be reviewed to confirm that it is sufficiently challenging (number of samples, number of positives/negatives, and optical density of the samples) to capture low-performance laboratories, or it should otherwise be optimized. A clear policy for investigative and corrective actions should also be in place.
 - The recording of all test results in all laboratories needs to be clear and easy to link to individual patients. It is important that the test results from the mother can easily be linked to the test result of her child, that pregnant women can be easily identified, and that also negative samples are reported. Furthermore, it is crucial to be able to exclude duplication of tests, e.g. several tests from the same women (at the same time and different times). All this might hopefully be solved when the new electronic eHealth system being under planning is widely implemented.
 - Regarding the wide use of RDTs (particularly at the HPPs), it is imperative to understand that the performance (sensitivity, specificity, etc.) of available RDTs highly differs. Accordingly, based on adequate validation data, the most sensitive and specific ones (ideally 4th generation tests) should be selected for use. It is also crucial to provide appropriate training and quality assurance, including a quality control programme, for RDTs. Finally, it is essential to ensure that all individuals with screening reactive samples attend the RAKUS/LIC for confirmatory testing (by escorting them or by adopting similar solutions) and if positivity to HIV is confirmed, that patients are adequately treated and/or followed up. Without this system (and as it currently is), a large number of true HIV positive individuals might never be confirmed and enrolled in treatment and follow up, and a number of screening reactive individuals (but false positive) will falsely consider themselves as HIV infected.
27. Recommendations on Human rights, gender equality and community engagement:
 - Ensure that all essential medicines are available for mothers living with HIV and children exposed to HIV without any restriction

- Reorganize the reimbursement system for HIV pre- and post-test counselling services, in order to secure that doctors have sufficient time and are paid for such tasks that are essential for HIV positive mothers.
- Consider the implementation of counselling services for serodiscordant couples and prenatal preparation, trainings to couples, provision of condoms.
- Review whether pregnant women with risky behaviours being referred by their GP to one of the labs for free testing are required to pay for pre- and post-counselling services, since this might create barriers to testing for at risk and vulnerable groups.
- Ensure obtainment of an informed consent from pregnant women tested for HIV; adolescents should have the right to consent for themselves.
- Protect confidentiality; ensure that it does not become a barrier for access to services for PLHIV.
- Prevent discrimination of PLHIV and their children.
- Ensure availability of free condoms for pregnant women belonging to at risk and vulnerable groups and for PLHIV.
- Prepare and distribute educational materials to medical professionals and train them on patients' rights, so that they can improve their attitudes towards vulnerable groups and especially towards mothers and children with HIV.
- Provide free formula to newborns exposed to HIV as required. It will also be an incentive to link mothers - especially those from key populations - to health care services.
- Provide adequate support and information to pregnant women with HIV on ART, PMTCT, delivery, prevention treatment for the newborn, breastfeeding, etc.
- Provide resources to HPPs, to allow their staff to accompany clients with reactive HIV test results for confirmatory testing and subsequent follow-up, so that linkage to care and treatment are ensured and adherence is supported and sustained.
- Improve treatment adherence of pregnant women. Take into consideration the involvement of CSOs in the achievement of such objective.
- Improve collaboration among different services and settings, in order to avoid that patients are lost to follow-up.

FINAL REMARKS

As an immediate impact of the mission the following progress has been achieved by the national HIV Program of Latvia on the implementation of recommendations given by the mission:

1. Following the mission recommendations to ensure the availability of NVP syrup so that the treatment can adhere to national guidelines which follow the WHO recommendations, the MOH of Latvia, in cooperation with RAKUS/LIC, NHS and Riga Maternity Hospital, has initiated the necessary procedures in order to resolve the issue. By the end of August, 2016 the process of the procurement preparation of NVP syrup has been started.
2. By the end of August, 2016 the MOH of Latvia has come up with the new initiative – infant formula provision for infants born to HIV-positive mothers (covered by State Budget). The procedures and logistics are to be finalised. It is planned that initiative will be implemented from 2017. The mission

would recommend to consult recently published WHO/UNICEF Guideline “Updates on HIV and infant feeding” and update national guidelines accordingly.

http://www.who.int/maternal_child_adolescent/documents/hiv-infant-feeding-2016/en/

3. The epidemiological investigation started (by CDPC Latvia) in order to examine the latest cases of late HIV detection in children, it is planned that the results will be available at the end of 2016, beginning of 2017.

4. The HIV/AIDS registry: there is working group attached to the CDPC, which works on creation of new detailed registry (instead of existing one), which is going to be integrated into the new e-health system

5. Testing of newborns: together with RAKUS/LIC, Maternity Hospital specialists adapted the existing instruction of sampling in order to make system of sampling and logistic requirements very clear. Maternity Hospital in Riga already implements this procedure. Regional hospitals still are under consideration since there is relatively short time in which samples shall be delivered to the Laboratory. Colleagues are working on this. The testing and sampling is to be included in Cabinet Regulations as strong recommendation.

ANNEX 1 – SCOPE AND PURPOSE

WORLD HEALTH ORGANIZATION
REGIONAL OFFICE FOR EUROPE

WELTGESUNDHEITSORGANISATION
REGIONALBÜRO FÜR EUROPA



ORGANISATION MONDIALE DE LA SANTÉ
BUREAU RÉGIONAL DE L'EUROPE

ВСЕМИРНАЯ ОРГАНИЗАЦИЯ ЗДРАВООХРАНЕНИЯ
ЕВРОПЕЙСКОЕ РЕГИОНАЛЬНОЕ БЮРО

**Mission to review progress achieved in Latvia
on the Elimination of Mother to Child
Transmission of HIV and assess readiness to
elimination validation
Latvia, 23 – 27 May 2016**

Scope and purpose

Background

The global community is now firmly committed to eliminating mother-to-child transmission (MTCT) of HIV and congenital syphilis (CS) as public health problems. These goals are central to the EMTCT Global Plan and to the UNAIDS 2020 treatment targets and 2030 ending AIDS targets and are highlighted in the draft WHO health sector strategy on HIV for 2016-2021. There are now clear global, regional and country targets to attain these ambitious goals and an emerging “Validation of Elimination” process, being led by WHO globally.

In September 2011, the WHO European Member States approved the European HIV/AIDS Action Plan 2012-2015 by Resolution 112571 endorsed at the Regional Committee session in Baku on 15 September 2011. The resolution commits Member States to aim for elimination of mother to child transmission (MTCT) of HIV by reducing the rate of MTCT of HIV to $\leq 2\%$ in non-breastfeeding population and $\leq 5\%$ in breastfeeding population. The participants of two regional technical consultations (April 2015 and December 2015, Astana, Kazakhstan) for 18⁸² (about 70 colleagues) and 27⁸³ (about 90 colleagues) selected countries of central, western and eastern Europe and central Asia respectively representing National HIV/AIDS, STI, PMTCT programmes, national and international civil society organisations, people living with HIV and affected communities, international experts, the UN family, major partners including TGF, US CDC, the WHO HQ, Regional and country offices and the WHO Collaborating Centres discussed and reached consensus on the decision that regional goals, targets, criteria and processes for the elimination of MTCT of HIV and CS in the WHO European Region follow Global ones suggested by the Global guidance on criteria and processes for validation of elimination of MTCT

⁸² Armenia, Azerbaijan, Belarus, Bulgaria, Denmark, Georgia, Estonia, Kazakhstan, Kyrgyzstan, Lithuania, Moldova, Russian Federation, Serbia, Slovakia, Tajikistan, UK, Ukraine, Uzbekistan

⁸³ 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

of HIV and congenital syphilis⁸⁴ except for HIV treatment coverage for pregnant women which in the WHO European region will be of $\geq 95\%$ (while Global one is of $\geq 90\%$).

The regional goals and targets for validation of elimination of MTCT of HIV and congenital syphilis are as follows:

- a case rate of new paediatric HIV infections due to MTCT ≤ 50 cases per 100,000 live births
- a case rate of congenital syphilis of ≤ 50 cases per 100,000 live births
- MTCT rate of HIV of $< 5\%$ in breastfeeding populations **OR** MTCT rate of HIV of $< 2\%$ in non-breastfeeding populations.
- Antenatal care (ANC) coverage (at least one visit) of $\geq 95\%$
- Coverage of HIV and/or syphilis testing of pregnant women of $\geq 95\%$
- Antiretroviral (ARV) coverage of HIV-positive pregnant women of $\geq 95\%$
- Treatment of syphilis-seropositive pregnant women of $\geq 95\%$

The WHO Regional Office for Europe, in partnership with UNAIDS and also UNICEF, UNFPA and other partners including ECDC and civil society leads the process for the elimination of MTCT of HIV and CS in the WHO European Region and provides secretariat support.

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, 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.

The major goal and objectives of the planned mission include the review of the progress achieved in Latvia on the Elimination of Mother to Child Transmission of HIV, the assessment of the country readiness for elimination validation and, depending on the mission findings, preparing recommendations to accelerate progress towards achieving elimination and elimination validation as appropriate.

The methodology The Regional Validation Team (RVT) will be formed by the Regional Validation Secretariat to accomplish the above mentioned goals and objectives. The tools that will be applied in Latvia will follow the globally agreed methodology described in the latest Global guidance on the implementation of country EMTCT validation missions. The following tools will be applied:

1. *Programmes and services assessment tool*: this tool reviews the programmatic components relevant to the elimination of HIV MTCT.

2. *Data verification and impact assessment tool*: this tool assesses the reliability of the data generated by the country to evaluate achievement of the elimination targets, and to ascertain that the elimination validation impact and coverage targets were achieved.

3. *Laboratory data assessment tool*: this tool verifies the existence of an adequate laboratory network to provide the services needed to achieve and maintain a programme for EMTCT of HIV and to ensure that the results generated by the laboratory network are accurate and reliable.

4. *Human rights, gender equality and community engagement tool*: this tool verifies that EMTCT targets have been achieved in a manner consistent with basic human rights and gender equality considerations, and that communities are meaningfully involved in the planning, delivery, and

⁸⁴ Global guidance on criteria and processes for validation Elimination of mother-to-child transmission (EMTCT) of HIV and syphilis <http://www.who.int/reproductivehealth/publications/rtis/9789241505888/en/>

monitoring and evaluation of programmes and services. This includes the engagement of civil society organizations (CSOs) as well as networks of women, young people and other people living with HIV.

Expected outcomes: the mission report containing mission findings and the recommendations.

ANNEX 2 - MISSION TEAM

NN	Name	Area of specialization	Details
1.	Lella Cosmaro	Human rights, gender equality and community engagement	Regional expert, Italy
2.	Lali Khotenashvili	Program and services	WHO Regional Office for Europe, Team lead
3.	Yuri Kobyshcha	Strategic Information	Regional expert, Ukraine
4.	Solvita Olsena	Human rights, gender equality and community engagement	National expert, lawyer
5.	Pablo Rojo	Clinical expert	Regional expert, Spain
6.	Marina Semchenko	Programs and services	UNAIDS Regional Support Team
7.	Magnus Unemo	Laboratory services	WHO Collaborating Centre, Orebro, Sweden

ANNEX 3 - LIST OF THE SITES VISITED BY THE MISSION

The list of the sites visited and colleagues met by the mission included those listed below:

1. The MOH staff leading and coordinating HIV prevention and control including MTCT prevention
2. RAKUS/LIC, the major clinic in the country performing HIV diagnosis and treatment, ensuring the work of the Reference laboratory for all infectious diseases, including HIV Reference laboratory, Outpatient / inpatient services for PLHIV, paediatric treatment and care and also prevention and care for HIV exposed newborns
3. Latvian Centre for Disease Prevention and Control of Latvia
4. Riga Municipality, Health Administration, Public Health Promotion and Prevention Unit
5. Pauls Stradiņš Clinical University Hospital (PSKUS) / Gynaecology and Maternity Unit
6. Riga (municipality) Maternity Hospital, services for parturients and newborns, outpatient services Medication supply chain, Laboratory - outsourcing (MNS Laboratory); Maternity and newborn care and treatment also for HIV-positive patients
7. Bauska hospital, hospital laboratory
8. Bauska HPP that leads work with vulnerable groups, HIV positive parturients, HIV-positive children
9. Riga Health Centre, Unit Ziepniekkalns, Outpatient services / Gynaecology, Maternity care, HIV voluntary testing
10. Riga Municipality Day Care Centre. Visiting facilities, meeting with GPs working at municipality's Day Centre for homeless and needy (GP cabinet, procedure cabinet),
11. CDPC, HIV/AIDS prevention point: HIV preventive work including free testing and counselling for HIV, hepatitis, STI including express tests; consultations with specialists on prevention and treatment issues; exchange of needles and syringes, condom distribution
12. Meetings with NGOs: HIV prevention and social programmes, Dia+Logs, AGIHAS, Papardes zieds, Baltic HIV Association, Society Association HIV.LV, NGO Association HIV.LV and AGIHAS.LV. Additional separate meetings were arranged with some of these NGOs (see ## 13 and 14 below).
13. NGO "Papardes zieds". Working with adolescents supporting expansion of accessibility of sexual and reproductive health services especially for marginalized and at risk groups; addressing also issue of abortion - protecting and supporting every woman's right to safe abortion, as well as promoting the use of modern contraception in order to reduce unwanted pregnancies and abortions; advocacy work
14. NGO "DIA+LOGS". The service provider for HIV prevention activities (medical supplies procured by CDPC)
15. Meeting with non-health sector on Human rights' issues: State Inspectorate for Protection of Children Rights; Child Rights, Ombudsman; Cross-sectoral Coordination Centre
16. The Health Inspectorate

17. Meetings at the MOH: briefing on first day of the mission highlighting mission's scope and purpose and debriefing (last day of the mission) sharing mission findings and recommendations

ANNEX 4 - MISSION AGENDA

Time	Venue		LVA representatives	WHO representatives
Monday, May 23, 2016				
9.00		Pick-up at the hotel and walk to the MoH	<i>Iveta Volkovska-Cielava, MoH</i>	
9.30-12.00 w coffee break	MoH, 309 72, Brivibas Str., Riga	Opening meeting, short presentations on current LVA situation and WHO mission Agenda: 1. WHO: scope and tasks of the mission, overview on validation of HIV vertical transmission 2. MoH: HIV prevention policy, Health system overview 3. CDPC: overview of CDPD role in HIV prevention, main challenges 4. NHS: financing and treatment in figures 5. RAKUS/LIC: experience and lessons learned 6. Riga Maternity Hospital: care and management of HIV cases	All parties	WHO experts: Yuri Kobyshcha (Surveillance), Magnus Unemo (Lab), Maria Luisa Cosmaro (Human rights/community engagement), Marina Semenchenko (UNAIDS, Programs/services), Lali Khotenashvili (Programs/services) Solvita Olsena, Attorney at law
		Lunch break/individual arrangements		

14.30-16.30	Latvian Centre for Disease Prevention and Control 22 Dunties Str., Riga	Develops proposals for health care and public health policy-making, Infectious disease epidemiological surveillance, monitoring and intelligence. Communicable disease prevention and control activities, including measures for population groups at increased risk of infection or belonging to special risk groups. Acquires, collects, processes and analyses public health and health care statistics; public health monitoring.	CDPC Dzintars Mozgis, Deputy Director Jurijs Perevoščikovs, Head of Department of Infectious Diseases Risk Analysis and Prevention Šarlote Konova, Public Health Analyst Irisa Zīle, Health care statistician Agnese Freimane, Senior Coordinator of Health Promotion. NHS Inga Brokere, Medical services department, Unit of Outpatient Services, Deputy Head Zinta Rugāja, Medicines and medical equipment department, Unit of Therapeutic evaluation, Head Viktorija Baire, Head of External Relations Astra Cīrule E-health Standards Unit, Head <i>Jana Feldmane, MoH</i>	WHO experts: Yuri Kobyshcha (Surveillance), Magnus Unemo (Lab), Lali Khotenashvili (Programs/services) (1st part)
14.30-15.30	NGOs MoH, 309 72, Brivibas Str., Riga	Meeting with NGOs	Latvian NGO: Agita Sēja, HIV prevention and social programmes, Dia+Logs Guna Zvirbule, AGIHAS Papardes zieds Anda Kīvīte, Baltic HIV Association,	WHO experts: Maria Luisa Cosmaro Marina Semenchenko

Aleksandrs Molokovskis,
Society Association HIV.LV

15.30-16.30	NGO Association HIV.LV and AGIHAS.LV MoH, 309 72, Brivibas Str., Riga	Services: harm reduction within drug users, reach out and integration into the community those who are recognized as dependent, HIV infected persons, ex- prisoners etc.	Aleksandrs Molokovskis, HIV.LV Guna Zvirbule, AGIHAS	WHO experts: Maria Luisa Cosmaro Marina Semenchenko
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Tuesday May 24, 2016

9.00 Pick-up at the hotel by minibus

9.30-12.00	Pauls Stradiņš Clinical University Hospital (PSKUS) / Gynaecology and Maternity Unit (Building #8, 3rd floor, conference room) 13, Pilsoņu Str., Riga	Maternity unit, specialises in parturients with chronic diseases and other health disorders (10 HIV-posit parturients out of total 62 in 2015, p.10) Report Maternity and newborn care and treatment also for HIV positives (as long as mother and child shall stay at the maternity hospital or unit) Initial testing, laboratory Hospital presentation, questions and answers; (10:40 – 11:20 visiting Laboratory and Units)	Maira Jansone, Head of Mother and Child Health Clinic, Dina Apele-Freimane, Acting Head of Newborn Intensive Therapy and Care Unit, Pauls Aldiņš, Infectologist, Consulting Service for Communicable Disease treatment and Hospital Epidemiology Dagnija Straupmane, Head of Joint Laboratory, Džineta Heinrihsone, Head of Treatment Quality <i>Iveta Volkovska-Cielava, MoH</i> <i>Jana Feldmane, MoH</i>	WHO experts: Yuri Kobyshcha (Surveillance), Magnus Unemo (Lab), Maria Luisa Cosmaro (Human rights/community engagement), Marina Semenchenko (UNAIDS, Programs/services), Lali Khotenashvili (Programs/services) Pablo Rojo Conejo, Clinical issues Solvita Olsena, Attorney at law
11.00-12.00	Outpatient services / Gynaecology Riga Health Centre, Unit Ziepniekkalns 57, Valdeķu Str., Riga	Outpatient service, Maternity care Procedure cabinet where blood samples may be taken and sent to the laboratory (usually private) Discussion with gynaecologist on maternity care, HIV voluntary testing	Inta Dinsberga, gynaecologist Ineta Zīriņa, Head of Board <i>Iveta Volkovska-Cielava, MoH</i>	Maria Luisa Cosmaro (Human rights/community engagement), Lali Khotenashvili (Programs/services)
Lunch break				
15.30-16.30	MoH, 424 72, Brivibas Str., Riga	Riga Municipality's view on health care and public health services and prophylaxis in HIV elimination (including HIV positive pregnant)	Inga Solovjova, Riga Municipality, Head of Health Administration Vivita Ķīkule, Public Health Promotion and Prevention Unit, Deputy Head of Health Administration <i>Jana Feldmane, MoH</i>	Maria Luisa Cosmaro (Human rights/community engagement) Maria Luisa Cosmaro (Human rights/community engagement), Solvita Olsena, Attorney at law)

17.00-18.00	NGO HIV Association, testing point 19-K2 (2nd building), Stabu Str., Riga	Baltic Services: Information and professional consultation on communicable diseases; Information on medical institutions and professionals; HIV, syphilis, hepatitis B and C express tests; free condoms.	Inga Upmace	Maria Luisa Cosmaro (Human rights/community engagement) Maria Luisa Cosmaro (Human rights/community engagement), Solvita Olsena, Attorney at law)
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Wednesday May 25, 2016

9.30-11.30 (end time variable)	Riga Maternity Hospital 45, Miera Str., Riga	Riga (municipality) Maternity Hospital covers all services for parturients and newborns as well as outpatient services (majority of total number of deliveries in the country) (38 HIV-posit parturients out of total 62 in 2015, Report p.10) (Medication supply chain Report p.13) Laboratory - outsourcing (MNS Laboratory) Maternity and newborn care and treatment also for HIV positives (as long as mother and child shall stay at the maternity hospital or unit) Collaboration among obstetric specialists, neonatologists, infectologists Lunch break	Dace Rezeberga, Chief Doctor, Riga Maternity Hospital other representatives Gunta Stūre, RAKUS/LIC representative <i>Jana Feldmane, MoH</i>	Yuri Kobyshcha (Surveillance), Magnus Unemo (Lab), Maria Luisa Cosmaro (Human rights/community engagement), Marina Semenchenko (UNAIDS, Programs/services), Lali Khotenashvili (Programs/services) Pablo Rojo Conejo, Clinical issues
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13.30-15.30 (end time variable)	RAKUS/LIC 3, Linezera Str., Riga	Major clinic in the country performing HIV diagnostic and treatment, ensuring the work of Reference laboratory for all infectious diseases, including HIV testing Reference laboratory Outpatient / inpatient services for HIV patients Paediatric care for HIV exposed newborns Patients, compliance Collaboration among obstetric specialists, neonatologists, infectologists	Gunta Stūre, Head of HIV/AIDS Unit, Inga Janušķēvica, Head of HIV/AIDS outpatient Unit, Santa Ansone, paediatrician at HIV/AIDS Unit, Tatjana Kolupajeva, Head of Viral infections Molecular Biology, Reference Laboratory, RAKUS/LIC Riga Maternity Hospital representatives <i>Jana Feldmane, MoH</i>	Magnus Unemo (Lab), Pablo Rojo Conejo, Clinical issues (1st part, due to the flight arrangements) Maria Luisa Cosmaro (Human rights/community engagement)
16.00-17.00	Health Inspectorate 7, Klijanu Str., Riga	Control of medical institutions; Access to health services and government spending monitoring and control; Control of Healthcare quality; Control of pharmaceutical companies and movement of medicinal products; Control of High risk objects; Factors affecting public health surveillance	Alla Nogotkova <i>Jana Feldmane</i>	Cancelled due to the non-attendance of experts
16.00-17.00	HIV prevention point 7, Klijanu Str., Riga	HIV preventive work - Variety of free tests, such as HIV, hepatitis, etc. STI express tests, specialist advice on health, prevention and treatment issues. Exchange of syringes, free condoms.	Inga Bulmistre, HPP <i>Agnese Freimane, CDPC</i> <i>Iveta Volkovska-Cielava, MoH</i>	Maria Luisa Cosmaro (Human rights/community engagement)

Thursday May 26, 2016

8.00-13.00 (pick-up from the hotel)	HIV prevention point / Bauska (1,5h drive) Bauska Hospital	Work with vulnerable groups, addictions, HIV positive parturients, HIV-positive children, risk factors, accessibility of services	Tatjana Kalniņa, worker, Mirdza Brazovska, Head of hospital <i>Agnese Freimane and Iveta Volkovska-Cielava</i>	Social nurse	Yuri Kobyshcha (Surveillance), Magnus Unemo (Laboratory services) Lali Khotenashvili (Programs/services) Marina Semenchenko (UNAIDS, Programs/services)
9.00-11.00	MoH, 424 72, Brivibas Str., Riga	Meeting with non-health sector Human rights' issues	Inga Krastiņa, State Inspectorate for Protection of Children Anna Krasanova, Child Rights, Ombudsman Ieva Kārkliņa, consultant, Cross-sectoral Coordination Centre <i>Jana Feldmane</i>	State Rights	WHO experts Solvita Olsena, Attorney at law Maria Luisa Cosmaro (Human rights/community engagement), Marina Semenchenko (UNAIDS, Programs/services)
10.30		Pick-up from the MoH by car to State Social care centre "Riga" > HPP in Ogre			
11.00-12.00	State Social care centre "Riga", Unit "Pļavnieki" 3, Zebiekstes Str., Riga	Long-term social care and social rehabilitation services for children orphaned and left without parental care, for children under two years of age, children with physical and mental disabilities and disabled children with severe mental disorders who have not attained the age of 18. Currently 4 HIV positive children in the custody. Provide Paediatrician, social worker, physiotherapy. RAKUS/LIC provides medication, paediatrician may take samples to be sent to the laboratory or children may be taken to the laboratory for analysis. Centre is under supervision of Ministry of Welfare	Paediatrician, social worker Līga Rīta, Ministry of Welfare <i>Jana Feldmane</i>		Maria Luiza Cosmaro (Human rights/community engagement)

Lunch break