



PREVENTING
MOTHER-TO-CHILD
TRANSMISSION OF HIV

A Practical Guide for
Providing HIV-Positive
Women with Family
Planning Services

2nd Edition



Preventing Mother-to-Child Transmission of HIV

A Practical Guide for
Providing HIV-Positive
Women with Family
Planning Services

2nd Edition

This guide was developed using the most recent treatment information available at the time of production by professionals in Ukraine for colleagues working in similar healthcare settings. In the rapidly changing field of HIV care and treatment, information can become outdated quickly. We encourage users to compare this data and its date of issuance with the latest information found on www.aidsknowledgehub.org and other relevant sites. AIHA disclaims any responsibility for any errors, omissions, or other possible problems associated with this publication. February 2005.



This guide is made possible through support provided by the US Agency for International Development (USAID), Bureau for Europe and Eurasia. The opinions expressed herein are those of the author(s) and do not necessarily reflect the views of USAID.

Developed by:

N.N. Nizova, MD, PhD,
Professor,
Odessa State Medical
University

S.P. Posokhova, MD,
Candidate in Medical
Sciences,
Assistant Professor,
Odessa Oblast
Clinical Hospital

Edited by:
V. Zaporozhan, MD, PhD,
member of the Ukrainian
Academy of Medical Science

Odessa 2002

2nd edition,
Odessa 2005

Cover photo: Sergey Kosintsev.
Image of mother and child
courtesy of Barbara Comnes,
Painet Inc.

Translation by EnRus Translation
Agency (www.enrus.ru), Moscow.

Since 1992, the American International Health Alliance (AIHA) has established and managed more than 100 volunteer-driven partnerships between healthcare institutions in the United States and their counterparts in Central and Eastern Europe and Eurasia. AIHA partnerships involve the twinning of hundreds of health systems, educational institutions, and communities, as well as the participation of thousands of clinicians, educators, and other health-related professionals. AIHA assistance has enabled the US healthcare sector to help address local healthcare issues by providing effective and coordinated assistance to the countries of these regions. AIHA also sponsors a number of supportive and collaborative activities, including conferences, workshops, and a multilingual Web-based clearinghouse of medical information. In an extraordinary demonstration of private-public collaboration and commitment, the US health sector is contributing more than one dollar in resources ranging from equipment and supplies to in-kind time for every federal dollar provided in support of the twinning programs.

AIHA's twinning partnerships have made many important contributions to health reform efforts in Central and Eastern Europe and Eurasia, including: (1) restructuring national, oblast (state), and city healthcare delivery systems by, for example, organizing regional perinatal and emergency networks; reorganizing key in- and outpatient hospital services at institutional and multi-institutional levels; and introducing new levels of care and services including hospice care and home health visits by nurses; (2) developing a network of more than 25 free-standing Women's Wellness Centers that provide comprehensive health care tailored to the specific needs of women; (3) reorganizing and improving health professions education by establishing some of the first residency-based training programs in the region for family physicians and other primary care providers; (4) supporting the development of the region's first schools and programs in health management, health administration, and public health; (5) establishing new skills-based training centers and programs for the in-service training of physicians, nurses, fieldshers, and administrators, such as the region's first programs in basic emergency care, disaster response, infection control, and neonatal resuscitation; (6) opening more than 23 high-quality, model Primary Care Centers that provide comprehensive medical care and emphasize community-based health promotion and wellness programs; (7) developing successful "healthy communities/healthy cities" twinning relationships that enable communities to address their own unique health and social welfare problems; (8) creating more than 130 Learning Resource Centers to promote evidence-based clinical practices and offer support to the dozens of nursing and other associations created to encourage professional development and broad health reform initiatives; and (9) developing a number of operational comprehensive, community-based model programs that target specific health priorities such as tuberculosis, cardiovascular disease, family violence, post-traumatic stress syndrome, diabetes, asthma, and preventing the risk of mother-to-child transmission of HIV.

AIHA operates primarily under cooperative agreements with the United States Agency for International Development (USAID)—the US government agency that finances programs and projects that promote broad-based and sustainable economic growth worldwide—and the US Department of Health and Human Services, Health Resources and Services Administration (HRSA). Additional funding has been provided through grants from the US Department of Energy, the Library of Congress's Open World Leadership Center, and various foundations. (February 2005)

AIHA's Regional Model for Preventing Mother-to-Child Transmission of HIV in Odessa, Ukraine

Central and Eastern Europe and Eurasia are currently experiencing the fastest increase of HIV infection in the world, bringing the total number of people living with the virus in the region to 1.5 million.¹ Although the number of children born to HIV-positive mothers in this area is still relatively low, two-thirds of the reported cases are in Ukraine² (population: 48 million, 2002).³ According to UNAIDS statistics, HIV prevalence in Ukraine is approaching 1% of the adult population.⁴ The number of children born to HIV-positive women in the country increased nearly 90%, from 737 reported cases in 2000, to 1,379 in 2002.⁵ The percentage of HIV cases registered among pregnant women has also skyrocketed, in some regions rising above 0.4 percent.⁶

Odessa oblast has one of the highest HIV infection rates in the country (361.3 per 100,000 people oblast-wide)⁷ and the number of children infected through vertical transmission has grown significantly during the last three years, with the number of births to HIV-positive mothers rising from 0.8% in 2001 to 1.0% in 2003.⁸ For comparison, in 2001, 0.4% of pregnant women tested positive for HIV in Ukraine; in 2002, 0.5% of pregnant women had a positive status.⁹

In response to this public health crisis, AIHA initiated a pilot project in 2001 aimed at preventing mother-to-child transmission (MTCT) of HIV in Odessa. Supported by USAID, AIHA's project is an integral part of a larger effort involving international donors including UNAIDS, WHO, UNICEF, Médecins Sans Frontières (MSF; also known as Doctors Without Borders), and Ukrainian government agencies and nongovernmental organizations. MSF, for example, is providing Odessan women with supplies, such as antiretroviral (ARV) drugs and infant formula crucial to preventing MTCT, and AIHA is cooperating closely with MSF to provide related technical assistance and training for healthcare workers to Odessa healthcare institutions.

In 2003, the World Health Organization Regional Office for Europe (WHO/Euro) joined with AIHA to establish the independent, non-governmental Regional Knowledge Hub for Care and Treatment of HIV/AIDS in Eurasia. Operating with funds provided by Deutsche Gesellschaft für Technische Zusammenarbeit (GTZ) and USAID, the Knowledge Hub serves as a crucial capacity-building mechanism for reaching WHO's "3 by 5" targets for the region.

Based in Ukraine at the Kiev Medical Academy of Post Graduate Education and closely affiliated with the Ukrainian National AIDS Center, the main objective of the Knowledge Hub is to create the human resource capacity necessary to provide care to HIV-infected individuals by developing expertise among healthcare professionals, cultivating training capacity,

and massing a body of evidence-based resources and informational materials.

Tasked with developing a cadre of well-trained, knowledgeable, and skilled professionals who will work in close collaboration with community-based organizations dedicated to providing care and social support to HIV-positive individuals, the Knowledge Hub will be part of a synergistic network that includes international experts, two similar centers—one focusing on harm reduction and the other on surveillance—and a cadre of strategic partners including AIDS Foundation East West (AFEW), International Association of Physicians in AIDS Care (IAPAC), and AIDS Healthcare Foundation-Global Immunity (AHF-GI).

AIHA's project in Odessa focuses primarily on implementing systemic and institutional changes related to the prevention and treatment of HIV/AIDS by:

- reorganizing and strengthening clinical service delivery to ensure that measures to stop vertical transmission of the disease are integrated into the obstetric, pediatric, and new family-centered primary care systems;
- revising treatment protocols to ensure that they are evidence based and effective within the region's changing social and economic context; and
- developing training materials and curricula for health professionals in important areas such as

counseling, obstetrics, occupational health, women's health, pediatric care, and family planning.

This effort builds upon more than a decade of highly successful AIHA programmatic activity throughout Ukraine, in general, and in Odessa, in particular.

With USAID support, AIHA is applying its proprietary twinning methodology—supplemented by expert resources—to the prevention of mother-to-child transmission (PMTCT) project in Odessa. Boulder Community Hospital and its collaborating institutions, including the University of Colorado Health Sciences Center and Children's Hospital of Denver, are serving as the lead US partners under a subgrant from AIHA. These partners, working closely with their counterparts in the Odessa Oblast Health Administration, the State Medical University of Odessa, and the Odessa Oblast Hospital—one of the largest public hospitals in the region—are providing training and capacity building related to the model program. In addition, AIHA is drawing upon the expertise of individual health professionals and key public institutions across the United States to supplement and expand upon this training and to provide expertise in the area of HIV/AIDS treatment and care.

Training to date has been specifically designed to increase the proficiency of medical professionals from Odessa in the areas of obstetrics and gynecology, neonatology, counseling, and clinical practice guidelines. While future training will continue to focus on

these important areas, additional emphasis is being placed on nursing, pediatrics, and laboratory support, as well as the development of high-quality primary care for mother and child.

As is the case in other AIHA twinning programs, US institutions and health professionals involved in the Ukraine PMTCT project are voluntarily providing professional support and material resources—including basic workplace infection control barriers and other important supplies—matching US government funding on a dollar-for-dollar basis.

As a result of the coordinated efforts by AIHA and others, the Odessa Oblast Hospital has been able to quickly demonstrate dramatic success in the prevention of MTCT; preliminary results at the end of 2002 indicated a 75% decrease in HIV-positive infants born to HIV-positive women at the hospital.¹⁰ Having demonstrated initial success in preventing MTCT among participating women, the project is increasingly focused on systematically identifying all women in the city and oblast who are at risk, enrolling them in family planning and prenatal services, and ensuring 100% case management through delivery and postdelivery. The project is also striving to provide all HIV-positive mother/child pairs with high-quality family care and, if necessary, specialized treatment.

In 2003, AIHA established the Southern Ukraine AIDS Education Center (SUAEC) in Odessa to disseminate the PMTCT model through hands-on, skills-based and methodological trainings. SUAEC

[P]reliminary results at the end of 2002 indicated a 75% decrease in HIV-positive infants born to HIV-positive women at the hospital.

currently serves as a regional training center for the Knowledge Hub in the areas of PMTCT and pediatric AIDS.

An overall goal of AIHA's model PMTCT project is to develop materials that can be used throughout the region. Companion products are a critical output of the project, and collaboration and consensus-building with the Ukrainian Ministry of Health and others is a key component of the project's work plan. Practical materials such as this guide are being developed using a collaborative approach in which the Ukrainian authors' drafts are circulated to US counterparts for review and comment. All documents are made available in both English and Russian.

Companion products and further information about the model PMTCT project, the Regional Knowledge Hub for the Care and Treatment of HIV/AIDS in Eurasia, USAID, and AIHA's partnership programs, and the HRSA-funded HIV/AIDS Twinning Center Program in Africa, Asia, and the Caribbean can be found at www.aiha.com. Further information about the Regional Knowledge Hub for the Care and Treatment of HIV/AIDS in Eurasia can be found at www.aidsknowledgehub.org (July 2004).

References

1. UNAIDS/WHO, AIDS epidemic update. December 2003.
2. R. Malyuta, "HIV Infection Among Women and Children: Review of Epidemic Development in Europe and NIS," presentation, May, 2003.
3. Intergovernmental Statistical Committee of the CIS [Межгосударственный статистический комитет СНГ], 2003.
4. UNAIDS, *Report on the Global HIV/AIDS Epidemic*, 2002.
5. R.A. Moiseyenko, "Implementation of the National Program,

"Reproductive Health 2001–2003," Report to the Conference on Monitoring and Assessment of the Vertical Transmission Prevention Program in Ukraine, Kiev, Ukraine (in Ukrainian), April 2003.

6. R.A. Moiseyenko, "Prevention of HIV Transmission from Mother to Child in Ukraine," report to the Regional Conference for Eastern Europe and Central Asia "Care, Support, and Treatment for People Living with HIV/AIDS," November 2002, Ukraine [Доклад на региональной конференции для стран Восточной Европы и Центральной Азии "Уход, поддержка и лечение для людей, живущих с ВИЧ/СПИДом", ноябрь 2002, Украина].
7. Ukrainian AIDS Center Reports, 2003.
8. Annual Reports of Odessa Oblast AIDS Center, 2001–2003 [Годовые отчеты Одесского областного центра СПИДа, 2001–2003].
9. Ministry of Health of Ukraine, Organization of PMTCT System in Ukraine, 2003.
10. Ministry of Health of Ukraine, "Organization of Mother-to-Child Transmission Prevention System in Ukraine: An Overview," Prevention of HIV Infection in Infants Review Meeting, Kiev, Ukraine, September 16–18, 2003.

Acknowledgements

The authors wish to extend their thanks for the review of the first edition of this guide to:

- Jill K. Davies, MD, assistant professor, Division of Maternal Fetal Medicine, Department of Obstetrics and Gynecology, University of Colorado School of Medicine, Denver, Colorado
- Kay Kinzie, RN, pregnancy coordinator, Denver Children's Hospital, Denver, Colorado
- Laure Lisk, RN, MS, director, Women and Family Services, Boulder Community Hospital, Boulder, Colorado
- Charles Steinberg, MD, physician, director, Beacon Clinic, Boulder Community Hospital, Boulder, Colorado
- Mary Macsalka, MD, physician, Boulder Community Hospital, Boulder, Colorado

The authors also wish to thank Barbara Fisher, vice president, Boulder Community Hospital, for her contribution to this project.

Table of Contents

Preface	i
Glossary of Terms	iv
Acronyms	vii
Chapter 1: Introduction and Background	1
Goals and Scope of the Practical Guide	2
Chapter 2: Provision of Family Planning Counseling and Medical Care	
A Modern Approach to Family Planning Counseling	5
Counseling HIV-Positive Women About Reproductive Health and Family Planning Issues	8
The Role of the Partner in Family Planning	14
Pre-conception Counseling and Care for HIV-Positive Women	14
Chapter 3: Selecting a Method of Contraception for HIV-Positive Women	
Hormonal Contraceptives	19
<i>Hormonal Contraceptive Methods</i>	20
Condoms	22
<i>Condoms</i>	25

Table of Contents

Spermicides	26
<i>Spermicides</i>	27
Intrauterine Devices (IUDs)	28
<i>Intrauterine Devices (IUDs)</i>	29
Other Barrier Methods	29
<i>Other Barrier Methods</i>	30
Voluntary Sterilization	31
<i>Voluntary Sterilization</i>	31
Chapter 4: General Principles Regarding the Use of Antiretroviral Agents in Pregnancy	33
References	39

Preface

As early as 1968, the United Nations proclaimed family planning and free responsible parentage an integral right of every citizen of the world. This right, of course, also extends to HIV-positive women. Issues of contraception for these patients must be addressed not only within a medical context but in terms of its social significance as well. The rights of HIV-positive patients must always be respected, and discrimination against them must not be tolerated, as has been stated in all legal documents addressing HIV/AIDS. Despite the severity of the disease, the task of healthcare workers is to ensure a decent quality of life for these patients, their children, and their partners, which suggests that a high priority be assigned to issues of family planning.¹

According to studies conducted by the Odessa State Medical University, only 7% of all HIV-positive pregnant women in the Odessa region had previously used contraceptives.² Therefore, when providing family planning counseling, providers must remember that devices that prevent contraception and the transmission of sexually transmitted infections (STIs) are still not used pervasively in Ukraine,

primarily because the public has not been sufficiently informed about the benefits of their use. Thus, each patient must be fully counseled on issues related to preventing unwanted pregnancies and STIs, without limiting such counseling to the prescription of one or another means of contraception. Physicians should provide information about all the ways one can prevent an unwanted pregnancy, noting their benefits, as well as their risks, and allowing the patient the opportunity to make an independent choice about which method to use.³

Counseling HIV-positive women on family planning and contraception issues, and preparing such women for childbirth, should be one of the medical services offered by outpatient and polyclinic facilities. Counseling should focus primarily on how specific decisions might affect the woman's health, as well as that of any future child, and must cover:

- The possible effect of the pregnancy on the mother's health and the subsequent progression of her infection
- The need for HIV-positive pregnant women to undergo additional observation and treatment, including taking medical drugs
- The effect of HIV on the course and outcome of labor
- The risk of transmitting the infection to the infant
- Prevention of HIV transmission from mother to child
- Disease prognosis in the neonate
- Issues of care for children who have lost parents

References

1. Ukrainian Ministry of Health and UNICEF, Preventing Mother-to-Child HIV Transmission, training module, Kiev, 2001.
2. T.Y. Rachok and I.A. Boychenko, Contraception for HIV-infected Patients (Third International Congress, Urgent Problems of Infectology and Gynecology, Ukrainian section of ESIDOG, Odessa, 2000).
3. Ukrainian Ministry of Health and UNICEF, 2001.

GLOSSARY OF TERMS

Acquired Immune Deficiency Syndrome

(AIDS): The terminal stage of an HIV infection.

Counseling: A confidential conversation between a counselor and client aimed at providing psychological support for and giving information on a particular topic to the client. Counseling helps clients develop skills for overcoming the difficulties of life circumstances and enables them to make critical decisions based upon accurate and complete information. In relation to HIV, counseling can help prevent the spread of the infection by encouraging a client's sense of responsibility for his/her behavior and, when necessary, guiding him/her to change risky lifestyle behaviors.

Counseling and testing (C&T): A process through which patients learn whether or not they are HIV-positive, what that means for their future, and the various decisions they may need to make after being given more information about their diagnosis. In HIV testing, blood or another biological fluid is checked for the presence of HIV antibodies or virus antigens. HIV testing must be strictly voluntary and performed only with the informed consent of the patient. Counseling accompanying HIV testing comprises a series of confidential meetings between a patient and counselor that allows the patient to determine the level of his/her knowledge about HIV, assess his/her behavior from the standpoint of the risk of infection and transmission, decide whether or not to be tested, and receive psychological

support when test results are given. The terms “HIV testing and counseling,” “voluntary testing and counseling” (VTC), and “voluntary and confidential counseling and testing” (VCCT) are synonymous. (Definition from *Increasing Access to Knowledge of HIV Status: Conclusions of a WHO Consultation*, Dec. 3–4, 2001.)

HIV: Human immunodeficiency virus; a retrovirus that causes AIDS. In this guide, HIV refers to HIV-1, as cases of vertical transmission of HIV-2 are extremely rare.

HIV status: (divided into four categories)

- **Indeterminate status:** A person who has not been tested for HIV, whose results of an HIV screening are unknown, or who has received a positive result on an HIV quick test.
- **HIV-infected:** A person who is infected with HIV, who may or may not know it.
- **HIV-negative:** A person who has tested negative for HIV and knows the results of the test. In the case of a child, the parent(s) have been notified.
- **HIV-positive:** A person who has tested positive for HIV, has a confirmed diagnosis, and knows the results of the diagnosis. In the case of a child, the parent(s) have been notified.

Informed consent: Permission given by a patient to a healthcare worker to perform HIV testing, certifying that the decision to be tested has been made on a voluntary basis, after giving

conscious consideration to all relevant information/facts. Because the knowledge and experiences of individuals are different, it is important that healthcare workers provide the patient with information the patient considers important. This may include details about the risks and advantages of being tested; the option to decline testing because of specific, personal situations; and the availability of testing options. Only after the patient feels fully informed can a decision about testing be made. Informed consent must always be obtained for HIV testing, because the HIV virus is a life-threatening disease that can have dangerous consequences for the patient. (Definition from *Increasing Access to Knowledge of HIV Status: Conclusions of a WHO Consultation, Dec. 3-4, 2001.*)

Mother-to-child transmission of HIV

(MTCT): In this guide, MTCT refers to the transmission of HIV from an HIV-positive woman to her child during pregnancy, delivery, or breast feeding. A woman can become infected with HIV through unprotected sexual contact with an HIV-positive partner, a blood transfusion, contact with a nonsterile instrument, or a medical procedure. She may not know her HIV status. The term MTCT, also known as vertical transmission, does not carry any hint of judgment.

Vertical transmission: See mother-to-child transmission of HIV.

ACRONYMS

AIDS: acquired immunodeficiency syndrome

ART: antiretroviral therapy

COC: combined oral contraceptives

CVD: cardiovascular disease

DVT: deep venous thrombosis

HAART: highly-active antiretroviral therapy

HBV: Hepatitis B virus

HCV: Hepatitis C virus

HDL: high-density lipoproteins

HIV: human immunodeficiency virus

HAI: hospital-acquired infection

IUD: intrauterine device

LDL: low-density lipoproteins

NRTI: nucleoside reverse transcriptase inhibitor

NNRTI: non-nucleoside reverse transcriptase inhibitor

PEP: postexposure prophylaxis

PID: pelvic inflammatory disease

PMS: premenstrual syndrome

PEP: postexposure prophylaxis

STI: sexually transmitted infection

UN: United Nations Organization

UNICEF: United Nations International Children's
Emergency Fund

UTI: urinary tract infection

WHO: World Health Organization

Chapter 1: Introduction and Background

According to the definition of the World Health Organization (WHO), family planning includes activities that assist individuals and couples

- avoid unwanted pregnancy
- have wanted children
- regulate the interval between pregnancies
- plan when to have children, based the parents' age and health
- determine the number of children to have¹

The majority of HIV-positive women in the United States use some form of contraception, most commonly condoms. Women using no form of contraception do not necessarily intend to become pregnant, but may lack significant power in their sexual relationship, be under pressure from their partner or family to have children, be unaware of their options concerning contraception, have a disorganized lifestyle that precludes consistent use of contraception; believe they cannot become pregnant, or simply have decided to take their chances. Unplanned does not necessarily mean unwanted; several studies show low rates of elective pregnancy termination in HIV-infected women.²

In Ukraine, by contrast, women use contraceptives far less frequently. An Odessa State Medical University study of 185 pregnant HIV-positive women from the Odessa region attests to the extremely low usage of contraceptive methods by these women. It found that only 7% of pregnant HIV-positive women had previously used methods to prevent pregnancy and that the majority (47%) of these practiced coitus interruptus, while 23% used intra uterine devices (IUDs), 12% used condoms, 7% used oral contraceptives, and 1% used Depo-Provera (Medroxyprogesterone acetate).³

GOALS AND SCOPE OF THE PRACTICAL GUIDE

This guide was developed to assist in the prevention of sexual and mother-to-child transmission (PMTCT) of HIV and to reduce the number of unwanted pregnancies in HIV-positive women. Further objectives are to improve the medical family planning counseling system for HIV-positive patients, identify the optimal contraceptive method in each individual case, and improve the quality of life for HIV-positive women in Odessa and the Odessa Oblast.

Adoption of this guide by outpatient clinics and obstetric and gynecological service providers will enable the inclusion of important HIV-prevention measures in their practices.

This guide is intended to provide healthcare workers with family planning guidelines, which are a com-

ponent of HIV-transmission prevention. It is intended for use by obstetricians and gynecologists, midwives, nurses, family practitioners, and physicians specializing in infectious diseases.

This guide is recommended for use at women's outpatient clinics, polyclinics, and maternity hospitals in Odessa and the Odessa Oblast.

Chapter 2: Provision of Family Planning Counseling and Medical Care

In accordance with recommendations published in the *Guide to Clinical Care of Women with HIV*, women who test positive for HIV should immediately be counseled and given patient information on reproductive health and family planning issues; providers should not wait until the women become pregnant to impart this knowledge. This is important as it allows the woman to make carefully thought out and timely decisions regarding contraception and pregnancy planning from on a fully informed standpoint.⁴

A MODERN APPROACH TO FAMILY PLANNING COUNSELING⁵

At the 1994 International Conference on Population and Development, in Cairo, which included an assessment of the current state of the HIV/AIDS epidemic and the prevalence of STIs, a proposal was made to review the emphasis of reproductive health and family planning programs on pregnancy prevention and to concentrate attention on such issues as the prevention and treatment of STIs, including HIV/AIDS.

Because the majority of national family planning

[W]omen who test positive for HIV should immediately be counseled and given patient information on reproductive health and family planning issues . . .

programs are more concerned with preventing unwanted pregnancies than with preventing the contraction of an STI, they pay insufficient attention to the use of condoms. Personnel at family planning services continue to encourage the use of highly effective methods of contraception that fail to provide protection from STIs or HIV. As a result, in recent decades the use of condoms for purposes of contraception has been significantly reduced. This factor has apparently facilitated the spread of HIV infections, especially in high-risk groups.

A working group, organized by WHO and UNAIDS, was held October 25-26, 1999, in Geneva to discuss the problem of STIs and HIV/AIDS in Eastern Europe and Eurasia. At the meeting, the use of condoms for “dual protection”—from unwanted pregnancy and from STI/HIV infection—was discussed.

The participants of the working group

- Affirmed the benefits of dual protection and confirmed that these may be achieved by the regular and correct use of a condom, including in combination with other methods of contraception.
- Recognized that dual protection should be considered one of the main goals of a family planning program and that clients should be provided with complete information about different contraceptive methods, not only in relation to their effectiveness in preventing unwanted pregnancy.

- Strongly recommended that the organizations that supported the working group make a joint political statement on this issue directed to all countries so that national policymakers may use this statement to form or review areas of activity that fall within the framework of national family planning programs.
- Called on international and governmental organizations to coordinate their approaches to dual protection.
- Proposed that all countries base decisions about who should receive dual protection recommendations based on the STI/HIV epidemiological situation, the frequency with which specific means of contraception are used, a review of the capabilities of family planning services, and an analysis of whether or not there are other services capable of participating in a solution to the problem.
- Appealed to international and national organizations to assist in the implementation of dual protection programs—ranging from issues of publicity and promotion to administrative concerns and the supply of quality condoms.
- Supported an expansion of scientific research in various key areas that, to a significant degree, would lead individual countries to include the dual protection strategy in their national programs.

COUNSELING HIV-POSITIVE WOMEN ABOUT REPRODUCTIVE HEALTH AND FAMILY PLANNING ISSUES

Counseling is an extremely important component of family planning services and is designed to assist patients

- ▮ make an informed choice regarding their reproductive options
- ▮ select a contraceptive method that suits them
- ▮ correctly and successfully use their chosen method

Family planning counselors working with HIV-positive patients⁶

- ▮ understand and respect the rights of their patients
- ▮ win their trust
- ▮ do not judge patients and, in doing so, demonstrate respect and kindness
- ▮ are informed about the advantages and drawbacks of all contraceptive methods, including limitations in terms of HIV infection
- ▮ provide only objective information
- ▮ understand the cultural and emotional factors that can influence the decision of a woman or couple to use a particular contraceptive method
- ▮ encourage patients to ask questions
- ▮ listen attentively to all of a patient's concerns
- ▮ understand the importance of nonverbal communication
- ▮ refer patient to appropriate specialists in situations in which he/she cannot provide complete assistance or answer all the patient's questions

The following recommendations for counseling of HIV-positive patients provides an outline of how to approach the patient and subject matter.

- ▮ Counseling must always take place in a strictly confidential setting.
- ▮ Begin the conversation with a polite welcome then tactfully ask the woman about her problems and her attitudes toward family planning issues. At the beginning of the conversation attempt to listen more than you speak; where necessary, use leading questions to ensure the conversation stays on course.
- ▮ Determine the high-priority areas for discussion based on the needs of the woman.

If the patient is not pregnant and is not planning a pregnancy in the near future

- ▮ It is necessary to tell her about all existing contraceptive methods, their advantages and disadvantages, and indications and contraindications, and then to help her determine the most acceptable contraceptive method (see “Selecting a Method of Contraception for HIV-positive Women”). Remember that the patient will make the final decision about what, if any, contraceptive method she will use and the counselor's task is to provide her with the most complete information for this purpose.

- After the woman has decided to use a specific contraceptive she must learn details about how to use it, the probability of pregnancy, possible side effects, and any serious complications that might occur, along with symptoms that should lead her to immediately consult a physician.

- The need to use an additional barrier method to protect oneself from contracting an STI or transmitting HIV to a sex partner should also be emphasized (see also “Condoms,” page 22).

- Plan a follow-up counseling session during which the woman may ask any questions she has regarding the chosen contraceptive method used. The patient should understand that she may seek counseling at any time, particularly if urgent questions or alarming symptoms arise, or she may change her contraceptive method for any other reason, if she wishes.
 - Briefly cover issues connected with pregnancy against a background of HIV infection (see below) so that the patient receives information necessary to make long-term life plans.

The patient is not pregnant but is planning a pregnancy in the near future:

- discuss the following topics (for more details on counseling such women, see “Preconceptional Counseling and Care for HIV-Positive Women,” page 14):⁷
 - the effect of HIV on the course and outcome of pregnancy

- the influence of pregnancy on the progression of an HIV infection
- other factors—such as consumption of drugs and/or alcohol, the mother’s age, and concomitant diseases, including arterial hypertension and diabetes, which can influence the course of pregnancy
- the long-term prognosis of the mother’s health and issues concerning care (guardianship) for children
- perinatal HIV transmission; the risk and possibility of prevention using drugs
- the use of antiretroviral drugs and other medication during pregnancy (see “General Principles for the Use of Antiretroviral Drugs During Pregnancy,” page 33)
- safe conception, if the partner is HIV-negative.

- Select an effective method of contraception, one that she can use until she is healthy enough to become pregnant, should she desire to do so (see “Selecting a Method of Contraception for HIV-Positive Women,” page 19).

- Emphasize the need to use an additional barrier method to protect oneself from contracting an STI or transmitting HIV to a sex partner (see also “Condoms,” page 22).

*The patient is pregnant but has not yet made a final decision regarding her pregnancy:*⁸

- Assess the patient’s psychological state and,

Let the woman know that at this time there are no reliable data confirming that pregnancy and childbirth have a negative effect on the course of an HIV infection . . .

speaking in terms she will understand, give her the most current information about the possible effect her HIV infection will have on the course of her pregnancy and health; the risk of transmitting the infection to her child as a fetus and infant; and the challenges of caring for a child whose parent may be incapacitated by, or who may die as a result of, an HIV infection or AIDS.

- Let the woman know that at this time there are no reliable data confirming that pregnancy and childbirth have a negative effect on the course of an HIV infection and that there is also a lack of reliable information concerning serious disorders in neonates born to mothers in the early stage of HIV, including cases in which the mother takes anti-retroviral drugs. Explain that such a possibility exists, but avoid using “scare” tactics.
- Inform her that the probability of infecting the child with HIV is 21–40%, but decreases to 8% if the available preventive drug regimens are indicated. Tactfully inform patients of the likely side effects of taking antiretroviral drugs.
- Explain to the patient that breast feeding is not recommended for HIV-positive mothers, because of the high probability that HIV will be transmitted to the infant (12–20%), and that this means that the family will incur the extra expense of infant formula.

- Discuss the long-term consequences for her family and advise her to discuss this matter with those who are close to her. If she does not wish to do so, do not coerce her; do not provide any information to her partner or other family members without her consent.
- Be respectful of her decisions. Remember that no one has the right to forbid a woman to become a mother—every woman must make her own informed, independent decision and not follow the rigid recommendations of a counselor.
- Provide the patient with complete information on drug-based prevention of perinatal HIV transmission and refer her to an HIV treatment specialist to resolve questions of commencing, changing, or temporarily halting antiretroviral therapy (ART), in connection with her pregnancy.
- Refer her for appropriate registration as a pregnancy patient.
- Inform her of the necessity to use an additional barrier method to protect herself from contracting an STI or transmitting HIV to her sex partners (see also “Condoms,” page 22).
- Discuss her future needs for contraception and provide information on suitable contraceptive methods (see above).

THE ROLE OF THE PARTNER IN FAMILY PLANNING⁹

The role of the partner of an HIV-positive woman in family planning is extremely important. Ideally, the partner will participate to an equal degree in the selection of a contraceptive method that protects one from STIs and will feel general responsibility for its application. Partners must be aware of possible side effects and be attentive toward their own health.

The participation of men in the family planning process, in cases in which one or both partners are HIV-positive, presupposes:

- The sharing of responsibility with the woman when deciding on the use of a specific contraceptive method and support in implementing the selected method; for example, reminding the woman each day of the need to take a pill.
- Understanding the need and always being willing to use condoms as protection from HIV infection—in this case the exchange of resistant strains of HIV—and STI transmission.
- Consideration of the possibility of non-penetrative safe sexual contact.

PRE-CONCEPTION COUNSELING AND CARE FOR HIV-POSITIVE WOMEN¹⁰

Many women infected with HIV—nearly 60% in some centers—enter pregnancy with a known

diagnosis, and nearly half of these women begin their first trimester receiving treatment with single or multi-agent ART. In addition, as many as 40% of women who have begun ART before becoming pregnant might require adjustment of their therapeutic regimen during the course of their pregnancy.

The American College of Obstetrics and Gynecology advocates extending to all women of childbearing age the opportunity to receive pre-conception counseling as a component of routine primary medical care. It is recognized that more than 40% of pregnancies may be unintended and that the diagnosis of pregnancy most frequently occurs late in the first trimester when organogenesis is nearly completed. Pre-conception care can identify risk factors—for example, age, diabetes, hypertension—for adverse maternal or fetal outcomes, provide education and counseling targeted to a patient's individual needs, and treat or stabilize medical conditions before conception to optimize maternal and fetal health.

For women with HIV, pre-conception care must also focus on maternal infection status, viral load, immune status, and ART regimen, as well as on education regarding perinatal transmission risks and prevention strategies, expectations for the child's future, and when desired, effective contraception until optimal maternal health is achieved.

The following components of pre-conception counseling are recommended for HIV-infected women:

For women with HIV, pre-conception care must also focus on maternal infection status, viral load, immune status, and ART regimen, as well as on education regarding perinatal transmission risks and prevention strategies . . .

- I Selection of an effective and appropriate contraceptive method to reduce the likelihood of unintended pregnancy.

- I Education and counseling about perinatal transmission risks, strategies to reduce those risks, and the potential effects of HIV or HIV treatment on the pregnancy and its outcomes.

- I Initiation or modification of ART:
 - Avoid agents with potential reproductive toxicity for the developing fetus, such as efavirenz and hydroxyurea
 - Choose agents effective in reducing the risk of perinatal HIV transmission
 - Attain a stable, maximally suppressed maternal viral load
 - Evaluate and control associated therapy side effects that may adversely affect maternal-fetal health outcomes; for example, hyperglycemia, anemia, and hepatic toxicity

- I Evaluation and appropriate prophylaxis for opportunistic infections and administration of medical immunizations for influenza, pneumococcal, or hepatitis B vaccines, for example, as indicated.

- I Optimization of maternal nutritional status.

- I Institution of standard measures for pre-conception evaluation and management, such as assessment of reproductive and familial

genetic history, screening for infectious diseases and STIs, and initiation of folic acid supplementats.

- I Screening for maternal psychological and substance abuse disorders.

- I Planning for perinatal consultation if desired or indicated.

HIV-positive women of childbearing age receive primary health-care services in various clinical settings; for example, family planning, family medicine, internal medicine, and obstetrics/gynecology clinics. It is imperative that primary healthcare providers consider the fundamental principles of pre-conception counseling an integral component of comprehensive primary health care as a way to improve maternal/child health outcomes.

It is imperative that primary healthcare providers consider the fundamental principles of pre-conception counseling an integral component of comprehensive primary health care as a way to improve maternal/child health outcomes.

Chapter 3: Selecting a Method of Contraception for HIV-Positive Women

In selecting a method of contraception for HIV-positive woman, the following should be considered:

- The condition of the woman's health, including the presence of concomitant somatic and infectious diseases, including STIs and allergies, as well as her mental status; for example, the presence or absence of HIV-encephalopathy or concomitant mental disorders.
- Whether any medication is being taken, including antiretroviral drugs, antibiotics, antihypertensive medication, etc.
- Characteristics of her sexual lifestyle, such as the number of sex partners and the possibility of reaching an agreement with a partner(s) to use a particular contraceptive method.
- The consumption of psychoactive substances.

HORMONAL CONTRACEPTIVE METHODS

At this time, because of their effectiveness, general level of safety, and ease of use, hormonal contra-

HORMONAL CONTRACEPTIVE METHODS

Method	Failure Rate* Typical Use	Perfect Use	Contraindications	Advantages	Disadvantages	Potential Side Effects	Convenience	Comments
Oral contraceptives	3	0.1	<ul style="list-style-type: none"> History of CVD, DVT, stroke High blood pressure High LDL/HDL ratio Age >35 and heavy smoking Severely impaired liver function Hepatocellular adenoma Headache with focal neurologic symptoms Diabetes with nephropathy, retinopathy, neuropathy, or vascular disease Breast cancer Major surgery with immobilization 	<ul style="list-style-type: none"> Decreased menstrual pain, PMS, and bleeding May diminish acne Decrease the incidence of: <ul style="list-style-type: none"> benign breast diseases functional ovarian cysts ovarian and endometrial cancer PID 	<ul style="list-style-type: none"> Does not protect against STIs May increase susceptibility to certain STIs Pills must be taken daily High cost 	<ul style="list-style-type: none"> Nausea Headache Weight gain Dizziness Breast tenderness Vaginal spotting Chloasma Depression 	<ul style="list-style-type: none"> Provides for spontaneous intercourse 	<ul style="list-style-type: none"> Potential drug interactions must be considered
Depomedroxy-progesterone acetate (DMPA)	.3	.3	<ul style="list-style-type: none"> Unexplained vaginal bleeding Breast cancer 	<ul style="list-style-type: none"> Decreased risk of seizures May have protective effect against <ul style="list-style-type: none"> PID and ovarian and endometrial cancer Decrease in menstrual blood loss and anemia Amenorrhoea 	<ul style="list-style-type: none"> Does not protect against STIs High cost 	<ul style="list-style-type: none"> Disruption of the menstrual cycle (vaginal spotting, bleeding at irregular intervals, amenorrhoea) Weight gain Breast tenderness Headache Adverse effect on lipids Depression 	<ul style="list-style-type: none"> Often causes amenorrhoea Only four injections per year No additional action required Provides for spontaneous intercourse 	<ul style="list-style-type: none"> Potential drug interactions must be considered
Levonorgestrel implant (Norplant)	.09	.09	<ul style="list-style-type: none"> See above 	<ul style="list-style-type: none"> See above 	<ul style="list-style-type: none"> Does not protect against STIs Invasive procedure for insertion and removal High cost 	<ul style="list-style-type: none"> Tenderness or infection at site Disruption of the menstrual cycle Hair loss Weight gain Breast tenderness Depression 	<ul style="list-style-type: none"> Effective for up to five years No additional action required Provides for spontaneous intercourse 	<ul style="list-style-type: none"> Potential drug interactions must be considered
Progestin-only pills	1.1-13.8	.5	<ul style="list-style-type: none"> See above 	<ul style="list-style-type: none"> See above 	<ul style="list-style-type: none"> Does not protect against STIs Higher ectopic pregnancy rate relative to other hormonal methods Must be taken daily High cost 	<ul style="list-style-type: none"> Disruption in menstrual cycle (vaginal spotting, irregular blood flow, amenorrhoea) Breast tenderness Weight gain Depression 	<ul style="list-style-type: none"> Provides for spontaneous intercourse 	<ul style="list-style-type: none"> Potential drug interactions must be considered

* Percent (%) of women experiencing accidental pregnancy within the first year of use.

Source: *A Guide to the Clinical Care of Women with HIV*, Edited by Jean R. Anderson, US Department of Health and Human Services, HRSA (2001), www.hab.hrsa.gov/publications/womencare.htm. Russian-language version.

When counseling HIV-positive women, particular attention should be paid to the need to always use condoms . . . male or female whatever other contraceptive method is used.

ceptives are the method of choice for HIV-positive women.¹¹ The following pages list current hormonal contraceptive methods, their effectiveness, side effects, contraindications, and advantages.

Interaction of Hormonal Contraceptives with Other Medication¹²

Hormonal methods of contraception, particularly oral contraceptives, can have significant drug interactions, resulting in either decreased contraceptive effectiveness or increased or decreased concentrations of the coadministered drug. Use of nelfinavir, ritonavir, amprenavir, lopinavir/ritonavir (Kaletra), and efavirenz may be associated with a decrease in oral contraceptive effectiveness and a possible increase in breakthrough bleeding. In this situation, therefore, an alternative method of birth control or additional methods of contraception should be used. Other medications known to interact with oral contraceptives—and in some cases with progestin-only contraceptives—include tetracyclines, penicillin, oral hypoglycemic agents, rifampin, tricyclic antidepressants, oral anticoagulants, beta-blockers, methyl-dopa, vitamin C, benzodiazepines, and seizure medications. Clinicians treating women who are at risk for drug interactions should review the possible need for an alternative contraceptive method or dose adjustment for the interacting agent.

CONDOMS

When counseling HIV-positive women, particular attention should be paid to the need to always use

condoms—male or female (see below)—whatever other contraceptive method is used.

Explain to the HIV-positive woman that only a condom is capable of protecting her sex partner from the infection. If both partners are HIV-positive, then unprotected sexual contact carries a theoretical risk that resistant strains of HIV could be transmitted from one to the other. It should also be emphasized that only a condom provides the highest level of protection for a woman against STIs which, against a background of HIV, can be especially harsh and more frequently lead to various complications.

The Male Condom

The efficacy of using male condoms with regard to the reduction of the risk of HIV transmission has been assessed in studies conducted among monogamous “serodiscordant” couples—couples in which only one of the partners was HIV-positive at the commencement of the study. The frequency of seroconversion was determined among HIV-negative partners in couples who regularly and never use condoms.¹³

Data from various studies indicate that the efficacy of using condoms is within the range of 60–96%. Using metaanalysis of a large number of such studies, it was established that the efficacy of condoms is, overall, 87%.¹⁴ At present, it is recommended that condoms that have a lubricant that does not contain the spermicide nonoxynol-9 (N-9) be used.¹⁵ It

If both partners are HIV-positive, then unprotected sexual contact carries a theoretical risk that resistant strains of HIV could be transmitted from one to the other.

must be emphasized that only the correct and regular use of condoms can maintain the health of the woman and her partner. Please note that condom usage applies to vaginal, anal, and oral sexual contact.

Instructions for the use of condoms

- Use a condom for **every sexual contact**. The condom packet should be opened carefully. Remember that teeth, nails, or jewelry may damage the condom. When using condoms, apply only water-based lubricant. Oil- or grease-based lubricants, such as Vaseline or lotions containing petroleum, reduce the protective properties of the condom. Keep condoms in a cool, dry place; do not keep condoms in a pocket or in a compartment in a car because the high temperature will destroy the material from which the condom is made. Do not use a condom after its expiration date (shown on the box or the individual condom package). Never use a condom that is stuck together or torn.

- Place the condom on the penis after the penis has become erect, but before it comes into contact with the partner. Pull back the foreskin before putting on the condom.

- When putting it on, press the tip of the condom to squeeze out any air. Leave a small, empty area in the tip for the semen. Unroll the condom down the entire length of the penis.

- If the condom breaks or falls off during sex,

CONDOMS		
Method	Male condom (latex, polyurethane, natural rubber)	Female condom**
Failure Rate*		
Typical Use	• 12	• 21
Perfect Use	• 3	• 5
Contraindications:	• Allergic to condom material	• Allergy to polyurethane
Advantages	• Protects against STIs, including HIV infection • Impedes premature ejaculation	• Protects against STIs, including HIV infection
Disadvantages	• Requires agreement of partner • Possible loss of spontaneity in sexual relations	• May be inconvenient to use • To some people, unattractive
Potential Side Effects	• Allergic or sensitivity to condom material • Decrease sensation	• Allergy or sensitivity to polyurethane • Decrease in sensation
Convenience	• Inexpensive and always available • Does not require prescription	• Controlled by the woman • Less likely to break • May be inserted as early as 8 hours prior to intercourse • Does not require a prescription • Inexpensive
Comments	• Recommended for HIV-positive patients	• Recommended for HIV-positive patients
* Percent (%) of women experiencing accidental pregnancy within the first year of use.		
** Data are limited		

Source: *A Guide to the Clinical Care of Women with HIV*, Edited by Jean R. Anderson, US Department of Health and Human Services, HRSA (2001), www.hab.hrsa.gov/publications/womencare.htm. Russian-language version.

stop immediately and put on a new condom. If a condom slips off, breaks, or leaks sperm, it is most often the result of human error versus a defect in the condom.

- After ejaculation, the penis must be removed before it becomes soft by holding the condom

to the penis at its base so that semen does not leak. **Do not use a condom twice.**

As the use of a male condom requires the consent of the partner, a woman should be tactfully asked by the counselor and/or her partner if there are any problems hindering the use of this method, and they discuss ways of overcoming such hindrances.

The Female Condom

The female condom has been available for use in the United States since 1993 and offers women more control over use than the male condom. The female condom is a sheath, closed at one end, with flexible rings at both ends. The device is inserted into the vagina by compressing the closed-end ring and pushing it against the cervix, while the outer ring covers the labia. Only one female condom—marketed under the name “Reality” in the United States and Canada and “Femidom” in other parts of the world—is currently available. Limited data are available on its efficacy in preventing HIV and STIs, although most experts have extrapolated from data on male latex and polyurethane condoms to conclude that, if used properly, female condoms would be impermeable to most viruses and other microorganisms.¹⁶

SPERMICIDES

Spermicides are active against HIV in vitro and are significantly active against gonorrhea and chlamydia; however, a recent study of a standard spermicidal dose of nonoxynol-9 (N-9) used daily for 1 week found an increase in irritation, colposcopic and

[F]indings raise concerns that regular use of spermicides may not only negate any protective effect but may potentially increase risk of HIV transmission.

histologic evidence of inflammation, and decreased numbers of vaginal lactobacilli in N-9 users, compared with placebo recipients. These findings raise concerns that regular use of spermicides may not only negate any protective effect but may potentially increase risk of HIV transmission.¹⁷

In January 2003, the US Food and Drug Administration (FDA) distributed a “Talk Paper” proposing the inclusion of a warning on non-prescription vaginal contraceptives containing N-9. The warn-

SPERMICIDES	
Failure Rate*	
Typical Use	• 21
Perfect Use	• 6
Contraindications	• Allergy to nonoxynol-9
Advantages	• Protection against some STIs, especially gonococcal and chlamydial infections • Effective in vitro against HIV
Disadvantages	• High failure rate if used without barriers
Potential Side Effects	• Vaginal and cervical mucosal irritation • Allergy • Vaginal or urinary tract infections
Convenience	• Controlled by the woman • Does not require prescription • Inexpensive and always available
Comments	• Use of contraceptives using nonoxynol-9 is not currently recommended
* Percent (%) of women experiencing accidental pregnancy within the first year of use.	

Source: *A Guide to the Clinical Care of Women with HIV*, Edited by Jean R. Anderson, US Department of Health and Human Services, HRSA (2001), www.hab.hrsa.gov/publications/womenscare.htm. Russian-language version.

ing would state that vaginal contraceptives containing N-9 do not protect against infection from HIV or other STIs and would also advise consumers that the use of these contraceptives can induce irritation of the vaginal mucous membrane, which may actually increase the possibility of transmitting HIV and other STIs from infected partners.

N-9 works by breaking down the cell membrane of sperm, and under laboratory conditions, it has been shown to break down the cell membranes of certain STI pathogens and to have an antiviral effect with regard to several viruses. Based on this data, it was concluded that this action also damages the mucous membranes of the vagina and the cervix, which increases the risk of STI transmission.¹⁸

INTRAUTERINE DEVICES

Intrauterine devices (IUDs) are not recommended for HIV-positive women. IUDs are associated with increased duration and bleeding during menstruation, and an inflammatory reaction to this foreign body is possible, which increases the risk of HIV transmission and anemia. Moreover, because of the high disease incidence of STIs, the risk of pelvic inflammatory disease (PID) for women who use IUDs is increased.¹⁹

INTRAUTERINE DEVICES (IUDs)	
Failure Rate*	
Typical Use	0.1-2.0**
Perfect Use•	0.1-1.5
Contraindications	<ul style="list-style-type: none"> • Recent (within less than three months) or recurrent PID postdelivery or postabortion metro-endometritis • Active STI • Women with high risk of STI • Severe deformity of the uterine cavity • HIV infection
Advantages	<ul style="list-style-type: none"> • None
Disadvantages	<ul style="list-style-type: none"> • Does not protect against STIs • Increased risk of PID
Potential Side Effects	<ul style="list-style-type: none"> • Menstrual cramping • Increased bleeding • Risk of PID and perforation of the uterine wall after insertion • Anemia
Convenience	<ul style="list-style-type: none"> • Effective for 1 (progesterone-releasing) to 8 (copper) years • No additional action by woman required • One-time expense
Comments	<ul style="list-style-type: none"> • Not recommended for HIV-positive women
<p>* Percent (%) of women experiencing accidental pregnancy within the first year of use. ** Depends on type of device.</p>	

Source: *A Guide to the Clinical Care of Women with HIV*, Edited by Jean R. Anderson, US Department of Health and Human Services, HRSA (2001), www.hab.hrsa.gov/publications/womencare.htm. Russian-language version.

OTHER BARRIER METHODS

The table on page 30 lists information about barrier contraception methods that give women control over their reproductive health.

OTHER BARRIER METHODS

Method	Cervical Cap	Diaphragm
Failure Rate* Typical Use	<ul style="list-style-type: none"> • 36 (parous women) • 18 (nulliparous women) 	<ul style="list-style-type: none"> • 18
Perfect Use	<ul style="list-style-type: none"> • 26 (parous women) • 9 (nulliparous women) 	<ul style="list-style-type: none"> • 6
Contraindications	<ul style="list-style-type: none"> • Allergy to latex • Anatomical distortion of the cervix or vagina • History of TSS or recurrent UTIs • Known or suspected malignancies of the cervix or uterus • Abnormal pap smear • Vaginal or cervical infection • Recent childbirth, spontaneous or induced abortion 	<ul style="list-style-type: none"> • Allergy to latex • Anatomical distortion of the vagina • History of TSS or recurrent UTIs
Advantages	<ul style="list-style-type: none"> • Partial protection against STIs 	<ul style="list-style-type: none"> • Partial protection against STIs • Decrease risk of PID
Disadvantages	<ul style="list-style-type: none"> • Efficacy based on woman's motivation • Use of spermicide must be repeated for every intercourse • Cannot be used during menstruation 	<ul style="list-style-type: none"> • Same as cervical cap, except may be used during menstruation
Potential Side Effects	<ul style="list-style-type: none"> • Pressure on pelvic organs • Irritation of the vagina • Allergy or sensitivity to latex • Vaginal or urinary tract infections 	<ul style="list-style-type: none"> • See cervical cap
Convenience	<ul style="list-style-type: none"> • Controlled by woman • May be inserted ahead of time 	<ul style="list-style-type: none"> • Controlled by the woman • May be inserted as early as 6 hours before intercourse • Inexpensive
Comments	<ul style="list-style-type: none"> • As it is strongly recommended that HIV-infected women always use condoms, these contraception methods are not suitable for them 	<ul style="list-style-type: none"> • See cervical cap

* Percent (%) of women experiencing accidental pregnancy within the first year of use.

Source: *A Guide to the Clinical Care of Women with HIV*, Edited by Jean R. Anderson, US Department of Health and Human Services, HRSA (2001), www.hab.hrsa.gov/publications/womencare.htm. Russian-language version.

VOLUNTARY STERILIZATION

The decision to undergo sterilization must be absolutely voluntary and should be made on the basis of complete information, including knowledge about the irreversibility of such an intervention. Particular attention should be paid to patients who express an interest in this choice; counselors should make sure the patient understands all its ramifications, and the decision should be verified. A voluntary informed consent form should be filled out by the patient before a sterilization procedure is undertaken.²⁰

VOLUNTARY STERILIZATION

Method	Sterilization of Women	Sterilization of Men
Failure Rate* Typical Use Perfect Use	<ul style="list-style-type: none"> • 0.4 • 0.4 	<ul style="list-style-type: none"> • 0.15 • 0.10
Contraindications	<ul style="list-style-type: none"> • Desire to become pregnant in the future 	<ul style="list-style-type: none"> • Desire to become a father in the future
Advantages	<ul style="list-style-type: none"> • Possible decrease in risk of ovarian cancer • Decreased risk of salpingitis 	<ul style="list-style-type: none"> • None known
Disadvantages	<ul style="list-style-type: none"> • Irreversible • Does not protect against STIs 	<ul style="list-style-type: none"> • See above, with the exception that the sterility does not occur immediately
Potential Side Effects	<ul style="list-style-type: none"> • Postoperative pain • Regrets • Increased risk of ectopic pregnancy if operation is unsuccessful 	<ul style="list-style-type: none"> • Postoperative pain • Regrets
Convenience	<ul style="list-style-type: none"> • Provides permanent contraception • No additional action by woman required • One-time expense 	<ul style="list-style-type: none"> • Man is permanently sterile • One-time expense

* Percent (%) of women experiencing accidental pregnancy within the first year of use.

Source: *A Guide to the Clinical Care of Women with HIV*, Edited by Jean R. Anderson, US Department of Health and Human Services, HRSA (2001), www.hab.hrsa.gov/publications/womencare.htm. Russian-language version.

Chapter 4: General Principles Regarding the Use of Antiretroviral Agents in Pregnancy²¹

Medical care of HIV-positive pregnant woman requires coordination and communication between the HIV specialist caring for the woman when she is not pregnant and her obstetrician. Decisions “regarding the use of antiretroviral drugs during pregnancy should be made by the woman after discussions with her healthcare providers about the known and unknown benefits and risks of such therapy. Initial evaluation of an infected pregnant woman should include an assessment of her HIV disease status and recommendations regarding ART, including possible alterations to her current regimen.

This assessment should include

- an evaluation of the degree of existing immunodeficiency determined by CD4+ count
- risk assessment of disease progression as determined by plasma RNA level
- a history of prior or current ART
- gestational age
- supportive care needs

Decisions regarding the initiation of therapy should be the same for women who are not

Decisions regarding the use of antiretroviral drugs during pregnancy should be made by the woman after discussions with her healthcare provider about the known and unknown benefits and risks of such therapy.

Decisions regarding the initiation of therapy should be the same for women who are not currently receiving ART for women who are not pregnant, with the additional consideration of the potential impact of such therapy on the fetus and infant.

currently receiving ART as for women who are not pregnant, with the additional consideration of the potential effect of such therapy on the fetus and infant. Similarly, for women currently receiving ART, decisions regarding alterations in therapy should involve the same considerations as those used for women who are not pregnant. The three-part ZDV chemoprophylaxis regimen, alone or in combination with other antiretroviral agents, should be discussed with and offered to all HIV-positive pregnant women to reduce the risk for perinatal transmission.

Decisions regarding the use and choice of antiretroviral drugs during pregnancy are complex; several competing risk/benefit factors must be weighed. Discussion regarding the use of antiretroviral drugs during pregnancy should include:

- what is known and not known about the effects of such drugs on the fetus and newborn, including lack of long-term outcome data on the use of any of the available antiretroviral drugs during pregnancy
- what treatment is recommended for the health of the HIV-positive woman
- the efficacy of ZDV for reduction of perinatal HIV transmission.

Results from preclinical and animal studies, as well as available clinical information about use of the various antiretroviral agents during pregnancy, should also be discussed. The hypothetical risks of these drugs during pregnancy should be placed in

perspective with the proven benefit of ART for the health of the infected woman and the benefit of ZDV chemoprophylaxis for reducing the risk of transmitting HIV to her infant.

Discussion of treatment options should be noncoercive, and the final decision regarding antiretroviral drug use should be considered the responsibility of the woman. Decisions regarding use and choice of antiretroviral drugs for persons who are not pregnant are becoming increasingly complicated as the standard of care moves toward simultaneous use of multiple antiretroviral drugs to suppress viral replication below detectable limits. These decisions are further complicated in pregnancy because the long-term consequences for the infant who has been exposed to antiretroviral drugs in utero are unknown. A woman's decision to refuse treatment with ZDV or other drugs should not result in punitive action or denial of care. Furthermore, use of ZDV alone should not be denied to a woman who wishes to minimize the exposure of the fetus to other antiretroviral drugs and who therefore, after counseling, chooses to receive only ZDV during pregnancy to reduce the risk of perinatal transmission.

A long-term treatment plan should be developed after discussion between the patient and the health-care provider and should emphasize the importance of adherence to any prescribed antiretroviral regimen. Depending on individual circumstances, provision of support services, men-

Discussion of treatment options should be noncoercive and the final decision regarding antiretroviral drug use should be considered the responsibility of the woman.

tal health services, and drug abuse treatment may be required. Coordination of services among prenatal care providers, primary care and HIV specialty care providers, mental health and drug abuse treatment services, and public assistance programs is essential to ensure the adherence of the infected woman to antiretroviral treatment regimens.

General counseling should include what is known regarding risk factors for perinatal transmission. Cigarette smoking, illicit drug use, and unprotected sexual intercourse with multiple partners during pregnancy have been associated with risk for perinatal transmission of HIV; discontinuing these practices might reduce this risk. In addition, the CDC recommends that infected women in the United States refrain from breastfeeding to avoid postnatal transmission to their infants through breast milk; these recommendations also should be followed by women receiving ART. Passage of antiretroviral drugs into breast milk has been evaluated for only a few antiretroviral drugs: ZDV, 3TC, and nevirapine can be detected in the breast milk of women, and ddI, d4T, abacavir, delavirdine, indinavir, ritonavir, saquinavir, and amprenavir can be detected in the breast milk of lactating rats. Limited data are available regarding either the efficacy of ART for the prevention of postnatal transmission of HIV through breast milk or the toxicity of long-term antiretroviral exposure of the infant through breast milk.

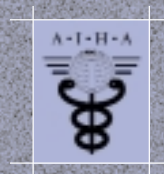
Women who must temporarily discontinue therapy because of pregnancy-related hyperemesis should not resume therapy until sufficient time has elapsed to ensure that the drugs will be tolerated. To reduce the potential for the emergence of resistance, if therapy requires temporary discontinuation for any reason during pregnancy, all drugs should be stopped and reintroduced simultaneously.

References

1. *Guide on Family Planning*, I.B. Vovk and N.N. Nizova, eds. (Kiev, 1998).
2. HRSA, *A Guide to the Clinical Care of Women with HIV*, J.R. Anderson, ed., US Department of Health and Human Services, (2001), www.hab.hrsa.gov/publications/womencare.htm. Russian-language version.
3. T.Y. Rachok and I.A. Boychenko, *Contraception for HIV-infected Patients*, Third International Congress, *Urgent Problems of Infectology and Gynecology*, Ukrainian section of ESIDOG, Odessa (2000).
4. HRSA, 2001, op. cit.
5. Family Planning #1, 2000, www.family-planning.ru.
6. *Guide on Family Planning*, 1998.
7. HRSA, 2001, op. cit.
8. Ukrainian Ministry of Health, UNICEF, *Preventing Mother-to-Child HIV Transmission, training module* (Kiev, 2001).
9. *Guide on Family Planning*, 1998.
10. US Public Health Service Task Force, *Recommendations for Use of Antiretroviral Drugs in Pregnant HIV-1-Infected Women for Maternal Health and Interventions to Reduce Perinatal HIV-1 Transmission in the United States*, June 16, 2003, aidsinfo.nih.gov/guidelines/perinatal/PER_061603.html.
11. HRSA, 2001, op. cit.
12. *ibid.*
13. K.R. Davis and S. Veller, "The effectiveness of condoms in reducing heterosexual transmission of HIV," *Family Planning Perspectives* 31 (6), Nov/Dec 1999.
14. CDC, "Barrier protection against HIV Infection and other sexually transmitted diseases," *MMWR* 42 (30), August 6, 1993.
15. CDC, "Notice to readers: *CDC statement on study results of product containing nonoxynol-9*," *MMWR* 49 (717), 2000 and "Nonoxynol-9: Spermicide fails to protect against HIV infection," *Contraceptive Technology Update* 21 (10), p. 119, October 2000.

References

16. HRSA, 2001, op. cit.
17. *ibid.*
18. Food and Drug Administration (FDA) *Talk Paper*, dated January 16, 2003;
www.fda.gov/bbs/topics/ANSWERS/2003/ANS01191.html.
19. HRSA, 2001, op. cit.
20. *Guide on Family Planning*, 1998.
21. US Public Health Service Task Force, 2003.



American International Health Alliance

aiha@aiha.com

www.aiha.com