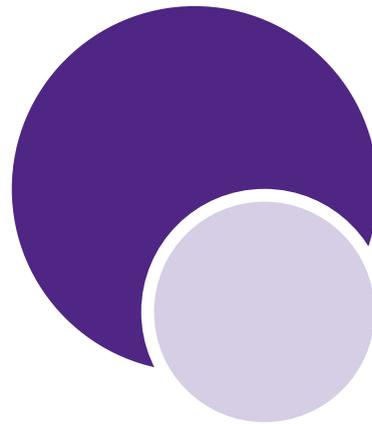


Screening and Management of Maternal HIV Infection

Implications for Mother and Infant

June 2016



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Screening and Management of Maternal HIV Infection

Implications for Mother and Infant

Revised Edition, 2016



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Information about HIV medications for pregnant and postpartum women and newborns outdates quickly. For current recommendations, contact:

- An infectious disease specialist knowledgeable about perinatal HIV
- Go to <http://aidsinfo.nih.gov/>
- Call the Centers for Disease Control and Prevention Information Hotline: 1-800-232-4636

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Executive Summary

The past 20 years have brought tremendous advances in the prevention of HIV transmission from mother to infant. Before zidovudine therapy was available, approximately 25–30 percent of HIV-positive women in the U.S. transmitted HIV to their infants. With zidovudine alone, the rate of infection fell to 5–8 percent. In the past decade, HIV-positive pregnant women who have good viral suppression on potent combination antiretroviral therapy (viral load <500 copies/ml) have a 1–2 percent rate of transmitting HIV to their infants. This same low rate can also be achieved for women with higher viral loads by performing a cesarean delivery prior to the onset of labor or ruptured membranes.

As health care providers for pregnant women, we have an obligation to care for both the mother and her fetus. Prevention of infant HIV transmission is a critical aspect of HIV care for the pregnant woman. However, we must also be certain that HIV treatment in pregnancy does not adversely affect a woman's health or compromise her choices for treatment in the future. Current treatment guidelines recommend offering comprehensive antiretroviral therapy to all HIV-positive pregnant women, even if they do not meet criteria for treatment outside of pregnancy. Optimizing maternal health will also increase chances of having a healthy infant, since maternal HIV viral load is the most important predictor of infant HIV infection.

With the current spectrum of anti-HIV drugs, the outlook for adults with HIV infection has brightened considerably. Compared to the early years of the epidemic, HIV-positive women can now expect to feel well and enjoy a full lifespan. For many HIV-positive women, having children is an important part of their life plan. The approach to these women should be similar to that for women with other chronic illnesses, such as diabetes or hypertension, who become pregnant.

Prevention remains the key to eradicating HIV disease. By screening for HIV in pregnancy, we can identify HIV-infected women and greatly decrease the risk of perinatal HIV transmission while improving maternal health. In addition, HIV testing in pregnancy provides the opportunity to counsel HIV-negative women about reducing their risk of HIV acquisition. The information in this handbook is intended to help us all with the continuing effort to prevent HIV infection in women and infants.

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HIV Testing in Washington State

According to the Centers for Disease Control and Prevention (CDC), over 1 million individuals are estimated to be infected with HIV in the United States. Of those, about 1 in 5 or 18 percent do not know their diagnosis.

In September 2006, the CDC revised recommendations to include routine testing of all patients 13 to 64 years old without regard to the patient's known risk for infection. They also recommended that state rules reduce testing barriers for physicians by including consent for HIV tests as part of general consent for other routine tests, and by eliminating requirements that physicians conduct pre-test counseling.

Beginning January 1, 2010, the Washington State Board of Health adopted these recommendations into Washington Administrative Code, Chapter 246-100.5. The revisions shift responsibility for counseling and partner notification to the local health officer and local health jurisdiction.

Revised rules require health care providers to:

- Obtain informed consent separately or as part of consent for a battery of other routine tests.
- Inform the individual verbally or in writing that a test for HIV is included.
- Offer an opportunity to ask questions and decline testing.
- Notify the local health officer when a person tests positive in order to provide post-test counseling.
- For pregnant women only, documentation of patient refusal of HIV test is still required.



HIV Testing During Pregnancy

Should all women be tested for human immunodeficiency virus (HIV) during pregnancy?

All pregnant women should be tested for HIV prior to pregnancy or as early in pregnancy as possible. Dramatic declines in reported pediatric HIV cases have been observed due to major advances in the treatment of HIV infection and prevention of perinatal transmission.

The Washington State Board of Health adopted revised rules for AIDS counseling for pregnant women. Effective July 6, 2002, these rules reduced barriers to routine HIV testing of pregnant women, consistent with the recommendations of the Centers for Disease Control and Prevention, the Institute of Medicine, the American College of Obstetricians and Gynecologists, and other national and state organizations.

In part, the amended rules require health care providers to:

1. Encourage all pregnant women to have a test for HIV, regardless of identified risk.
2. Obtain the verbal or written consent of the pregnant woman prior to testing. The consent may be part of the general consent for other tests provided that the woman is informed that a test for HIV is included. If the test is refused, refusal must be documented in the patient's medical record.
3. Provide information, either verbally or in writing, addressing:
 - All pregnant women are recommended to have an HIV test
 - HIV is the cause of AIDS and how HIV is transmitted
 - A woman may be at risk for HIV infection, and not know it
 - The efficacy of treatments to reduce vertical transmission
 - Anonymous testing is available, and why confidential testing is recommended
 - The need to report HIV infection
 - Public funds are available to assist eligible infected women to receive HIV care
 - Women who decline testing will not be denied care for themselves or their infants
 - Provide counseling to those women who identify a behavioral risk for HIV, based on the risk assessment

HIV and Pregnancy fact sheet series for women:

http://aidsinfo.nih.gov/contentfiles/Perinatal_FS_en.pdf

In Washington State, heterosexual sex was identified as the exposure risk for almost two-thirds of the HIV-infected women. Sex partners of many of these women were identified as HIV-infected or at high risk of HIV infection, although infection status or risk behavior of these partners may not have been known to these women until they were diagnosed with HIV.

Data has shown that nationwide, even in areas of high HIV prevalence, half of the HIV-infected women were not aware of having HIV risk factors. The following cases are illustrative.

CASE #1:

A 32-year-old woman with three children from a previous marriage acquired a new partner. Neither she nor her new partner had any HIV risk factors. He was HIV negative. She had a lifetime history of less than five heterosexual partners, none of whom, to her knowledge, exhibited high risk behavior. During the fourth pregnancy, she tested HIV positive and received antiretroviral therapy. This child has remained HIV negative and is currently one year of age. Unfortunately, her other children (ages 6, 4, and 2) are HIV-infected. Too late, she learned that her former husband had HIV. She had been unaware of his risk taking behaviors. Had she been tested during previous pregnancies, she may have known her HIV status early enough to possibly prevent her older children from becoming infected.

CASE #2:

A 27-year-old single woman was a regular blood donor. The last time she donated (before her pregnancy), she was informed that she was HIV positive. She had no risk factors other than approximately 10 lifetime sex partners, none of whom, to her knowledge, exhibited high-risk behavior. Too late, she learned that one of her partners was HIV-infected. He was aware of his HIV status during their relationship but did not reveal this information to her.

Factors conveying increased risk for HIV infection in pregnant women include:

- Injection drug use
- History of sexually transmitted diseases
- Blood transfusions or artificial insemination prior to 1985
- Sexual partners (current or past) who are:
 - HIV infected or having unprotected sex with an HIV infected partner
 - Injection drug users
 - Having unprotected sex with multiple partners
 - Current infection or history of sexually transmitted diseases
 - Recipients of blood transfusions prior to 1985
 - Immigration from geographic region with high HIV seroprevalence

What are the laboratory HIV diagnostic tests?

Screening Antibody Test: Enzyme Immunoassay (EIA or ELISA)*

- Sensitivity and specificity >99 percent
- Positive predictive value of a reactive Enzyme Immunoassay ranges from 20 percent to over 95 percent, with lower values in low HIV prevalence populations (based on sensitivity of the Enzyme Immunoassay, as well as prevalence of HIV in the population tested)
- Specificity of <100 percent necessitates use of a confirmatory assay to ensure that the antibody reaction is specific for HIV Test Interpretation: Reactive or Non-Reactive

* *This test alone cannot be used to provide a positive result according to Washington State law and CDC guidelines.*

Rapid Testing During Labor

Timely rapid HIV test results may allow providers to initiate antiretroviral therapy to decrease the risk of mother-to-child HIV transmission. If rapid HIV test results are available before delivery, antiretroviral therapy can be provided to the mother intrapartum. Antiretroviral prophylaxis should also be provided to the infant as soon as possible after delivery. Rapid HIV test results may also allow providers to avoid some common obstetric practices that may increase the risk of HIV transmission (artificial rupture of membranes and fetal scalp electrode placement). In addition, knowledge of a positive rapid HIV result allows the prenatal provider time to advise the mother to avoid breastfeeding her infant and to initiate other counseling regarding her new HIV diagnosis while awaiting confirmation of the rapid test results.

Routinely offering rapid HIV testing to women whose HIV status is unknown during labor and delivery provides the opportunity to reduce transmission even among women who do not seek care until labor begins. The rapid HIV test kits now licensed in the United States make test results available in 20 minutes or less. Findings from the CDC-sponsored Mother-Infant Rapid Intervention at Delivery study indicate that offering voluntary HIV testing during labor is feasible in obstetric settings and that currently available rapid tests deliver accurate and timely test results. However, a positive rapid HIV test must be confirmed using a conventional HIV testing algorithm, including enzyme immunoassay.

The CDC recommends that hospitals adopt a policy of routine, rapid HIV testing using an opt-out approach for women who have undocumented HIV test results when presenting to labor and delivery. American College of Obstetricians and Gynecologists recommends rapid testing for women with undocumented HIV test results. (Committee Opinion Number 635, June 2015)

Confirmatory HIV Testing

In 2014, the Centers for Disease Control and Prevention revised its guidelines for HIV testing. The new recommendations include methods for differentiating HIV-1 from HIV 2 infection and for detecting acute HIV infection. The Western Blot assay, the long-standing standard, is no longer recommended. The revised recommendations can be found at <http://stacks.cdc.gov/view/cdc/23447>.

Key changes recommended for laboratories performing diagnostic HIV testing on serum or plasma specimens are:

1. Initiate testing for HIV with a 4th generation antigen/antibody combination immunoassay.
2. Test specimens with a repeatedly reactive antigen/antibody immunoassay results with an antibody immunoassay that differentiates HIV-1 antibodies from HIV-2 antibodies. As of July, 2016, the Multispot differentiation assay will be discontinued. The recommended replacement assay is the Geenius HIV 1/2 Supplemental Assay manufactured by Bio-Rad Laboratory as it will be the only assay approved by the Food and Drug Administration for this application. Geenius™ is appropriate for use in the CDC recommended laboratory HIV diagnostic testing algorithm: [CDC-Recommended Laboratory HIV Diagnostic Testing Algorithm](#)
3. Specimens that are reactive on the initial 4th generation immunoassay and nonreactive or indeterminate on the HIV-1/HIV-2 antibody differentiation immunoassay should be tested with an HIV-1 nucleic acid test (NAT).
4. Laboratories should use this same testing algorithm, beginning with a 4th generation immunoassay, with serum or plasma specimens submitted for testing after a reactive (preliminary positive) result from any rapid HIV test (including the HIV-1/HIV-2 antibody differentiation assay, when it is used as an initial rapid test, and the HIV-1/HIV-2 antigen/antibody combination rapid test). No further testing is required if the result of the laboratory's initial 4th generation immunoassay is nonreactive.
5. The HIV-1 Western blot is no longer part of the recommended algorithm for HIV testing.

Results of all laboratory tests performed as part of the testing algorithm, as well as the overall interpretation, should be reported to the provider. All states, the District of Columbia, and United States territories and dependent areas require that laboratories report test results indicative of HIV infection to public health authorities in the patient's jurisdiction of residence. Results from the testing algorithm with a negative overall interpretation should not be reported to the health department. If the interpretation of the testing algorithm is positive, indicating the presence of HIV infection, or if all tests in the algorithm are not completed and the interpretation is inconclusive, laboratories should report the results of all laboratory tests that were performed and the overall interpretation to the health department.

For more information on Laboratory Testing for the diagnosis of HIV infection, see Appendix D.

Tests for Virus

- HIV antibodies may not be detected for a “window period” of 2–4 weeks following infection
- Two commonly used tests can detect HIV infection before the appearance of a complete antibody pattern:

HIV–1 RNA (Viral Load)

HIV-1 RNA copies by either bDNA or RTPCR methodology. Viral load can be used to confirm a reactive EIA. The viral load may have false positive results and should not be the sole basis for diagnosing HIV.

HIV–1 Proviral DNA polymerase chain reaction (HIV DNA PCR)

- Enzymatically amplifies and detects specific DNA sequences
- Highly sensitive and specific methodology used to detect HIV-1 proviral DNA in infected cells
- Blood must be collected in EDTA or ACD tubes (heparin anticoagulant is not acceptable because it interferes with PCR assays)
- Useful as a supplement to sort out indeterminate serology results and to determine infection status of infants born to HIV-infected women

HIV–1 Total Nucleic Acid (HIV TNA)

- Measures both HIV DNA and RNA
- Is a qualitative assay
- Is replacing the HIV-1 DNA PCR in many labs
- Is useful to determine the infection status of infants born to HIV-infected women

What are the points to cover in post-test counseling for women with a negative test result?

- Review the purpose of the test and explain that it detects antibodies to HIV
- Give test results
- Reinforce the need for retesting if the woman has had recent risks or if new risks occur
- Encourage condom use if at risk

What if my patient has an indeterminate result?

- Review purpose of the test, explaining that it detects antibodies to HIV
- Give test results
- Encourage condom use if at risk
- Discuss various circumstances that can cause a reactive EIA (other than HIV):
 - Autoimmune diseases
 - Liver disease
 - Vaccines (flu vaccine)
 - Being a multiparous female
 - Rh negative person who has received Rh immunoglobulin

- Having recently had influenza
- Having received immunoglobulins
- **If the repeat test is negative, reassure the woman that she is negative.**
- **If the repeat test is indeterminate:**
 - Patient has no risk factors
 - All sexual partners within the last three months are HIV-negative

Then, reassure the woman that she is not HIV-positive. Explain that she will be excluded from blood donation and that she may have to explain the results to obtain life insurance.
- **If the repeat test detects additional bands**, then the woman may be seroconverting to HIV and needs aggressive antiretroviral therapy for her own health and to reduce risk of perinatal transmission. (See page 10 for counseling for a positive result.)
- **If the repeat test meets criteria for positive result** (see page 10), the woman has seroconverted.

What do I do if my patient has a positive result?

- **Give test results, allowing the woman to absorb information.**
 - Assess her psychological well-being and need for support
- **Discuss the meaning of seropositive results.** A positive test does not mean AIDS; it does mean that the patient is infected and can transmit HIV by sex and needle sharing. Pregnant women can pass HIV to their offspring during pregnancy, at birth, and by breastfeeding.
- **Stress to the woman the need to protect others from infection by:**
 - Practicing abstinence or safer sex practices
 - Not sharing personal items that might contain blood or vaginal fluids (razors, toothbrushes, sex toys)
- **Assess clinical signs and symptoms, CD4 lymphocyte count, and viral load.**
 - Discuss treatment options
- **Reiterate that successful treatment of HIV in pregnancy** reduces the risk of perinatal transmission from 25 percent to 2 percent or less. Scheduled Cesarean delivery may also reduce the risk of transmission if the viral load is not suppressed (see page 18). The woman's decision should be supported regardless of whether or not she accepts or refuses antiretroviral therapy. Refusal of antiretroviral therapy should not result in denial of care or punitive action.
- **Assist the woman in identifying needs for further support** or referral by calling the HIV Client Services (toll free 1-877-376-9316):
 - To help the woman pay for HIV care and treatment.
 - For referral to Community Case Management.

- **When the woman is ready, the following should be addressed:**
 - Discuss the relationship between immune system functioning and the development of AIDS.
 - If the woman discloses current substance use, discuss benefits of treatment and assist with referrals.
 - Stress the need to promote optimal immune system functioning by avoiding cigarettes, non-prescription drugs and excess alcohol, and by eating healthy foods.
- **Partner notification**
 - Strongly advise the woman of the importance of notifying sexual and/or needle sharing partners from the period of possible exposure. Federal legislation requires spousal notification if it can be determined that the spouse could have been infected up to 10 years ago. Exposure times depend on the information that the client gives providing evidence of possible exposure to HIV.
 - Provide assistance to women in notifying partners, including spouses; confirm those partners have been notified.
 - Arrange for the local health department to provide assistance in notifying partners. To find the patient's local health jurisdiction, go to: www.doh.wa.gov/AboutUs/PublicHealthSystem/LocalHealthJurisdictions.aspx
 - Offer to help refer partners for counseling and testing.
 - Confidentiality must be maintained at all times. A system must be in place to avoid documenting the names of referred partners in the permanent record of the woman being counseled.
 - If the woman has partners she is unwilling or unable to notify, the health care provider must report the information and identity of exposed partner(s) to the Washington State Department of Health Office of HIV/AIDS at 1-800-272-2437. In King County, providers should contact Edith Allen at 206-744-4377 or Michelle Perry at 206-744-2726 (Partner Notification Services at Public Health of Seattle and King County).



Perinatal HIV Transmission

If the pregnant woman is HIV positive, what are the chances of infant infection?

- There is a 20–30 percent risk of infant infection with no treatment. ACTG Study 076 was a randomized, double-blind trial of maternal oral zidovudine for a mean of 12 weeks antepartum, IV zidovudine during the intrapartum period, and oral zidovudine treatment of the infant during the first 6 weeks of life. This study showed a reduction of infant infection from 25 percent to 8 percent in the zidovudine-treated group.
- Subsequent observational studies have demonstrated that women on potent combination antiretroviral therapy consisting of at least three drugs, and with a plasma viral load of <5000 copies per milliliter, have 1–2 percent risk of perinatal HIV transmission.
- Intrapartum zidovudine plus scheduled cesarean delivery done prior to the onset of labor or rupture of membranes reduces the risk of perinatal transmission to approximately 2 percent, even in women not on antiretroviral therapy in pregnancy or whose plasma viral load is >1,000 copies/ml (see page 18).
- No combination of therapies can guarantee that a newborn will not become infected.
- Perinatal transmission can occur even at undetectable maternal viral loads.

When does perinatal HIV transmission occur?

Antepartum (during pregnancy, prior to the onset of labor)

- Approximately 30 percent of infections probably occur before labor
- Risk factors may include:
 - Advanced maternal HIV disease
 - High viral load in pregnancy
 - Anything that would introduce maternal blood into the amniotic fluid
 - Amniocentesis
 - Fetomaternal hemorrhage
 - Abruptio placenta

Intrapartum

- Without antiretroviral therapy, approximately 70 percent of infected infants acquire the infection at the time of delivery
- Factors that increase the risk of infection include:
 - Viral load above 500–1,000 copies per milliliter; risk increases progressively with viral load
 - Rupture of membranes for >4 hours

- Maternal smoking
- Clinical or histologic chorioamnionitis
- Prematurity
- Other concerns include:
 - Use of fetal scalp electrode
 - Anything that might break the integrity of the skin or mucus membranes of the infant (forceps/vacuum extractor)
 - Anything that would increase the presence of maternal blood in the birth canal (early episiotomy)

Postpartum

- Infection occurs by breastfeeding
- Additional transmission risk estimates vary from 16–35 percent in different studies
- In the U.S., breastfeeding is not recommended

If I identify an HIV-infected pregnant woman, what resources are available for care and/or consultation?

For care and/or consultation for mother and baby:

Refer to a Maternal-Fetal Medicine or Infectious Diseases specialist with expertise in caring for HIV-infected women and their infants. One resource is UWMC Maternal-Infant Care Clinic. For appointments, call 206-598-4070, or go online: <http://www.uwmedicine.org/patient-care/making-an-appointment>

Additional resources include:

Telephone consultations available via MedCon

1-800-326-5300

<http://depts.washington.edu/medcons/>

Washington State Ryan White Part D Network

HIV Client Services: 1-877-376-9316

Division of Pediatric Infectious Disease

Seattle Children's: 206-987-2073 (office)

206-987-7777 (physician to physician consult line)

Local, State, and County Health Departments

www.doh.wa.gov/AboutUs/PublicHealthSystem/LocalHealthJurisdictions.aspx

Laboratory Tests for Pregnant Women

What laboratory tests need to be obtained for a pregnant woman with HIV?

- CBC with differential and platelet count
- Comprehensive metabolic panel
- T-cell subsets (CD4 cell count and percentage)
- Quantitative HIV RNA, “viral load”
- HIV genotype, prior to initiating antiretroviral therapy in pregnancy, and in the setting of virologic failure

If not done as part of routine prenatal care, then also draw:

- Toxoplasmosis IgG
- CMV IgG
- Hepatitis A IgG
- Hepatitis B s Ag, surface Ab and core Ab
- Hepatitis C IgG
- Herpes simplex virus type-specific serology

In addition, women newly diagnosed with HIV during pregnancy should have a repeat HIV EIA to confirm the diagnosis.

What other laboratory tests are to be drawn before deciding on treatment for the HIV-infected pregnant woman?

Lab Schedule for HIV-Infected Pregnant Women

	After Treatment Began			
	Prior to Treatment	At One Month	Monthly Thereafter to Evaluate for Toxicity	Every 2–3 Months During Pregnancy
CBC with differential and platelets ¹		✓	✓	
T-cell subsets ²	✓	✓		✓
Quantitative HIV RNA ² or HIV Total Nucleic Acid ³	✓	✓		✓
Comprehensive metabolic panel	✓	✓	✓	
Genotype ⁴	✓			

¹ CBC with differential and platelets may need to be drawn with T-cell subsets; check with your lab for test results.

² Some experts would follow T Cell subsets and HIV RNA every 4 weeks until HIV RNA is undetectable.

³ HIV Total Nucleic Acid 9 HIV-1TNA) is a qualitative assay to detect HIV-1 nucleic acid (RNA and proviral DNA). Blood must be collected in EDTA or ACD tubes (heparin anticoagulant is not acceptable because it interferes with PCR assays. Useful as a supplement to sort out indeterminate serology results and to determine infection status of infants born to HIV-infected women.

⁴ Obtain genotype if viral load plateaus or rebound occurs after suppression.

Please consult HIV/AIDS treatment guidelines for additional details:

www.aidsinfo.nih.gov

Reporting

As of September 1, 1999, asymptomatic HIV infection became reportable in Washington State. If you are a King County provider, please report HIV cases of any classification to the Public Health–Seattle & King County HIV/AIDS Epidemiology Program at 206-296-4645. If you are a provider working outside King County, please contact your local health department or the Washington State Department of Health at 1-888-367-5555 or 253-395-6731 to report HIV cases.

Medications and Treatment During Pregnancy, Labor, and Delivery

What are the currently licensed medications used to treat HIV?

Consult the Public Health Service Task Force Recommendations for Use of Antiretroviral Drugs in Pregnant HIV-infected Women in Maternal Health and Interventions to Reduce Perinatal HIV Transmission in U.S. (2014) for the current list of licensed medications used to treat HIV in pregnancy.

<http://aidsinfo.nih.gov/contentfiles/lvguidelines/perinatalgl.pdf>

What are the current treatment recommendations for HIV-positive pregnant women?

- Antiretroviral treatment is recommended for maternal health under the following conditions:
 - Nadir CD4 count $<500/\text{mm}^3$ and/or symptomatic HIV disease in this case
 - Potent antiretroviral therapy consistent with standard of care for non-pregnant adults
 - Continue antiretroviral therapy postpartum
- If pregnant woman does not require antiretroviral therapy for her own health:
 - Potent antiretroviral therapy should still be offered, regardless of maternal CD4 count and viral load, to prevent HIV maternal-to-child transmission
 - The decision to continue or stop antiretroviral therapy after delivery should be individualized (see page 21). Many providers would recommend lifelong antiretroviral therapy once started because of the potential health risks of stopping antiretroviral medications.

Antiretroviral Medications for HIV-Positive Pregnant Women

- Potent antiretroviral therapy (3–4 drugs) with the goal of complete viral suppression.
- Ideally, choose antiretroviral therapy for which there are data regarding maternal and infant safety, and pharmacokinetics in pregnancy.
- Efavirenz is contraindicated in first trimester of pregnancy due to concern for teratogenicity in animal studies and human case reports. However, if conception has occurred on Efavirenz, this medication should be continued.
- For women with CD4 <200 or symptomatic HIV, start as soon as possible including in first trimester. Otherwise, treatment initiation can be deferred until ~14 weeks, until organogenesis has been completed and pregnancy-related nausea has improved.

- HIV-positive women who become pregnant while on antiretroviral therapy:
 - Continue the pre-pregnancy regimen if successful and well-tolerated.
 - With regard to antiretroviral therapy in the first trimester, balance the risk of viral rebound and developing viral resistance (potentially increasing transmission or causing disease progression) against uncertain risks of drug toxicity and teratogenicity in pregnancy. In general, the risk/benefit ratio favors continuing antiretroviral therapy.
 - If antiretroviral therapy is stopped in the first trimester, all drugs should be stopped and restarted simultaneously, which may decrease risk of the virus developing resistance to the drugs.
- Prevention of opportunistic infections during pregnancy:
 - All pregnant women with a CD4 count <200 should receive Pneumocystis carinii pneumonia prophylaxis with TMP-SMX, 1 DS or 1 SS PO qd or Dapsone, 100 mg PO qd.

Are there any concerns about treating pregnant women with the same medications that are used to treat HIV-infected men and non-pregnant women?

For more information:

Consult Special Considerations Regarding the Use of Antiretroviral Drugs by HIV-Infected Pregnant Women and Their Infants:

<http://aidsinfo.nih.gov/guidelines/html/3/perinatal-guidelines/0>

- Efavirenz may be associated with birth defects in animal studies and human case reports. It should not be started in the first trimester and should not be prescribed to women who are planning a pregnancy. (FDA Category D) (Efavirenz drug label)
- Nevirapine has been associated with hepatic toxicity in women with CD4 counts ≥ 250 cell/m and should not be used in this group. If nevirapine is used in women with CD4 counts <250, intensive laboratory plus clinical monitoring is recommended (see product insert for details). (Hitti, 2004)
- In general, many protease inhibitors appear to have less than the expected drug levels in the third trimester of pregnancy. The clinical significance of this and possible requirement for dose escalation is unclear.
- **The Antiretroviral Pregnancy Registry** is an epidemiologic project to collect observational data on antiretroviral exposure during pregnancy with the intention of defining risks for antiretroviral therapy. The registry is maintained by antiretroviral manufacturers and the CDC. Send anonymized prospective reports of HIV-infected pregnant women who are receiving antiretrovirals to:

Registrar Antiretroviral Pregnancy Registry

115 North 3rd Street, Suite 306, Wilmington, NC 28401

Phone: 1-800-258-4263

FAX: 1-800-800-1052

www.apregistry.com

Because of the complexities of antiretroviral therapy and rapidly changing information about HIV medications in pregnancy, consultation with an infectious disease specialist knowledgeable about HIV and pregnancy is strongly recommended.

History and physical exam of HIV-infected pregnant women

Should there be added routines in the history and physical exam of the HIV-positive pregnant woman?

History

- A woman who tests HIV positive in pregnancy should be asked about previous deliveries. She should be encouraged to have her other children tested for HIV, unless she was known to be HIV negative throughout those pregnancies.
- The health care provider should inquire about constitutional signs and symptoms:
 - Fevers
 - Night sweats
 - Respiratory problems
 - Nausea/vomiting
 - Diarrhea

Physical exam

- Inspect the patient's mouth for thrush and oral hairy leukoplakia.
- Palpate all lymph nodes because a swollen, tender lymph node may be a harbinger of a more serious infection or malignancy.
- Palpate the abdomen for liver/spleen enlargement.
- Observe the skin for rash, seborrheic dermatitis.
- Conduct a neurologic exam, including deep tendon reflexes, for neuropathies.
- For women newly diagnosed with HIV, do a Pap smear:
 - If normal, repeat every 6 months x 2, then annually
 - If abnormal, refer for colposcopy and directed biopsies as indicated
- If CD4 count <100/mm³, refer to an ophthalmologist for baseline funduscopy exam to rule out Cytomegalovirus retinitis.

Preventive health care

- Immunization for Hepatitis A and B if susceptible.
- Immunizations for influenza and TDap should also be given as routine for pregnant women.

Medication during labor and delivery

What medications should be used for the HIV-positive pregnant women in labor?

The standard of care for all known HIV-positive pregnant women is as follows:

- Continue all oral antiretroviral medications (see comments about Combivir and Trizivir in box below).

Is intrapartum IV zidovudine still necessary for prevention of perinatal HIV transmission?

- Intravenous zidovudine is indicated if maternal viral load is $>1,000$ prior to labor.
- Current USPHS guidelines suggest that IV zidovudine may be omitted if maternal viral load is undetectable. This recommendation is based on a relatively small number of patients, and the major rationale to limit IV zidovudine has to do with resource allocation.
- We strongly recommend continued use of IV zidovudine for all pregnant women if this medication is available.
- Administer IV zidovudine at the onset of labor or ruptured membranes, or beginning 3–4 hours prior to planned Cesarean delivery, at the following doses:

IV zidovudine 2 mg/kg over 1 hour as a loading dose

- Once the loading dose is completed, administer:
Continuous IV infusion of 1 mg/kg/hour until delivery Stop IV zidovudine after the umbilical cord has been cut. Continue other antiretroviral medications orally, on schedule, during labor or prior to a scheduled Cesarean. However, if the woman is on oral zidovudine in combination with other medications (Combivir or Trizivir), be sure not to give zidovudine both orally and IV.
- If taking Combivir: give lamivudine orally, plus IV zidovudine
- If taking Trizivir: give lamivudine plus abacavir orally, plus IV zidovudine

For HIV-infected pregnant women presenting intrapartum who are not on antiretroviral therapy, the most strongly recommended regimen is:

Mother:	Same zidovudine regimen as in box above Consider Cesarean delivery if not in active labor
Newborn:	Zidovudine 4 mg/kg PO q 12 hrs for 6 weeks Consider additional newborn antiretroviral therapy in consultation with a pediatric HIV specialist.

Information about HIV medications for pregnant and postpartum women and newborns outdates quickly. For current recommendations, contact:

- An infectious disease specialist knowledgeable about perinatal HIV
- Go to <http://aidsinfo.nih.gov> for updated perinatal treatment guidelines
- Call the CDC Hotline: 1-800-232-4636
- Call Maternal Infant Care Clinic, University of Washington Medical Center, Seattle: 206-598-4070 (clinic appointments/medical)

Labor and birth checklists

Guidelines for labor and birth management of HIV positive pregnant women have been developed by the Department of Health, Washington State Ryan White Part D Network, University of Washington School of Medicine, Seattle Children's, and the Northwest Regional Perinatal Program. These checklists for hospitals and prenatal providers outline appropriate in-hospital care, including lab tests and medications for laboring mothers and their newborns. These checklists are available for posting and also as Word documents that can be individualized and placed in the medical record.

- **Prenatal provider checklist:**
<http://here.doh.wa.gov/materials/prenatal-checklist-HIV-pregnancy>
- **Hospital preparation checklist:**
<http://here.doh.wa.gov/materials/hospital-checklist-HIV-pregnancy>

Cesarean birth

Does a Cesarean birth decrease the risk of infant HIV infection?

Early studies indicated a significant relationship between the mode of delivery and vertical transmission of HIV. This body of evidence, accumulated mostly before the use of fully suppressive antiretroviral therapy and without any data regarding maternal viral load, showed that scheduled Cesarean delivery (performed before the onset of labor and/or rupture of membranes) reduces the risk of vertical transmission of HIV compared with either unscheduled Cesarean or vaginal deliveries. This finding holds true whether or not the woman received zidovudine therapy. Whether Cesarean delivery offers any benefit to women on highly active antiretroviral therapy or to women with a low or undetectable viral load is unknown, but appears unlikely.

Maternal morbidity is greater with Cesarean delivery than with vaginal delivery in HIV-infected women, especially among women who have a low CD4 count. (American College of Obstetricians and Gynecologists Committee Opinion, 2000 and reaffirmed 2015; Grubert et al., 1999; Stringer et al., 1999; The European Mode of Delivery Collaboration, 1999; The International Perinatal HIV Group, 1999)

Although many issues remain unresolved because of insufficient data, the American College of Obstetricians and Gynecologists (American College of Obstetricians and Gynecologists Bulletin #234, May 2000, reaffirmed 2015) makes the following recommendations:

HIV-infected pregnant women should be appropriately counseled regarding:

- Risk of vertical transmission:
 - Probability of transmission from an untreated mother to fetus/infant is about 25 percent
 - With zidovudine treatment, risk of transmission is reduced to 5–8 percent
 - With highly active antiretroviral therapy consisting of 3 or more drugs, and suppression of plasma HIV to a low level (viral load <1,000 copies/ml), transmission is reduced to about 2 percent
 - Without highly active antiretroviral therapy, or with a viral load >1,000 copies, zidovudine plus a scheduled Cesarean delivery at 38 weeks gestation can also reduce the risk of transmission to about 2 percent or less
 - No combination of therapies or scheduled Cesarean delivery can guarantee that a newborn will not become infected
- Maternal risks associated with Cesarean delivery for HIV-infected women:
 - Postoperative fever
 - Endometritis
 - Wound infection
 - Urinary tract infection
- Scheduled Cesarean delivery should be offered to women with a viral load >1,000 copies/ml, whether or not they are taking antiretroviral therapy.
- Risks of Cesarean delivery—which are greater for the mother—must be balanced with the benefits expected for the neonate, and the choice of delivery must be individualized.
- The woman’s autonomy should be respected in making her own informed decision regarding route of delivery.

Avoiding risk of transmission

What can be done in labor to minimize the risk of newborn infection?

Intravenous zidovudine should be provided (see page 17) and the pregnancy antiretroviral therapy regimen continued. In addition, whenever possible:

AVOID

- Amniocentesis
- Fetal scalp electrode and intrauterine pressure catheter
- Forceps and vacuum extractor

- Artificial rupture of membranes
 - Studies show an increased risk of infection with rupture of membranes over 4 hours
 - If membranes rupture before labor, begin oxytocin augmentation as soon as possible
- Episiotomy

What can be done to try to minimize infection in the newborn immediately after birth?

- At birth, avoid vigorous suctioning of the mouth and nose
- Handle the newborn carefully to avoid trauma
- Wash the newborn with soap (per hospital procedure) before giving injections or drawing blood
- Start oral zidovudine within the first 6–12 hours, ideally after the first infant blood draw, or start other regimen according to current guidelines (see page 23)



Postpartum Management

Should the woman continue to be treated after delivery?

It depends on her health, current drug regimen, and HIV disease status.

- Women with a nadir CD4 count >500 prior to therapy, and no current or past HIV-associated symptoms, do not have strong clinical indications to continue treatment after delivery. Some experts are concerned that stopping antiretroviral therapy after delivery might affect the woman's health in the future, although at present there is no clear evidence to support or refute this concern. The decision to continue or stop antiretroviral therapy should be individualized, and will depend on these considerations, patient and provider preference and other factors.
- If a woman continues antiretroviral treatment after delivery, the provider should help her develop strategies that will promote adherence to her regimen during the postpartum period.
- All women should have a repeat CD4 count and viral load 6 weeks after delivery and then approximately every 4-6 months thereafter, regardless of whether they stay on antiretroviral therapy.

What is the postpartum care for an HIV-infected woman?

- Advise not to breastfeed
 - Transmission of HIV via breast milk has been well documented
- Give routine postpartum care, including contraception
 - Provide family planning education, method, or referral services
- Assess needs for psychological support
 - Address maternal fears of infant infection
 - Provide support services as needed (case management, mental health services)
- **Avoid methergine to treat postpartum hemorrhage in women on Protease Inhibitors and Non-nucleoside/Nucleotide Reverse Transcriptase Inhibitors. It can cause a severe hypertensive drug interaction.**

What contraception should be used for the HIV-positive woman?

In 2014, the World Health Organization released new recommendations in regard to HIV and hormonal contraceptives. The statement and accompanying annexes can be downloaded from the following webpage: http://www.who.int/reproductivehealth/publications/family_planning/HC_and_HIV_2014/en/

Most contraceptive methods may be considered. There is no increased risk of disease progression in women using injectables, implants, pills, and IUDs.

Condoms

Always recommended, even if her partner is HIV-positive. However, the unintended pregnancy rate is still 10–15 percent even with consistent condom use. Condoms are not the most effective birth control method. Providers should encourage use of **dual** method contraception. Provide information about emergency contraception if the woman does not have a second contraceptive method. There appears to be an 80 percent reduction in HIV acquisition and transmission with consistent use of condoms.

Hormonal

Recent research indicates that hormonal contraception does not influence drug levels or effectiveness of most antiretroviral therapy (one exception is fosamprenavir). However, protease inhibitors and non-nucleoside reverse transcriptase inhibitors may interact with the estrogen component of combined hormonal contraception. This may affect the hormone levels and potential contraceptive tolerability and efficacy (Contraceptive Technology Update, 2011). For this reason, we prefer progesterone-based hormonal methods (DMPA, Levonorgestral IUD) over combined hormonal contraception.

Hormonal contraception does not appear to increase a woman's risk of HIV infection or progression of disease.

What education should be provided to the HIV-infected woman before she is discharged from the hospital?

The mother should:

- Hold, hug, and kiss her baby.
 - She does not need to wear gloves to touch her baby or change diapers
 - Stress good hand washing
- Encourage friends and family to hold the baby.
 - An infected baby will not transmit the virus by holding or hugging
- Continue giving her baby oral zidovudine syrup every 12 hours for the first 6 weeks of life, or other regimen according to clinician. The mother should **not**:
 - Breastfeed
 - Bite off the baby's fingernails or toenails
 - Pre-chew food for infant
 - Hold the baby's pacifier in the mother's mouth
 - Share a toothbrush with anyone, especially children
 - Expose others to blood or exudate from her wounds or lesions

The HIV-Exposed Infant

What laboratory tests should be done on the HIV-exposed newborn, ideally within the first 24 hours of life?

- CBC with differential and platelets
- ALT
- HIV DNA PCR, HIV RNA PCR or HIV Total Nucleic Acid (HIV-1 TNA) to test for viral infection for high risk infants only. Risk includes mother started treatment late, mother with detectable viral load at delivery, follow up not assured.
 - Do not use cord blood because of potential maternal contamination leading to a false positive result .

Note: Maternal zidovudine use can cause anemia and elevated liver enzymes in the newborn. Infant zidovudine treatment can cause anemia and neutropenia. Repeat measurement of CBC with differential at 4–6 weeks of age is recommended.

Data are limited concerning potential toxicities in infants whose mothers received highly active antiretroviral therapy. More intensive monitoring of hematologic and serum chemistry during the first few weeks of life is advised in these infants. Contact a pediatric HIV specialist at 206-987-2073 or 206-987-7777 (physician to physician consult line) for recommendations.

Are HIV-exposed neonates treated with any medications?

On the basis of 076 study, neonates are treated with:

**Zidovudine syrup 4 mg/kg/dose PO every 12 hrs
(for a total of 8 mg/kg/day) for the first 6 weeks of life**

If the neonate cannot take zidovudine orally and needs IV treatment:

**3 mg/kg/dose IV every 12 hours, for a total
of 6 mg/kg/day**

- Ideally, infant labs are drawn before starting zidovudine; however, the goal is to start the drug within the first 6–12 hours of life, even if labs have not been drawn.
- Dosage for premature infants will be different. Consult the DHHS Guidelines for the Use of Antiretroviral Agents in Pediatric HIV Infection at: www.aidsinfo.nih.gov/guidelines/html/2/pediatric-arv-guidelines/0

- Infants may be placed on TMP-SMX for PCP. Dose of 150mg/m² of the TMP component is divided BID, either daily or three days/week. If two viral detection tests are negative (DNA PCR, quantitative HIV RNA, one obtained on or after 2 weeks of age and one on or after 1 month of age), or one test on or after 2 months of age is negative, then PCP prophylaxis can either **not** be started or be discontinued as appropriate. Pediatric DHHS Guidelines:
<http://aidsinfo.nih.gov/Guidelines/HTML/2/pediatric-treatment-guidelines/0>

Management of infants with high risk for HIV transmission

Infants born to women who did not receive antiretroviral medications during pregnancy, have known antiretroviral resistance mutations, or with high viral loads (HIV RNA PCR or HIV-1 TNA) prior to delivery, are at greater risk of acquiring HIV and may benefit from additional antiretroviral medications. Consultation with an HIV specialist is highly recommended.

What are the options for follow-up testing of the HIV-exposed infant?

For testing and consultation, refer to:

Pediatric Infectious Disease Group – Seattle Children’s

Seattle 206-987-2073 (office) or 206-987-7777 (physician to physician consult line)

Local State and County Health Departments

www.doh.wa.gov/AboutUs/PublicHealthSystem/LocalHealthJurisdictions.aspx

Community Clinics

<http://www.wacmhc.org/?page=A12>

What is the schedule for HIV testing of the infant born to an HIV-positive mother?

For early diagnosis, specific viral tests should be done on a regular basis.

Recommended Schedule of Tests for the Diagnosis of HIV-1 Exposed Infants

Age	HIV Serology EIA	CBC with Differential	HIV DNA or RNA PCR ^a	ZDV/TMP-SMX Prophylaxis	Other
At birth			Optional. Consider if infant is at high risk.	Start ZDV ^b (AZT) 4mg/kg q 12 hrs x 6 wks (different dosing for premature infants).	Maternal atazanavir. Watch for neonatal hyperbilirubinemia.
2–4 weeks			✓	✓	
4–8 weeks		✓	✓	Start TMP-SMX for PCP prophylaxis at 6 wks. Can stop (or not start) TMP-SMX if the 2-week and 4-week HIV PCR tests are negative. ^c	
4–6 months			✓ ^d		
18 months	✓ ^e				

- a** HIV DNA PCR should be obtained **from the infant** (not cord blood). Alternatively, the HIV DNA PCR can be replaced by a quantitative RNA PCR. Any positive quantitative HIV RNA or DNA PCR should be confirmed with a repeat test. The birth testing is optional for infants born to women on antiretrovirals and with viral load suppression at delivery.
- Quant HIV-RNA requires the plasma from 3 ml of blood in a purple top EDTA tube. The plasma should be separated and frozen, preferably within 4 hours, and then sent frozen.
 - HIV DNA PCR requires 1–2 ml of blood collected in a purple top EDTA tube sent at room temperature.
 - For high-risk infants initiating combination antiretroviral medications, birth testing should be done. HIV RNA PCR or HIV Total Nucleic Acid may be most useful in this situation due to the more rapid turn-around time for results.
- b** If the mother has known resistance to zidovudine or other antiretroviral medications, or has a viral load >1000 copies/ml at delivery, alternate therapy for the infant may be indicated. **Please contact Infectious Disease at Seattle Children's to discuss options: 206-987-2073 (office) or 206-987-7777 (physician to physician consult line).**
- c** Infants may be placed on TMP-SMX for PCP. Dose of 150mg/m² of the TMP component is divided BID, either daily or three days/week. If two viral detection tests are negative (DNA PCR, quantitative HIV RNA, one obtained on or after 2 weeks of age and one on or after 1 month of age), or one test on or after 2 months of age is negative, then PCP prophylaxis can either not be started or be discontinued as appropriate. (Pediatric DHHS Guidelines: <http://aidsinfo.nih.gov/Guidelines/HTML/2/pediatric-treatment-guidelines/0>).
- d** Definitive exclusion of HIV requires two negative virologic tests: one on or after 1 month and one on or after 4 months, or two negative serologic tests after 6 months of age. (Pediatric DHHS Guidelines: <http://aidsinfo.nih.gov/Guidelines/HTML/2/pediatric-treatment-guidelines/0>).
- e** HIV serology may be positive until the 18-month check, if all the previous PCR tests have been negative. Positive HIV serologic tests prior to 18 months do not indicate infection.

How is HIV infection diagnosed in a child <18 months of age who is known to be born to an HIV-positive mother?

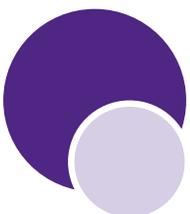
- A child <18 months is tested by using specific viral HIV detection tests.

These tests include:

- Proviral DNA polymerase chain reaction (PCR)
- Quantitative HIV RNA PCR
- HIV Total Nucleic Acid

Child is infected if there are two separate positive specific viral HIV detection tests from two different dates, excluding cord blood.

- A child is not infected under age 18 months if there are two negative tests, one at least over one month of age and the other over four months.
- A positive HIV antibody test (serology) indicates exposure but not HIV infection in child <18 months because:
 - Passive transfer of maternal antibody from the pregnant woman to her fetus occurs during pregnancy
 - A child under 18 months of age is expected to be antibody positive for HIV, reflecting maternal antibody
- By 18 months of age, the maternal HIV antibody should be gone, so an antibody test is appropriate for screening.



Appendix A: Resource Directory

Maternal Infant Care Clinic

University of Washington Medical Center
1959 NE Pacific Street
Seattle, WA 98195
206-598-4070

www.uwmedicine.org/patient-care/our-services/find-a-clinic/pages/clinic.aspx?clinicid=436

- Obstetric, gynecologic, and medical care
- Consultation on management of HIV-infected pregnant women
- Information on clinical trials for HIV-positive women and information about maternal and pediatric HIV clinical trials
- Access to Maternity Support Services

Washington State Ryan White Part D Network

Washington State Department of Health, HIV Client Services
1-877-376-9316

www.doh.wa.gov/YouandYourFamily/IllnessandDisease/HIVAIDS/HIVCareClientServices.aspx

- Assistance with transportation, shelter, food, substance abuse outpatient care, access to research opportunities
- Support provision of treatment through Early Intervention Program
- Payment of insurance premiums through Evergreen Health Insurance Program.

BABES Network – YWCA

1118 Fifth Avenue
Seattle, WA 98101
206-720-5566 or 1-888-292-1912
the_staff@babesnetwork.org

www.babesnetwork.org/

Spanish resources and bilingual staff available

- Peer counseling
- Support groups
- Gatherings
- Advocacy
- Self-advocacy training
- Educational forums
- Retreats
- Monthly bilingual newsletter

UW Medcon Line – Medicine Consult Service

1-800-326-5300

<http://depts.washington.edu/medcons/>

Seattle Children’s

Pediatric Infectious Disease Group

4800 Sandpoint Way N.E., R-5441

Seattle, WA 98105

206-987-2073 (office) or 206-987-7777 (physician to physician consult line)

- Information and medical care for HIV-infected and exposed children
- Information about and access to maternal and pediatric HIV clinical trials

All Washington State and Local Health Jurisdictions

www.doh.wa.gov/AboutUs/PublicHealthSystem/LocalHealthJurisdictions.aspx

- HIV and STD information, testing, and counseling referrals
- Partner notification
- HIV/AIDS reporting

Public Health (Seattle and King County)

HIV/AIDS Program

206-296-4649 (main number)

www.kingcounty.gov/healthservices/health.aspx

- HIV/AIDS Epidemiology: 206-296-4645
For health care providers in King County to report HIV/AIDS cases
- Partner Counseling and Referral Services: 206-744-4377 or 206-744-2726
For health care providers in King County
- HIV/AIDS and STD Hotline: 206-205-7837
For information and testing referrals
(outside Seattle :1-800-272-AIDS)

Alcohol/Drug Hotline – Washington Recovery Helpline

1-866-789-1511

- Provides statewide referral information about treatment, counseling, and support services by county/city for teens and adults

Washington State Department of Health

Washington State HIV/AIDS Hotline: 1-800-272-2437

HIV/AIDS Prevention and Education

www.doh.wa.gov/YouandYourFamily/IllnessandDisease/HIVAIDS/Prevention.aspx

- Waiting room pamphlets for health care provider offices
- Literature requests
- PrEP Resources (Pre-Exposure Prophylaxis):
www.cdc.gov/hiv/risk/prep/index.html

HIV Care – Client Services

www.doh.wa.gov/YouandYourFamily/IllnessandDisease/HIVAIDS/HIVCareClientServices.aspx

- Referrals to other state offices and resources
HIV Client Services: 1-877-376-9316
- To help pay for HIV care and treatment
- For referral to Community Case Management

Northwest AIDS Education & Training Center

Seattle, WA 206-543-2704

<http://depts.washington.edu/nwaetc/>

- Clinical training and educational support for health care professionals

AIDS Clinical Trials Washington State

206-744-3293

<http://depts.washington.edu/actu/>

- HIV/AIDS ACTG clinical trials and treatment for adult residents (age 13 and over) of Washington State

AIDS Information – Guidelines, Drugs, Vaccines, and Clinical Trials

1-800-874-2572

- National information hotline for clinical trials
- ATIS and AIDS Clinical Trials Information Services have been merged into AIDSinfo, a service of the U.S. Department of Health and Human Services:
www.aidsinfo.nih.gov
- Central resource for federally-approved treatment guidelines for HIV and AIDS

CDC HIV/AIDS Resources

CDC HIV/AIDS hotline (24 hour): 1-800-CDC-INFO (232-4636)

www.cdc.gov/hiv/

- Ordering client or professional education materials

Starting Point: Resources for Children with Special Health Care Needs in Washington State

www.cshcn.org

- List of statewide health and social service resources for children and families

American College of Obstetricians and Gynecologists (ACOG)

202-638-5577 or 1-800-673-8444

www.acog.org

- Patient and clinician educational materials on HIV testing and pregnancy

POCAAN (People of Color Against AIDS Network)

Seattle (Main Office)

206-322-7061

- Spanish resources and bilingual staff available

Lifelong AIDS Alliance

1002 East Seneca

Seattle, WA 98122

www.lifelongaidsalliance.org

206-328-8979 (main)

206-957-1717 (information and referral line)

TDD 206-323-2685

FAX 206-325-2689

- Seattle-based organization serving individuals with HIV/AIDS and other chronic conditions
 - Case management
 - Housing
 - Recovery support services
 - Insurance program
 - Food program
 - Prevention and education

US Department of Health and Human Services – Region X

Seattle Washington

Erick Seelbach, HIV/AIDS Regional Resource Consultant

Erick.Seelbach@HHS.gov

206-615-2475

Appendix B: Free Regional and National Telephone Consultation

Medcon (24 hours)

206-543-5300 or 1-800-326-5300

- University of Washington medical consultation
- For medical providers in Washington, Alaska, Montana, and Idaho, linking providers with medical school faculty

The Perinatal Hotline 888-448-8765

<http://nccc.ucsf.edu/clinician-consultation/perinatal-hiv-aids/>

- National Perinatal HIV Consultation and Referral Service.
This service provides 24-hour advice from HIV experts on indications and interpretations of HIV testing in pregnancy, and consultation on treating HIV-infected pregnant women and their infants.
- Perinatal Hotline answers callers' immediate questions, solves urgent perinatal HIV issues, and assists clinicians in linking HIV-infected pregnant women and HIV-exposed infants to the most appropriate care. Callers are referred to a national network of education, training, and consultation services available from regional AIDS Education and Training Centers (AETCs).
The Perinatal Hotline is available 24 hours, seven days a week.

Warmline

1-800-933-3413

www.nccc.ucsf.edu/clinician-consultation/hiv-aids-management

- Free National HIV telephone consultation service for health care providers
- The Warmline is staffed by physicians and clinical pharmacists and is available Monday through Friday, 6:00 a.m. to 5:00 p.m. Pacific Standard Time. Voice mail is available 24 hours a day.

Pepline

1-888-HIV-4911

<http://nccc.ucsf.edu/clinician-consultation/pep-post-exposure-prophylaxis/>

- National clinicians' post-exposure prophylaxis hotline. PEpline clinicians will respond to your call between 9 a.m. and 2 a.m. Eastern Standard Time.

CDC HIV/AIDS Hotline

24 hour hotline: 1-800-CDC-INFO (232-4636)

www.cdc.gov/hiv/

- Patient and clinician information

National AIDS Information Clearinghouse – CDC Information

1-800-458-5231

- CDC information on HIV/AIDS

National STD Hotline – American Sexual Health Association

1-800-227-8922 or 1-800-243-7889 TDD

www.ashastd.org/

- Information on sexual health and sexually transmitted diseases/infections



Appendix C: Websites

HIV/AIDS Treatment Information Service

www.aidsinfo.nih.gov

Central resource for federally-approved treatment guidelines for HIV and AIDS

- Link to Public Health Service Task Force Recommendations for use of Antiretroviral Drugs in Pregnant HIV-infected Women in Maternal Health and Interventions to Reduce Perinatal HIV Transmission in U.S, 2012.
https://aidsinfo.nih.gov/contentfiles/lvguidelines/Peri_Recommendations.pdf
- HIV and Pregnancy – Fact Sheets, 2012.
http://aidsinfo.nih.gov/contentfiles/Perinatal_FS_en.pdf

Northwest AIDS Education and Training Center

<http://depts.washington.edu/nwaetc/>

- What's new, courses and services, provider resources, associated centers

National AIDS Education and Training Centers – National Resource Center website

www.AIDSetc.org

- The AIDS Education and Training Centers conduct targeted, multidisciplinary education and training programs for health care providers treating persons living with HIV/AIDS. This website provides a central repository for AETC program and contact information and for training materials developed within the AETC network.

HRSA HIV/AIDS Program

www.hab.hrsa.gov

United States Department of Health and Human Services Health Resources and Services Administration

- National HIV/AIDS program information and resources

Washington State Department of Health HIV/AIDS Program

www.doh.wa.gov/YouandYourFamily/IllnessandDisease/HIVAIDS.aspx

- Washington State HIV/AIDS information and resources

Women and HIV

Francois-Xavier Bagnoud Center

- HIV Information for OBGYNs and Their Patients
<http://www.womenandhiv.org/francois-xavier>

- **HIV and Preconception Care Toolkit**

Francois-Xavier Bagnoud Center, in collaboration with the CDC's Expert Panel for Preconception and Reproductive Health of HIV-Infected Persons and the CDC's Elimination of Mother-to-Child Transmission (EMCT) Stakeholder Group on Family Planning and Preconception Care, developed the toolkit to assist primary care providers in addressing reproductive health issues with their HIV-positive patients, including preconception care, family planning, and safer conception for HIV sero-discordant couples. The toolkit includes training slides, recorded webinars, healthcare provider resources (including an algorithm on preconception counseling and care, and a provider's guide to preconception counseling) and educational materials for patients.

In addition to the toolkit, Women and HIV also offers online CMEs on Gynecologic Care for Women with HIV from the American College of Obstetricians and Gynecologists (ACOG), and resources on HIV screening, testing, and policy.

- **Are you HIV-positive and thinking about having a baby?**

http://fxbcenter.org/downloads/Client_brochure_HIV_Preconception_Care.pdf

- **Preconception counseling tool for clinicians**

http://fxbcenter.org/downloads/Counseling_Tool_HIV_Preconception_Care.pdf

Contraception Resources

- **CDC's United States Medical Eligibility Criteria (US MEC) for Contraceptive Use, 2010**

The *United States Medical Eligibility Criteria for Contraceptive Use* is intended to assist health care providers when counseling women, men, and couples about contraceptive method choice. The USMEC provides guidance on the safety of contraceptive method use for women with specific characteristics and medical conditions. This document is not intended to be a substitute for professional medical advice. Persons should seek advice from their health care providers when determining family planning options.

www.cdc.gov/reproductivehealth/UnintendedPregnancy/USMEC.htm

- **U.S. Selected Practice Recommendations (US SPR) for Contraceptive Use, 2013**

These recommendations for health care providers addresses a select group of common—yet sometimes complex—management issues around the initiation and use of specific contraceptive methods. The US SPR is a companion document to CDC's previously published contraceptive guidance document, *United States Medical Eligibility Criteria for Contraceptive Use, 2010* (US MEC).

www.cdc.gov/reproductivehealth/UnintendedPregnancy/USSPR.htm

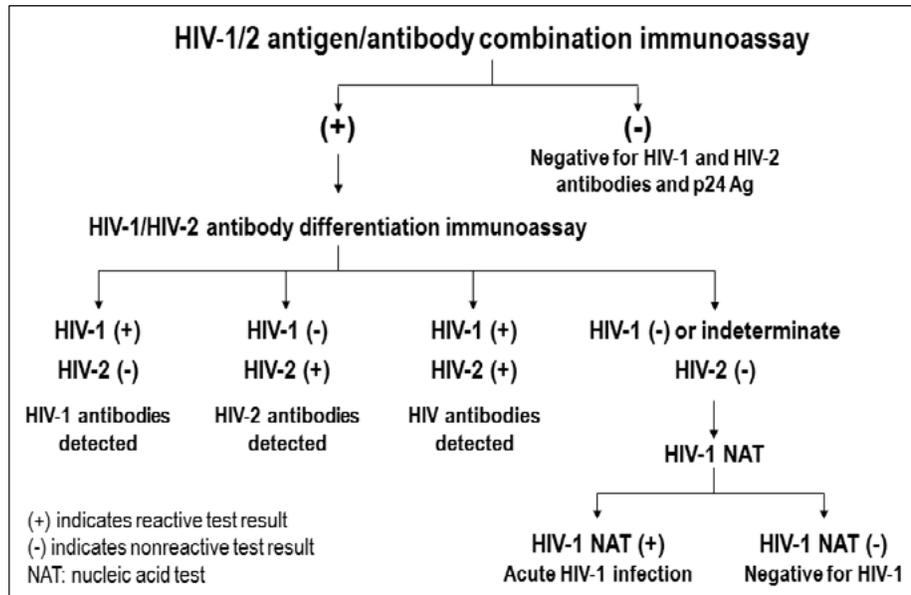
- **The World Health Organization. 2014. Hormonal Contraceptive Methods for Women at High Risk of HIV and Living with HIV 2014 Guidance Statement.**

www.who.int/reproductivehealth/publications/family_planning/HC_and_HIV_2014/en/



Appendix D: CDC Quick Reference Guide for Laboratory Testing for the Diagnosis of HIV Infection

Recommended Laboratory HIV Testing Algorithm for Serum or Plasma Specimens



- Laboratories should conduct initial testing for HIV with an FDA-approved antigen/antibody combination immunoassay* that detects HIV-1 and HIV-2 antibodies and HIV-1 p24 antigen to test for established HIV-1 or HIV-2 infection and for acute HIV-1 infection. No further testing is required for specimens that are nonreactive on the initial immunoassay.
- Specimens with a reactive antigen/antibody combination immunoassay result (or repeatedly reactive, if repeat testing is recommended by the manufacturer or required by regulatory authorities) should be tested with an FDA-approved antibody immunoassay that differentiates HIV-1 antibodies from HIV-2 antibodies. Reactive results on the initial antigen/antibody combination immunoassay and the HIV-1/HIV-2 antibody differentiation immunoassay should be interpreted as positive for HIV-1 antibodies, HIV-2 antibodies, or HIV antibodies, undifferentiated.
- Specimens that are reactive on the initial antigen/antibody combination immunoassay and nonreactive or indeterminate on the HIV-1/HIV-2 antibody differentiation immunoassay should be tested with an FDA-approved HIV-1 nucleic acid test (NAT).
 - A reactive HIV-1 NAT result and nonreactive HIV-1/HIV-2 antibody differentiation immunoassay result indicates laboratory evidence for acute HIV-1 infection.
 - A reactive HIV-1 NAT result and indeterminate HIV-1/HIV-2 antibody differentiation immunoassay result indicates the presence of HIV-1 infection confirmed by HIV-1 NAT.
 - A negative HIV-1 NAT result and nonreactive or indeterminate HIV-1/HIV-2 antibody differentiation immunoassay result indicates a false-positive result on the initial immunoassay.
- Laboratories should use this same testing algorithm, beginning with an antigen/antibody combination immunoassay, with serum or plasma specimens submitted for testing after a reactive (preliminary positive) result from any rapid HIV test.

* Exception: As of April 2014, data are insufficient to recommend use of the FDA-approved single-use rapid HIV-1/HIV-2 antigen/antibody combination immunoassay as the initial assay in the algorithm.

Reporting results from the HIV diagnostic testing algorithm to persons ordering HIV tests and public health authorities

Test performed	Test results	Final interpretation for provider report	Test results to be reported to public health authorities
1. HIV-1/2 Ag/Ab combination immunoassay	1. Nonreactive	Negative for HIV-1 antigen and HIV-1/HIV-2 antibodies. No laboratory evidence of HIV infection. If acute HIV infection is suspected, consider testing for HIV-1 RNA.	Reporting this test result is not required.
1. HIV-1/2 Ag/Ab combination immunoassay 2. HIV-1/HIV-2 antibody differentiation immunoassay	1. Reactive 2. HIV-1 reactive and HIV-2 nonreactive	Positive for HIV-1 antibodies. Laboratory evidence consistent with established HIV-1 infection is present.	Report test results 1 and 2.
1. HIV-1/2 Ag/Ab combo immunoassay 2. HIV-1/HIV-2 antibody differentiation immunoassay	1. Reactive 2. HIV-1 nonreactive and HIV-2 reactive	Positive for HIV-2 antibodies. Laboratory evidence of HIV-2 infection is present.	Report test results 1 and 2.
1. HIV-1/2 Ag/Ab combination immunoassay 2. HIV-1/HIV-2 antibody differentiation immunoassay 3. HIV-1 RNA assay	1. Reactive 2. Nonreactive or indeterminate 3. RNA not detected	HIV antibodies were not confirmed and HIV-1 RNA was not detected. No laboratory evidence of HIV-1 infection. Follow-up testing for HIV-2 should be performed if clinically indicated.	Reporting this test result is not required.
1. HIV-1/2 Ag/Ab combination immunoassay 2. HIV-1/HIV-2 antibody differentiation immunoassay 3. HIV-1 RNA assay	1. Reactive 2. Nonreactive 3. RNA detected	Positive for HIV-1. Laboratory evidence consistent with acute HIV-1 infection is present.	Report test results 1, 2, and 3.
1. HIV-1/2 Ag/Ab combination immunoassay 2. HIV-1/HIV-2 antibody differentiation immunoassay 3. HIV-1 RNA assay	1. Reactive 2. Indeterminate 3. RNA detected	Positive for HIV-1 antibodies. Laboratory evidence of HIV-1 infection confirmed by HIV-1 RNA.	Report test results 1, 2, and 3.
1. HIV-1/2 Ag/Ab combination immunoassay 2. HIV-1/HIV-2 antibody differentiation immunoassay	1. Reactive 2. HIV-1 and HIV-2 reactive	Positive for HIV antibodies. Laboratory evidence of HIV infection is present. HIV antibodies could not be differentiated as HIV-1 or HIV-2. Additional testing for HIV-1 RNA or HIV-2 RNA should be performed if clinically indicated.	Report test results 1 and 2.
1. HIV-1/2 Ag/Ab combination immunoassay 2. HIV-1/HIV-2 antibody differentiation immunoassay	1. Reactive 2. Nonreactive or indeterminate	HIV-1 antibodies were not confirmed and HIV-1 RNA testing was not performed. Testing of this specimen is incomplete. Follow-up testing for HIV antibodies and HIV-1 RNA is recommended as soon as possible.	Report test results 1 and 2.

Abbreviations: Ag/Ab, antigen/antibody; RNA, ribonucleic acid.

Adapted from *Interim Guidelines for Laboratories on the Use of a New Diagnostic Testing Algorithm for Human Immunodeficiency Virus (HIV) Infection*. New York State Department of Health (http://www.health.ny.gov/diseases/aids/providers/regulations/testing/docs/guidelines_diagnostic_testing.pdf).

Quick Reference Guide - Laboratory Testing for the Diagnosis of HIV Infection: Updated Recommendations

June 27, 2014

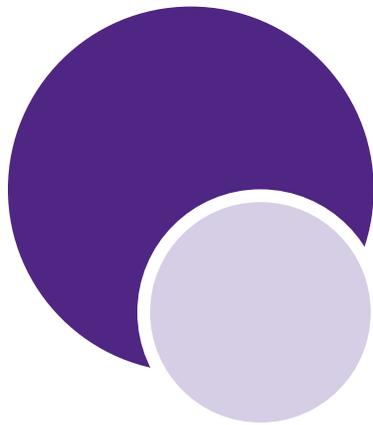
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