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Maternal and Child Health Initiative



**CLINICAL-ORGANIZATIONAL
GUIDELINES ON PREVENTION OF HIV
MOTHER-TO-CHILD TRANSMISSION**



First edition

Moscow 2005

**Please send any comments or suggestions regarding these Guidelines to
Maternal and Child Health Initiative**

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Preface

The development of the Clinical-Organizational Guidelines was initiated by the Maternal and Child Health Initiative (MCHI), implemented by John Snow, Inc., USA. The guidelines have been completed within the framework of the Russian-American Intergovernmental Cooperation and Bilateral Committee on Health, led in Russia by the Ministry of Health and Social Development of the Russian Federation. MCHI's work is funded by the U.S. Agency for International Development.

The goal of MCHI is to improve the health of women and children through improving the quality and accessibility of healthcare. MCHI's work aims to refine progressive perinatal techniques and their introduction into maternal and children's health care services. The Initiative is being implemented in 16 regions of the Russian Federation (RF): Republic of Komi, Republic of Sakha (Yakutia), Kaluzhskaya, Novgorodskaya, Permskaya, Vologodskaya, Tyumenskaya, Irkutskaya, Murmanskaya, Omskaya, Orenburgskaya, Sakhalinskaya regions, Altaisky, Krasnoyarsky, Khabarovsky, and Primorsky Krai.

Prevention of vertical HIV transmission from the mother to her child (PMTCT) is one of the major goals of the MCHI project. Within this framework, a task force comprising representatives of MCHI project regions has been established to analyze the current PMTCT situation and address and solve existing problems. This task force includes managers of maternal and childcare services and those of AIDS centers. The task force's efforts have confirmed the need to develop clinical-organizational guidelines to refine the work on preventing vertical HIV transmission, thus reducing the risk a mother will infect her child.

Work on the Clinical-Organizational Guidelines on Prevention of HIV Mother-to-Child Transmission began in September 2004. The Maternal and Child Health Initiative organized a meeting of the representatives of maternal and childcare services and regional AIDS centers and national and international HIV/AIDS experts. During the meeting, ideas and suggestions for the organization of effective healthcare aiming to prevent vertical HIV transmission were presented. The Federal Scientific-Methodological Center for Quality Assurance at the Central Health Organization and Informatization Scientific-Research Institute (CHOISRI) summarized all suggestions received from the regions and proposed the format of the Clinical-Organizational Guidelines.

The current guidelines are based on the principles of methodology of healthcare quality assurance developed within the framework of the Project on Quality Management – Russia, which is financially supported by the US Agency for International Development. At present, this Project is being developed and supported by the Federal Scientific-Methodological Center for Quality Assurance at CHOISRI.

The guidelines have been developed jointly with the Department of Medical-Social Problems of Family, Maternity, and Childhood of the RF Ministry of Health and Social Development, Federal Service on Supervision in Protection of Consumer Rights and Human Wellbeing, and the Scientific-Practical Center for Assistance to Pregnant Women and Children with HIV Infection, in cooperation with CHOISRI, and with the consultative help of the Federal Scientific-Methodological Center for AIDS Prevention.

The guidelines have been discussed at several MCHI meetings of regional representatives and experts. The final version has been submitted to and approved by the national and regional HIV/AIDS authorities and experts.

In developing the guidelines, modern approaches to preventing HIV vertical transmission based on evidence-based medicine were used, including materials from the Centers for Disease Control and Prevention (USA), principles articulated in the Basic Strategy of the World Health Organization on HIV prophylaxis in neonates in Europe, and the rich experiences of the Russian regions.

Representatives of UNICEF have provided significant consultative help in developing the guidelines. A selection of data published in the informational-analytical review, "Children, Women, and HIV-Infection in the Russian Federation" (RF Ministry of Health and Social Development, UNICEF, 2004) is presented in the guidelines. UNICEF will be supporting dissemination of the Guidelines among healthcare workers in the RF regions.

The guidelines also drew on the experience of the Prevention of Perinatal HIV Transmission in St. Petersburg and the Leningrad Region project, implemented by the the Elizabeth Glaser Pediatric AIDS Foundation (USA), as well as on materials prepared by the American International Health Alliance. A booklet on counseling women has been developed jointly with the Healthy Russia project. All listed projects are funded by the US Agency for International Development.

The guidelines take into consideration Russian policies and regulations pertaining to control of HIV/AIDS, and will be updated regularly. The Maternal and Child Health Initiative appreciates all suggestions and comments that would improve the guidelines.

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List of acronyms

AIDS	Acquired Immune Deficiency Syndrome
ARV prophylaxis	Prophylaxis of mother-to-child HIV transmission with antiretroviral drugs
CHOISRI	The Central Health Organization and Informatization Scientific-Research Institute of the RF MoH
ELISA	Enzyme-Linked Immunosorbent Assay
FMS	Feldsher-Midwife Station
HCI	Healthcare Institution
MoH&SD	Ministry of Health and Social Development
PMTCT	Prevention of HIV mother-to-child transmission
UNAIDS	Joint United Nations Program on HIV/AIDS
UNICEF	United Nations Children's Fund

1. Outline of the Guidelines

1.1 Structure of the Guidelines

Section One is devoted to descriptions of goals, objectives, structure, and target audience of the guidelines. It contains descriptions of all elements of the system of healthcare provision to women and children with focus on preventing vertical HIV transmission. This section gives a general impression of organizing this system's work.

Section Two provides explicit descriptions of each element of preventing vertical HIV transmission.

Section Three describes the methods of preventing occupational HIV infection transmission.

Requirements for human resource development and major principles of organizing education for healthcare workers on preventing vertical HIV transmission are presented in **Section Four**.

Indicators of monitoring and evaluation of the work done on prevention of HIV vertical transmission are described in **Section Five**.

Section Six presents evidence-based literature sources.

In Section Seven – Appendices – A glossary is included, as well as explanations to the terms used in the Guideline. The most recent regulations of the Ministry of Health and Social Development pertaining to the prevention of vertical HIV transmission, a booklet for counseling women, and a plan for management of an HIV-infected woman during her pregnancy are included in the Appendices; these materials are necessary for organizing activities according to the guidelines.

In the Clinical-Organizational Guideline, figures and charts are used for depicting algorithms of the described processes adopted in the international literature.

1.2 Guidelines' significance

The most significant number of HIV-infected people officially reported in Eastern Europe and Central Asia live in the Russian Federation. According to the Federal Service on Supervision on protection of consumer rights and human wellbeing (July 2005):

- The total number of HIV cases reported in the RF is 324,88, since the beginning of registration on January 1, 1987.
- Average prevalence of HIV among the population is 215.8 per 100,000 people
- 62% of HIV-infected individuals are men. 38% of HIV-infected individuals are women.

The actual number of those HIV-infected in the RF may be significantly higher. The Joint United Nations Program on HIV/AIDS (UNAIDS) estimates there are 860,000 people living with HIV/AIDS in Russia, within a range of 420,000 to 1.4 million, of whom 290,000 are women. The majority are people of 15-29 years of age.

Detection of HIV infection among pregnant women has significantly increased. According to the Department of Medical-Social Problems of Family, Maternity, and Childhood of the MoH&SD, as of the end of 2004, the HIV identification rate among women was as high as 111.4 per 100,000 screened pregnant women. This rate is nearly 600 times higher than that of 1995. Over the course of the epidemic, 21,000 children have been born to HIV-infected women. More than 13,000 children require follow-up to identify their HIV status because they have antibodies to HIV. Diagnosis of HIV infection as a result of mother-to-child transmission has been confirmed in more than 2,000 children. In some children, HIV status is unknown due to various reasons, such as the lack of data concerning their place of residence and unwillingness of the family to have further contact with healthcare workers.

Vertical HIV transmission means transmission of the HIV infection from an HIV-infected woman to her child during pregnancy, delivery, or breastfeeding. In case prophylactic measures are lacking,

risk of mother-to-child HIV transmission is as high as 15-25% in developed countries and 25-45% in developing ones.

Prevention of HIV vertical transmission (PMTCT) is a set of measures for preventing transmission of HIV from the HIV-infected woman to the fetus or the baby during pregnancy, delivery, or breastfeeding. Main PMTCT modalities are: giving the woman prophylaxis with antiretroviral drugs (ARV prophylaxis) during pregnancy and delivery and to the baby after birth; planned selective Caesarian; and restricting invasive procedures during pregnancy and delivery, excluding breastfeeding. If all the above-mentioned activities are carried out in a correct manner, risk of HIV mother-to-child transmission does not exceed 2%.

Currently, assessing risk of HIV transmission from mother-to-child in the RF is difficult. Data from St. Petersburg indicates an average rate of 9% of vertical HIV transmission, with significant variations depending on the presence or absence of prenatal care.¹ In those instances when the woman didn't receive any care during her current pregnancy, risk of child's infection increased to 26%, compared to 4% when prenatal care was provided. Rates of neonatal infection vary from one region of the Russian Federation to another.² Research has been conducted by UNICEF and the Scientific-Practical Center for Assistance to Pregnant Women and Children with HIV infection among children with perinatal exposure to HIV. The proportion of such children born in 1987–2003 in 10 Russian territories who had a confirmed HIV diagnosis ranged from 13 to 33%.

Experience of the Maternal and Child Health Initiative in 14 regions of the RF shows that one of the major problems in organizing effective prophylaxis of HIV vertical transmission is insufficient cooperation between maternal and children's health services and AIDS centers.

These guidelines are meant to improve coordination between maternal and children's health services and AIDS centers and offers some clinical-organizational algorithms for refining care provided to women with HIV infection and their newborn babies.

1 Khaldeeva N, Hillis SD, Voronin E, Rakhmanova A, Yakovlev A, Jamieson DJ and Ryder RW. HIV-1 seroprevalence rates in women and relinquishment of infants to the State in St Petersburg, Russia, 2002. *Lancet* 2003; 362 (9400): 1981-1982.

² Report on the research on children with perinatal HIV contact born in 1987-2003 in 10 territories of the RF. This research has been done by the Scientific-practical Center for Assistance to Pregnant Women and Children with HIV infection with the support of the UN Children's Fund.

The Goal of the Clinical-Organizational Guidelines is to organize care to be provided to women and their newborn children to reduce risk of HIV vertical transmission.

Major Objectives of the Guidelines:

1. Establishing a standardized methodological approach to introducing activities on prevention of mother-to-child HIV transmission (PMTCT).
2. Defining PMTCT clinical algorithms at various stages of healthcare provision.
3. Defining standardized PMTCT indicators for control and evaluation of healthcare.
4. Educating health personnel on PMTCT.

1.3 Purpose of the Guidelines

1.3.1 Subject of the Guidelines

The subject of these guidelines are clinical and organizational issues of providing care in maternity hospitals to women, focusing on prevention of HIV vertical transmission at the stages of prenatal care, during delivery, and postpartum and to the baby after birth.

1.3.2 Task forces

These guidelines determine the practice of providing care to pregnant women at the stage of HIV testing; to HIV-infected women during prenatal care provided on an ambulatory basis; and to women in labor and postpartum women and their newborn infants in maternity hospitals and AIDS centers.

1.3.3 Professional designation

These guidelines have been developed for doctors and mid-level personnel in outpatient-ambulatory institutions, maternity hospitals, and AIDS centers, and employees of the sanitary-epidemiological surveillance. They are also intended for healthcare authorities of various levels.

1.3.4 Outcomes expected from using the Guidelines

- Establishing an effective system of preventing HIV mother-to-child transmission
- Reducing risk of HIV mother-to-child transmission
- Reducing the number of HIV-infected babies born to HIV-infected women.

1.4 Short description of system elements

The present guidelines determine the scope of PMTCT activities to be carried out in maternal and child healthcare services, jointly with the AIDS Center, at the following stages:

1. Therapeutic-diagnostic and prophylactic care of the HIV-infected woman.
2. Providing care to the HIV-infected woman in labor.
3. Providing care to the newborn infant right after birth.
4. Providing care to the newborn infant in the neonatal unit/patient room for mutual stay [rooming-in].
5. Early postpartum care of the HIV-infected woman.
6. Care of the woman and neonate after their discharge from a maternity hospital.

Stage 1. Care of the pregnant woman in ambulatory-outpatient institutions.

Pre-test counseling of pregnant women on HIV infection is conducted in ambulatory-outpatient institutions of maternal and children's healthcare services. Once voluntary and informed consent for HIV testing is obtained, blood is drawn for identifying and confirming HIV status. If the result of the test is positive, post-test counseling is conducted, including providing explanations of the test result.

Additional follow-up and management of the HIV-infected pregnant woman is carried out jointly by maternal and children's care institutions and AIDS centers. The following types of professionals participate in the provision of care to the HIV-infected pregnant woman: obstetricians-gynecologists and/or midwives of a territorial ambulatory-outpatient institution (women's clinic or feldsher-midwife station), authorized, trusted doctors of a territorial healthcare institution (HCI) on all issues of HIV/AIDS treatment; and specialists of municipal and regional AIDS centers. According to the Russian legislation, a pregnant woman has a right to choose a healthcare institution that will follow up with her during pregnancy.

Medical work-up of the pregnant woman, including determining her immune status (CD4 counts), viral loads, and HIV-disease stage is completed at AIDS centers. Center staff identify, prescribe, and distribute antiretroviral drugs (ARVs), control the adherence to taking medications, and monitor for possible adverse effects. Staff of the centers and the obstetrician-gynecologist who follow up with the patient discuss pregnancy and delivery management. Discussed topics include the institution at which delivery will take place, delivery mode, and a date of elective hospitalization. Counseling is provided to the pregnant woman on the importance of bottle-feeding for MTCT prevention. At this stage, an obstetrician-gynecologist of the hospital where delivery is scheduled to take place gets involved.

Stage 2. Healthcare provision to the HIV-infected woman in labor.

Upon admission to a maternity hospital of a woman with confirmed information on her HIV-positive status, counseling is provided regarding ARV prophylaxis in labor and delivery mode.

If the woman in labor gets admitted to the maternity hospital or maternity ward of a general hospital without her prenatal care chart or data on her HIV status, she is offered rapid diagnosis HIV testing after pre-test counseling. Having received test results, the woman in labor receives post-test counseling. If the rapid test turns out to be positive, she is offered ARV prophylaxis. In such a situation, the obstetrician-gynecologist independently initiates ARV prophylaxis in accordance with the conventional protocols, chooses the method of prophylaxis, and delivers the baby (conservatively or surgically) after obtaining the woman's informed consent.

Stages 3 and 4. Provision of care to the newborn after birth.

The infant born to the HIV-infected woman is given ARV prophylaxis in accordance with the conventional protocol. After birth, the baby is not put to the breast. The woman is counseled on the necessity for bottle-feeding.

Stage 5. Provision of postpartum care to the HIV-infected woman.

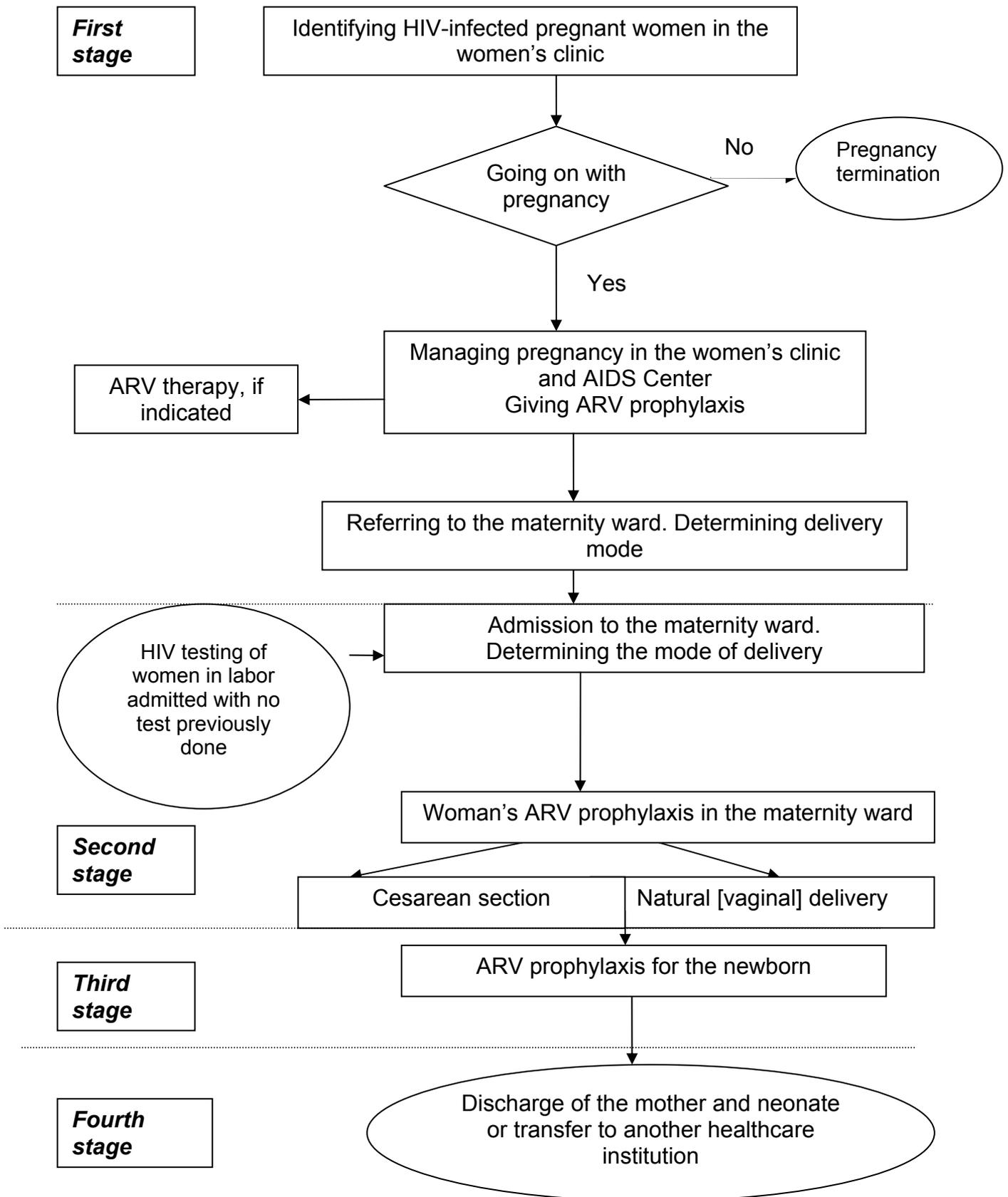
In the postpartum unit or patient room for mutual stay, the woman is provided with the care needed postpartum. She receives counseling on methods for terminating lactation, and upon her consent, she is given relevant medications. The woman also receives counseling on family planning methods. The most preferred contraception method is determined and prescribed. She is further provided with psychological support, an important opportunity for her to seek consultation of a social worker and other professionals, as needed.

Stage 6. A woman and her child being discharged from the maternity ward or, if necessary, transferred for follow-up and treatment to other healthcare institutions. Later, the woman and her child are followed up at their residence by the children's polyclinic/women's clinic and AIDS Center. A plan for follow-up is developed and steps for follow-up are specified.

At all stages, care is provided to the HIV-infected woman with strict adherence to the principles of ethics and confidentiality.

The general outline of the healthcare system with emphasis on PMTCT is presented in Figure 1. Indicators of evaluating effectiveness of the activities on preventing vertical HIV transmission may be found in the Appendix.

Figure 1. General diagram of the system of preventing HIV vertical transmission



1.5 Personnel

According to current Russian legislation, care for HIV-infected women is provided on common grounds in any HCI. High preparedness of all personnel for providing care is necessary for efficient prevention of HIV vertical transmission in any healthcare institution.

The obstetrician-gynecologist/midwife at the woman's place of residence directs the management of the pregnancy, in cooperation with AIDS center specialists. The midwife and obstetrician-gynecologist in the maternity ward also manage delivery. In the regions, delivering babies born to HIV-infected women is done in any maternity hospital or in the maternity ward designated for delivering babies born to women with infectious diseases. The neonatologist follows up with the baby after birth. Upon discharge from the maternity ward, an area pediatrician continues to follow up with the baby, with the AIDS center specialist's consultation.

If possible, social workers and representatives of a non-governmental organization providing support to HIV-infected people get involved at each stage.

1.6 Equipment

To implement PMTCT, maternity wards should have sufficient storage space for HIV rapid tests and ARV prophylaxis drugs, in accordance with the "Preventing HIV Transmission from the Mother to the Fetus" standards. The rest of the equipment involved in the process of providing care to the HIV-infected woman include standard HCI devices and supplies (gloves, disinfectants, eye protection, etc.). These institutions must have an approved plan for activities should occupational injury or needlestick occur that would lead to unprotected exposure of a healthcare worker's non-intact skin or mucous membranes to blood or other body fluids infected with HIV, including protocols for post-exposure prophylaxis with ARVs.

For carrying out efficient prevention of perinatal HIV transmission, AIDS centers ought to be supplied with sufficient quantities of antiretroviral drugs, provided with the capability to check CD4+ counts and viral loads. Centers should also possess the capacity to conduct enzyme-linked immunosorbent assay for HIV with confirmation by immune blotting; otherwise, they should refer blood and plasma specimens to the appropriate laboratory geared for this kind of diagnosis.

1.7 Regulatory and methodological coverage

At present, the following documents present the regulatory-legal basis for preventing HIV mother-to-child transmission in Russia:

- Federal Law of the RF of 03.30.1995 #38-ÔÇ. This law covers prevention of the spread of the disease caused by HIV across the Russian Federation.
- Federal Law of the RF of 08.12.1996 # 112-ÔÇ. This law covers making changes in the above-mentioned law.
- Disposition of the Government of the Russian Federation #1344-ð of 10.21.2004. This disposition is about approving the list of essential and the most important drugs».
- Decree of the RF Ministry of Health of 02.10.2003 #50. This disposition is about refining obstetric-gynecological care provided in ambulatory-outpatient settings.
- Decree of the Ministry of Health of December 19, 2003 # 606. This decree is an instruction on PMTCT and a sample of informed consent for ARV prophylaxis (see Appendix).
- Statement of RF Chief State Sanitary Doctor of 01.14.2004 #2. This statement is about intensifying activities aiming at counteraction of the HIV infection's spread in the RF.
- Decree of the RF Ministry of Health of 01.19.2004 # 9. This decree is about approving the temporary reporting form #313/ó, a notification about the case of completed pregnancy by the HIV-infected woman.
- Statement of the Government of the Russian Federation of 12.27.2004 #856. This statement is about approving the regulations on free pharmaceutical coverage for treating HIV infection in outpatient settings in federal specialty healthcare institutions.
- Decree of the RF Ministry of Health and Social Development of May 30, 2005 #375. This decree is about approving PMTCT standards (see Appendix).

2. Techniques and organization of preventing HIV vertical transmission

2.1 Prevention of HIV vertical transmission during pregnancy

Key statements

- *Counseling women on prophylaxis of HIV infection*
- *Counseling HIV-infected women on prophylaxis of HIV vertical transmission*
- *Testing women on HIV during pregnancy*
- *Organizing regular follow-up of the HIV-infected woman*
- *Measuring viral load and CD4 counts*
- *Prophylaxis of HIV vertical transmission with the use of antiretroviral drugs*
- *Psychological and social support to the woman*
- *Respecting confidentiality*

2.1.1 Testing

On the woman's initial visit to a women's clinic for her pregnancy, history is taken and obstetric-gynecological examination is done. Possible risk factors for HIV infection are clarified and risk factors for pregnancy are identified. The woman is offered laboratory tests recommended for pregnancy.

In accordance with the Decree of the Ministry of Health #606 and Decree of the MoH&SD #375, the HIV test is included in the list of routine tests offered during pregnancy to all women planning to preserve their pregnancy. Russian legislation reads that HIV testing of the pregnant woman is voluntary and should be accompanied by pre- and post-test counseling. While following up with the pregnant woman in the women's clinic, two tests are done consecutively, on initial visit for pregnancy and, if infection is not identified the first time, a second test in the third trimester (34-36 weeks).

2.1.1.1 HIV testing

At present, standard laboratory testing for HIV detects antibodies to HIV on **enzyme-linked immunosorbent assay** (ELISA). Modern kits for ELISA used in the Russian Federation allow for the detection of antibodies to HIV during the first 3 months following infection in the majority of cases. On rare occasions, these kits detect antibodies 4-9 months after infection with HIV. In case positive test results are yielded, repeated ELISA for HIV is conducted. If the positive result is confirmed, immune-blotting reaction is done.

Immune blotting is a more specific immune enzyme testing with detection of antibodies to HIV antigens. A positive result of this test gives final confirmation of HIV infection. Ambiguous results of immune blotting require repeated tests 2 weeks, 3 months, and 6 months later. If in half a year after the first test a woman maintains ambiguous test results on immune blotting with the absence of clinical symptoms of HIV or risk factors of HIV, the results are considered false positives.

Testing on HIV is accompanied by counseling that consists of pre- and post-test sessions. Specialists who received appropriate training do counseling. Pregnant women's pre-test counseling in the women's clinic is done by the obstetrician-gynecologist or midwife who sees primary patients.

2.1.1.2 Counseling related to HIV testing

To reduce the time of conducting **pre-test counseling**, the pregnant woman is asked to familiarize herself with a booklet (see Appendix) in which the following issues are discussed:

- What HIV is
- HIV transmission modes and how to prevent HIV

- What HIV infection includes, sequence of testing and communicating results, what kind of test results are to be anticipated, and what the benefits are of being tested
- Risk of HIV transmission to the child during pregnancy, delivery, and breastfeeding
- Possibility of preventing HIV mother-to-child transmission.

The doctor then answers the woman's questions and discusses the booklet's content with her to make sure that she understands the information.

There are other methods of pre-test counseling. In some regions, audio and/or videotapes containing all aforementioned information are used. Women who seek assistance in the women's clinic for the first time over the course of their pregnancy get acquainted with these tapes. After that, the doctor discusses with the woman the issues, challenging her understanding of presented information.

Another option currently utilized is counseling a group of pregnant women by the healthcare worker, followed by individual communication should questions remain.

Regardless of the counseling type selected, a woman must confirm her voluntary agreement on HIV counseling and testing.

Post-test counseling is done after the receipt of HIV test results.

If the HIV test result is negative, then antibodies to HIV are not detected and the woman is informed about the necessity for having the HIV test repeated at 34-36 weeks. This is done in order to rule out recent infection, as the period of the seronegative window after getting infected with HIV when antibodies to HIV are not detectable yet, and to rule out HIV infection over the course of pregnancy after the first test is done. The woman is reminded of the measures for reducing risk of HIV infection. On repeating the HIV test at 34-36 weeks, the same schedule of pre- and post-test counseling is applied.

Post-test counseling of pregnant women whose HIV-positive status is identified is done by employees who have been specially trained in counseling (obstetrician-gynecologist, psychologist, sociologist). If this type of training has been provided to all staff of the women's clinic, post-test counseling is offered by the obstetrician-gynecologist who is following up with the woman. Counseling is carried out with respect to all confidentiality rules.

For post-test counseling, information detailed during pre-test counseling is reiterated, with consideration of woman's psychological status and with empathy. Jointly with the woman, a plan for future actions to cope with psychological stress and preserve health must be developed. During post-test counseling, issues related to HIV and current pregnancy are to be covered. Upon the woman's request, it is possible to go into details of post-test counseling topics and more explicitly elucidate on specific issues associated with HIV, available methods of its treatment, and prevention of vertical transmission.

After post-test counseling, the HIV-infected pregnant woman is referred to the territorial AIDS center. An infectious disease doctor of the center conducts thorough and detailed post-test counseling, with mandatory coverage of the following topics:

- Course of HIV infection;
- Risk of HIV transmission from the mother to her child and what is available for risk reduction;
- Other risk factors enhancing HIV transmission to the fetus during pregnancy: smoking, drugs, unprotected sex with multiple partners;
- Plausible outcomes of the HIV-infected woman's pregnancy;
- Methods of preventing HIV mother-to-child transmission;
- Necessity for medical follow-up of the woman and her child;
- Refusal of neonate's breastfeeding, and adoption of bottle feeding;
- Diagnosis of HIV in the child;
- Modern contraception methods for preventing unintended pregnancy;
- Confidentiality of medical follow-up;
- Possibilities for receiving social-psychological support; and

- Need for prophylaxis of HIV transmission to other persons and reminding of HIV prevention methods.

If the HIV status of the woman is known in advance and she is definitely pregnant, counseling the woman on the aforementioned subjects is also conducted.

It is important to assess the risk of negative consequences of informing about HIV status and to figure out whether the woman possesses any support from a part of others. It is likely that the assistance of a psychologist or psychiatrist is necessary. The possibility of informing her partner, trusted friends, and/or relatives to gain their support is discussed with the woman.

2.1.2 Decisions on preserving pregnancy

According to Russian legislation, women have the right to make an independent choice concerning childbirth. If the woman **intends to terminate her pregnancy**, she is referred to a gynecology unit near her place of residence. In the women's clinic and gynecology unit, counseling is done regarding post-abortion contraception and rehabilitation (see the Clinical-Organizational Guideline on Providing Care to Women after Abortion of the Maternal and Child Health Initiative). Further follow-up of the woman is performed by the AIDS center and by her gynecologist in the area women's clinic or in other healthcare institution chosen by the woman. Follow-up in the Center comprises monitoring of viral load and immunology indicators. The gynecologist does follow-up in order to preserve reproductive health and prepare the woman for the intended pregnancy to improve the pregnancy's outcomes and/or effective contraception.

Standards of managing HIV-infected women who plan on getting pregnant should include assessment of reproductive health, taking somatic history, testing for infectious diseases and sexually transmitted infections, prescribing folic acid, and refining nutritional patterns. Social-psychological support is provided.

If pregnancy is not planned, the gynecologist counsels the woman regarding acceptable contraception methods; if possible, the woman should be provided with the chosen method of family planning free of charge. While counseling female drug users, it is important to remember possible disorders of their period (amenorrhea) that require additional doctor's explanations for assuring efficient contraception in this group of women. Women must be referred to drug abuse centers and rehabilitation or harm reduction programs when appropriate.

As needed, therapy for HIV infection is initiated. While treating women of reproductive age prior to their pregnancy, it is preferable to administer effective ARVs preventing HIV perinatal transmission with low risk of negative impact on the fetus, since diagnosis of pregnancy in a number of cases is made after the completion of fetal organogenesis.

2.1.3 Follow-up and testing during pregnancy

2.1.3.1 Follow-up by the obstetrician-gynecologist

The woman who preserves her pregnancy continues to be followed-up by the obstetrician-gynecologist at her place of residence at the women's clinic, feldsher-midwife station, or by the gynecologist in the healthcare institution chosen by the woman, as well as by the specialist of the AIDS center. In some regions, a system of trusted doctors is used, in which a doctor who received training on PMTCT and is informed about woman's HIV status follows up with the woman.

To manage the HIV-infected pregnant woman jointly, using the chart of joint follow-up is proposed. A part of this document is a follow-up plan developed by the obstetrician-gynecologist and specialist of the AIDS center; the plan ought to be simple, clear, and understandable. Pregnancy management plans should be discussed with the woman in detail (see the sample follow-up plan in Appendix). This follow-up plan is kept by the woman and the copy is kept in the follow-up chart.

The importance of being followed-up on a regular basis by the obstetrician-gynecologist and AIDS center specialist must be explained to the woman, clarifying the feasibility of regular medical follow-up. It may be difficult for the woman to adhere to her follow-up schedule because of remote

place of residence, transportation expenses, etc. Thus, the most important dates for mandatory visits to the obstetrician-gynecologist and the AIDS center specialist should be determined.

For a normal pregnancy course, routine follow-up of the pregnant woman in the women's clinic is done. In accordance with the Decree of the RF Ministry of Health #50, for physiological course of pregnancy, frequency of follow-up visits may be established by the obstetrician-gynecologist at 6-8 times during pregnancy. This may be scheduled as long as the woman is receiving regular follow-up provided by a specially trained midwife starting at 28 weeks of gestation. According to the above-mentioned Decree, the use of a gravidogram is recommended for timely evaluation of possible deviations in the pregnancy and the fetus' development. Ultrasonic examination is done also according to the Decree; it is especially important to conduct this examination at 18-20 weeks of gestation to detect developmental defects of the fetus. In case of complicated pregnancy or a threatening miscarriage, relevant care is provided. Invasive curative and diagnostic procedures are to be avoided.

Regular control of visits is important. According to Decree #50, it is mandatory for either a midwife or obstetrician-gynecologist to visit those women who missed their medical appointment for pregnancy at home. Home visits must include checking adherence to taking prescribed ARVs.

If she lives faraway from the Regional AIDS Center, follow-up and prescribing ARVs is done by the district hospital staff trained at the territorial AIDS Center.

It is necessary to repeatedly explain to the woman the importance of precisely following directions regarding prescriptions, the necessity for regular and timely taking of ARVs in indicated doses, and the sequelae of being non-adherent to the ART regimen and/or quitting these medications. Women must write in their prescription drugs' diary; arranging a container with the set of daily medications is also helpful.

For improving adherence to medical follow-up and taking ARVs, it is helpful to involve loved ones as well as employees of non-governmental organizations that support HIV-infected persons.

Specialists of the AIDS centers and a doctor of the women's clinic determine the delivery mode preferred for the woman, with the knowledge that Caesarean section significantly reduces risk of HIV vertical transmission. The woman is explained the most suitable method of delivery. Taking into consideration the woman's wishes, a maternity hospital is identified where delivery will take place. There are positive examples in Russia when the woman is allowed during her pregnancy to visit the maternity ward in which she plans to have her baby and to discuss elective hospitalization. Planned admission of the woman to the maternity hospital is recommended at 36-38 weeks of gestation for performing elective C-section.

Possible concurrent problems

If **concurrent problems are identified**, the woman is referred to consultations of relevant specialty doctors. For instance, if gonorrhea or syphilis are suspected or diagnosed, she is referred to the skin and venereal disease specialist; if tuberculosis is suspected, she is referred to the TB doctor [phthysiatrist]. Aforementioned specialty physicians, jointly with obstetrician-gynecologist, discuss planned diagnostic interventions and treatments.

Drug use by the woman presents a threat to both her and the fetus. Women suffering from **drug addiction** are at greater risk of premature delivery and having a low birth weight infant. This condition increases the risk of HIV infection in the child. Moreover, women who use drugs during pregnancy are at risk of placenta abruption and stillbirth.

Public condemnation and fear that go with drug use often lead to non-willingness of women to admit their drug use; these women seek medical care less frequently.

Diagnostic criteria of drug abuse include peculiar features of behavior (agitation, disorientation, euphoria, and mood swings), consecutive visits to different doctors (in order to obtain a desirable drug, i.e. a hypnotic or a prescription for it), visible signs (injection scars on the body, pronounced vegetative disturbances), depriving of parent rights, and unexplained frequent accidents.

If alcohol or drug use is detected, a pregnant woman should be convinced to seek attention of a psychiatrist-narcologist for the sake of preserving her health and that of her future baby. The obstetrician-gynecologist and psychiatrist/narcologist compile a plan for joint pregnancy management.

Societal stigma associated with drug addiction, family matters, and peculiarities of surroundings and social situation influence decisions regarding initiation of treatment for drug

addiction in women. It is important not only to provide care to the woman but also to help her solve problems related to circumstances of her life. Factors facilitating making a decision concerning treatment are trusting healthcare, accessibility of healthcare, favorable impression of an HCI's performance, accessibility of social support, feeling of being supported by healthcare personnel, and simplicity of treatment regimen.

For people who are not ready to be treated for their dependence on psychoactive substances, it is necessary to carry out activities aimed at reducing harm as a result of risky behaviors. These behaviors, in particular, comprise sharing needles and other injecting tools, having multiple sexual partners, and promiscuity. Activities include counseling by healthcare workers regarding safe sex, informing women about public programs of needle exchange, and condom distribution if such programs exist in the region, as well as other projects that permit the promotion of women's awareness of drug abuse treatment modalities and PMTCT methods.

Nevertheless, active use of psychoactive substances (alcohol, cocaine, and heroin) often leads to non-adherence to treatment regimens, and readiness of the patient for receiving antiretroviral drugs should be thoroughly evaluated on an individual basis. Thus, those who have received a course of treatment for drug dependence may be more adherent to the therapeutic regimen than a general group of untreated women.

Despite exhibiting behavioral irregularities, people with drug dependence retain the right to be treated with respect and equality, regardless of any differences in values and beliefs between the patient and her doctor.

2.1.3.2 Follow-up at the AIDS Center

Follow-up by the specialist at the AIDS center comprises consulting with an infectious disease physician for HIV infection follow-up, diagnostic work-up, and treatment. The infectious disease doctor identifies the most acceptable ART regimen depending on the health status of the woman, counsels the woman on the importance of adhering to the ARV regimen and of making regular visits to the AIDS center specialists. The center manages control of ARV prophylaxis, side effects, and adherence to the prescribed treatment. Jointly with the woman, a long-term plan for follow-up at the AIDS center is developed. In accordance with Decree of the Ministry of Health #606, the first elective diagnostic work-up at the center is conducted two weeks prior to initial testing, the second work-up is completed four weeks after initiation (equivalent to two weeks after initial testing) and every four weeks thereafter.

The plan for diagnostic work-up at the AIDS center includes checking CD4 counts and viral load and conducting complete blood count and blood biochemical tests.

CD4 lymphocyte counts in blood serum is measured to assess the immune system's status, select a regimen for ARV prophylaxis and ART, evaluate the effectiveness of prophylaxis and risk of adverse events, and expedite corrections of prescriptions. According to Decree #606, measuring CD4 counts is done at the end of 4, 8, and 12 weeks of gestation prior to initiation of ART—four weeks before the estimated term that she is due. In accordance with Decree #375 of the MoH&SD, measuring lymphocyte population, identifying a proportion of CD4(+)- $\hat{\text{O}}$ -lymphocytes and CD8- $\hat{\text{O}}$ -lymphocytes and their absolute numbers is done four times during pregnancy. Low CD4 counts (less than 0.2 billion/L) dictate the necessity for preventing pneumonia caused by *Pneumocystis carinii*.

Level of HIV RNA (viral load) in plasma determines the progression of HIV infection and is measured for choosing the ARV prophylaxis' regimen, evaluating effectiveness of ARV therapy and prophylaxis, and selecting the mode of delivery. Convincing data shows that on taking ARVs with undetectable viral loads or when this indicator is lower than 1,000 copies/mL, risk of HIV vertical transmission is lower than 2%.

It is recommended that viral loads are measured at 4 and 12 weeks after initiation of ARV prophylaxis. It is essential to do this test prior to ARV prophylaxis initiation for choosing an ARV regimen, and then two weeks prior to the estimated delivery date (36-38 weeks), for choosing the delivery mode. If viral load exceeds 1,000 copies/mL, elective C-section is recommended at 38 weeks of gestation.

Levels of HIV RNA and CD4 counts help forecast the risk of HIV mother-to-child transmission.

The hemogram and some biochemical parameters (bilirubin and transaminases) are evaluated for control of adverse affects related to taking ARVs.

Thus, if **ARV prophylaxis is initiated at 28 weeks**, work-up at the AIDS center should include:

26 weeks – CD4 counts, viral load, complete blood count and blood biochemical tests, selecting regimen for ARV prophylaxis

28 weeks – initiation of ARV prophylaxis

32 weeks – CD4, viral load, complete blood count and blood biochemical tests, effectiveness and tolerability of ARV prophylaxis

36-38 weeks – CD4, viral load, selecting ARV prophylaxis in labor, selecting a site for delivery.

2.1.4 ARV prophylaxis during pregnancy

2.1.4.1 Objectives of ARV prophylaxis during pregnancy and counseling

The goal of administering ARVs to the woman during pregnancy and delivery and to the newborn after birth is to prevent the infection's transmission from the mother to her child.

All HIV-infected pregnant women seeking medical attention are to be offered prevention of HIV mother-to-child transmission in a timely manner through the use of ARVs. The objective of giving ARVs during pregnancy is to suppress as much as possible the multiplication of the HIV virus in the woman's body. The AIDS center specialist administers ARVs for PMTCT purpose. ARVs are provided based on:

1. Stages and phases of HIV-disease
2. CD4 counts
3. Viral load level
4. Past and/or current antiretroviral therapy
5. Gestation age
6. Presence of concomitant diseases

Before ARV prophylaxis, the doctor counsels the woman, including:

- Goal of ARV prophylaxis: reducing risk of HIV transmission to the child during pregnancy
- Regimen and duration of taking ARVs, importance of ongoing and regular taking of ARVs during pregnancy, followed by receiving treatment in labor or prior to C-section
- Compliance with all types of PMTCT (taking ARVs regularly, elective C-section, non-initiating breastfeeding), the risk of infecting the child is reduced 40-fold, whereas irregular taking of ARVs significantly increases the risk of HIV transmission.
- Possible negative influences of ARV on the body of the woman and her child. Information on plausible side effects occurring as a result of ARVs is provided (GI disorders, eruptions). She is instructed how to act in case of adverse events. It is emphasized that the positive actions of ARV in preventing HIV infection in the child significantly outweighs the risk of adverse events caused by these drugs.
- Delivery through C-section is justified
- Breastfeeding is not recommended

Women ought to clearly understand that effectiveness of ARV prophylaxis is determined by their conscientiousness in staying adherent to all medical prescriptions. Often, a single counseling session conducted by the doctor is not sufficient to make the woman fully realize the necessity of taking ARVs regularly or to prepare her for taking all prescribed medications. This is related to many factors, including but not limited to the cultural and educational levels of the woman, complicity of her drug regimen, her social level, etc. To overcome such problems, a woman is prepared for ARV prophylaxis prior to ARV initiation. This preparation may consist of individual and group training sessions, at which the following is explained in an understandable format:

- What the human immune deficiency virus is and how it penetrates into and multiplies in the human body;
- What immunity is and what immune cells are impaired by the virus;
- What ARVs are and how they impact the virus;
- What resistance to ARVs is, when it occurs, and how to avoid it;
- Possible side effects due to taking ARVs and how to cope with them; and
- Methods to simplify memorizing the medication regimen, reminders of the time to take medications, and keeping ART confidential (if needed).

Sessions are to be conducted by the doctor, trained nurse, or specially trained volunteer from the HIV-positive patients' cohort. Sessions are carried out in an interactive manner.

One may utilize a role-playing format in preparation to taking ARVs. For instance, one week before the estimated initiation of taking medications, the patient is given candies of three different colors along with precise directions on how to take them as if those are real ARVs. If the patient has taken all distributed candies correctly during the week than likelihood of further correct taking ARVs is much higher.

If HIV is identified in the third trimester, time may be insufficient to conduct such sessions; in these cases, after one-time counseling ART must be started with an emphasis on follow-up by healthcare personnel, including weekly home visits by the nurse and, if possible, NGO staff.

Prior to taking ARVs, the woman is asked to sign **informed consent** for ARV prophylaxis (see Appendix – Decree of the MoH #606).

In accordance with the current legislation, the woman is provided with drugs for ARV prophylaxis free of charge.

ARVs are distributed at the AIDS center with certain periodicity. The scheme of ARV distribution is determined on an individual basis, with consideration of what's most convenient for the woman. As a rule, monthly drug supply is given at one time. If doubts concerning adherence to ARVs exist, it may be helpful at the initial stage to distribute drugs in smaller batches and in shorter intervals, starting daily and then every 2-4 weeks thereafter.

2.1.4.2 Terms for initiating ARV prophylaxis during pregnancy and medication regimens

The term at which ARV is to be initiated during pregnancy should be seriously considered, taking into account gestation age and stage of infection. Given that organogenesis (the period when the fetus is most susceptible to potential teratogenic effects) takes place at 3-12 weeks of gestation, it is recommended to start taking antiretroviral drugs after 14 weeks of gestation.

At present, it is believed that the highest risk of intrauterine infection is in the third trimester. Hence, it is expedient to initiate ARV prophylaxis at **28 weeks of gestation**. This point of ARV initiation allows reduction of the duration of influence on the fetus, compared with earlier administration. Another advantage of initiating ARV at this time is improving adherence to ARVs.

However, if the risk of HIV disease progression exceeds ART side effects, the latter is administered at any gestation term with preferential use of regimens with the least teratogenic potential. **Before 28 weeks**, ARVs must be given to women who have one of the conditions as follows:

- Acute phase of HIV-disease,
- Risk of premature delivery.

If HIV infection in the pregnant woman has been identified **later in the course of pregnancy**, ARVs should be taken from the time of diagnosis of HIV, even if there are only a few days left before delivery.

According to the Standard on PMTCT (Decree of the Ministry of Health and Social Development #375), the following **ARVs** drugs may be used **during pregnancy**:

- Zidovudine
- Phosphasid
- Lamivudine

- Nevirapine
- Nelfinavir
- Saquinavir/Ritonovir

According to experts from the Centers for Disease Control and Prevention (USA), administering **one ARV** (zidovudine) for the purpose of preventing HIV vertical transmission during pregnancy is justified in women with preserved immunity, normal CD4 counts with viral load lower than 1,000 copies/mL, and when triple ARV therapy is not tolerated.

Zidovudine (Azidotimidine, Retrovir, Timazid) is given orally 0.2 grams (200 mg) every 8 hours (3 times a day, daily dose 0.6 g). If taking medications three times a day is either not feasible or inconvenient, 0.3 grams (300 mg) of zidovudine may be given every 12 hours (twice a day, daily dose 0.6 g) every day.

According to Decree #606, if zidovudine is not tolerated, phosphasid may be given for PMTCT; however, at present, **scientific evidence is not available** to prove the clinical effectiveness of administering phosphasid (Nikavir) orally 0.2 grams every 8 hours (3 times a day, daily dosage 0.6g) daily over the course of pregnancy until delivery.

For PMTCT during pregnancy, administering **a combination of three antiretroviral drugs** is more efficient than using a single ARV. Regimens are preferred that combine nucleoside reverse transcriptase inhibitors and a protease inhibitor, incorporating drugs with the least risk of adverse effects for the pregnant woman and the fetus. Of nucleoside reverse transcriptase inhibitors, zidovudine, phosphasid, and lamivudine are used for PMTCT; of non-nucleoside reverse transcriptase inhibitors, nevirapine; of protease inhibitors, nelfinavir or saquinavir in a combination with ritonavir.

Below, possible regimens of combination therapy with ARVs during pregnancy are presented ³:

1. Zidovudine (300 mg) + lamivudine (150 mg) + nelfinavir (1250 mg) twice a day
2. Zidovudine (300 mg) + lamivudine (150 mg) + nevirapine (200 mg) twice a day
3. Zidovudine (300 mg) + lamivudine (150 mg) + saquinavir/ritonavir (1,000 mg /100 mg) twice a day ⁴

If ARV prophylaxis is initiated at 34-35 weeks of gestation, use of the two-drug therapy is feasible: zidovudine 300 mg + lamivudine 150 mg orally twice a day.

If the woman doesn't require taking these medications for her health conditions, they should all be discontinued at the same time right after the baby is born.

If ART has been administered to the woman before the current pregnancy, it is recommended to continue treatment with ARVs over the course of entire pregnancy, delivery, and afterwards. Efavirenz is an exception to this rule, as this drug is shown to possess pronounced teratogenic property. Once pregnancy is confirmed in the HIV-infected woman receiving this medication, it is mandatory to substitute it as soon as possible with nevirapine or nelfinavir. If possible, it is recommended avoiding regimens comprising indinavir: this drug is potentially toxic to the fetus. If the female patient was treated with indinavir before her pregnancy, it is recommended replacing indinavir with another protease inhibitor. Moreover, prescribing stavudine is not recommended in a combination with didanosine due to the threat of developing pancreatitis and neuropathy; in pregnant women, such a combination is associated with the higher risk of developing an extremely dangerous complication, lactic acidosis.

³ Quoted doses of ARVs are extensively used in clinical practice; they are proven effective in clinical trials. Doses are indicated for patients with the normal function of their liver and kidneys. For renal or hepatic failure, dose correction may become necessary according to the pharmaceutical company –drug's manufacturer – insert. Besides, it is needed to clarify the information on possible interactions of antiretroviral drugs with other medications.

⁴ There is a combined drug available containing Zidovudine and Lamivudine – Combivir.

For **HIV disease progression**, modifying prescribed ARVs is required. The experienced specialist of the AIDS center counsels women and selects an ART regimen. Counseling on ART during pregnancy comprises explanation of the possible impact on woman's health and that of the child-would-be, initiation, continuation, discontinuation, and refusal to administer certain ARVs. Complete recommendations on ART are presented in Decree #606, as well as in the WHO Protocols for CIS countries, "Provision of Care and Treatment for HIV infection and AIDS," 2004, Version 1.

It is important to remember that **adverse events from taking ARVs** may be observed in almost 80% of women received combination therapy. The most common side effects are anemia, nausea/vomiting, diarrhea, skin rash and itching, and liver function disturbances. For control over side effects, complete blood count and biochemical blood tests are conducted. If certain drugs are not tolerated, prescriptions are adjusted:

- If zidovudine is not tolerated or anemia occurs, stavudine may be substituted for zidovudine.
- If CD4 counts $> 250 \mu\text{L}^{-1}$ risk of nevirapine's undesirable impact on the liver increases 12 times. It is expedient during the first 18 weeks of treatment with nevirapine to regularly check indicators of liver functions. If nevirapine toxicity occurs (indicators of liver enzymes' activity elevated 5 and more times), nevirapine may be substituted with another ARV or treatment shall continue with single zidovudine.
- One of the possible complications of taking medication of the protease inhibitor group (lopinovir, nelfinavir) is hyperglycemia; in pregnant women receiving this drug, glucose blood level should be tested not less frequently that once in two weeks. For self-control purposes, they have to get informed about signs of hyperglycemia.

All manifestations of drug side effects must be documented in the medical follow-up chart.

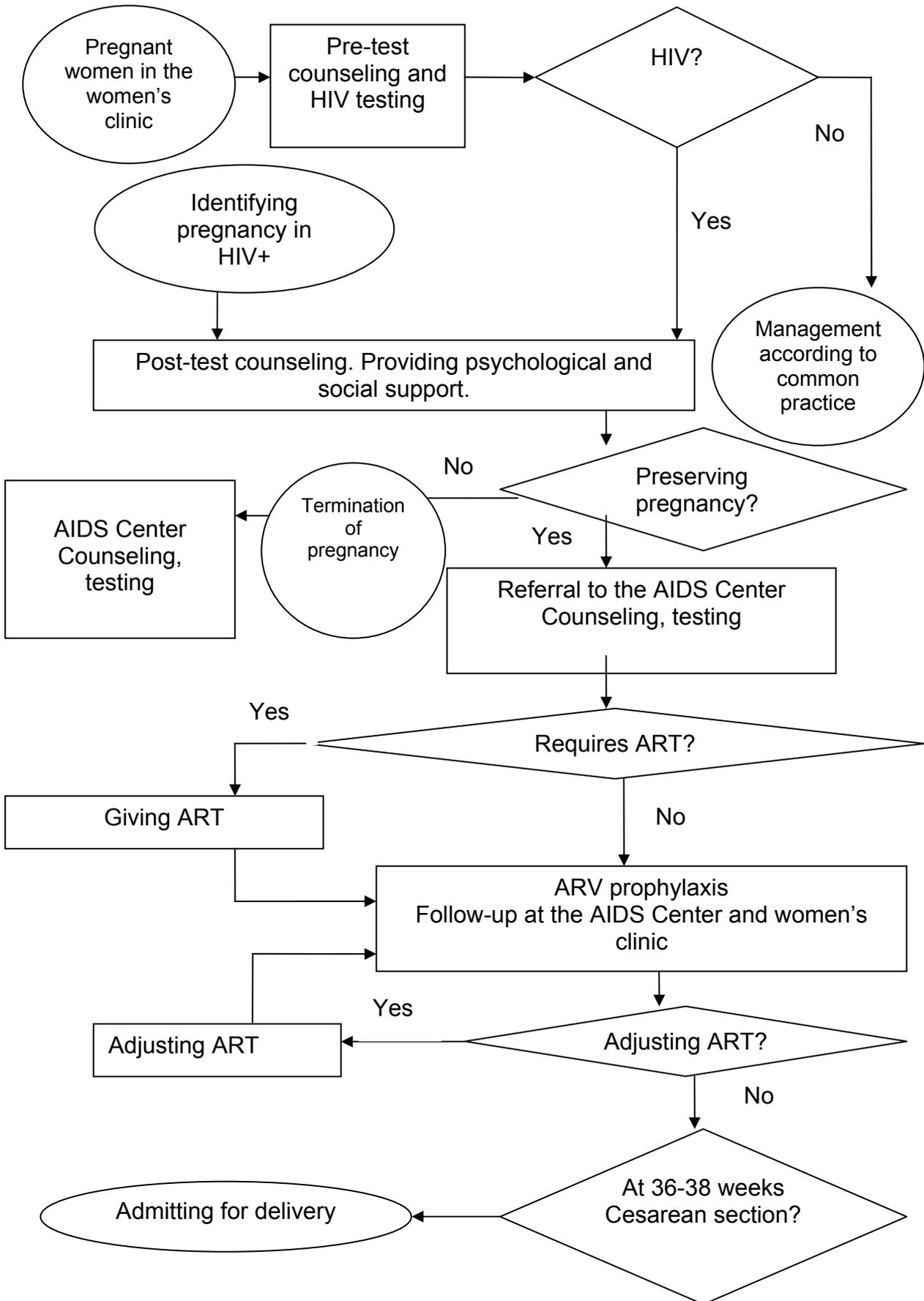
Refusal of the woman to take antiretroviral drugs should not lead to depriving her of healthcare. Any opportunity ought to be used to convince the woman to start taking ARVs and remain adherent to antiretroviral therapy.

2.1.4.3 Resistance to ARVs

Resistance to antiretroviral drugs occurs as a result of administering ineffective and incomplete ART regimens and to a lack of adherence to medications on the part of the patient. Taking one or two ARVs is associated with significantly higher risk of resistance development compared to simultaneous intake of three ARVs. Resistance to ARVs leads to increased risk of perinatal HIV transmission and limits opportunities for treating the woman. Prevalence of resistance to ARVs varies among countries and populations and may amount to 25%.

Testing HIV sensitivity to ARVs during pregnancy should be conducted. It is essential to test resistance in presence of the following factors: acute phase of the infection, if viral lode is not going down despite taking ARVs and if risk of getting infected with resistant HIV strain is present.

Figure 2. Algorithm of preventing HIV vertical transmission during pregnancy



2.2 Prevention of HIV vertical transmission in labor

Key statements

- *Counseling and rapid testing of women who didn't have HIV testing during pregnancy*
- *Determining delivery strategy (surgical vs. conservative delivery)*
- *Performing elective C-section at 38 weeks*
- *Receiving antiretroviral drugs in labor*

2.2.1 Organization of healthcare delivery in labor

2.2.1.1 Admission to the maternity hospital

The goal of preventing HIV vertical transmission in labor is providing optimal maternity services to HIV-infected women, which includes giving antiretroviral drugs and selecting the mode of delivery.

In Russian regions, any territorial maternity hospital or specialty maternity ward may deliver babies of HIV-infected women. Delivery in the specialty maternity ward may be justified in case extreme financial constrains in healthcare of the region (when it is feasible to provide the only facility with everything what's needed) and/or if HIV infection is extremely prevalent. Nonetheless, it is important to remember that the HIV-infected woman with known or unknown HIV-status may be admitted to any maternity hospital; therefore, any maternity ward should have some storage of ARVs for preventing HIV vertical transmission (nevirapine pills, nevirapine suspension, zidovudine pills, zidovudine syrup). Storage of rapid tests for identifying HIV should also be present, or a system should be in place for the express delivery of ARVs and rapid tests 24 hours a day, as needed.

Upon admission, the woman in labor is routinely examined. All manipulations related to exposure to blood and mucous membranes of the woman should be performed while wearing gloves.

In the maternity ward, the woman is recommended to use her own slippers and personal hygiene items. In case the woman doesn't have clothes of her own suitable for delivery, or upon request, she is given an individual kit containing a shirt, towel, sheet, and gown. Participation of woman's loved ones in delivery and visits of relatives postpartum are allowed as approved by and enacted in the institutional policies or regulations.

With consideration of all infection control requirements, babies may be delivered in any patient room of labor and delivery rooms on the obstetric floor; allocating a special isolation room is not required (see "Clinical-organizational Guideline on the Work of the Obstetric Inpatient Ward" of the Maternal and Child Health Initiative).

2.2.1.2 Rapid testing in the maternity ward

Key statements:

- *Instruction on rapid testing*
- *Storage of rapid tests*
- *Accessibility for healthcare workers on duty of the place rapid tests are stored*
- *Documenting testing and its results*

Information on the HIV status of the pregnant woman is obtained in the emergency room of the obstetric hospital. Pregnant women admitted for delivery to maternity hospitals whose HIV status is unknown or those who had just one HIV test are eligible for HIV testing with the use of rapid tests.

Rapid testing is not suitable for laboratory confirmation of HIV diagnosis; however, positive test results give the grounds for prevention of vertical transmission in labor.

Rapid or express testing of women in labor is done in accordance with the existing national and local regulations. For rapid testing of women in labor admitted to the maternity wards, only those HIV rapid tests that are approved by the MoH&SD for use within the RF territory may be utilized.

Women are eligible for rapid testing if they meet the following criteria:

- Not tested for HIV during pregnancy;
- Tested once with a negative result at 34 weeks of gestation;
- In premature labor and gestation age less than 34 weeks when the first HIV test, yielded a negative result, but a second one has not been done yet;
- If the woman has been tested on HIV at the set term but during the last 12 weeks she has been at increased risk of getting HIV infected (injecting drug use, promiscuous sexual relation without using condoms, etc.).

Experience of the Prevention of HIV Perinatal Transmission in St. Petersburg and the Leningrad Region project, run by the Elizabeth Glazer Pediatric AIDS Foundation, showed that in case the pregnant woman has been tested once with a negative test result during the period of 34-36 weeks of gestation or later, rapid testing on HIV is purposeless.

Upon admission to the maternity hospital of a pregnant woman requiring testing, blood for HIV rapid testing should be drawn as soon as possible. Rapid testing is to be done in the maternity ward because sending specimens to the laboratory prolongs the time to obtain test results. Testing is done according to instructions. Rapid tests are simple to use and may be done by any healthcare worker after short training.

Modern rapid techniques permit obtaining test results within 10-30 minutes from testing. Practice shows that the entire procedure of testing and counseling takes no longer than 45 minutes.

Currently, none of the existing tests is 100% specific, which means that in some single cases, the result may be false positive. Nevertheless, ARV prophylaxis is done to all women in whom rapid testing gives positive results.

Before rapid testing on HIV, woman should receive pre-test counseling, as opposed to the provision of post-test counseling after obtaining rapid test results.

A trained healthcare worker (midwife or doctor) does **pre-test counseling** of the woman, conveying to her following information:

- HIV may be transmitted to the baby during pregnancy, delivery, and while breastfeeding; administering effective antiretroviral drugs may significantly reduce the risk of HIV transmission to her child.
- Rapid testing is done on all women who have not been tested on HIV admitted for labor in order to protect health of the child.
- Negative test results mean that the woman is likely not infected with HIV; however, this test may not reveal the infection if it occurred recently.
- Positive test results are preliminary and will be confirmed with another test. Nonetheless, immediately after obtaining positive results, a woman will be offered medication for her and her newborn baby, which may prevent transmission of HIV to the child.

The patient confirms her informed consent for testing, after which a **rapid test** is done. The woman is explained when the test results will be ready.

Interpretation of test results:

- Negative result of rapid testing is viewed as absence of HIV infection. If there was a risk of infection during last three months of pregnancy, the woman is recommended to have a repeated testing on HIV.
- Positive result is considered a preliminary one confirming presence of HIV infection.

Should rapid HIV test results be positive, the provider must explain to the woman that, despite the fact that the result is preliminary, she and her child need to take ARVs to reduce the risk of transmitting the virus to the baby. **Post-test counseling** is done. The woman is explained that:

- Rapid test identified her HIV status with high degree of probability; however, it shall be confirmed with other methods. Repeated testing will be done immediately in order to clarify her HIV status, but results will be available only after delivery.
- It is necessary to start taking ARVs as soon as possible to reduce the risk of HIV transmission to the child.
- In the maternity ward, there are efficacious antiretroviral medications available that will be given to the woman once her consent is obtained.
- Regimen of giving drugs to the woman and her baby after birth is explained.
- The woman must not feed her baby with breast milk. Her child will be fed with adapted baby formulas.
- If HIV-status turns out to be negative, taking drugs shall be discontinued, and the woman will be able to feed the baby with her breast milk.

Counseling and testing is done with consideration of confidentiality principles. The possibility of communicating the information regarding HIV status to her partner, relatives, or close friends is clarified with woman.

If the woman agrees to ARV prophylaxis for her and her baby, she signs an informed consent form and ARVs are given.

Results of rapid testing are thoroughly documented. In an appropriate logbook, tests' shelf life [expiration date] is written down.

Results of all rapid tests should be consequently confirmed. Along with rapid testing, standard blood HIV testing (ELISA) is done for each case. Post-test counseling is provided after obtaining ELISA and immune blotting test results. It is necessary to try to make confirmatory test results available before the woman and her baby are discharged from the maternity hospital. If there is a discrepancy between rapid tests and ELISA results, repeated rapid testing and ELISA and consultation of the infectious disease doctor are recommended.

2.2.2 Administering ARVs in labor

Risk of HIV vertical transmission is significantly higher shortly before and in labor. Therefore, the goal of ARV prophylaxis in labor is to give the woman those medications that quickly reach the placenta and provide high concentration of ARVs in the fetus, in the birth passages, and in blood.

ARV prophylaxis in labor with antiretroviral drugs is given to all women in whom HIV infection is identified with testing (ELISA or rapid tests). If ARV prophylaxis was initiated during pregnancy, it is continued according to the prescribed regimen.

If rapid HIV testing is not feasible in the non-tested woman admitted to the maternity hospital, in accordance with Decree #606, epidemiological history is taken for clarifying risk factors for HIV infection, including :

- Use of injecting psychoactive substances
- If the woman had been tested for HIV at the set term but had multiple sexual contacts without condoms during the last 12 weeks
- If the woman has been tested for HIV at the set term but had sexual contact without condoms with a sexual partner who is either HIV-infected or uses injecting drugs during the last 12 weeks

If valid data on HIV infection risk is not available, the decision on initiating ARV prophylaxis is made on the individual basis by the obstetrician-gynecologist who delivers the baby. The woman is counseled on the following issues: .

- Presence of risk of HIV
- Risk of transmitting HIV to the newborn during delivery
- Routine testing for HIV infection, results of which will become available only after birth
- Necessity for initiation of antiretroviral therapy as soon as possible to reduce risk of transmitting HIV infection to the child.

- In the maternity hospital, there are efficacious antiviral medications available that will be given to the woman once her consent is obtained.
- Regimen of giving drugs to the woman and her baby after birth..
- Prior to getting test results confirming the absence of HIV infection, woman must not feed the baby with her breast milk; child should be fed with adapted baby formulas.

On surgical delivery, prophylaxis with ARVs should be initiated no later than 3 hours before the operation. On vaginal delivery, ARVs should be initiated at the beginning of labor.

According to the standards on PMTCT in labor, the following ARVs are used:

- Zidovudine
- Nevirapine
- Phosphazid

If the woman was receiving a **combination ARV regimen** during pregnancy, it is recommended to continue the same regimen **in labor**.

Possible ARV regimens:

1. **Zidovudine** (Azidotimedine, Retrovir) – intravenously at the rate of 2 mg/kg/hour during the first hour since treatment’s initiation and then 1 mg/kg/hour until after the baby is born. If zidovudine is not available for intravenous administration, it may be given in pills (Timazid) 300 mg every 3 hours during labor.

2. **Adding nevirapine to zidovudine in labor** significantly decreases risk of transmitting HIV to the newborn. In this case, 200 mg of nevirapine (Viramune) in single dose is given to the woman per os. This regime indicated to a woman who **didn’t receive any ARVs during pregnancy**

3. **When capacity for only nevirapine exists** from the beginning of labor, administering single does of oral nevirapine is recommended – 1 pill 0.2 g (200 mg). If the baby is not born within 24 hours after nevirapine was taken, 200 mg of this drug should be taken again.

2.2.3 Delivery

Decision about the mode of delivery is made according to the specific situation depending on a viral load level in the woman with consideration of interest of both mother and fetus. Risk factors of HIV transmission in labor are as follows:

- Prolonged ruptured membrane period
- Lack of ARV prophylaxis in labor
- Invasive procedures: amniotomy, invasive fetal monitoring

Elective Cesarean section performed before the beginning of labor and rapture of the membranes reduces risk of HIV mother-to-child transmission twofold, preventing prolonged exposure of the fetus infectious secrets of mother’s birth passages. Research shows that the prophylactic effect of C-section is maintained while the mother is taking ARVs. Thus, C-section performed before the beginning of labor and rapture of the membranes is an independent additional method of preventing HIV vertical transmission.

In many countries, standards [clinical paths] on managing delivery with routine performing elective C-section in HIV-infected women when their vial load exceeds 1,000 copies/mL shortly before labor, regardless of any ART/ARV prophylaxis the woman was receiving during pregnancy.

If the information about viral load is absent and/or ARV prophylaxis is not feasible, elective C-section may be used as an independent modality for preventing HIV transmission during delivery.

It is most expedient to perform C-section at 38 weeks of gestation. This is stipulated by the best clinical outcomes for the woman and her child, and is an opportunity to avoid premature rapture of the membranes. Woman must get counseling regarding the advantages and possible complications of C-section.

While performing C-section, prophylaxis must be given with antibiotics. Perioperative antibiotic prophylaxis is done in standard dosage according to the protocols adopted in a healthcare institution.

Research has not shown any significant increase of postoperative complications' risk in HIV-infected women compared to women who are not infected with HIV. Should complications occur, treatment is carried out according to conventional approaches.

In the active phase of delivery, four hours after membranes' rapture, performing C-section is not expedient.

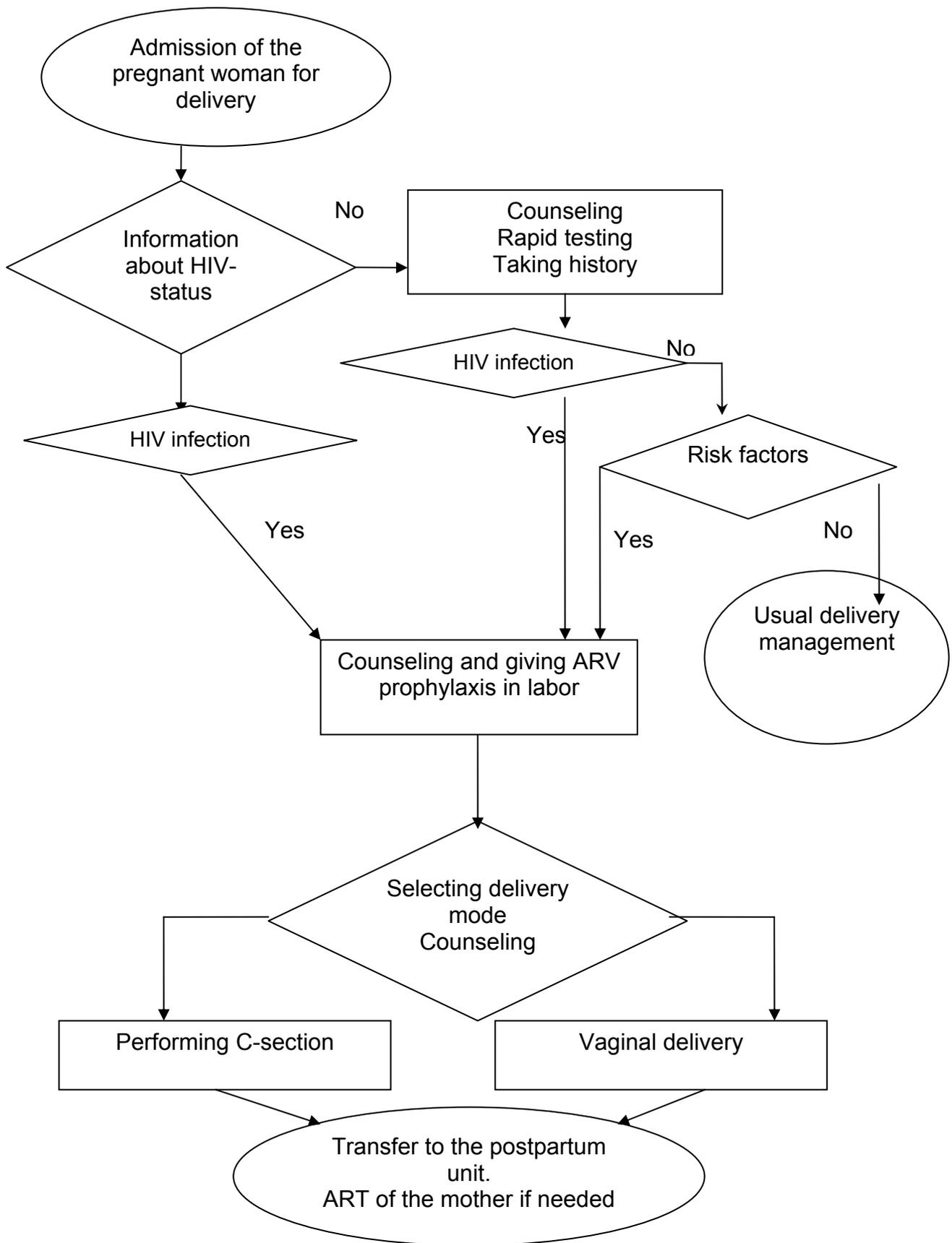
The final decision about performing elective C-section for the purpose of preventing vertical HIV transmission is to be made by the woman, who confirms her informed consent for surgical operation in writing.

During vaginal delivery, any invasive interventions increasing risk of vertical transmission must be excluded if possible, such as amniotomy, direct fetal cardiotocography, etc. Management of safe delivery is presented in the MCHI course, "Partners in Birth."

All invasive procedures are performed during delivery for clearly defined obstetric indications. If the membrane rapture occurs prior to labor, an option of administering Oxytocin is considered. While managing vaginal delivery, it is recommended to treat the vagina with 0.25% water solution of chlorhexidine upon admission for delivery (during the first vaginal examination). In the presence of colpitis, this solution should be administered on each subsequent vaginal examination. Efficacy of this manipulation is proven only in labor that lasts longer than for four hours after the membrane ruptures; in this case, chlorhexidine is topically applied every 2 hours.

Unless there are contraindications, postpartum woman with her child are transferred to the room for mutual stay or a regular postpartum ward, or she stays in the delivery room where her baby was delivered if facilities for the full birthing cycle established on the floor.

Figure 3. Providing care to the HIV-infected woman in labor



2.3 Provision of therapeutic and prophylactic care to the newborn

Key statements

- *Administering prophylaxis with antiretroviral drugs*
- *Counseling the woman and feeding the baby with adapted baby formulas*

2.3.1 Organizing provision of care of the newborn in the delivery room

It is recommended to exclude splashing maternal blood on the infant, which is why the neonate takes a hygienic bath. Babies should be cleaned prior to the beginning of any procedures. The child is put onto the woman's belly but not put to her breast. The woman is counseled concerning the threat of infecting the baby with HIV through breastfeeding and the need for instead feeding the baby with adapted baby formulas.

If the newborn requires resuscitation, it is done according to current regulations, including those of infection control. If the newborn infant is still in severe condition, it remains in the neonatal intensive care unit under observation. The baby receives treatment appropriate to its identified problems.

In accordance with PMTCT standards (Decree #375), **blood is drawn from the peripheral vein** of the child for complete blood count and biochemical laboratory tests while in the delivery room right after birth and cutting the umbilical cord. If polymerization chain reaction is available, blood is drawn for this test.

Polymerization chain reaction (PCR) is a modern method of making preliminary diagnosis of HIV in newborns. PCR is done within 48 hours after birth. This test facilitates the detection of HIV in 40% of infected babies. PCR sensitivity rises to 98% when the baby turns 2 months.

Final status of the child will be identified according to Russian policies by the 18th month of its life, because before that time, maternal antibodies circulate in blood of the child. At the same time, virology testing should be used that facilitates early diagnosis of child's HIV infection.

Unless there are contraindications postpartum, the child and its mother are transferred to the patient room for mutual stay or remains with the mother in the delivery room where it was delivered (full birthing cycle patient rooms), or transferred to the neonatal unit.

2.3.2 ARV prophylaxis in the newborn

ARV prophylaxis of HIV infection is done in all children born to women with established HIV-positive status, regardless of whether ARV prophylaxis was given to the mother during pregnancy and delivery. The issue of ARV prophylaxis for the baby is also considered in instances when HIV status of the mother is unknown. Risk factors of being infected are evaluated, and the woman is counseled.

If the woman has not been counseled prior to delivery, she is explained the need for administering antiretroviral drugs to her child and she signs informed consent. Counseling includes:

- Woman's risk factors
- Risk of HIV transmission to the child
- Methods and terms of HIV-testing of the woman and her child
- Regimen of giving the baby antiretroviral drugs after birth before the receipt of woman's test results is explained.
- Woman should not feed the baby with her breast milk but with adapted baby formulas until after woman's test results are obtained.

If the woman didn't receive ARV prophylaxis during pregnancy and/or delivery (rapid test results becomes known after delivery, delivery at home, fulminant delivery, and other causes), **antiretroviral drugs** are given to the baby immediately (not later than 6-12 hours).

If the HIV-infected woman received ARV prophylaxis during pregnancy and delivery, ARV prophylaxis for the infant should be given beginning at the eighth hour of life, but not later than 72 hours after birth.

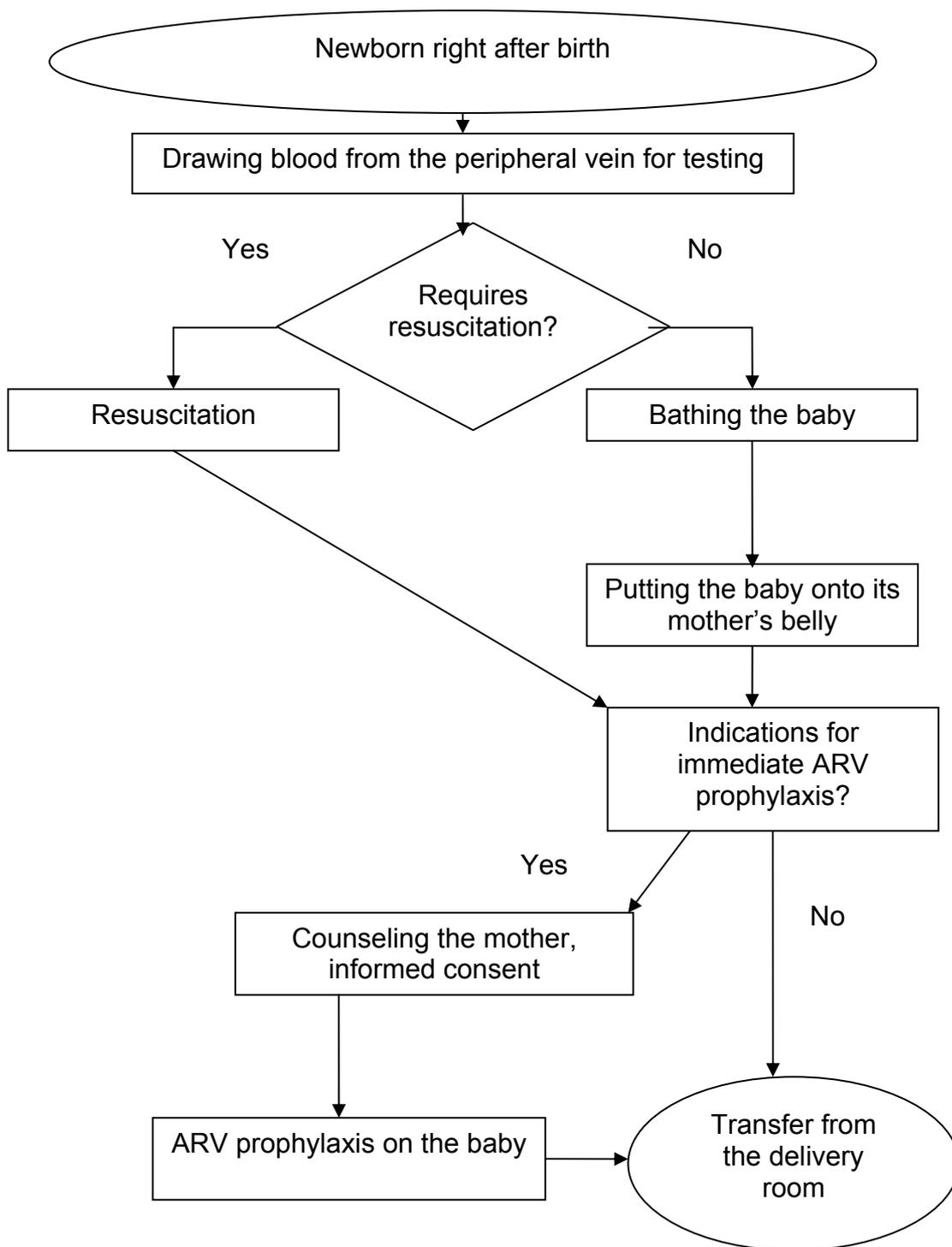
According to the PMTCT standards, newborns may be given following medications:

- Zidovudine
- Nevirapine

Possible ARV regimes for a child:

1. **Zidovudine** (Azidotimidine, Retrovir) in daily dosage 4 mg/kg divided to 2 oral doses in syrup **during 7 days**. Necessary one-time dose is drawn with a syringe coming with a vial. In accordance with the recommendation of the MoH of 2003 (Decree #606), regimen of giving zidovudine in syrup – 2 mg/kg every 6 hours **during 6 weeks**. Compliance with this regimen may be justified in children born to those women **who didn't receive ARVs during pregnancy**.
2. Another possible regimen of ARV prophylaxis is oral administration of **nevirapine** (Viramune) 2 mg/kg in suspension as single dose.
3. **If the woman didn't receive ARVs during pregnancy, it is expedient to give the baby both zidovudine and nevirapine simultaneously.**

Figure 4. Prevention of HIV in the neonate born to the HIV-infected woman following birth



2.3.3 Organizing provision of care after transferring from the delivery room

Key statements

- *Administering antiretroviral drugs*
- *Bottle-feeding*
- *Social support*

Providing ARV drugs to a child (if recommended)

If a woman's HIV status remains unknown after she is transferred from the delivery room, the baby is not fed with the mother's breast milk until her final HIV test results are obtained (on condition of the mother's consent). In the meantime, the mother's lactation is being preserved by squeezing her milk. Upon confirmation of woman's positive HIV status, she is given recommendations on lactation suppression, and relevant medications are prescribed.

If the baby was put to its mother's breast or fed with her squeezed milk and didn't receive ARV prophylaxis, the baby must be weaned; in cases of chemoprophylaxis of HIV, this should be initiated.

Issues concerning the newborn's immunization are considered. Regulations of the RF Ministry of Health of 2003 (Decree #109) limit BCG vaccination of children born to HIV-infected women. However, while reviewing vaccination possibilities, the epidemiological situation in the region regarding tuberculosis and other infections should be taken into account, as should the clinical-immunology indicators of the child. A neonatologist makes the decision concerning vaccination jointly with an infectious disease doctor.

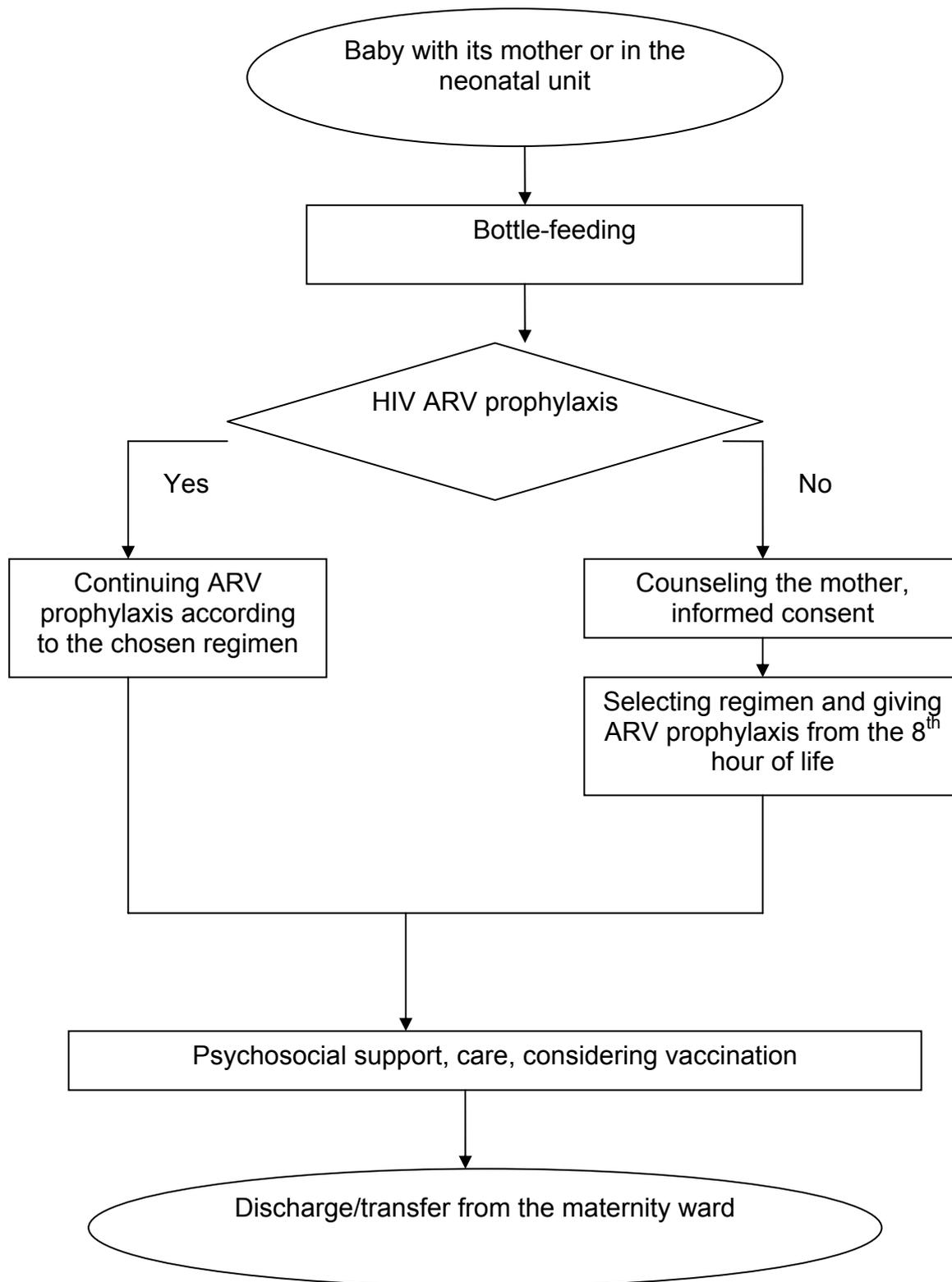
The woman's continued ARV adherence after her baby's birth helps obtain clinical and immunological indications. The ARV treatment regimen that was used during pregnancy is maintained; as needed, prescribed ARVs are adjusted.

In the maternity ward, woman should receive comprehensive psychological and social support. Support may be provided by a psychologist of the maternity hospital and/or AIDS Center, social worker, or representative of a non-governmental organization. All aforementioned employees are invited only upon a woman's consent, with consideration of confidentiality.

Social follow-up comprises assistance in getting allowances and documents and solving issues concerning life arrangements of the mother and her child. In case there are no means to live on, relatives are approached in order to organize support, identify a source of income, and provide temporary housing. With the woman's consent, the social worker's preliminary visit to the house in which the baby will live is extremely helpful in developing a plan for the social support to be provided to the woman upon her discharge.

In case the woman abandons her baby, her closest relatives are contacted and counseled in order to return the child to its biological family. Employees of guardianship and patronage services look for and find a substitution family for the baby.

Figure 5. Providing care to the neonate born to an HIV-infected woman after their transfer from the delivery room to the patient room for mutual stay or neonatal unit



2.4 Discharge from the maternity hospital

Key statements

- *Developing the detailed plan for following up with the baby at the AIDS center and discussing it with the woman*
- *Taking ARVs*
- *Bottle feeding*
- *Counseling the woman on family planning issues*
- *Social and psychological support*

2.4.1 Organizing discharge from the maternity hospital

Discharge of the newborn and postpartum woman from the maternity hospital is done according to common practice. If the mother and baby are in satisfactory condition, they may be discharged to be followed-up at home by the polyclinic pediatrician and AIDS center specialist. Before her discharge, the following issues are discussed with the woman:

1. Discuss the plan for medical follow-up of the woman and her child
2. Emphasize adherence to ARVs, explain the medication regimen, and provide a written form of recommendations. Upon discharge, the woman must be provided with a certain amount of ARVs, after which medications are distributed at the AIDS center.
3. Administer Trimethoprim-sulfamethoxazole at the age of 4-6 weeks to prevent *Pneumocystis carinii* pneumonia.
4. Test baby's blood periodically to determine its HIV status, up to the age of 18 months.
5. Emphasize the importance of excluding breastfeeding.
6. Explain mechanisms of receiving social support, including the receipt of adapted baby formulas.
7. Counsel the woman on postpartum contraception. If possible, she is provided with a modern method of effective contraception free of charge.

If the woman allowed informing her partner and/or family members about her HIV status, they also must participate in this conversation.

2.4.2 Identifying HIV status of the child

The target is to identify the child's HIV status as soon as possible for timely initiation of antiretroviral therapy. At present, there are techniques available that permit identification of HIV status within the first months of a child's life and adjustment of the ARV regimen accordingly.

PCR diagnosis facilitates a child's early diagnosis of HIV. This test is done when the baby is 2 and 4 months old. **HIV infection is diagnosed with the two consecutive positive virology tests not less than 1 month apart regardless of child's age.** At this stage, the infectious disease physician may make a decision about giving the child combined antiretroviral therapy.

Another method possessing some prognostic value for diagnosing HIV in the child is measuring viral load. Having this test is feasible at the 2nd week of child's life.

In accordance with Decree #375, identification of antibodies to HIV with ELISA is done at 9, 12, and, if needed, at 15 and 18 months. Positive results are to be confirmed with identifying a fraction of anti-HIV antibodies on immune blotting at the age of 15 and 18 months.

Two or more negative tests for immune globulin G (IgG) antibodies to HIV not less than 1 month apart are conducted on a child older than 12 months. In addition, lack of other clinical and/or virology laboratory signs of HIV infection testify to the absence of HIV infection.

Discontinuing follow-up of a child born to an HIV-infected woman is done in accordance with Decree #606:

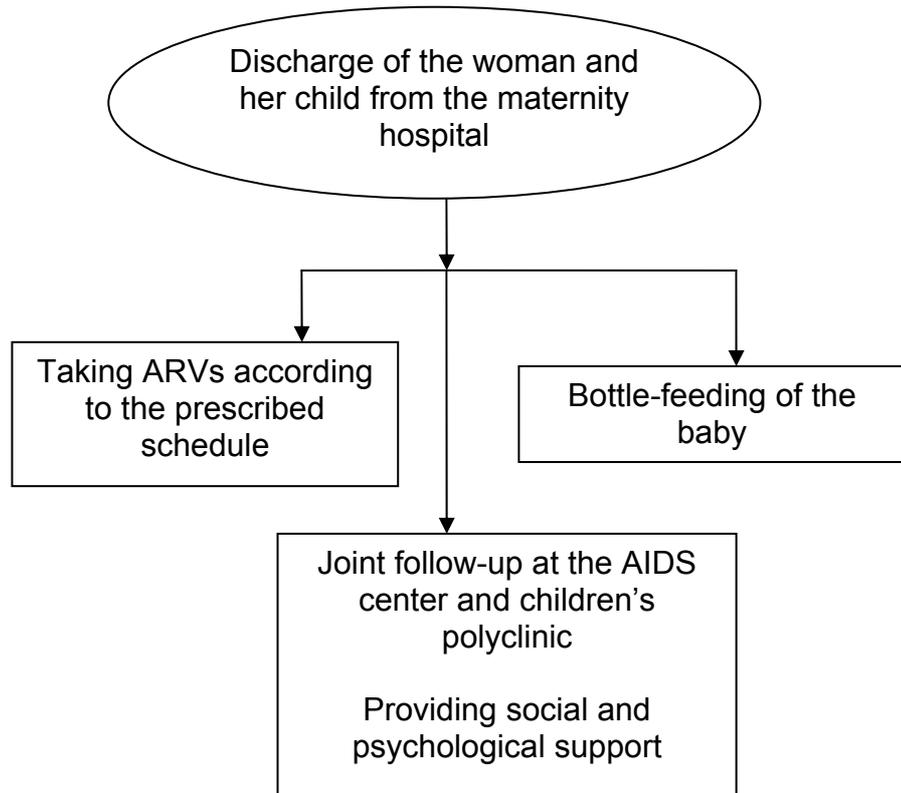
- At the age of 18 months
- Negative results of testing for antibodies to HIV on ELISA
- Absence hypo- γ -globulinemia

- Absence of HIV clinical manifestations.

After discharge from the maternity hospital, it is necessary, with the woman's consent, to organize regular home visits by the social worker.⁵

⁵ Developing a model of providing social support to HIV-infected women and their children as well as abandoned children with perinatal exposure to HIV is done within the framework of Helping Orphans in Russia, a Russian-American program.

Figure 6. Providing care to the neonate born to the HIV-infected woman after discharge from the maternity hospital



3. Prophylaxis of HIV infection in the workplace

Modern data show that there is a 0.3% risk of HIV infection as a result of exposure to blood due to needlestick injuries or cuts. Blood splashes on mucous membranes of the mouth, eyes, and nose amount to a 0.1% risk, and blood splashes on the intact skin encounter a less than 0.1% risk; thus, small volumes of blood splashed on the intact skin probably do not present any threat of infection. Limiting exposure of healthcare personnel to potentially infectious substances is the basis for prophylaxis of occupational HIV infection. Blood and other bodily fluids are to be considered potentially infectious substances requiring appropriate handling. Health personnel can avoid exposure of their clothes, skin, mucous membranes, eyes, and mouth to potentially infectious substances by these means of individual protection:

- Gloves
- Lab coat
- Facial shield
- Protective eye gear
- Mask
- First aid kit

After exposure to blood, bodily fluids, and contaminated items, washing hands is mandatory. Hands must be washed after taking off gloves and in between patients anyway. Gloves should be worn in anticipation of any contact with blood, including drawing blood, and other body fluids, mucous membranes, and non-intact skin, as well as items contaminated with potentially infectious substances. Performing all invasive procedures while wearing gloves is strongly recommended. On surgical operations, deliveries, and other interventions, during which splashing blood or other body fluids is anticipated, healthcare personnel are obliged to wear masks and protective facial shields. Research shows that double gloving permits operating room personnel to reduce risk of direct contact with blood.

Needle and other sharps require especially cautious handling; they are to be stored in safe and durable containers. Not recapping, not bending, and not breaking used needles should become a routine practice. Over the course of a surgical operation, it is preferable not to pass sharp instruments (needles, scalpels, etc.) directly hand-to-hand; they are rather put onto a tray or basin.

If blood splashes on the intact mucous membranes (eye, nose, mouth) and skin, these surfaces should be thoroughly washed with water and soap. Wounds or needlestick injuries are also washed with water and soap. Using any chlorine-containing detergents to clean the skin and mucous membranes is not recommended.

Each healthcare institution ought to have a developed action plan that includes rules for personnel handling blood and other bodily fluids, a post-exposure prophylaxis plan for contact with blood or secretions that are potentially infected with HIV, and an occupational health plan. Those in the HCI in charge of work safety and hygiene are to be notified of all cases associated with HIV infection in the workplace. Identifying risk of HIV infection and selecting a regimen for ARV prophylaxis is to be determined by the specialist of the AIDS center and/or staff of a HCI educated and trained at the center.

4. Education of healthcare workers

Trainings of healthcare workers of women's clinics, maternity wards, children's polyclinics, and AIDS centers on preventing HIV vertical transmission must be conducted on a regular basis.

Those who should receive training:

- Obstetricians, gynecologists, fellows, interns, family doctors, midwives, nurses, neonatologists, pediatricians, infectious disease physicians
- Laboratory staff should also receive regular training on quality assurance of collecting specimens and carrying out laboratory tests.

Those who should provide training:

- Trainers educated and/or based in the regional/national AIDS centers

Training content should include:

- Local, regional, and national statistics on HIV
- Requirements of testing all women, rather than those at risk
- Nationally- and regionally-approved requirements to prevent vertical HIV transmission
- Factors determining HIV mother-to-child transmission during pregnancy, delivery, and postpartum
- Methods of preventing HIV vertical transmission during pregnancy, delivery, and postpartum
- Requirements of testing and techniques of rapid testing for HIV in the maternity hospital
- Regulations on ARV prophylaxis
- Requirements of respecting confidentiality
- Rules of communicating news to and counseling women during pregnancy, delivery, and postpartum on prevention of HIV vertical transmission
- Diagnostic methods and interpretation of test results
- Interdisciplinary approach to providing proper prevention of vertical transmission and social support to the woman

Didactic sessions and independent studies are the most up-to-date teaching techniques. Teaching with computers and Internet data is helpful for informing healthcare workers about HIV statistics, factors influencing upon perinatal HIV transmission, current research, ARV prophylaxis, and requirements of testing.

Discussions regarding case presentation in small groups may be useful for building skills, looking for solutions to problems, and learning approaches to solving the problem. Each case presentation may take up to 30 minutes.

Role-playing may be employed separately or along with case presentation to refine skills of counseling and testing women during pregnancy, delivery, and postpartum. One role-play may take longer than 45 minutes.

PMTCT issues ought to be incorporated in advanced training courses for healthcare workers. These trainings must become a requirement to obtaining a relevant certificate (neonatologist, obstetrician-gynecologist, etc.), as well as a component of professional category evaluation.

5. Indicators of evaluating PMTCT effectiveness

The following table lists major indicators of work on preventing vertical HIV transmission at all stages of providing care to the woman during pregnancy, delivery, and postpartum and to the child immediately after birth.

A sample of indicator calculations is presented below:

$$\text{Proportion of pregnant women tested for HIV in the women's clinic (\%)} = \frac{\text{Number of pregnant women tested for HIV in the clinic} \times 100 \text{ (coefficient [\%])}}{\text{Number of pregnant women followed-up in the clinic}}$$

Monitoring these indicators will allow healthcare authorities to evaluate the implementation of all activities aiming at prevention of mother-to-child infection transmission and their effectiveness.

Indicator	Numerator	Denominator	Coefficient
Prenatal care			
Proportion of pregnant women tested for HIV in the women's clinic at the set term (twice)	Number of pregnant women tested for HIV in the women's clinic at the set term (twice)	Number of pregnant women followed-up in the clinic	100
Proportion of identified HIV-infected pregnant women of those tested	Number of identified HIV-infected pregnant women	Number of pregnant women tested for HIV infection	100
Proportion of HIV-infected pregnant women who received counseling on prevention of vertical HIV transmission at the set term	Number of pregnant women with positive HIV test results who received counseling	Number of pregnant women with positive HIV test results	100
Proportion of HIV-infected pregnant women who terminated their pregnancies	Number of HIV-infected pregnant women who terminated their pregnancies	Number of HIV-infected pregnant women	100
Proportion of HIV-infected pregnant women receiving ARV prophylaxis during pregnancy	Number of HIV-infected pregnant women receiving ARV prophylaxis during pregnancy	Number of HIV-infected pregnant women who preserved their pregnancies	100
Proportion of HIV-infected women followed-up at the women's clinic	Number of HIV-infected women who are followed-up	Number of HIV-infected pregnant women who preserved their pregnancies	100
Proportion of HIV-infected women followed-up by the specialist of the AIDS center	Number of HIV-infected women who are followed up by the specialist of the AIDS center	Number of HIV-infected pregnant women who preserved their pregnancies	100
Admission for delivery			
Indicator	Numerator	Denominator	Coefficient
Proportion of women tested for HIV during pregnancy	Number of women tested for HIV during pregnancy	Number of women admitted for delivery	100

Proportion of women who had rapid testing for HIV in the maternity hospital	Number of women who had rapid testing for HIV in the maternity hospital	Number of women admitted for delivery	100
Proportion of deliveries through C-section in HIV-infected women	Number of deliveries through C-section in HIV-infected women	Number of deliveries in HIV-infected women	100
Proportion of children born to HIV-infected women who started receiving ARV prophylaxis in the delivery room	Number of children who started receiving ARV prophylaxis in the delivery room	Number of children born to HIV-infected women who didn't receive ARV prophylaxis during pregnancy	100
Postpartum unit			
Proportion of children born to HIV-infected women who received ARV prophylaxis within the first 72 hours of their life	Number of children who received ARV prophylaxis within the first 72 hours of their life	Number of children born to HIV-infected women	100
Proportion of children born to HIV-infected women who were breastfed in the maternity hospital	Number of breastfed children	Number of children born to HIV-infected women	100
After discharge from the maternity hospital			
Proportion of children born to HIV-infected women who were followed up for 18 months	Number of children born to HIV-infected women followed-up up to 18 months	Number of children born to HIV-infected women	100
Proportion of children born to HIV-infected women who were breastfed after discharge from the maternity hospital	Number of children born to HIV-infected women who were breastfed	Number of children born to HIV-infected women	100
General indicator of system's performance			
Proportion of pairs (HIV-infected woman and her child older than 6 weeks) who received the completed PMTCT course	Number of pairs (HIV-infected woman and her child older than 6 weeks) who received the completed PMTCT course	Number of pairs (HIV-infected woman and her child older than 6 weeks)	100
Proportion of HIV-infected children born to HIV-infected women	Number of HIV-infected children born to HIV-infected women	Number of children born to HIV-infected women who turned 18 months	100

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7. Appendix

7.1 Booklet. Pregnant woman's pre-test counseling prior to HIV testing PREVENTION OF HIV MOTHER-TO-CHILD TRANSMISSION

What is the human immune deficiency virus (HIV)?

This is one of the most dangerous human viruses. It affects the immune system depriving it of the ability to defend the body from various infections. Diseases that under normal circumstances are hardly noticeable become severe in HIV-infected individuals.

End-stage of HIV-disease is the syndrome of acquired immune deficiency (AIDS), at which the completely exhausted immune system cannot protect the human body from interchanging and overlapping severe ailments.

How can one acquire HIV?

HIV may be acquired through blood while sharing needles for injecting drug use, donor blood transfusion, or using non-sterile medical instruments.

One may get infected through intimate contacts: the virus is transmitted through vaginal secretions and sperm. An infection risk always exists because we cannot be completely sure that one of the sexual partners is not HIV-infected. The only reliable means of protection is permanent and correct use of condoms.

The child may get HIV infection from its mother during pregnancy, delivery, and breastfeeding.

HIV is not transmitted through touching, shaking hands, kissing, sharing bed linen and dishes, coughing and sneezing, or through insect bites.

What is the risk of HIV infection in pregnant women and newborns?

Over recent years, HIV infection has been identified not only in promiscuous women and those using injecting drugs. More and more often, HIV is detected in accidental testing of women who seem to be not at risk. At the same time, the majority live normal lives and plan pregnancies without suspecting this infection. As a result, for timely diagnosis of possible infection, healthcare workers offer all pregnant women HIV testing.

This is important for carrying out a number of activities to protect the fetus and the baby from HIV. If this prophylactic treatment starts at early pregnancy term, the likelihood that a healthy baby will be born to the HIV-infected woman is very high.

When and how is HIV testing done?

The major goal of testing, which is recommended to all pregnant women, be it complete blood count or urinalysis, is to identify the woman's existing health problems for initiating her timely treatment and prevent diseases in the newborn. In this respect, HIV testing doesn't differ from other tests. It is done two times during pregnancy along with tests for hepatitis B and syphilis.

HIV testing permits identification in woman's blood of specific antibodies, proteins that are produced for fighting bacteria and viruses penetrating into the human body.

The first HIV test is to be done at 6-10 weeks of gestation. Positive test results (antibodies to HIV are detected in blood) at this stage will help the woman make a judicious decision – either preserve or terminate her pregnancy – as well as to start taking medications in a timely manner that reduce the risk of HIV infection transmission to the baby.

If, for whatever reason, testing has not been done at the set term, the first opportunity that arises should be taken for this.

Usually, HIV testing is repeated at later pregnancy term (at 34-36 weeks). The second test is very important, since there are no guarantees that the infection did not occur after the first test. Besides, at the time of initial testing, antibodies in the blood of already infected woman could have been absent: the time when antibodies become detectable after getting infected varies from two weeks to six months.

Who can reduce the threat of child's infection?

It wouldn't be an overestimation to say that the pregnant woman herself may promote giving birth to the healthy child: the earlier she has tests, the earlier and more effective appropriate treatment may be initiated if the presence of HIV infection is confirmed.

Prophylactic treatment of the woman and the fetus with special drugs during the entire pregnancy and delivery is very efficacious: the probability of infecting the fetus and the child is minimized (under 2%). Optimal success is achieved if taking medications starts not later than at 28 weeks. If HIV infection is identified later, treatment is prescribed anyway even though just a few days are left before delivery. Both long and abridged course of prophylactic treatment, indeed, may protect the fetus and newborn from getting HIV-infected.

Along with the use of medications, doctors are eager to interrupt all possible modes of infection transmission from the pregnant woman to the newborn infant: unless there are problems, the baby is delivered through C-section in most cases, and the mother is strongly recommended not to breastfeed. These are mandatory and essential measures, since the delivery and breastfeeding stages are the most dangerous when considering possibility of the infection's transmission.

What are the peculiar features of follow-up of children born to HIV-infected mothers?

In order to know whether the newborn has HIV infection, special tests are done.

It is important to keep in mind that maternal antibodies circulate in blood of children born to HIV-infected mothers during the first one and a half years of their life. Therefore, even if the results of a newborn's blood test turned out to be positive, they cannot be considered as a sign of infection of the child until after this age.

By 18 months, when a child's blood doesn't have maternal antibodies, negative test results (antibodies to HIV are not detected in blood) give grounds for regarding the child as healthy.

In postpartum period, a newborn is administered the course of prophylactic treatment that takes several weeks. Effectiveness of treatment depends on the time of its initiation.

Since the HIV-infected woman is recommended not to breastfeed, she may use any adapted baby formula meant for bottle-feeding of newborns.

This information must be remembered under all circumstances!

HIV is a disaster affecting many millions of people worldwide. Those infected become victims of the virus not only because of their risky behavior but also often due to a lack of knowledge or circumstances beyond their control.

The earlier the woman learns about her HIV infection, the more chances exist to preserve and promote her health.

No one is within her or his right to make the woman either preserve or terminate her pregnancy. This decision can only be made by the woman.

No one can say that the baby born to an HIV-infected woman is doomed: treatment initiated at early pregnancy term significantly increases its chances to be born healthy.

Each woman, regardless of her HIV status, has rights of confidentiality, receipt of quality healthcare, and social support.

7.2 Sample plan for pregnancy management to prevent HIV perinatal transmission (handout)

Term of gestation	Healthcare	Date (indicate)
Initial visit	Examination by the obstetrician-gynecologist. Follow-up at the women's clinic Complete blood count (CBC) Blood type and Rh-factor Wassermann reaction Hepatitis A and N Urinalysis Microscopic examination of the vaginal secretions Ultrasound examination ELISA for HIV Immune blotting Consultation of the infection disease doctor. Follow-up at the AIDS center Viral load Checking CD4 counts Involvement of other professionals as needed	
12 weeks	Consultation of the obstetrician-gynecologist	
16 weeks	Consultation of the obstetrician-gynecologist	
20 weeks	Consultation of the obstetrician-gynecologist Gravidogram Ultrasound examination	
26 weeks	Consultation of the infection disease doctor/specialist of the AIDS center Viral load Checking CD4 counts CBC and biochemical blood test	
28 weeks	Consultation of the obstetrician-gynecologist Gravidogram Consultation of the infection disease doctor/specialist of the AIDS center Administering ARVs	
32 weeks	Obstetrician-gynecologist Gravidogram Ultrasound examination Biochemical blood test	
36 weeks	Consultation of the obstetrician-gynecologist Gravidogram Consultation of the infection disease doctor/specialist of the AIDS Center Checking CD4 counts Viral load Evaluating effectiveness of ARV prophylaxis Selection of the delivery mode	
38 weeks	Admission to the maternity hospital	

Name, last name, contact information of the attending obstetrician-gynecologist/trusted doctor...

Name, last name, contact information of the attending infection disease doctor/trusted doctor

Name, last name, contact information of other necessary professionals

7.3 Glossary

7.4 DECREE of the MoH #606 “About approving the instruction on preventing mother-to-child HIV transmission and a sample of informed consent for ARV prophylaxis of HIV” of December 19, 2003.

7.5 DECREE of MoH&SD#375 “About approving the standard of preventing mother-to-child HIV transmission” of May 30, 2005