Reducing HIV/AIDS Infection in Babies

and

Improving the Health of Pregnant Women with HIV/AIDS

A Legislative Rx
Subject: Reducing HIV/AIDS Infection in Babies and Improving the Health of Pregnant Women with HIV/AIDS—States Urged to Update Testing Requirements for Pregnant Women

Dear State Legislators, State Health Lobbyists, Maternal/Child Health and HIV/AIDS Advocates, and Colleagues:

Most states operate under outdated HIV/AIDS testing laws and regulations, adopted more than a decade ago, that require specific informed consent (opt-in testing approach) and thus, pose a barrier to testing. This packet is designed to assist states in updating their HIV testing requirements for pregnant women to be consistent with current recommendations that no longer require specific informed consent. The Institute of Medicine (IOM), the Centers for Disease Control and Prevention (CDC), the American College of Obstetricians and Gynecologists (ACOG), and the American Academy of Pediatrics (AAP) recommend universal HIV testing with patient notification as a routine component of prenatal care. This means that all pregnant women are notified that they will be tested for HIV as part of the routine battery of prenatal blood tests unless they decline (opt-out testing approach). The use of patient notification provides women the opportunity to decline testing but eliminates the requirement to obtain specific informed consent. Data from medical record surveys show that requiring specific informed consent (opt-in testing approach) results in lower testing rates than does the recommended opt-out testing approach. Additionally, requiring state-prescribed counseling and instruction also has been shown to result in lower testing rates.

Approximately 40,000 new HIV infections still occur in the United States each year. Of these new infections, nearly 11,000 are women and approximately 200 are babies born to infected mothers. Although the infection rate for women has nearly doubled since 1992, the use of antiretroviral medications has significantly reduced the rate of mother to child transmission. It is clear that the best way to prevent spreading the infection to newborns is through early identification and treatment of all HIV-positive pregnant women. This regimen also can greatly improve the health of the mother. In light of the increased risk of infection to women and their unborn children and with the availability of effective treatment for HIV-positive women during pregnancy and for exposed infants, states should reexamine their HIV/AIDS testing requirements for pregnant women and make the necessary changes now.

Materials in this packet include:

- CDC and IOM Recommendations
- Data and Survey Reports
- Suggested Language
- ACOG/AAP Joint Recommendation
- ACOG Committee Opinion

Although many states have adopted elements of the recommended opt-out testing approach and others are moving to introduce opt-out testing legislation, some states continue to follow an opt-in testing approach. We believe that the information contained in this packet will assist state lawmakers and advocates in their understanding of the issues surrounding mother to child HIV transmission and the benefits of the opt-out testing approach. Additionally, we hope that this information will be an impetus for change in states that either do not have specific prenatal HIV/AIDS testing requirements or may not be aware of the need to update their existing laws/regulations to be consistent with current recommendations.

Sincerely,

Hal C. Lawrence, MD
Vice President, Practice Activities

Enclosures
The American College of Obstetricians and Gynecologists (ACOG)

Reducing HIV/AIDS Infection in Babies and
Improving the Health of Pregnant Women with HIV/AIDS

A Tool for State Lawmakers*

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Introduction:
States are urged to update their prenatal HIV testing requirements to reflect the new scientific/medical recommendations that no longer require specific informed consent. We hope that the materials contained in this packet will help you to understand the issues and to present an effective argument for this change.

ACOG staff is available to assist you with questions and concerns.

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ACOG materials may be viewed on the Perinatal HIV web page at http://www.acog.org/goto/HIV and may be ordered online at sales.acog.org or by calling 800-762-2264.
HIV Testing of Pregnant Women:  
Suggested Legislative Language

Explanation: In 1999, The Institute of Medicine (IOM) issued a recommendation on HIV testing of pregnant women that called for universal HIV testing, with patient notification, as a routine component of prenatal care. The woman would have the right to refuse (or opt-out of) the test. This approach does not require informed consent. In the same year, the American College of Obstetricians and Gynecologists (ACOG) issued a joint policy statement with the American Academy of Pediatrics (AAP) echoing this recommendation for an opt-out testing approach. ACOG restated that policy in 2004 in Committee Opinion #304 “Prenatal and Perinatal Human Immunodeficiency Virus Testing: Expanded Recommendations.” Since 1999, the Centers for Disease Control and Prevention (CDC) have released several recommendations on perinatal HIV prevention. CDC’s most recent (2003) guidance recommends implementation of the opt-out testing approach, in which “pregnant women are notified that an HIV test will be routinely included in the standard battery of prenatal tests for all pregnant women, but they can decline HIV testing.” In spite of these recommendations, prenatal HIV screening is not yet universal and there continue to be women arriving in labor with undocumented HIV status.

In 2004, ACOG and CDC issued recommendations for rapid HIV testing at labor and delivery. Although early diagnosis and treatment is the best way to prevent mother to child HIV transmission, rapid testing technology provides an opportunity to identify a woman’s HIV status during labor. This allows providers to begin antiretroviral treatment for women with newly diagnosed infection and for their infants within hours of birth.

ACOG urges state lawmakers to update laws and regulations to be consistent with the current scientific/medical recommendations for prenatal HIV testing that no longer require informed consent and for rapid HIV testing during labor for women with undocumented HIV status. When reviewing HIV testing laws/regulations for pregnant women in your state, please be aware that existing requirements may be in statutes, administrative codes, or health department guidelines. Additionally, requirements may be addressed in more than one section of your state’s statutes or regulations, such as requirements for HIV testing, informed consent, infectious diseases, or sexually transmitted diseases. Also, some states do not have specific regulations for prenatal HIV testing, and general HIV testing requirements apply to pregnant women.

On the following page you will find Suggested Legislative Language developed from and consistent with current ACOG and CDC recommendations for prenatal and perinatal HIV screening. We hope lawmakers will use this language to amend existing laws and regulations or to craft new legislation.
References


HIV Testing of Pregnant Women:  
Suggested Legislative Language*  
November 30, 2005

Prenatal HIV Screening

Physicians and other health care providers authorized by the state to provide prenatal medical care to pregnant women shall:

(a) notify each of their pregnant patients that they will be tested for HIV infection as part of the routine battery of prenatal blood tests. The test will be administered unless the patient declines the test. It should be documented in the medical record if the patient declines the test;

(b) offer an HIV test in the third trimester to pregnant women who were not tested earlier in pregnancy;

(c) offer a repeat HIV test in the third trimester, preferably before 36 weeks of gestation, to each of their pregnant patients at high risk for acquiring HIV. Criteria for repeat testing can include the following risk factors:
   - a history of a sexually transmitted disease
   - illicit drug use or the exchange of sex for money or drugs
   - multiple sex partners during pregnancy or sex partner(s) known to be HIV-positive or at high risk
   - signs or symptoms suggestive of acute HIV infection at any time during pregnancy;

(d) consider routinely offering a repeat HIV test in the third trimester to all pregnant women at health care facilities in areas with high rates of HIV prevalence among women of childbearing age (i.e., 5 per 1,000 or 0.5% or greater).

Labor and Delivery Screening

Physicians and other health care providers authorized by the state to provide labor or delivery services to pregnant women shall:

(a) offer a rapid HIV test in labor to pregnant women with unknown or undocumented HIV status;

(b) offer antiretroviral prophylaxis without waiting for the results of the confirmatory test if a rapid HIV test in labor is positive.

Disclaimer

This suggested legislative language is based on national guidance for prenatal and perinatal HIV testing from the American College of Obstetricians and Gynecologists (ACOG) and the Centers for Disease Control and Prevention (CDC) and is current as of this date (November 30, 2005). Although not anticipated, it is possible that national guidelines for testing pregnant women for HIV infection could change over time. Therefore, when writing new or amended laws/regulations you are advised to consult the ACOG (http://www.acog.org) and CDC (http://www.cdc.gov/hiv) web sites for any updates and/or revisions.
Does the Removal of Informed Consent Erode a Pregnant Woman's Rights?

**Explanation:** Over the last quarter century medical advances have transformed the AIDS epidemic and the social status of HIV-infected individuals in the United States. In a seminal article in 1991 entitled “Public Health Policy and the AIDS Epidemic. An End to Exceptionalism?” Bayer¹ noted that the era when HIV, by dint of its lethality and the social devastation that followed in its wake, had to be distinguished from all other illnesses was at an end. That article was published fourteen years ago. Since then life expectancy for infected individuals with access to therapy has improved remarkably, and the possibility of an end to the pediatric HIV epidemic in the United States has been heralded by the New York Times.² In this new era some have questioned whether the move away from distinguishing HIV from other illnesses has come at too high a cost and have argued that the recommended testing approach that no longer requires a pregnant woman to consent for the HIV test represents a slippery slope down which the rights of pregnant women will slide. A question and answer format will be used to respond to what are perceived to be some of the concerns of those who are hesitant to embrace the Institute of Medicine's (IOM's), the American College of Obstetricians and Gynecologists' (ACOG's), the American Academy of Pediatrics' (AAP's), and the Centers for Disease Control and Prevention's (CDC's) recommended approach to prenatal HIV testing.

**First of all, what is the recommended approach?**
ACOG, AAP and the CDC support the IOM recommendation for an opt-out testing approach to prenatal HIV screening in which *universal HIV testing with patient notification is a routine component of prenatal care*. A pregnant woman is notified that she will be tested for HIV as part of the routine battery of prenatal blood tests unless she declines. It is important to point out that this is not the equivalent of a mandatory testing policy. The use of patient notification provides women the opportunity to decline testing while eliminating the requirement to obtain specific informed consent for the test. With this opt-out testing approach women have an unrestricted right to refuse to be tested, and their autonomy remains inviolate.

**Why should prenatal HIV tests be more like other ob-gyn tests?**
Almost all physicians would consider the wide-spread use of Pap smear screening for women of reproductive age a major public health success. Imagine if prior to having a Pap test women were told that Pap smears screen for a disease caused by a sexually
transmitted organism and they also were told that they needed to sign a specific consent for the test. Some women might think that signing the consent form would be a "confession" of sexual risk. It is possible that Pap smear screening would become sporadic rather than common. If prenatal HIV testing is universal and routine and there is no requirement for a specific informed consent, pregnant women should feel as comfortable having this test that is potentially life saving for themselves and their children as they do when having a routine Pap test. Further, this opt-out testing approach maintains the balance between public and individual health on the one hand and a woman's autonomy on the other.

**Will women be driven from prenatal care?**
Some people have expressed concern that “mandatory” testing may drive women away from prenatal care. First, as noted above, universal routine testing with patient notification is not mandatory testing; the pregnant patient always retains the right to refuse the test (or opt-out). Further, even in those circumstances in which testing more closely approximating a mandatory approach has been implemented, patterns of care have not been altered. For example, several years ago New York State introduced mandatory newborn screening for HIV. This resulted in de facto mandatory testing of mothers since heel stick results reflect the mother’s infection status, not the baby’s. Mothers could have avoided finding out their results by not returning with their child for newborn visits. However, data collected at the time revealed no evidence of changes in health seeking behaviors. Thus, if mandatory newborn screening, which ACOG does not support, did not influence mothers' contacts with health providers, it seems unlikely that implementation of the opt-out testing approach would cause women to abandon their prenatal care providers.

**Might a woman’s identification as HIV-infected threaten her insurability?**
It is certainly a possibility that a woman’s identification as being infected with the HIV virus might threaten her insurability. However, this fact does not distinguish HIV from other chronic diseases. Unfortunately, whenever a physician performs a screening test, whether it is a urine analysis or a Pap smear, the possibility exists that the denouement of that evaluation will be a diagnosis (in the cited examples, diabetes or cervical cancer) that will make it difficult for someone without health insurance to obtain a new policy. All physicians should be cognizant of this fact and should try to advocate for a health care system that is responsive to the needs of all individuals with chronic diseases.

In sum, ACOG, AAP (and the CDC and the IOM) are well aware of the many past attempts to erode the rights of women infected with HIV, including refusals by clinicians to provide services ranging from dental to infertility, and would not encroach upon women’s autonomy for the sake of increasing testing rates. Additionally, they recognize that current approaches to testing may not further the interests of women and their children. Requiring informed consent for screening makes HIV unique among prenatal blood tests and perpetuates the attendant stigma. By simplifying the testing process while preserving the woman’s right to refuse the test, the opt-out testing approach will vouchsafe both the health of women and children and the medical profession’s recognition of the sanctity of patient autonomy.


JOINT STATEMENT OF ACOG/AAP ON HUMAN IMMUNODEFICIENCY VIRUS SCREENING

The problem of perinatal transmission of HIV infection was first appreciated in 1982. In 1991, the Institute of Medicine (IOM) recommended a policy of routine counseling and offering testing (with specific informed consent) for HIV infection to all pregnant women. Since 1991, there have been major advances in the treatment of HIV infection, including demonstration in 1994 of the efficacy of zidovudine to reduce perinatal transmission. The U.S. Public Health Service subsequently issued guidelines for use of zidovudine to reduce perinatal transmission and for counseling and voluntary testing for pregnant women. Dramatic declines in reported pediatric AIDS cases have been observed as a consequence of implementation of these guidelines. However, for a variety of reasons, screening pregnant women in the United States has been far from universal and infected babies continue to be born to undiagnosed infected women. Further reduction in the rate of perinatal HIV infection will require wider application of both screening to identify infected women, and treatments, which have demonstrated efficacy in reducing vertical transmission.

The IOM recently completed a study of interventions that would be helpful to further reduce the rate of perinatal HIV infection in the United States (Reducing the Odds). They have recommended that “the United States should adopt a national policy of universal HIV testing, with patient notification, as a routine component of prenatal care”. Early diagnosis of HIV infection in pregnant women allows them to institute effective antiretroviral therapy for their own health and to reduce the risk of HIV transmission to their infants. The use of “patient notification” provides women the opportunity to decline to be tested but eliminates the obligation to provide extensive pretest counseling, which has been a barrier to testing in many settings. Care providers would be charged with responsibility for the details of how the notification would take place. The IOM has recommended universal testing for two reasons. First, attempts to identify those “at risk” for infection inevitably fail to identify some infected individuals. Second, universal testing of all pregnant women avoids stereotyping and stigmatizing any social or ethnic group. The IOM recognizes in its report that many states now have laws requiring a formal, and in many cases written informed consent process prior to testing. They recommend that the Federal government adopt policies that will encourage these states to change their laws.

The AAP and the ACOG strongly support efforts to further reduce the rate of perinatal transmission of HIV in the United States. We therefore support the recommendation of the IOM for universal HIV testing with patient notification as a routine component of prenatal care. If a patient declines testing, this should be noted in the medical record. We recognize that current
laws in some states may prevent implementation of this recommendation at this time. We encourage our members and Fellows to include counseling as a routine part of care, but not as a prerequisite for, and barrier to, prenatal HIV testing.

Approved by the ACOG Executive Board, May 1999
Approved by the AAP Executive Board, May 1999
Reaffirmed by the AAP Executive Board, September 2005
Reaffirmed by the ACOG Executive Board, July 2006
Committee on Obstetric Practice

This document reflects emerging clinical and scientific advances as of the date issued and is subject to change. The information should not be construed as dictating an exclusive course of treatment or procedure to be followed.

The Centers for Disease Control and Prevention (CDC) estimates that 40,000 new cases of human immunodeficiency virus (HIV) infection still occur in the United States each year (1). This figure includes approximately 138 infants infected via mother-to-child (vertical) transmission (2). Antiretroviral medications given to women with HIV perinatally and to their newborns in the first weeks of life reduce the vertical transmission rate from 25% to 2% or less (3–6). Even instituting maternal prophylaxis during labor and delivery, or neonatal prophylaxis within 24–48 hours of delivery, or both can substantially decrease rates of infection in infants (4). A retrospective review of HIV-exposed infants in New York State showed a transmission rate of approximately 10% when zidovudine prophylaxis was begun intrapartum or if given to newborns within 48 hours of life. There is no significant reduction of neonatal transmission if therapy is started after 3 days of life (4). Early identification and treatment of pregnant women and prophylactic treatment of newborns in the first hours of life are essential to prevent neonatal disease.

Prenatal Human Immunodeficiency Virus Testing

The American College of Obstetricians and Gynecologists makes the following recommendations: obstetrician–gynecologists should follow opt-out prenatal HIV screening where legally possible; repeat conventional or rapid HIV testing in the third trimester is recommended for women in areas with high HIV prevalence, women known to be at high risk for acquiring HIV infection, and women who declined testing earlier in pregnancy; rapid HIV testing should be used in labor for women with undocumented HIV status following opt-out screening; and if a rapid HIV test result in labor is positive, immediate initiation of antiretroviral prophylaxis should be recommended without waiting for the results of the confirmatory test.

Committee on Obstetric Practice

This document reflects emerging clinical and scientific advances as of the date issued and is subject to change. The information should not be construed as dictating an exclusive course of treatment or procedure to be followed.

Prenatal Human Immunodeficiency Virus Testing: Expanded Recommendations

ABSTRACT: Early identification and treatment of all pregnant women with human immunodeficiency virus (HIV) is the best way to prevent neonatal disease and improve the woman’s health. Human immunodeficiency virus screening is recommended for all pregnant women after they are notified that they will be tested for HIV infection as part of the routine panel of prenatal blood tests unless they decline the test (ie, opt-out screening). Repeat testing in the third trimester, or rapid HIV testing at labor and delivery as indicated or both also are recommended as additional strategies to further reduce the rate of perinatal HIV transmission. The American College of Obstetricians and Gynecologists makes the following recommendations: obstetrician–gynecologists should follow opt-out prenatal HIV screening where legally possible; repeat conventional or rapid HIV testing in the third trimester is recommended for women in areas with high HIV prevalence, women known to be at high risk for acquiring HIV infection, and women who declined testing earlier in pregnancy; rapid HIV testing should be used in labor for women with undocumented HIV status following opt-out screening; and if a rapid HIV test result in labor is positive, immediate initiation of antiretroviral prophylaxis should be recommended without waiting for the results of the confirmatory test.
oral or written information about HIV (1, 7) that includes an explanation of HIV infection, a description of interventions that can reduce HIV transmission from mother to infant, the meanings of positive and negative test results, and the opportunity to ask questions and decline testing (1). If a patient declines HIV testing, this should be documented in the medical record and should not affect access to care. Women who decline an HIV test because they have had a previous negative test result should be informed of the importance of retesting during each pregnancy (1). The American College of Obstetricians and Gynecologists, the American Academy of Pediatrics (7), and the CDC (1, 8) recommend opt-out HIV screening for pregnant women. Since the release of CDC recommendations in September 2006 (1), some states have changed their state laws and regulations to opt-out screening. Obstetrician–gynecologists should be aware of and comply with their states’ legal requirements for perinatal HIV screening. Legal requirements for perinatal HIV testing may be verified by contacting state or local public health departments. The National HIV/AIDS Clinicians’ Consultation Center at the University of California–San Francisco maintains an online compendium of state HIV testing laws that can be a useful resource (see Resources). The Centers for Disease Control and Prevention recommend that jurisdictions with barriers to routine prenatal screening using opt-out screening consider addressing them (9).

**Perinatal Human Immunodeficiency Virus Testing**

The conventional HIV testing algorithm, which may take up to 2 weeks to complete if a result is positive, begins with a screening test, the enzyme-linked immunosorbent assay (ELISA) that detects antibodies to HIV; if the results are positive, it is followed by a confirmatory test, either a Western blot or an immunofluorescence assay (IFA). A positive ELISA test result is not diagnostic of HIV infection unless confirmed by the Western blot or IFA. The sensitivity and specificity of ELISA with a confirmatory Western blot test are greater than 99%. The false-positive rate for ELISA with a confirmatory Western blot test is 1 in 59,000 tests. If the ELISA test result is positive and the Western blot or IFA test result is negative, the patient is not infected and repeat testing is not indicated.

If the ELISA test result is repeatedly positive and the Western blot result contains some but not all of the viral bands required to make a definitive diagnosis, the test result is labeled indeterminate. Most patients with indeterminate test results are not infected with HIV. However, consultation with a health care provider well versed in HIV infection is recommended. This specialist may suggest viral load testing or repeat testing later in pregnancy to rule out the possibility of recent infection.

If the screening (eg, ELISA) and confirmatory test (eg, Western blot or IFA) results are both positive, the patient should be given her results in person. The implications of HIV infection and vertical transmission should be discussed with the patient. Additional laboratory evaluation, including CD4 count, HIV viral load, resistance testing, hepatitis C virus antibody, hepatitis B surface antigen, complete blood count with platelet count, and baseline chemistries with liver function tests, will be useful before prescribing antiretroviral prophylaxis.

A rapid HIV test is an HIV screening test with results available within hours. Obstetrician–gynecologists may use rapid testing as their standard outpatient test and should also use rapid testing in labor and delivery (see details as follows regarding labor and delivery). A negative rapid test result is definitive. A positive rapid test result is not definitive and must be confirmed with a supplemental test, such as a Western blot or IFA test. Rapid test results usually will be available during the same clinical visit that the specimen (eg, blood, or oral swab) is collected. Health care providers who use these tests must be prepared to provide counseling to pregnant women who receive positive rapid test results the same day that the specimen is collected. Pregnant women with positive rapid test results should be counseled regarding the meaning of these preliminary positive test results and the need for confirmatory testing. As with conventional HIV testing, consultation with a health care provider well versed in HIV infection is recommended. To code for rapid testing, the modifier 92 (92067-92070) is added to the basic HIV testing Current Procedural Terminology (CPT®) code 86701-86703 (10). If the results of the rapid test and the confirmatory test are discrepant, both tests should be repeated and consultation with an infectious disease specialist is recommended.

Any woman who arrives at a labor and delivery facility with undocumented HIV status should be screened with a rapid HIV test unless she declines (opt-out screening) in order to provide an opportunity to begin prophylaxis of previously undiagnosed infection before delivery (1). Data from several studies indicate that 40–85% of infants infected with HIV are born to women whose HIV infection is unknown to their obstetric provider before delivery (11–14). If a rapid test is used in labor and HIV antibodies are detected, immediate initiation of antiretroviral prophylaxis should be recommended without waiting for the results of the confirmatory test to further reduce possible transmission to the infant. All antiretroviral prophylaxis should be discontinued if the confirmatory test result is negative (11). Recommendations for the use of antiretroviral medications in pregnant women infected with HIV are available at www.aidsinfo.nih.gov and are updated frequently.

The rapid HIV antibody screening tests, which are approved by the U.S. Food and Drug Administration, all have sensitivity and specificity equal to or greater than

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As with all screening tests, the likelihood of a false-positive result is higher in populations with low HIV prevalence when compared with populations with high HIV prevalence. Additionally, at present it is not known how the false-positive rate for rapid testing will compare with the false-positive rate for conventional testing.

If the rapid HIV test result at labor and delivery is positive, the obstetric provider should take the following steps:

1. Tell the woman she may have HIV infection and that her neonate also may be exposed
2. Explain that the rapid test result is preliminary and that false-positive results are possible
3. Assure the woman that a second test is being done right away to confirm the positive rapid test result
4. Immediate initiation of antiretroviral prophylaxis should be recommended without waiting for the results of the confirmatory test to reduce the risk of transmission to the infant
5. Once the woman gives birth, discontinue maternal antiretroviral therapy pending receipt of confirmatory test results
6. Tell the woman that she should postpone breast-feeding until the confirmatory result is available because she should not breast-feed if she is infected with HIV
7. Inform pediatric care providers (depending on state requirements) of positive maternal test results so that they may institute the appropriate neonatal prophylaxis

**Recommendations**

Given the enormous advances in the prevention of perinatal transmission of HIV, it is clear that early identification and treatment of all pregnant women with HIV is the best way to prevent neonatal disease and also may improve the women’s health. Therefore, the American College of Obstetricians and Gynecologists makes the following recommendations:

- Screen all pregnant women for HIV as early as possible during each pregnancy following opt-out prenatal HIV screening where legally possible
- Repeat HIV testing in the third trimester is recommended for women in areas with high HIV prevalence, women known to be at high risk for acquiring HIV infection, and women who declined testing earlier in pregnancy
- Use conventional or rapid HIV testing for women who are candidates for third-trimester testing
- Use rapid HIV testing in labor for women with undocumented HIV status following opt-out screening
- If a rapid HIV test result in labor is positive, immediate initiation of antiretroviral prophylaxis should be recommended without waiting for the results of the confirmatory test

**Resources**

- AIDSinfo
  - PO Box 6303
  - Rockville, MD 20849-6303
  - 1-800-448-0440
  - www.aidsinfo.nih.gov
- The American College of Obstetricians and Gynecologists
  - 409 12th Street SW, PO Box 96920
  - Washington, DC 20090-6920
  - 800-673-8444 or (202) 638-5577
  - www.acog.org
- Perinatal HIV page: www.acog.org/goto/HIV
- ACOG Bookstore: www.acog.org/bookstore
- Centers for Disease Control and Prevention
  - 1600 Clifton Road NE
  - Atlanta, GA 30333
  - (404) 639-3311 or 800-232-4636
  - www.cdc.gov
- HIV/AIDS page: www.cdc.gov/hiv
- National AIDS Hotline: 800-342-AIDS (2437) (English); 800-344-7432 (Spanish); 800-243-7889 (TTY, deaf access)
- www.cdc.gov/hiv
- National HIV/AIDS Clinicians’ Consultation Center
  - UCSF Department of Family and Community Medicine at San Francisco General Hospital
  - 1001 Potrero Ave., Bldg. 20, Ward 22
  - San Francisco, CA 94110
  - (415) 206-8700
- Perinatal HIV Hotline: 1-888-448-8765
- www.nccc.ucsf.edu

**Repeat Human Immunodeficiency Virus Testing in the Third Trimester**

Repeat testing in the third trimester should be considered in jurisdictions with elevated HIV or AIDS incidence and in health care facilities in which prenatal screening identifies at least one HIV-infected pregnant woman per 1,000 women screened (1). Additionally, although physicians need to be aware of and follow their states’ perinatal HIV screening requirements, repeat testing in the third trimester, preferably before 36 weeks of gestation, is recommended for pregnant women at high risk for acquiring HIV. Criteria for repeat testing can include (1):

- Have been diagnosed with another sexually transmitted disease in the last year
- Injection drug use or the exchange of sex for money or drugs
- A new or more than one sex partner during this pregnancy or a sex partner(s) known to be HIV-positive or at high risk

Women who are candidates for third-trimester testing, including those who declined testing earlier in pregnancy, should be given a conventional or rapid HIV test rather than waiting to receive a rapid test at labor and delivery (as allowed by state laws and regulations).
References


tal disease. Pregnant women universally should be tested for HIV infection with patient notification as part of the routine battery of prenatal blood tests unless they decline the test (opt-out approach). The American College of Obstetricians and Gynecologists, the American Academy of Pediatrics, and the CDC recommend the opt-out approach (8, 9). There are encouraging results from the MIRIAD Study Group (16) and other evidence (3–6, 11) to suggest that antiretroviral prophylaxis started in labor and delivery and for the infant in the first hours of life also can substantially reduce vertical transmission of the HIV virus. Therefore, the Committee on Obstetric Practice makes the following recommendations:

- Follow an opt-out prenatal HIV testing approach where legally possible
- Repeat offer of HIV testing in the third trimester to women in areas with high HIV prevalence, women known to be at high risk for HIV infection, and women who declined testing earlier in pregnancy, as allowed by state laws and regulations
- Use conventional HIV testing for women who are candidates for third-trimester testing
- Use rapid HIV testing in labor for women with undocumented HIV status
- If a rapid HIV test result is positive, initiate antiretroviral prophylaxis (with consent) without waiting for the results of the confirmatory test

References


Resources

Publications


Organizations
American College of Obstetricians and Gynecologists (http://www.acog.org; http://sales.acog.org)

CDC Division of HIV/AIDS Prevention: (404) 639-0900
Centers for Disease Control and Prevention (http://www.cdc.gov/hiv)
National AIDS Hotline: 800-342-AIDS (2437) (English); 800-344-7432 (Spanish); 800-243-7889 (TTY)
National HIV Telephone Consultation Service (for physician consultation only): 800-933-3413
State public health departments
All pregnant women should be screened for human immunodeficiency virus (HIV) infection as early as possible during each pregnancy. Human immunodeficiency virus screening should occur after the patients are notified that it is recommended for all pregnant women and that they will receive the test as part of the routine panel of prenatal tests unless they decline (opt-out screening). Opt-out screening is recommended by the American College of Obstetricians and Gynecologists (ACOG), the American Academy of Pediatrics (AAP), and the Centers for Disease Control and Prevention (CDC). Obstetrician–gynecologists should be aware of and comply with their states’ legal requirements for perinatal HIV screening. Legal requirements for perinatal HIV testing may be verified by contacting state or local public health departments. The National HIV/AIDS Clinicians’ Consultation Center at the University of California–San Francisco maintains an online compendium of state HIV testing laws that can be a useful resource (www.nccc.ucsf.edu). If a patient declines HIV testing, it should be documented in the medical record and should not affect access to care.

When notifying pregnant patients about HIV testing in states using opt-out screening, obstetric providers may find it helpful to preface the conversation with the following suggested script:

“I test all my pregnant patients for HIV as part of the panel of routine tests to alert me to any conditions that require regular attention or treatment to promote the best possible outcome in pregnancy. This patient information, HIV and Other Important Pregnancy Tests, will explain the importance of each test. When you have finished reading this information, I would be glad to answer any questions you have. You will be tested for HIV today unless you tell me not to.”
To assist obstetric providers with prenatal HIV screening, ACOG offers a Patient Education Pamphlet entitled HIV and Pregnancy and the enclosed HIV and Other Important Pregnancy Tests, a convenient-to-use tear pad describing in simple language the recommended blood tests for all pregnant women. This tear pad also answers frequently asked questions about HIV testing, treatment, and risks to exposed babies. Obstetric providers may use the tear pad to notify pregnant women about HIV testing, but used alone the information in the tear pad may not meet informed consent requirements in individual states.

**More Resources**
American College of Obstetricians and Gynecologists
409 12th Street SW, PO Box 96920
Washington, DC 20090-6920
800-673-8444 or 202-638-5577
Perinatal HIV page: www.acog.org/goto/HIV

National HIV/AIDS Clinicians’ Consultation Center
UCSF Department of Family and Community Medicine at San Francisco General Hospital
1001 Potrero Ave., Bldg. 20, Ward 22
San Francisco, CA 94110
415-206-8700
Perinatal HIV Hotline: 1-888-448-8765
www.nccc.ucsf.edu

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What blood tests are recommended for all pregnant women?
As part of good prenatal care, doctors recommend certain routine blood tests to detect infections and other conditions in pregnancy. If a problem is found, treatment can reduce the risk of harm to pregnant women and their babies.

Routine blood testing for pregnant women should include:

- **Complete blood count.** This test examines the number and size of red and white blood cells and can detect conditions like anemia, infection, or clotting problems.
- **Hepatitis B test.** Hepatitis B is a viral infection of the liver. If the mother has this infection, there is a chance that without treatment the baby will be infected. The baby can be treated at birth to prevent infection in almost all cases.
- **Rubella (German measles) test.** A German measles infection during pregnancy can lead to severe birth defects. If a woman is not immune, a vaccine can be given to her after the baby is born to prevent infection in future pregnancies.
- **Blood type (A, B, AB, O) and Rh factor (Rh negative or Rh positive) test.** A pregnant woman who is Rh negative may need to receive a blood product called anti-D immune globulin. This product prevents the development of antibodies in the mother’s body that can break down the baby’s red blood cells. This latter condition, called hemolytic disease, can lead to severe problems in the newborn if not treated.
- **Syphilis test.** Syphilis is a sexually transmitted disease. If it is found in pregnancy, complications can be treated. A syphilis test often is required by public health agencies.
- **HIV test.** HIV is the virus that causes AIDS. It is possible to have HIV for years and not know it or not feel sick. Many women who have been found to have HIV did not know they were at risk. To get early help for herself and to reduce the risk of infecting her baby, a pregnant woman needs to know for sure. If she has HIV, even without symptoms, there is a 1 in 4 chance she could pass it to her baby. This risk can be greatly reduced with treatment.

What if I have HIV and I am pregnant?
You can pass HIV to your baby during pregnancy, at delivery, or during breastfeeding. Appropriate medical care during pregnancy and delivery, which includes taking special medication, can greatly improve your health as well as protect the health of your baby. Your doctor will recommend that you take special medication for HIV while you are pregnant and, in some cases, may recommend that you undergo a cesarean delivery. This medication allows almost 99% of infected women to have uninfected babies. However, without treatment, 1 in 4 babies will become infected.

If I have HIV, what happens after my baby is born?
- Right after birth and for the next 6 weeks, your baby will be given special medication to further reduce his or her chance of becoming infected with HIV. Also, your baby will be tested for HIV.
- Your baby could get HIV from breast milk. Women who are HIV positive should not breast-feed.

What if I decide not to have the HIV test?
- You will be given the same prenatal care as other women. However, if you have HIV and don’t know it, your doctor won’t know to give you special medication for HIV to protect you and your baby.
- You may be asked to have a rapid HIV test when you are in labor if you are not tested now.
- Some states require testing of your baby if you are not tested before he or she is born.
If I have the HIV test, who will know the results?
If you have HIV, your baby’s doctor also may be notified so that the baby's treatment can begin immediately after birth. States have different requirements about reporting new HIV cases. If you are concerned about this, ask your doctor about your state’s policy and where you can get more information.

When do I get tested for HIV?
You should be tested for HIV at the same time you are given other pregnancy blood tests, which usually are obtained at your first prenatal visit.

What happens when I am tested for HIV?
A small amount of blood is taken from your arm (at the same time blood is taken for the other routine tests in pregnancy). Your doctor will have the final test result in about 2 weeks. Sometimes your doctor may use a rapid HIV test. If the rapid test result is negative, you will know the same day and will not have to have further testing. If the rapid test is positive, your doctor will talk to you about the meaning of this preliminary result, the need for confirmatory testing, and possible treatment options. If any final results are positive, your doctor will talk to you about treatment options. More detailed information can be found in the Patient Education Pamphlet, HIV and Pregnancy, by the American College of Obstetricians and Gynecologists, and similar resources.

What if the HIV test result is negative?
In most cases, it takes about 4–8 weeks after you are infected with HIV for signs of it to show up in your blood. If the HIV test result is negative, it usually means you are not infected with HIV. In rare cases, you may be infected but the infection has not yet shown up in your blood.

If you have unprotected sex or share needles with someone who has HIV (and may not know it), you could get HIV at any time, even during pregnancy. Using condoms every time you have sex helps to protect against HIV. Also, do not share needles. If you continue these high-risk behaviors, you should be retested later in pregnancy. In some instances your doctor may recommend a second HIV test later in pregnancy even if you do not have high-risk behaviors.

Facts About HIV Infection
In summary, the most important facts for you to know are:
• HIV can be passed from a mother to her baby during pregnancy, at delivery, or during breast-feeding.
• Knowing you have HIV infection means you can get the special care you need during pregnancy and delivery. This care includes taking special medication for HIV and, sometimes, undergoing a cesarean delivery. With treatment, almost 99% of infected women have uninfected babies.
• However, without treatment, 1 in 4 babies will become infected.
• Taking medication for HIV can greatly improve your own health.
• HIV can be spread from an infected person by having sex without a condom or by sharing needles.

To Learn More
Your doctor can provide more information on HIV or refer you to other sources for education and counseling. Also, you may contact these sources for free, private information:

American College of Obstetricians and Gynecologists
409 12th Street SW, PO Box 96920
Washington, DC 20090-6920
800-673-8444 or 202-638-5577
Perinatal HIV page: www.acog.org/goto/HIV

Centers for Disease Control and Prevention
1600 Clifton Road NE
Atlanta, GA 30333
National AIDS Hotline: 1-800-342-AIDS (2437)
Spanish Hotline: 1-800-344-SIDA (7432)
TTY: 1-800-243-7889
www.cdc.gov/hiv

Your state health department
www.fda.gov/oca/sthealth.htm

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¿Cuáles pruebas de sangre se recomiendan a todas las mujeres embarazadas?

Como parte de una atención prenatal adecuada, los médicos recomiendan ciertas pruebas de sangre de rutina para detectar infecciones y otros problemas durante el embarazo. Si se detecta un problema, el tratamiento puede reducir el riesgo del daño a la mujer embarazada y su bebé.

Las pruebas de sangre de rutina para las mujeres embarazadas deben consistir en:

- **Recuento sanguíneo (hemograma) completo.** Este examen analiza la cantidad y el tamaño de los glóbulos rojos y blancos y puede detectar enfermedades como la anemia, infecciones o problemas de la coagulación.

- **Prueba de la hepatitis B.** La hepatitis B es un virus que infecta el hígado. Si la madre está infectada, es probable que su bebé se infecte. El bebé puede recibir tratamiento al nacer para prevenir la infección en casi todos los casos.

- **Prueba de la rubéola (sarampión alemán).** La infección de sarampión alemán durante el embarazo puede causar defectos congénitos graves. Si la mujer no es inmune, se le puede administrar una vacuna después de que nazca el bebé para prevenir esta infección en embarazos futuros.

- **Prueba del tipo sanguíneo (A, B, AB, O) y del factor Rh (Rh negativo o Rh positivo).** Las mujeres embarazadas que son Rh negativas necesitarán recibir un producto sanguíneo que se denomina inmunoglobulina anti-D. Este producto previene la formación de anticuerpos en el cuerpo de la madre que pueden destruir los glóbulos rojos del bebé. Este padecimiento, que se llama enfermedad hemolítica, puede producir problemas graves en el recién nacido si no se recibe tratamiento.

- **Prueba de sífilis.** La sífilis es una enfermedad de transmisión sexual. Si se detecta durante el embarazo, es posible tratar las complicaciones que produce. Las agencias de salud pública a menudo exigen realizar una prueba de sífilis.

- **Prueba del VIH.** El VIH es el virus que causa el SIDA. Es posible tener VIH durante varios años y no saberlo ni sentirse enferma. Muchas mujeres a quienes se les ha detectado VIH no sabían que estaban en peligro de presentar esta enfermedad. Para que la mujer pueda recibir ayuda desde un principio y reducir el riesgo de infectar al bebé, las mujeres embarazadas deben saberlo con certeza. Si tiene VIH, aún si no presenta síntomas, la mujer tiene un 25% de probabilidad de transmitir la enfermedad a su bebé. Este riesgo se puede reducir en gran medida con tratamiento.

¿Qué sucede si tengo VIH y estoy embarazada?

Puede transmitir el VIH a su bebé durante el embarazo, el parto o al amamantar. Cuando se proporciona atención médica adecuada durante el embarazo y el parto, que incorpora el uso de ciertos medicamentos, es posible mejorar en gran medida su salud y proteger la salud de su bebé. Su médico le recomendará que tome medicamentos especiales para el VIH mientras está embarazada y, en algunos casos, podría recomendar que el parto se realice por cesárea. Estos medicamentos permiten que casi un 99% de las mujeres infectadas tengan bebés sin presentar la infección. Sin embargo, sin tratamiento, 1 de cada 4 bebés contraerá la infección.

Si tengo VIH, ¿qué sucederá después de que nazca mi bebé?

- Inmediatamente después del parto y durante las próximas 6 semanas, su bebé recibirá medicamentos especiales para reducir aún más su probabilidad de infectarse con el VIH. Además, se le hará una prueba de VIH al bebé.
- Su bebé puede contraer el VIH por medio de la leche materna. Las mujeres cuyos resultados en las pruebas del VIH son positivos no deben amamantar.

¿Qué sucede si decidí no hacerme la prueba del VIH?

- Recibirá la misma atención prenatal que las demás mujeres. Sin embargo, si tiene VIH y no lo sabe, su médico no sabrá que debe darle los medicamentos especiales para el VIH destinados a protegerlos a usted y su bebé.
- Los podrían pedir que se haga una prueba rápida del VIH cuando esté de parto si no se la ha hecho hasta ese momento.
- Algunos estados requieren una prueba del VIH para el bebé si usted no se hace la prueba antes del nacimiento del bebé.
Si me hago la prueba del VIH, ¿quién sabrá los resultados?
Si tiene VIH, se le notificará el resultado al médico de su bebé también para que se pueda comenzar el tratamiento del bebé inmediatamente después del parto. Los estados han establecido distintos requisitos con respecto a notificar nuevos casos de VIH. Si le preocupa esto, pregúntele a su médico cuál es la norma de su estado y dónde puede obtener más información.

¿Cuándo me harán la prueba del VIH?
La prueba del VIH se debe hacer a la misma vez que reciba las demás pruebas de sangre durante el embarazo, que por lo general se realizan durante la primera visita prenatal.

¿Qué sucede durante la prueba del VIH?
Se toma una pequeña cantidad de sangre del brazo (a la misma vez que se extrae sangre para las demás pruebas de rutina durante el embarazo). Su médico recibirá los resultados finales de la prueba al cabo de 2 semanas más o menos. A veces, los médicos usan una prueba rápida del VIH. Si el resultado de dicha prueba es negativo, usted lo sabrá ese mismo día y no tendrá que someterse a ninguna otra prueba. Si el resultado de la prueba rápida es positivo, su médico le explicará el resultado de esta prueba preliminar, la importancia de hacer una prueba definitiva y las posibles opciones de tratamiento. Si el resultado final es positivo, su médico le explicará sus opciones de tratamiento. Puede obtener información más detallada en el folleto de educación para los pacientes titulado El VIH y el embarazo (HIV and Pregnancy), del Colegio Americano de Obstetras y Ginecólogos (American College of Obstetricians and Gynecologists), y de otras fuentes informativas similares.

¿Qué sucede si el resultado de la prueba del VIH es negativo?
En la mayoría de los casos, los indicios de la enfermedad se detectan en la sangre al cabo de aproximadamente 4 a 8 semanas después de contraer la infección del VIH. Si la prueba del VIH es negativa, generalmente quiere decir que no está infectada con este virus. En casos raros, es posible estar infectada con la enfermedad aunque la infección no aparezca aún en la sangre.

Si tiene relaciones sexuales sin protección o comparte agujas con una persona con VIH (y no lo sabe) puede contraer VIH en cualquier momento, incluso durante el embarazo. El uso de condones cada vez que tenga relaciones sexuales ayuda a protegerla contra el VIH. Además, no comparta agujas. Si sigue teniendo estos comportamientos de alto riesgo, debe volver a tener otra prueba más adelante en el embarazo. En algunos casos, su médico podría recomendar una segunda prueba del VIH más adelante en el embarazo incluso si no muestra una conducta de alto riesgo.

Datos sobre la infección del VIH
En resumen, los datos más importantes que debe saber son:

- Una madre puede transmitir el VIH a su bebé durante el embarazo, el parto o al amamantarla.
- Es importante saber si tiene la infección del VIH para que pueda recibir los cuidados especiales necesarios durante el embarazo y el parto. Estos cuidados consisten en tomar medicamentos especiales para el VIH y, a veces, tener un parto por cesárea. Con tratamiento, casi un 99% de las mujeres infectadas tienen bebés sin la infección. Sin embargo, sin tratamiento, 1 de cada 4 bebés contraerá la infección.
- Tomar los medicamentos para el VIH puede mejorar en gran medida su propia salud.
- Una persona infectada puede transmitir el VIH al tener relaciones sexuales sin el uso de un condón o al compartir agujas.

Si desea obtener más información
Su médico puede proveerle más información sobre el VIH o remitirla a otros recursos educativos y asesoramiento. Puede además comunicarse con estas fuentes informativas para recibir información gratis y confidencial:

American College of Obstetricians and Gynecologists
409 12th Street SW, PO Box 96920
Washington, DC 20090-6920
800-673-8444 o 202-638-5577
Página perinatal sobre el VIH: www.acog.org/goto/HIV

Centers for Disease Control and Prevention
1600 Clifton Road NE
Atlanta, GA 30333
Línea directa de ayuda para el SIDA: 1-800-342-AIDS (2437)
Línea directa de ayuda en español: 1-800-344-SIDA (7432)
TTY: 1-800-243-7889
www.cdc.gov/hiv

El departamento de salud de su estado
www.fda.gov/oca/sthealth.htm

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**ACOG's Perinatal HIV Survey**

**CDC HIV Prevention Grant**

**September 30, 2002 - September 29, 2007**

**Introduction**

Achieving the CDC’s goal of "maximally reducing" the rate of mother-to-child HIV transmission will require that barriers to universal testing of pregnant women with notification be identified and eliminated. In ACOG's previous CDC perinatal HIV prevention grant (1999–2001), ACOG used pre- and post-distribution surveys to determine that professional and patient educational tools (distributed with grant funding) are associated with a reduction in testing barriers (insufficient time decreased from 71.8% to 14.3% and burdensome consent process decreased from 69.2% to 33.3% pre- and post-distribution, respectively) and improved prenatal HIV testing rates (increased from 91.6% to 92.6% pre- and post-distribution, respectively). To aid in the development and revision of tools to further reduce barriers, grant staff developed and distributed (in July 2003 and March 2006) a questionnaire to survey the current perinatal HIV testing practices of 1,000 randomly selected, actively practicing ACOG Fellows representing all 50 states and all ACOG districts. The new survey instrument was a revised and expanded version of the 2000 questionnaire and included: 1) questions regarding the reasons pregnant women give when declining HIV testing and the steps taken by providers to re-encourage testing; 2) a list of potential barriers to repeat testing; and 3) questions concerning the use of rapid HIV testing at labor and delivery for women with unknown HIV status.

**Design**

The 2006 survey yielded 414 responses (41.4%). This was comparable to the response rate of the 2003 survey (45.1%). Current survey responses were compared with results from the 2003 survey and were analyzed to identify statistically significant changes. The correlation between respondents’ practice patterns and whether they reported practicing in a high or low HIV seroprevalence area also was examined.

Based on CDC statistics, high seroprevalence cities (9.3% of respondents in 2006, 8.4% in 2003) included Atlanta, Chicago, District of Columbia, Houston, Los Angeles, Miami, New York, Philadelphia, and San Francisco. All other cities were defined as low seroprevalence areas (90.7% of respondents in 2006, 91.6% in 2003).

Similar to the previous surveys, approximately two-thirds of respondents reported practicing in suburban and urban non-inner city areas. Approximately 9% work in the urban cities with the highest HIV seroprevalence rates in...
Despite an increase in the percentage of total female ACOG Fellows from 28% in 2000 to 35% in 2003 and 47% in 2007, the male and female response rates have remained fairly stable across the different phases of the survey. In 2006, 59.2% of respondents were male and 40.8% were female. In addition, this sample indicated a continued decrease in the percentage of Fellows who completed their residency within the past 10 years from 43.3% in 2000 to 35.8% in 2003 and to 23.5% in 2006. A corresponding increase from 54.4% to 64.3% to 76.5% in those who completed their residency more than 10 years ago also was observed.

**Evaluation and Results**

In 2006, survey respondents indicated that 67.8% of their patients are covered by private insurance, 24.0% use Medicare or Medicaid, 6.7% are uninsured, and 1.5% have unspecified coverage. This corresponded closely with the 2003 distribution.

The most common practice type reported was an obstetrician-gynecologist partnership or group at 43.7% (48.3% in 2003). Over a quarter (28.1% in 2006, 22.4% in 2003) of respondents were in a solo practice. Multi-specialty partnerships accounted for 9.3% of responses (10.8% in 2003). Another 9.8% of respondents (10.8% in 2003) reported employment in full-time university faculty positions.

After excluding those who do not practice obstetrics and adjusting for missing responses, 17.1% of the sample reported practicing obstetrics up to 25% of the time. Nearly one-half of respondents (38.8% in 2006, 48.4% in 2003) reported that obstetric patients make up 26-50% of their patient load. Approximately one-quarter (22.3% in 2006, 24.6% in 2003) see obstetric patients 51-75% of the time; and the remaining 5.8% (8.6% in 2003) manage obstetric patients between 75% and 100% of the time. The distribution of practice type and percentage of obstetric patients may prove useful in future analyses to assess prenatal HIV testing needs. Respondents who reported spending less than 1% of their time managing obstetric patients were excluded from the following analyses.

When questioned about pre-test counseling practices, the majority (66.5%) of respondents indicated that the obstetrician discussed HIV screening with the pregnant woman, an increase from 61.9% in 2003. In addition, nearly 62% of respondents reported discussion with patients by the office nurse. This also was an increase from 57% in 2003. Additionally, the patient was given written information 45.3% of the time, compared to 43.8% in 2003. These data suggest overlap and reinforcement of the information in some instances. They also represent a continued rise in all three methods of information dissemination from the initial pre-distribution survey distributed in 2000. The use of "other" methods to provide HIV testing information increased from 2.4% in 2003 to 5.6% in 2006.

A key result of the 2006 survey is that 98.1% of sampled ACOG Fellows recommend HIV testing with consent to all pregnant patients. This is a continued increase over earlier survey results that indicated 91.6% (2000 pre-distribution), 92.6% (2000 post-distribution), and 96.7% (2003 survey) of Fellows who do not practice obstetrics and adjusting for missing responses, 17.1% of the sample reported practicing obstetrics up to 25% of the time. Nearly one-half of respondents (38.8% in 2006, 48.4% in 2003) reported that obstetric patients make up 26-50% of their patient load. Approximately one-quarter (22.3% in 2006, 24.6% in 2003) see obstetric patients 51-75% of the time; and the remaining 5.8% (8.6% in 2003) manage obstetric patients between 75% and 100% of the time. The distribution of practice type and percentage of obstetric patients may prove useful in future analyses to assess prenatal HIV testing needs. Respondents who reported spending less than 1% of their time managing obstetric patients were excluded from the following analyses.

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recommended testing to all pregnant patients. These percentages suggest that the perinatal HIV prevention efforts undertaken by CDC, ACOG, AAP, and other national organizations may have provided increased awareness of the importance of universal HIV testing for pregnant women. Similar to both the 2000 and 2003 surveys, 70.9% of respondents indicated that only 0-5% of their pregnant patients are at high risk for HIV infection. The number of respondents reporting that they consider 21% or more of their patients to be at high risk for HIV infection has increased slightly, from 5.7% in 2003 to 6.3% in 2006. The low percentage of patients believed to be at high risk and the high percentage of respondents recommending HIV testing imply that this sample views prenatal HIV screening as a routine practice that is not dependent on HIV risk. Additionally, the high rate of test recommendation in combination with the high percentage of privately insured patients seen by the sample group (reported above) seems to dispel the commonly held perception that obstetricians frequently do not offer HIV testing to pregnant women with private insurance.

Sometimes pregnant women decline HIV testing. In 2006, approximately 98% of respondents reported taking one or more steps in response to a patient refusal: 84.2% (84.1% in 2003) document a refusal in the patient's medical record, 63.7% (57% in 2003) inquire as to the patient’s reason, 57.8% (50% in 2003) repeat the recommendation for screening, 40.7% (34% in 2003) re-offer testing later in pregnancy, and 41.0% (34% in 2003) have the patient sign a refusal form. The most commonly indicated reasons for patient refusal of testing (including "very common" and "somewhat common") were no perceived benefit of treatment (72.4% in 2006, 91% in 2003), and confidentiality concerns (73.3% in 2006, 87% in 2003). Less common were the pregnant woman perceiving herself as low-risk (19.2% in 2006, 21% in 2003) and other non-specified reasons (6.6% in 2006, 11% in 2003). Of those who re-offer testing later in pregnancy to patients who previously declined, 73.9% (72.7% in 2003) reported re-offering testing to all pregnant women, compared to 19.4% (23.1% in 2003) who only re-offer testing to high-risk pregnant patients.

As previously stated, most Fellows surveyed (98.1%) indicated that they recommend HIV testing to all pregnant women; however, 12.7% reported a variety of testing barriers that influenced their decision to recommend HIV testing to all pregnant patients. Of this 12.7%, in 2006, the barriers reported to significantly or moderately influence Fellows were a perceived low-risk population (48.8%); insufficient time or personnel (31.7%); and concerns about managing a woman who refuses testing (24.4%). Additionally, some Fellows (24.4%) indicated that a lack of appropriate patient education materials for routine prenatal HIV testing significantly or moderately influenced their testing decision. Other respondents noted that they are significantly or moderately influenced against recommending HIV testing to all women because it is not current ACOG policy (22.0%) or because state pre-test counseling/consent guidelines are too burdensome (19.5%). The proportion of Fellows reporting that a particular barrier significantly or moderately influenced their testing decision decreased for all barrier categories from
2003 to 2006 (See Table 1).

Obstetrician-gynecologists are likely to encounter women at labor and delivery whose HIV status is either unknown or has not been documented. In 2003, 36.5% of respondents reported recommending rapid testing at labor and delivery for these women. In 2006, the percentage of respondents reporting that they recommend rapid testing at labor and delivery was 45.2%, a statistically significant increase (p<.0001). As in 2003, 2006 survey respondents who practice in a high seroprevalence city were significantly more likely to recommend rapid testing (82.8%) than respondents practicing in low seroprevalence cities (41.3%; p<.0001). This may be explained, in part, by the finding that respondents practicing in low seroprevalence cities were more likely to report that rapid testing was not available at their hospital (37.4%) than those respondents practicing in high seroprevalence cities (10.3%; p<.0001). However, it is important to note that the total number of respondents practicing in high prevalence cities was low (n=29).

Conclusions
While the 2006 ACOG survey indicates an increase in prenatal HIV screening since 2000, there still are obstacles that hinder testing every pregnant woman (i.e., low-risk population, insufficient time or personnel, concerns about managing women who refuse testing, and lack of appropriate educational materials).

Although 98% of obstetrician-gynecologists take one or more steps in response to a patient's refusal of HIV testing, survey response indicated that less than half (40.7%) re-offer testing later in pregnancy to patients who previously refused. However, of those respondents who do re-offer HIV testing later in pregnancy for patients who declined earlier, 73.9% re-offer testing to all pregnant patients, and just 19.4% re-offer only to high-risk pregnant patients. The fact that 45.2% of obstetrician-gynecologists offer rapid testing at labor and delivery for women with unknown or undocumented HIV status is surprisingly high given that utilization of rapid test technology currently is not standard of care. Further research is needed to evaluate means to 1) reduce remaining barriers to universal testing, 2) devise more effective means to encourage testing for women who initially refuse, and 3) increase the rate of rapid testing at labor and delivery if this becomes standard of care.
### Table 1: Barriers that influence decision to recommend HIV testing to all pregnant women (2003 n=38, 2006 n=41)*

<table>
<thead>
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<th>Barrier</th>
<th>Percent indicating barrier “significantly” or “moderately” influences decision 2003</th>
<th>n</th>
<th>Percent indicating barrier “significantly” or “moderately” influences decision 2006</th>
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<td>Insufficient time or personnel</td>
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<td>Language barrier</td>
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<td>Late entry into prenatal care</td>
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<td>17.1</td>
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<td>Reimbursement issues</td>
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*Percentage calculated from number of respondents who indicated any barriers prevented them from recommending prenatal HIV screening to all pregnant patients (10.3% of total sample in 2003 and 12.7% in 2006)
Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings
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Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings

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Summary

These recommendations for human immunodeficiency virus (HIV) testing are intended for all health-care providers in the public and private sectors, including those working in hospital emergency departments, urgent care clinics, inpatient services, substance abuse treatment clinics, public health clinics, community clinics, correctional health-care facilities, and primary care settings. The recommendations address HIV testing in health-care settings only. They do not modify existing guidelines concerning HIV counseling, testing, and referral for persons at high risk for HIV who seek or receive HIV testing in nonclinical settings (e.g., community-based organizations, outreach settings, or mobile vans). The objectives of these recommendations are to increase HIV screening of patients, including pregnant women, in health-care settings; foster earlier detection of HIV infection; identify and counsel persons with unrecognized HIV infection and link them to clinical and prevention services; and further reduce perinatal transmission of HIV in the United States. These revised recommendations update previous recommendations for HIV testing in health-care settings and for screening of pregnant women (CDC. Recommendations for HIV testing services for inpatients and outpatients in acute-care hospital settings. MMWR 1993;42[No. RR-2]:1–10; CDC. Revised guidelines for HIV counseling, testing, and referral. MMWR 2001;50[No. RR-19]:1–62; and CDC. Revised recommendations for HIV screening of pregnant women. MMWR 2001;50[No. RR-19]:63–85).

Major revisions from previously published guidelines are as follows:

For patients in all health-care settings

- HIV screening is recommended for patients in all health-care settings after the patient is notified that testing will be performed unless the patient declines (opt-out screening).
- Persons at high risk for HIV infection should be screened for HIV at least annually.
- Separate written consent for HIV testing should not be required; general consent for medical care should be considered sufficient to encompass consent for HIV testing.
- Prevention counseling should not be required with HIV diagnostic testing or as part of HIV screening programs in health-care settings.

For pregnant women

- HIV screening should be included in the routine panel of prenatal screening tests for all pregnant women.
- HIV screening is recommended after the patient is notified that testing will be performed unless the patient declines (opt-out screening).
- Separate written consent for HIV testing should not be required; general consent for medical care should be considered sufficient to encompass consent for HIV testing.
- Repeat screening in the third trimester is recommended in certain jurisdictions with elevated rates of HIV infection among pregnant women.
Introduction

Human immunodeficiency virus (HIV) infection and acquired immunodeficiency syndrome (AIDS) remain leading causes of illness and death in the United States. As of December 2004, an estimated 944,306 persons had received a diagnosis of AIDS, and of these, 529,113 (56%) had died (1). The annual number of AIDS cases and deaths declined substantially after 1994 but stabilized during 1999–2004 (1). However, since 1994, the annual number of cases among blacks, members of other racial/ethnic minority populations, and persons exposed through heterosexual contact has increased. The number of children reported with AIDS attributed to perinatal HIV transmission peaked at 945 in 1992 and declined 95% to 48 in 2004 (1), primarily because of the identification of HIV-infected pregnant women and the effectiveness of antiretroviral prophylaxis in reducing mother-to-child transmission of HIV (2).

By 2002, an estimated 38%–44% of all adults in the United States had been tested for HIV; 16–22 million persons aged 18–64 years are tested annually for HIV (3). However, at the end of 2003, of the approximately 1.0–1.2 million persons estimated to be living with HIV in the United States, an estimated one quarter (252,000–312,000 persons) were unaware of their infection and therefore unable to benefit from clinical care to reduce morbidity and mortality (4). A number of these persons are likely to have transmitted HIV unknowingly (5).

Treatment has improved survival rates dramatically, especially since the introduction of highly active antiretroviral therapy (HAART) in 1995 (6). However, progress in effecting earlier diagnosis has been insufficient. During 1990–1992, the proportion of persons who first tested positive for HIV <1 year before receiving a diagnosis of AIDS was 51% (7); during 1993–2004, this proportion declined only modestly, to 39% in 2004 (1). Persons tested late in the course of their infection were more likely to be black or Hispanic and to have been exposed through heterosexual contact; 87% received their first positive HIV test result at an acute or referral medical care setting, and 65% were tested for HIV antibody because of illness (8).

These recommendations update previous recommendations for HIV testing in health-care settings (9,10) and for screening of pregnant women (11). The objectives of these recommendations are to increase HIV screening of patients, including pregnant women, in health-care settings; foster earlier detection of HIV infection; identify and counsel persons with unrecognized HIV infection and link them to clinical and prevention services; and further reduce perinatal transmission of HIV in the United States.

Single copies of this report are available free of charge from CDC’s National Prevention Information Network, telephone 800-458-5231 (Mondays–Fridays, 9:00 a.m.–8:00 p.m. ET).

Background

Definitions

Diagnostic testing. Performing an HIV test for persons with clinical signs or symptoms consistent with HIV infection.

Screening. Performing an HIV test for all persons in a defined population (12).

Targeted testing. Performing an HIV test for subpopulations of persons at higher risk, typically defined on the basis of behavior, clinical, or demographic characteristics (9).

Informed consent. A process of communication between patient and provider through which an informed patient can choose whether to undergo HIV testing or decline to do so. Elements of informed consent typically include providing oral or written information regarding HIV, the risks and benefits of testing, the implications of HIV test results, how test results will be communicated, and the opportunity to ask questions.

Opt-out screening. Performing HIV screening after notifying the patient that 1) the test will be performed and 2) the patient may elect to decline or defer testing. Assent is inferred unless the patient declines testing.

HIV-prevention counseling. An interactive process of assessing risk, recognizing specific behaviors that increase the risk for acquiring or transmitting HIV, and developing a plan to take specific steps to reduce risks (13).

Evolution of HIV Testing Recommendations in Health-Care Settings and for Pregnant Women

In 1985, when HIV testing first became available, the main goal of such testing was to protect the blood supply. Alternative test sites were established to deter persons from using blood bank testing to learn their HIV status. At that time, professional opinion was divided regarding the value of HIV testing and whether HIV testing should be encouraged because no consensus existed regarding whether a positive test predicted transmission to sex partners or from mother to infant (14). No effective treatment existed, and counseling was designed in part to ensure that persons tested were aware that the meaning of positive test results was uncertain.
During the next 2 years, the implications of positive HIV serology became evident, and in 1987, the United States Public Health Service (USPHS) issued guidelines making HIV counseling and testing a priority as a prevention strategy for persons most likely to be infected or who practiced high-risk behaviors and recommended routine testing of all persons seeking treatment for STDs, regardless of healthcare setting (15). “Routine” was defined as a policy to provide these services to all clients after informing them that testing would be conducted (15).

In 1993, CDC recommendations for voluntary HIV counseling and testing were extended to include hospitalized patients and persons obtaining health care as outpatients in acute-care hospital settings, including emergency departments (EDs) (10). Hospitals with HIV seroprevalence rates of >1% or AIDS diagnosis rates of >1 per 1,000 discharges were encouraged to adopt a policy of offering voluntary HIV counseling and testing routinely to all patients aged 15–54 years. Health-care providers in acute-care settings were encouraged to structure counseling and testing procedures to facilitate confidential, voluntary participation and to include basic information regarding the medical implications of the test, the option to receive more information, and documentation of informed consent (10). In 1994, guidelines for counseling and testing persons with high-risk behaviors specified prevention counseling to develop specific prevention goals and strategies for each person (client-centered counseling) (16). In 1995, after perinatal transmission of HIV was demonstrated to be substantially reduced by administration of zidovudine to HIV-infected pregnant women and their newborns, USPHS recommended that all pregnant women be counseled and encouraged to undergo voluntary testing for HIV (17,18).

In 2001, CDC modified the recommendations for pregnant women to emphasize HIV screening as a routine part of prenatal care, simplification of the testing process so pretest counseling would not pose a barrier, and flexibility of the consent process to allow multiple types of informed consent (11). In addition, the 2001 recommendations for HIV testing in health-care settings were extended to include multiple additional clinical venues in both private and public health-care sectors, encouraging providers to make HIV counseling and testing more accessible and acknowledging their need for flexibility (9). CDC recommended that HIV testing be offered routinely to all patients in high HIV-prevalence health-care settings. In low prevalence settings, in which the majority of clients are at minimal risk, targeted HIV testing on the basis of risk screening was considered more feasible for identifying limited numbers of HIV-infected persons (9).

In 2003, CDC introduced the initiative Advancing HIV Prevention: New Strategies for a Changing Epidemic (19). Two key strategies of this initiative are 1) to make HIV testing a routine part of medical care on the same voluntary basis as other diagnostic and screening tests and 2) to reduce perinatal transmission of HIV further by universal testing of all pregnant women and by using rapid tests during labor and delivery or postpartum if the mother was not screened prenatally (19). In its technical guidance, CDC acknowledged that prevention counseling is desirable for all persons at risk for HIV but recognized that such counseling might not be appropriate or feasible in all settings (20). Because time constraints or discomfort with discussing their patients’ risk behaviors caused some providers to perceive requirements for prevention counseling and written informed consent as a barrier (12,21–23), the initiative advocated streamlined approaches.

In March 2004, CDC convened a meeting of health-care providers, representatives from professional associations, and local health officials to obtain advice concerning how best to expand HIV testing, especially in high-volume, high-prevalence acute-care settings. Consultants recommended simplifying the HIV screening process to make it more feasible and less costly and advocated more frequent diagnostic testing of patients with symptoms. In April 2005, CDC initiated a comprehensive review of the literature regarding HIV testing in health-care settings and, on the basis of published evidence and lessons learned from CDC-sponsored demonstration projects of HIV screening in health-care facilities, began to prepare recommendations to implement these strategies. In August 2005, CDC invited health-care providers, representatives from public health agencies and community organizations, and persons living with HIV to review an outline of proposed recommendations. In November 2005, CDC convened a meeting of researchers, representatives of professional health-care provider organizations, clinicians, persons living with HIV, and representatives from community organizations and agencies overseeing care of HIV-infected persons to review CDC’s proposed recommendations. Before final revision of these recommendations, CDC described the proposals at national meetings of researchers and health-care providers and, in March 2006, solicited peer review by health-care professionals, in compliance with requirements of the Office of Management and Budget for influential scientific assessments, and invited comment from multiple professional and community organizations. The final recommendations were further refined on the basis of comments from these constituents.
Rationale for Routine Screening for HIV Infection

Previous CDC and U.S. Preventive Services Task Force guidelines for HIV testing recommended routine counseling and testing for persons at high risk for HIV and for those in acute-care settings in which HIV prevalence was ≥1% (9,10,24). These guidelines proved difficult to implement because 1) the cost of HIV screening often is not reimbursed, 2) providers in busy health-care settings often lack the time necessary to conduct risk assessments and might perceive counseling requirements as a barrier to testing, and 3) explicit information regarding HIV prevalence typically is not available to guide selection of specific settings for screening (25–29).

These revised CDC recommendations advocate routine voluntary HIV screening as a normal part of medical practice, similar to screening for other treatable conditions. Screening is a basic public health tool used to identify unrecognized health conditions so treatment can be offered before symptoms develop and, for communicable diseases, so interventions can be implemented to reduce the likelihood of continued transmission (30).

HIV infection is consistent with all generally accepted criteria that justify screening: 1) HIV infection is a serious health disorder that can be diagnosed before symptoms develop; 2) HIV can be detected by reliable, inexpensive, and noninvasive screening tests; 3) infected patients have years of life to gain if treatment is initiated early, before symptoms develop; and 4) the costs of screening are reasonable in relation to the anticipated benefits (30). Among pregnant women, screening has proven substantially more effective than risk-based testing for detecting unsuspected maternal HIV infection and preventing perinatal transmission (31–33).

Rationale for New Recommendations

Often, persons with HIV infection visit health-care settings (e.g., hospitals, acute-care clinics, and sexually transmitted disease [STD] clinics) years before receiving a diagnosis but are not tested for HIV (34–36). Since the 1980s, the demographics of the HIV/AIDS epidemic in the United States have changed; increasing proportions of infected persons are aged <20 years, women, members of racial or ethnic minority populations, persons who reside outside metropolitan areas, and heterosexual men and women who frequently are unaware that they are at risk for HIV (37). As a result, the effectiveness of using risk-based testing to identify HIV-infected persons has diminished (34,35,38,39).

Prevention strategies that incorporate universal HIV screening have been highly effective. For example, screening blood donors for HIV has nearly eliminated transfusion-associated HIV infection in the United States (40). In addition, incidence of pediatric HIV/AIDS in the United States has declined substantially since the 1990s, when prevention strategies began to include specific recommendations for routine HIV testing of pregnant women (18,41). Perinatal transmission rates can be reduced to <2% with universal screening of pregnant women in combination with prophylactic administration of antiretroviral drugs (42,43), scheduled cesarean delivery when indicated (44,45), and avoidance of breast feeding (46).

These successes contrast with a relative lack of progress in preventing sexual transmission of HIV, for which screening rarely is performed. Declines in HIV incidence observed in the early 1990s have leveled and might even have reversed in certain populations in recent years (47,48). Since 1998, the estimated number of new infections has remained stable at approximately 40,000 annually (49). In 2001, the Institute of Medicine (IOM) emphasized prevention services for HIV-infected persons and recommended policies for diagnosing HIV infections earlier to increase the number of HIV-infected persons who were aware of their infections and who were offered clinical and prevention services (37). The majority of persons who are aware of their HIV infections substantially reduce sexual behaviors that might transmit HIV after they become aware they are infected (5). In a meta-analysis of findings from eight studies, the prevalence of unprotected anal or vaginal intercourse with uninfected partners was on average 68% lower for HIV-infected persons who were aware of their status than it was for HIV-infected persons who were unaware of their status (5). To increase diagnosis of HIV infection, destigmatize the testing process, link clinical care with prevention, and ensure immediate access to clinical care for persons with newly identified HIV infection, IOM and other health-care professionals with expertise (25,37,50,51) have encouraged adoption of routine HIV testing in all health-care settings.

Routine prenatal HIV testing with streamlined counseling and consent procedures has increased the number of pregnant women tested substantially (52). By contrast, the number of persons at risk for HIV infection who are screened in acute-care settings remains low, despite repeated recommendations in support of routine risk-based testing in health-care settings (9,10,15,34,53,54). In a survey of 154 health-care providers in 10 hospital EDs, providers reported caring for an average of 13 patients per week suspected to have STDs, but only 10% of these providers encouraged such patients to be tested for HIV while they were in the ED (54). Another 35% referred patients to confidential HIV testing sites in the
community; however, such referrals have proven ineffective because of poor compliance by patients (55). Reasons cited for not offering HIV testing in the ED included lack of established mechanisms to ensure follow-up (51%), lack of the certification perceived as necessary to provide counseling (45%), and belief that the testing process was too time-consuming (19%) (54).

With the institution of HIV screening in certain hospitals and EDs, the percentage of patients who test positive (2%–7%) often has exceeded that observed nationally at publicly funded HIV counseling and testing sites (1.5%) and STD clinics (2%) serving persons at high risk for HIV (53,56–59). Because patients rarely were seeking testing when screening was offered at these hospitals, HIV infections often were identified earlier than they might otherwise have been (29). Targeted testing programs also have been implemented in acute-care settings; nearly two thirds of patients in these settings accept testing, but because risk assessment and prevention counseling are time-consuming, only a limited proportion of eligible patients can be tested (29). Targeted testing on the basis of risk behaviors fails to identify a substantial number of persons who are HIV infected (34,35,39). A substantial number of persons, including persons with HIV infection, do not perceive themselves to be at risk for HIV or do not disclose their risks (53,56,59). Routine HIV testing reduces the stigma associated with testing that requires assessment of risk behaviors (60–63). More patients accept recommended HIV testing when it is offered routinely to everyone, without a risk assessment (54,56).

In 1999, to increase the proportion of women tested for HIV, IOM recommended 1) adopting a national policy of universal HIV testing of pregnant women with patient notification (opt-out screening) as a routine component of prenatal care, 2) eliminating requirements for extensive pretest counseling while requiring provision of basic information regarding HIV, and 3) not requiring explicit written consent to be tested for HIV (12). Subsequent studies have indicated that these policies, as proposed by IOM and other professional organizations (12,64,65), reflect an ethical balance among public health goals, justice, and individual rights (66,67). Rates of HIV screening are consistently higher at settings that provide prenatal and STD services using opt-out screening than at opt-in programs, which require pretest counseling and explicit written consent (52,68–74). Pregnant women express less anxiety with opt-out HIV screening and do not find it difficult to decline a test (68,74). In 2006, approximately 65% of U.S. adults surveyed concurred that HIV testing should be treated the same as screening for any other disease, without special procedures such as written permission from the patient (75).

Adolescents aged 13–19 years represent new cohorts of persons at risk, and prevention efforts need to be repeated for each succeeding generation of young persons (63). The 2005 Youth Risk Behavior Survey indicated that 47% of high school students reported that they had had sexual intercourse at least once, and 37% of sexually active students had not used a condom during their most recent act of sexual intercourse (76). More than half of all HIV-infected adolescents are estimated not to have been tested and are unaware of their infection (77,78). Among young (aged 18–24 years) men who have sex with men (MSM) surveyed during 2004–2005 in five U.S. cities, 14% were infected with HIV; 79% of these HIV-infected MSM were unaware of their infection (56). The American Academy of Pediatrics recommends that clinicians obtain information from adolescent patients regarding their sexual activity and inform them how to prevent HIV infection (79). Evidence indicates that adolescents prefer to receive this information from their health-care providers rather than from their parents, teachers, or friends (80). However, fewer than half of clinicians provide such guidance (81). Health-care providers’ recommendations also influence adolescents’ decision to be tested. Among reasons for HIV testing provided by 528 adolescents who had primary care providers, 58% cited their provider’s recommendation as their reason for testing (82).

The U.S. Preventive Services Task Force recently recommended that clinicians screen for HIV all adults and adolescents at increased risk for HIV, on the basis that when HIV is diagnosed early, appropriately timed interventions, particularly HAART, can lead to improved health outcomes, including slower clinical progression and reduced mortality (24). The Task Force also recommended screening all pregnant women, regardless of risk, but made no recommendation for or against routinely screening asymptomatic adults and adolescents with no identifiable risk factors for HIV. The Task Force concluded that such screening would detect additional patients with HIV, but the overall number would be limited, and the potential benefits did not clearly outweigh the burden on primary care practices or the potential harms of a general HIV screening program (24,83). In making these recommendations, the Task Force considered how many patients would need to be screened to prevent one clinical progression or death during the 3-year period after screening. On the basis of evidence available for its review, the Task Force was unable to calculate benefits attributable to the prevention of secondary HIV transmission to partners (84). However, a
recent meta-analysis indicated that HIV-infected persons reduced high-risk behavior substantially when they became aware of their infection (5). Because viral load is the chief biologic predictor of HIV transmission (85), reduction in viral load through timely initiation of HAART might reduce transmission, even for HIV-infected patients who do not change their risk behavior (86). Estimated transmission is 3.5 times higher among persons who are unaware of their infection than among persons who are aware of their infection and contributes disproportionately to the number of new HIV infections each year in the United States (87). In theory, new sexual HIV infections could be reduced >30% per year if all infected persons could learn their HIV status and adopt changes in behavior similar to those adopted by persons already aware of their infection (87).

Recent studies demonstrate that voluntary HIV screening is cost-effective even in health-care settings in which HIV prevalence is low (26,27,86). In populations for which prevalence of undiagnosed HIV infection is ≥0.1%, HIV screening is as cost-effective as other established screening programs for chronic diseases (e.g., hypertension, colon cancer, and breast cancer) (27,86). Because of the substantial survival advantage resulting from earlier diagnosis of HIV infection when therapy can be initiated before severe immunologic compromise occurs, screening reaches conventional benchmarks for cost-effectiveness even before including the important public health benefit from reduced transmission to sex partners (86).

Linking patients who have received a diagnosis of HIV infection to prevention and care is essential. HIV screening without such linkage confers little or no benefit to the patient. Although moving patients into care incurs substantial costs, it also triggers sufficient survival benefits that justify the additional costs. Even if only a limited fraction of patients who receive HIV-positive results are linked to care, the survival benefits per dollar spent on screening represent good comparative value (26,27,88).

The benefit of providing prevention counseling in conjunction with HIV testing is less clear. HIV counseling with testing has been demonstrated to be an effective intervention for HIV-infected participants, who increased their safer behaviors and decreased their risk behaviors; HIV counseling and testing as implemented in the studies had little effect on HIV-negative participants (89). However, randomized controlled trials have demonstrated that the nature and duration of prevention counseling might influence its effectiveness (90,91). Carefully controlled, theory-based prevention counseling in STD clinics has helped HIV-negative participants reduce their risk behaviors compared with participants who received only a didactic prevention message from health-care providers (90).

A more intensive intervention among HIV-negative MSM at high risk, consisting of 10 theory-based individual counseling sessions followed by maintenance sessions every 3 months, resulted in reductions in unprotected sex with partners who were HIV infected or of unknown status, compared with MSM who received structured prevention counseling only twice yearly (91).

Timely access to diagnostic HIV test results also improves health outcomes. Diagnostic testing in health-care settings continues to be the mechanism by which nearly half of new HIV infections are identified. During 2000–2003, of persons reported with HIV/AIDS who were interviewed in 16 states, 44% were tested for HIV because of illness (8). Compared with HIV testing after patients were admitted to the hospital, expedited diagnosis by rapid HIV testing in the ED before admission led to shorter hospital stays, increased the number of patients aware of their HIV status before discharge, and improved entry into outpatient care (92). However, at least 28 states have laws or regulations that limit health-care providers’ ability to order diagnostic testing for HIV infection if the patient is unable to give consent for HIV testing, even when the test results are likely to alter the patient’s diagnostic or therapeutic management (93).

Of the 40,000 persons who acquire HIV infection each year, an estimated 40%–90% will experience symptoms of acute HIV infection (94–96), and a substantial number will seek medical care. However, acute HIV infection often is not recognized by primary care clinicians because the symptoms resemble those of influenza, infectious mononucleosis, and other viral illnesses (97). Acute HIV infection can be diagnosed by detecting HIV RNA in plasma from persons with a negative or indeterminate HIV antibody test. One study based on national ambulatory medical care surveys estimated that the prevalence of acute HIV infection was 0.5%–0.7% among ambulatory patients who sought care for fever or rash (98). Although the long-term benefit of HAART during acute HIV infection has not been established conclusively (99), identifying primary HIV infection can reduce the spread of HIV that might otherwise occur during the acute phase of HIV disease (100,101).

Perinatal HIV transmission continues to occur, primarily among women who lack prenatal care or who were not offered voluntary HIV counseling and testing during pregnancy. A substantial proportion of the estimated 144–236 perinatal HIV infections in the United States each year can be attributed to the lack of timely HIV testing and treatment of pregnant women (102). Multiple barriers to HIV testing have been identified, including language barriers; late entry into prenatal care; health-care providers’ perceptions that their patients are at low risk for HIV; lack of time for counseling
and testing, particularly for rapid testing during labor and delivery; and state regulations requiring counseling and separate informed consent (103). A survey of 653 obstetrical providers in North Carolina suggested that not all health-care providers embrace universal testing of pregnant women; the strength with which providers recommended prenatal testing to their patients and the numbers of women tested depended largely on the providers’ perception of the patients’ risk behaviors (21). Data confirm that testing rates are higher when HIV tests are included in the standard panel of screening tests for all pregnant women (52,69,104). Women also are much more likely to be tested if they perceive that their health-care provider strongly recommends HIV testing (105). As universal prenatal screening has become more widespread, an increasing proportion of pregnant women who had undiagnosed HIV infection at the time of delivery were found to have seroconverted during pregnancy (106). A second HIV test during the third trimester for women in settings with elevated HIV incidence (≥17 cases per 100,000 person-years) is cost-effective and might result in substantial reductions in mother-to-child HIV transmission (107).

Every perinatal HIV transmission is a sentinel health event, signaling either a missed opportunity for prevention or, more rarely, a failure of interventions to prevent perinatal transmission. When these infections occur, they underscore the need for improved strategies to ensure that all pregnant women undergo HIV testing and, if found to be HIV positive, receive proper interventions to reduce their transmission risk and safeguard their health and the health of their infants.

**Screening for HIV Infection**

- In all health-care settings, screening for HIV infection should be performed routinely for all patients aged 13–64 years. Health-care providers should initiate screening unless prevalence of undiagnosed HIV infection in their patients has been documented to be <0.1%. In the absence of existing data for HIV prevalence, health-care providers should initiate voluntary HIV screening until they establish that the diagnostic yield is <1 per 1,000 patients screened, at which point such screening is no longer warranted.
- All patients initiating treatment for TB should be screened routinely for HIV infection (108).
- All patients seeking treatment for STDs, including all patients attending STD clinics, should be screened routinely for HIV during each visit for a new complaint, regardless of whether the patient is known or suspected to have specific behavior risks for HIV infection.

**Consent and Pretest Information**

- Screening should be voluntary and undertaken only with the patient’s knowledge and understanding that HIV testing is planned.
- Patients should be informed orally or in writing that HIV testing will be performed unless they decline (opt-out screening). Oral or written information should include an explanation of HIV infection and the
meanings of positive and negative test results, and the patient should be offered an opportunity to ask questions and to decline testing. With such notification, consent for HIV screening should be incorporated into the patient’s general informed consent for medical care on the same basis as are other screening or diagnostic tests; a separate consent form for HIV testing is not recommended.

- Easily understood informational materials should be made available in the languages of the commonly encountered populations within the service area. The competence of interpreters and bilingual staff to provide language assistance to patients with limited English proficiency must be ensured.
- If a patient declines an HIV test, this decision should be documented in the medical record.

**Diagnostic Testing for HIV Infection**

- All patients with signs or symptoms consistent with HIV infection or an opportunistic illness characteristic of AIDS should be tested for HIV.
- Clinicians should maintain a high level of suspicion for acute HIV infection in all patients who have a compatible clinical syndrome and who report recent high-risk behavior. When acute retroviral syndrome is a possibility, a plasma RNA test should be used in conjunction with an HIV antibody test to diagnose acute HIV infection (96).
- Patients or persons responsible for the patient’s care should be notified orally that testing is planned, advised of the indication for testing and the implications of positive and negative test results, and offered an opportunity to ask questions and to decline testing. With such notification, the patient’s general consent for medical care is considered sufficient for diagnostic HIV testing.

**Similarities and Differences Between Current and Previous Recommendations for Adults and Adolescents**

Aspects of these recommendations that remain unchanged from previous recommendations are as follows:

- HIV testing must be voluntary and free from coercion. Patients must not be tested without their knowledge.
- HIV testing is recommended and should be routine for persons attending STD clinics and those seeking treatment for STDs in other clinical settings.

- Access to clinical care, prevention counseling, and support services is essential for persons with positive HIV test results.

Aspects of these recommendations that differ from previous recommendations are as follows:

- Screening after notifying the patient that an HIV test will be performed unless the patient declines (opt-out screening) is recommended in all health-care settings. Specific signed consent for HIV testing should not be required. General informed consent for medical care should be considered sufficient to encompass informed consent for HIV testing.
- Persons at high risk for HIV should be screened for HIV at least annually.
- HIV test results should be provided in the same manner as results of other diagnostic or screening tests.
- Prevention counseling should not be required as a part of HIV screening programs in health-care settings. Prevention counseling is strongly encouraged for persons at high risk for HIV in settings in which risk behaviors are assessed routinely (e.g., STD clinics) but should not have to be linked to HIV testing.
- HIV diagnostic testing or screening to detect HIV infection earlier should be considered distinct from HIV counseling and testing conducted primarily as a prevention intervention for uninfected persons at high risk.

**Recommendations for Pregnant Women**

These guidelines reiterate the recommendation for universal HIV screening early in pregnancy but advise simplifying the screening process to maximize opportunities for women to learn their HIV status during pregnancy, preserving the woman’s option to decline HIV testing, and ensuring a provider-patient relationship conducive to optimal clinical and preventive care. All women should receive HIV screening consistent with the recommendations for adults and adolescents. HIV screening should be a routine component of preconception care, maximizing opportunities for all women to know their HIV status before conception (109). In addition, screening early in pregnancy enables HIV-infected women and their infants to benefit from appropriate and timely interventions (e.g., antiretroviral medications [43], scheduled cesarean delivery [44], and avoidance of breastfeeding* [46]). These

*To eliminate the risk for postnatal transmission, HIV-infected women in the United States should not breastfeed. Support services for use of appropriate breast milk substitutes should be provided when necessary. In international settings, UNAIDS and World Health Organization recommendations for HIV and breastfeeding should be followed (46).
HIV Screening for Pregnant Women and Their Infants

Universal Opt-Out Screening

- All pregnant women in the United States should be screened for HIV infection.
- Screening should occur after a woman is notified that HIV screening is recommended for all pregnant patients and that she will receive an HIV test as part of the routine panel of prenatal tests unless she declines (opt-out screening).
- HIV testing must be voluntary and free from coercion. No woman should be tested without her knowledge.
- Pregnant women should receive oral or written information that includes an explanation of HIV infection, a description of interventions that can reduce HIV transmission from mother to infant, and the meanings of positive and negative test results and should be offered an opportunity to ask questions and to decline testing.
- No additional process or written documentation of informed consent beyond what is required for other routine prenatal tests should be required for HIV testing.
- If a patient declines an HIV test, this decision should be documented in the medical record.

Addressing Reasons for Declining Testing

- Providers should discuss and address reasons for declining an HIV test (e.g., lack of perceived risk; fear of the disease; and concerns regarding partner violence or potential stigma or discrimination).
- Women who decline an HIV test because they have had a previous negative test result should be informed of the importance of retesting during each pregnancy.
- Logistical reasons for not testing (e.g., scheduling) should be resolved.
- Certain women who initially decline an HIV test might accept at a later date, especially if their concerns are discussed. Certain women will continue to decline testing, and their decisions should be respected and documented in the medical record.

Timing of HIV Testing

- To promote informed and timely therapeutic decisions, health-care providers should test women for HIV as early as possible during each pregnancy. Women who decline the test early in prenatal care should be encouraged to be tested at a subsequent visit.
- A second HIV test during the third trimester, preferably <36 weeks of gestation, is cost-effective even in areas of low HIV prevalence and may be considered for all pregnant women. A second HIV test during the third trimester is recommended for women who meet one or more of the following criteria:
  - Women who receive health care in facilities in which prenatal screening identifies at least one HIV-infected pregnant woman per 1,000 women screened.
  - Women who are known to be at high risk for acquiring HIV (e.g., injection-drug users and their sex partners, women who exchange sex for money or drugs, women who are sex partners of HIV-infected persons, and women who have had a new or more than one sex partner during this pregnancy).
  - Women who have signs or symptoms consistent with acute HIV infection. When acute retroviral syndrome is a possibility, a plasma RNA test should be used in conjunction with an HIV antibody test to diagnose acute HIV infection (96).

Rapid Testing During Labor

- Any woman with undocumented HIV status at the time of labor should be screened with a rapid HIV test unless she declines (opt-out screening).
- Reasons for declining a rapid test should be explored (see Addressing Reasons for Declining Testing).
- Immediate initiation of appropriate antiretroviral prophylaxis (42) should be recommended to women on the basis of a reactive rapid test result without waiting for the result of a confirmatory test.

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† A second HIV test in the third trimester is as cost-effective as other common health interventions when HIV incidence among women of childbearing age is ≥17 HIV cases per 100,000 person-years (107). In 2004, in jurisdictions with available data on HIV case rates, a rate of 17 new HIV diagnoses per year per 100,000 women aged 15–45 years was associated with an AIDS case rate of at least nine AIDS diagnoses per year per 100,000 women aged 15–45 years (CDC, unpublished data, 2005). As of 2004, the jurisdictions listed above exceeded these thresholds. The list of specific jurisdictions where a second test in the third trimester is recommended will be updated periodically based on surveillance data.
Postpartum/Newborn Testing
- When a woman's HIV status is still unknown at the time of delivery, she should be screened immediately postpartum with a rapid HIV test unless she declines (opt-out screening).
- When the mother’s HIV status is unknown postpartum, rapid testing of the newborn as soon as possible after birth is recommended so antiretroviral prophylaxis can be offered to HIV-exposed infants. Women should be informed that identifying HIV antibodies in the newborn indicates that the mother is infected.
- For infants whose HIV exposure status is unknown and who are in foster care, the person legally authorized to provide consent should be informed that rapid HIV testing is recommended for infants whose biologic mothers have not been tested.
- The benefits of neonatal antiretroviral prophylaxis are best realized when it is initiated \(<12\) hours after birth (110).

Confirmatory Testing
- Whenever possible, uncertainties regarding laboratory test results indicating HIV infection status should be resolved before final decisions are made regarding reproductive options, antiretroviral therapy, cesarean delivery, or other interventions.
- If the confirmatory test result is not available before delivery, immediate initiation of appropriate antiretroviral prophylaxis (42) should be recommended to any pregnant patient whose HIV screening test result is reactive to reduce the risk for perinatal transmission.

Similarities and Differences Between Current and Previous Recommendations for Pregnant Women and Their Infants
Aspects of these recommendations that remain unchanged from previous recommendations are as follows:
- Universal HIV testing with notification should be performed for all pregnant women as early as possible during pregnancy.
- HIV screening should be repeated in the third trimester of pregnancy for women known to be at high risk for HIV.
- Providers should explore and address reasons for declining HIV testing.
- Pregnant women should receive appropriate health education, including information regarding HIV and its transmission, as a routine part of prenatal care.
- Access to clinical care, prevention counseling, and support services is essential for women with positive HIV test results.

Aspects of these recommendations that differ from previous recommendations are as follows:
- HIV screening should be included in the routine panel of prenatal screening tests for all pregnant women. Patients should be informed that HIV screening is recommended for all pregnant women and that it will be performed unless they decline (opt-out screening).
- Repeat HIV testing in the third trimester is recommended for all women in jurisdictions with elevated HIV or AIDS incidence and for women receiving health care in facilities with at least one diagnosed HIV case per 1,000 pregnant women per year.
- Rapid HIV testing should be performed for all women in labor who do not have documentation of results from an HIV test during pregnancy. Patients should be informed that HIV testing is recommended for all pregnant women and will be performed unless they decline (opt-out screening). Immediate initiation of appropriate antiretroviral prophylaxis should be recommended on the basis of a reactive rapid HIV test result, without awaiting the result of confirmatory testing.

Additional Considerations for HIV Screening

Test Results
- Communicating test results. The central goal of HIV screening in health-care settings is to maximize the number of persons who are aware of their HIV infection and receive care and prevention services. Definitive mechanisms should be established to inform patients of their test results. HIV-negative test results may be conveyed without direct personal contact between the patient and the health-care provider. Persons known to be at high risk for HIV infection also should be advised of the need for periodic retesting and should be offered prevention counseling or referred for prevention counseling. HIV-positive test results should be communicated confidentially through personal contact by a clinician, nurse, mid-level practitioner, counselor, or other skilled staff. Because of the risk of stigma and discrimination, family or friends should not be used as interpreters to disclose HIV-positive test results to patients with limited English proficiency. Active efforts are essential to ensure that HIV-infected patients receive their positive
test results and linkage to clinical care, counseling, support, and prevention services. If the necessary expertise is not available in the health-care venue in which screening is performed, arrangements should be made to obtain necessary services from another clinical provider, local health department, or community-based organization. Health-care providers should be aware that the Privacy Rule under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) prohibits use or disclosure of a patient’s health information, including HIV status, without the patient’s permission.

- **Rapid HIV tests.** Because of the time that elapses before results of conventional HIV tests are available, providing patients with their test results can be resource intensive and challenging for screening programs, especially in episodic care settings (e.g., EDs, urgent-care clinics, and STD clinics) in which continuing relationships with patients typically do not exist. The use of rapid HIV tests can substantially decrease the number of persons who fail to learn their test results and reduce the resources expended to locate persons identified as HIV infected. Positive rapid HIV test results are preliminary and must be confirmed before the diagnosis of HIV infection is established (111).

- **Participants in HIV vaccine trials.** Recipients of preventive HIV vaccines might have vaccine-induced antibodies that are detectable by HIV antibody tests. Persons whose test results are HIV positive and who are identified as vaccine trial participants might not be infected with HIV and should be encouraged to contact or return to their trial site or an associated trial site for the confirmatory testing necessary to determine their HIV status.

- **Documenting HIV test results.** Positive or negative HIV test results should be documented in the patient’s confidential medical record and should be readily available to all health-care providers involved in the patient’s clinical management. The HIV test result of a pregnant woman also should be documented in the medical record of her infant. If the mother’s HIV test result is positive, maternal health-care providers should, after obtaining consent from the mother, notify pediatric care providers of the impending birth of an HIV-exposed infant and of any anticipated complications. If HIV is diagnosed in the infant first, health-care providers should discuss the implications for the mother’s health and help her to obtain care.

### Clinical Care for HIV-Infected Persons

Persons with a diagnosis of HIV infection need a thorough evaluation of their clinical status and immune function to determine their need for antiretroviral treatment or other therapy. HIV-infected persons should receive or be referred for clinical care promptly, consistent with USPHS guidelines for management of HIV-infected persons (96). HIV-exposed infants should receive appropriate antiretroviral prophylaxis to prevent perinatal HIV transmission as soon as possible after birth (42) and begin trimethoprim-sulfamethoxazole prophylaxis at age 4–6 weeks to prevent *Pneumocystis* pneumonia (112). They should receive subsequent clinical monitoring and diagnostic testing to determine their HIV infection status (113).

### Partner Counseling and Referral

When HIV infection is diagnosed, health-care providers should strongly encourage patients to disclose their HIV status to their spouses, current sex partners, and previous sex partners and recommend that these partners be tested for HIV infection. Health departments can assist patients by notifying, counseling, and providing HIV testing for partners without disclosing the patient’s identity (114). Providers should inform patients who receive a new diagnosis of HIV infection that they might be contacted by health department staff for a voluntary interview to discuss notification of their partners.

### Special Considerations for Screening Adolescents

Although parental involvement in an adolescent’s health care is usually desirable, it typically is not required when the adolescent consents to HIV testing. However, laws concerning consent and confidentiality for HIV care differ among states (79). Public health statutes and legal precedents allow for evaluation and treatment of minors for STDs without parental knowledge or consent, but not every state has defined HIV infection explicitly as a condition for which testing or treatment may proceed without parental consent. Health-care providers should endeavor to respect an adolescent’s request for privacy (79). HIV screening should be discussed with all adolescents and encouraged for those who are sexually active. Providing information regarding HIV infection, HIV testing, HIV transmission, and implications of infection should be regarded as an essential component of the anticipatory guidance provided to all adolescents as part of primary care (79).
Prevention Services for HIV-Negative Persons

- **Risk screening.** HIV screening should not be contingent on an assessment of patients’ behavioral risks. However, assessment of risk for infection with HIV and other STDs and provision of prevention information should be incorporated into routine primary care of all sexually active persons when doing so does not pose a barrier to HIV testing. Even when risk information is not sought, notifying a patient that routine HIV testing will be performed might result in acknowledgement of risk behaviors and offers an opportunity to discuss HIV infection and how it can be prevented. Patients found to have risk behaviors (e.g., MSM or heterosexuals who have multiple sex partners, persons who have received a recent diagnosis of an STD, persons who engage in substance abuse) and those who want assistance with changing behaviors should be provided with or referred to HIV risk-reduction services (e.g., drug treatment, STD treatment, and prevention counseling).

- **Prevention counseling.** In health-care settings, prevention counseling need not be linked explicitly to HIV testing. However, because certain patients might be more likely to think about HIV and consider their risks at the time of HIV testing, testing might present an ideal opportunity to provide or arrange for prevention counseling to assist with behavior changes that can reduce risks for acquiring HIV infection. Prevention counseling should be offered or made available through referral in all health-care facilities serving patients at high risk for HIV and at facilities (e.g., STD clinics) in which information on HIV risk behaviors is elicited routinely.

HIV/AIDS Surveillance

- **Risk-factor ascertainment for HIV-infected persons.** CDC recommends that providers ascertain and document all known HIV risk factors (115). Health-care providers can obtain tools and materials to assist with ascertainment and receive guidance on risk factors as defined for surveillance purposes from HIV/AIDS surveillance professionals in their state or local health jurisdiction. This risk-factor information is important for guiding public health decisions, especially for prevention and care, at clinical, local, state, and national levels.

- **HIV/AIDS case reporting.** All states require that health-care providers report AIDS cases and persons with a diagnosis of HIV infection to the state or local health department. Case report forms are available from the state or local health jurisdiction.

- **Pediatric exposure reporting.** CDC and the Council for State and Territorial Epidemiologists recommend that all states and territories conduct surveillance for perinatal HIV exposure and contact providers after receiving reports of exposed infants to determine the infant’s HIV-infection status. Information concerning dates of maternal HIV tests, receipt of prenatal care, maternal and neonatal receipt of antiretroviral drugs, mode of delivery, and breastfeeding is collected on the pediatric HIV/AIDS case report form (115).

Monitoring and Evaluation

Recommended thresholds for screening are based on estimates of the prevalence of undiagnosed HIV infection in U.S. health-care settings, for which no accurate recent data exist. The optimal frequency for retesting is not yet known. Cost-effectiveness parameters for HIV screening were based on existing program models, all of which include a substantial counseling component, and did not consistently consider secondary infections averted as a benefit of screening. To assess the need for revised thresholds for screening adults and adolescents or repeat screening of pregnant women and to confirm their continued effectiveness, screening programs should monitor the yield of new diagnoses of HIV infection, monitor costs, and evaluate whether patients with a diagnosis of HIV infection are linked to and remain engaged in care. With minor modifications, laboratory information systems might provide a practical alternative for clinicians to use in determining HIV prevalence among their patients who are screened for HIV.

Primary Prevention and HIV Testing in Nonclinical Settings

These revised recommendations are designed to increase HIV screening in health-care settings. Often, however, the population most at risk for HIV includes persons who are least likely to interact with the conventional health-care system (47,116). The need to maintain primary prevention activities, identify persons at high risk for HIV who could benefit from prevention services, and provide HIV testing for persons who are at high risk for HIV in nonclinical venues remains undiminished. New approaches (e.g., enlisting
HIV-infected persons and HIV-negative persons at high risk for HIV to recruit persons from their social, sexual, and drug-use networks for counseling, testing, and referral) have demonstrated considerable efficacy for identifying persons who were previously unaware of their HIV infection (117).

**Regulatory and Legal Considerations**

These public health recommendations are based on best practices and are intended to comply fully with the ethical principles of informed consent (67). Legislation related to HIV and AIDS has been enacted in every state and the District of Columbia (118), and specific requirements related to informed consent and pretest counseling differ among states (119). Certain states, local jurisdictions, or agencies might have statutory or other regulatory impediments to opt-out screening, or they might impose other specific requirements for counseling, written consent, confirmatory testing, or communicating HIV test results that conflict with these recommendations. Where such policies exist, jurisdictions should consider strategies to best implement these recommendations within current parameters and consider steps to resolve conflicts with these recommendations.

**Other Guidelines**

Issues that fall outside the scope of these recommendations are addressed by other USPHS guidelines (Box 1). Because concepts relevant to HIV management evolve rapidly, USPHS updates recommendations periodically. Current updates are available from the National Institutes of Health at http://AIDSinfo.nih.gov. Additional guidelines have been published by CDC and the U.S. Department of Health and Human Services, Office for Civil Rights (Box 2).

**BOX 1. Recent U.S. Public Health Service HIV treatment guidelines**

- Guidelines for the use of antiretroviral agents in HIV-infected adults and adolescents
- Guidelines for the use of antiretroviral agents in pediatric HIV infection
- Recommendations for use of antiretroviral drugs in pregnant HIV-1-infected women for maternal health and interventions to reduce perinatal HIV-1 transmission

**Acknowledgment**

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Continuing Nursing Education (CNE). This activity for 1.8 contact hours is provided by CDC, which is accredited as a provider of continuing education in nursing by the American Nurses Credentialing Center’s Commission on Accreditation.
Goal and Objectives

This report provides the rationale for expanded human immunodeficiency virus (HIV) testing and revised recommendations for HIV screening of adults and adolescents in health-care settings, including pregnant women, and for diagnostic HIV testing. These recommendations were developed by CDC in collaboration with scientists, public health officials, clinicians, ethicists, members of affected communities, and representatives from professional associations. The goal of this report is to provide information for clinicians and policymakers on which to base decisions regarding HIV testing in health-care settings. Upon completion of this educational activity, the reader should be able to (1) describe the rationale for HIV screening of adolescents and adults in health-care settings, (2) describe the concept and practice of “opt-out” screening for HIV infection, (3) describe the health-care settings in which HIV screening is recommended for all adults and adolescents, (4) describe recommendations for documentation of informed consent for HIV screening, (5) describe recommended HIV screening practices for pregnant women, and (6) describe conditions in which a second HIV screening test should be performed during the third trimester of pregnancy.

To receive continuing education credit, please answer all of the following questions.

1. Of the more than 1 million persons estimated to be living with HIV in the United States at the end of 2003, how many are estimated to have been unaware of their infection?
   A. Approximately one half (452,000–512,000 persons).
   B. Approximately one quarter (252,000–312,000 persons).
   C. Approximately 10% (91,000–105,000 persons).
   D. Approximately 5% (48,000–54,000 persons).
2. HIV screening is consistent with the criteria for an acceptable routine screening test for which of the following reasons?
   A. HIV infection can be detected by reliable, inexpensive, noninvasive screening tests.
   B. HIV-related disease is a serious health disorder that can be diagnosed before symptoms develop.
   C. HIV-infected patients have years of life to gain if treatment is initiated early, before symptoms develop.
   D. The costs of screening are reasonable in relation to the anticipated benefits.
   E. All of the above.
3. In which of the following health-care settings is HIV screening recommended for all patients?
   A. Emergency departments.
   B. Sexually transmitted infection clinics.
   C. Primary care practices caring for adults and adolescents aged >13 years.
   D. Prenatal care settings.
   E. All of the above.
4. How frequently should providers conduct HIV screening for persons likely to be at high risk for HIV infection?
   A. Every 2 years.
   B. At least annually.
   C. Every 3 months.
   D. Only once.
5. The term “opt-out screening” is defined as…
   A. the requirement that a patient sign a document indicating consent for testing.
   B. mandatory screening without the patient’s consent.
   C. routine testing without the patient’s knowledge.
   D. routinely performing an HIV test after notifying the patient that the test will be done and that the patient may decline or defer testing.
   E. screening of certain population groups at high risk for HIV.
6. Separate written documentation of informed consent for HIV screening in medical settings is…
   A. not recommended by CDC because general consent for medical care is sufficient to encompass consent for HIV testing.
   B. mandated by federal law.
   C. required by certain states.
   D. A and C.
7. Which of the following statements about HIV prevention counseling are true?
   A. It is an interactive process of assessing risk and developing a plan to take specific steps to reduce risks.
   B. It has been shown to be effective in decreasing risk behaviors among HIV-infected persons.
   C. It need not be conducted as a requirement for HIV testing in health-care settings.
   D. A, B, and C.
   E. A and B only.
8. The recommended testing strategy for pregnant women can best be described as…
   A. universal HIV screening as a routine part of prenatal care.
   B. routine counseling and targeted testing.
   C. voluntary counseling and testing.
   D. targeted counseling and testing.
9. Which of the following is a recommended component of prenatal care or HIV screening for pregnant women?
   A. HIV screening should be included in the routine panel of prenatal testing for all pregnant women, and the test should be performed unless the woman declines.
   B. HIV screening should be conducted for all women who have undocumented HIV status at the time of labor unless the woman declines.
   C. Pregnant women should receive appropriate health education, including information about HIV and its transmission, as a routine part of prenatal care.
   D. A repeat HIV test is recommended in the third trimester for all women in jurisdictions with elevated incidence of HIV or acquired immunodeficiency syndrome (AIDS) and for women receiving health care in facilities with at least one diagnosed case of HIV per 1,000 pregnant women.
   E. All of the above.
10. A second HIV test during the third trimester of pregnancy is specifically recommended for which of the following?
    A. Women who receive health care in states or territories with elevated incidence of HIV or AIDS among women aged 15–45 years.
    B. Women who receive health care in facilities in which prenatal screening identifies at least one HIV-infected pregnant woman per 1,000 women screened.
    C. Women who are known to be at high risk for acquiring HIV.
    D. Women who have signs or symptoms consistent with acute HIV infection.
    E. All of the above.
11. Which best describes your professional activities?
    A. Physician.
    B. Nurse.
    C. Health educator.
    D. Office staff.
    E. Other.
Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings

To receive continuing education credit, you must
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15. [ ] A [ ] B [ ] C [ ] D [ ] E

Fill in the appropriate blocks to indicate your answers. Remember, you must answer all of the questions to receive continuing education credit.

12. I plan to use these recommendations as the basis for... (Indicate all that apply).
A. Health education materials.
B. Local reimbursement policies.
C. Medicaid guidelines.
D. Public policy.
E. Other.

13. Overall, the length of the report was...
A. Much too long.
B. A little too long.
C. Just right.
D. A little too short.
E. Much too short.

14. After reading this report, I am confident I can describe the concepts and practice of "opt-out" screening for HIV infection.
A. Strongly agree.
B. Agree.
C. Undecided.
D. Disagree.
E. Strongly disagree.

15. After reading this report, I am confident I can describe the rationale for HIV screening of adults and adolescents.
A. Strongly agree.
B. Agree.
C. Undecided.
D. Disagree.
E. Strongly disagree.

16. After reading this report, I am confident I can describe recommended practice of HIV screening of adolescents and adults in health-care settings.
A. Strongly agree.
B. Agree.
C. Undecided.
D. Disagree.
E. Strongly disagree.

17. After reading this report, I am confident I can describe recommended practices for documentation of informed consent for HIV screening.
A. Strongly agree.
B. Agree.
C. Undecided.
D. Disagree.
E. Strongly disagree.

18. After reading this report, I am confident I can describe recommended practices for HIV screening of pregnant women.
A. Strongly agree.
B. Agree.
C. Undecided.
D. Disagree.
E. Strongly disagree.
19. After reading this report, I am confident I can describe conditions in which a second HIV screening test should be performed during the third trimester of pregnancy.
   A. Strongly agree.    D. Disagree.
   B. Agree.            E. Strongly disagree.
   C. Undecided.

20. The learning outcomes (objectives) were relevant to the goals of this report.
   A. Strongly agree.    D. Disagree.
   B. Agree.            E. Strongly disagree.
   C. Undecided.

21. The instructional strategies used in this report (text and boxes) helped me learn the material.
   A. Strongly agree.    D. Disagree.
   B. Agree.            E. Strongly disagree.
   C. Undecided.

22. The content was appropriate given the stated objectives of the report.
   A. Strongly agree.    D. Disagree.
   B. Agree.            E. Strongly disagree.
   C. Undecided.

23. The content expert(s) demonstrated expertise in the subject matter.
   A. Strongly agree.    D. Disagree.
   B. Agree.            E. Strongly disagree.
   C. Undecided.

24. Overall, the quality of the report was excellent.
   A. Strongly agree.    D. Disagree.
   B. Agree.            E. Strongly disagree.
   C. Undecided.

25. These recommendations will improve the quality of my practice.
   A. Strongly agree.    D. Disagree.
   B. Agree.            E. Strongly disagree.
   C. Undecided.

26. The availability of continuing education credit influenced my decision to read this report.
   A. Strongly agree.    D. Disagree.
   B. Agree.            E. Strongly disagree.
   C. Undecided.

27. The MMWR format was conducive to learning this content.
   A. Strongly agree.    D. Disagree.
   B. Agree.            E. Strongly disagree.
   C. Undecided.

28. Do you feel this course was commercially biased? (Indicate yes or no; if yes, please explain in the space provided.)
   A. Yes.               B. No.

29. How did you learn about the continuing education activity?
   A. Internet.
   B. Advertisement (e.g., fact sheet, MMWR cover, newsletter, or journal).
   C. Coworker/supervisor.
   D. Conference presentation.
   E. MMWR subscription.
   F. Other.
Dear Colleague:

The prevention of perinatal HIV transmission requires routine HJV screening of all pregnant women and the use of appropriate antiretroviral and obstetrical interventions that begin during pregnancy. Together, these actions can reduce the rate of mother-to-child HIV transmission to 2 percent or lower. Recently, new data have emerged indicating that higher testing rates are associated with testing strategies that routinely incorporate HIV tests in the standard battery of tests for all pregnant women. In light of this information, the Centers for Disease Control and Prevention (CDC) recommends that HIV testing be a routine screening procedure. CDC also recommends implementing rapid HIV testing in postnatal settings for infants of women not tested prenatally. Considering the potential for preventing transmission, no child should be born in this country whose HIV status, or whose mother’s status, is unknown.

CDC published data on recent prenatal HIV testing rates in the United States and Canada in the Morbidity and Mortality Weekly Report (MMWR,) of November 15, 2002. This study examined HIV prenatal testing rates associated with three different prenatal testing approaches from data gathered from 16 states and 5 Canadian provinces. A brief description of the testing approaches and data findings follows:

1. “Opt-in”: Pregnant women receive pre-HIV test counseling and must specifically consent to an HIV antibody test, usually in writing. This is the most common prenatal HIV testing approach in the United States. Among eight states using the “opt-in” approach where data were collected from medical records for 1998—1999, testing rates ranged from 25 percent to 69 percent. Canadian testing rates in three “opt-in” provinces ranged from 54 percent to 83 percent.

2. “Opt-out”: Pregnant women are notified that an HIV test will be routinely included in the standard battery of prenatal tests for all pregnant women, but they can decline HIV testing. Currently, Arkansas, Michigan, Tennessee, and Texas have adopted some version of this approach. In Tennessee, where this approach was used, a testing rate of 85 percent was reported. Two Canadian provinces using this approach showed a testing rate of 98 percent and 94 percent.

3. Mandatory newborn screening: If the mother’s HIV status is unknown at delivery, newborns are tested for maternal HIV-antibody, with or without the mother’s consent. Results must be available within 48 hours of testing. Connecticut and New York have implemented these approaches (in combination with an opt-in approach for pregnant women). In these two states, data indicate that prenatal testing rates rose from 52 percent to 83 percent in a seven-county area of New York, and from 31 percent to 81 percent in Connecticut, during the periods just before and just after implementation of mandatory newborn testing. In 2001, New York reported a statewide prenatal HIV testing rate of 93 percent based on newborn metabolic screening of all live births.
Prenatal HIV Screening

Based on information presented in the MMWR, the available data indicate that both “opt-out” prenatal maternal screening and mandatory newborn screening achieve higher maternal screening rates than “opt-in” prenatal screening. Accordingly, CDC recommends that clinicians routinely screen all pregnant women for HIV infection, using an “opt-out” approach, and that jurisdictions with statutory barriers to such routine prenatal screening consider revising them.

Newborn HIV Screening

In addition, CDC encourages clinicians to test for HIV any newborn whose mother’s HIV status is unknown. Jurisdictions should consider whether a mandatory screening policy for these infants is the best way to achieve such routine screening. Data demonstrate that detection of HIV infection during pregnancy through HIV testing of all pregnant women affords the best opportunity to deliver interventions when they are most efficacious. When intervention does not begin until the intrapartum or neonatal periods, 9 percent to 13 percent transmission rates are achievable based on clinical trial and observational data. Recent experience from the CDC funded Mother-Infant Rapid Intervention at Delivery (MIRIAD) study indicates that HIV rapid testing of women can be done during labor, and that antiretroviral interventions can be quickly delivered to HIV-infected mothers and their infants. Therefore, for those women whose HIV status is unknown at labor, CDC recommends routine, rapid testing. When the mother’s HIV status is unknown prior to the onset of labor and rapid HIV testing is not done during labor, CDC recommends rapid testing of the infant immediately post-partum, so that antiretroviral prophylaxis can be offered to HIV-exposed infants.

The federal Food and Drug Administration has approved three rapid HIV test kits (SUDS Oraquick and Reveal which can be used at delivery. When rapid test results are positive, antiretroviral interventions can be offered to the mother intrapartum and to her infant based on the preliminary results. Confirmatory testing should occur as soon as possible after delivery.

Sincerely,

Julie Louise Gerberding, M.D., M.P.H.
Director

Harold W. Jaffe, M.D.
Director
National Center for HIV, STD, and
TB Prevention
References

1 CDC. Revised recommendations for HIV screening of pregnant women. MMWR 2001; 50(RR-19):59-86.
6 CDC. Notice to readers: Approval of new rapid test for HIV antibodies. MMWR 2002; 51:1051-2.

Since 1994, the availability of increasingly effective antiretroviral drugs for both the prevention of perinatal human immunodeficiency virus (HIV) transmission and maternal treatment has resulted in a greater emphasis on prenatal HIV testing and substantial increases in prenatal testing rates. In 2000, preliminary data indicated that 766 (93%) of 824 HIV-infected women in 25 states knew their HIV status before delivery (CDC, unpublished data, 2002). However, an estimated 280–370 perinatal HIV transmissions continue to occur in the United States each year (1). The primary strategy to prevent perinatal HIV transmission is to maximize prenatal HIV testing of pregnant women. States and Canadian provinces have implemented three different prenatal HIV-testing approaches. To assess their effectiveness, CDC reviewed prenatal HIV-antibody testing rates associated with these approaches. Medical record data suggest that the “opt-in” voluntary testing approach is associated with lower testing rates than either the “opt-out” voluntary testing approach or the mandatory newborn HIV testing approach.

Under the opt-in approach, women typically are provided pre-HIV test counseling and must consent specifically to an HIV-antibody test. Under the opt-out approach, women are notified that an HIV test will be included in a standard battery of prenatal tests and procedures and that they may refuse testing (2). Under mandatory newborn HIV testing, newborns are tested for HIV, with or without the mother’s consent, if the mother’s HIV status is unknown at delivery.

Three methods were used to estimate prenatal testing rates among all women who delivered, regardless of whether they received prenatal care. First, eight U.S. areas that participated during 1998–1999 in CDC’s Active Bacterial Core Surveillance/Emerging Infections Program (ABC) Network assessed HIV testing during prenatal care and ≤2 days before delivery by reviewing a stratified random sample of labor and delivery records and prenatal records forwarded to birthing hospitals (3); in collaboration with CDC, network staff received a sample of records from all birthing hospitals in the surveillance areas and weighted testing rates to represent all liveborn infants in those areas. Second, public health investigators in each of the five Canadian provinces tallied the number of HIV tests among pregnant women that were submitted to provincial laboratories and divided the total by an estimate of all live and stillborn births in each province during the same year. Third, CDC analyzed weighted data collected in 1999 by interviewers in nine states for CDC’s Pregnancy Risk Assessment Monitoring System (PRAMS) (an ongoing, population-based survey conducted in 32 states and New York City among women who have given birth during the preceding 2–6 months [4]), who had asked women if they had been tested for HIV during pregnancy. Data on state prenatal HIV-testing policies were obtained from the American College of Obstetricians and Gynecologists (5).

HIV-testing rates varied depending on which approach to testing was used. Rates for states using the opt-in approach to prenatal HIV testing included in the ABC Network ranged from 25% to 69% (Table 1), testing rates in Canada ranged from 54% to 83% (Table 2), and rates derived from PRAMS data ranged from 61% to 81% (Table 3). Two U.S. states (Arkansas and Tennessee) and two Canadian provinces (Alberta, and Newfoundland and Labrador) reported using...
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...an opt-out prenatal HIV-testing policy. ABC Network data indicated that Tennessee had a testing rate of 85% (Table 1). Canada’s population-based data indicated a 98% testing rate in Alberta and a 94% testing rate in Newfoundland and Labrador (Table 2). PRAMS interview data indicated a 71% testing rate in Arkansas (Table 3), compared with a 57% testing rate early in 1997 before the law was implemented (Arkansas Department of Health, personal communication, 2002). Two states (New York and Connecticut) require HIV testing of newborns whose mothers were not tested during pregnancy. In New York, an ABC Network review of medical records in seven counties in the Rochester area indicated that the proportion of pregnant women who received a prenatal HIV test increased from 52% of 438 charts during January 1998–July 1999 to 83% of 112 charts during August–December 1999 after New York required that newborn HIV testing results be made available within 48 hours of specimen collection (Table 1). PRAMS data for 1999 indicated that the proportion of women statewide who reported having received an HIV test during pregnancy increased from 69% of 758 women during January–July to 93% of 502 during August–December (Table 3). In separate, statewide analyses of prenatal testing reported on newborn metabolic screening forms from all live-born infants, New York reported prenatal HIV-testing rates of 89% in 2000 and 93% in 2001 (New York State Department of Health, personal communication, 2002). In Connecticut, an ABC Network review of 668 charts indicated a testing rate of 31% during January 1998–September 1999, compared with 81% of 93 charts reviewed during October–December 1999 after enactment of the mandatory newborn testing law (Table 1).

**Reported by:** A Roome, PhD, J Hadler MD, Connecticut Dept of Public Health. G Birkhead, MD, AIDS Institute, New York State Dept of Health. S King, MD, The Hospital for Sick Children, Toronto; C Archibald, MD, Health Canada. S Schrag, DPhil, Active Bacterial Core Surveillance/Emerging Infections Program Network, Div of Bacterial and Mycotic Diseases, National Center for Infectious Diseases; A Lansky, PhD, Pregnancy Risk Assessment Monitoring System, Div of Reproductive Health, National Center for Chronic Disease Prevention and Health Promotion; S Sansom, PhD, M Fowler, MD, I Onorato, MD, J Anderson, PhD, Div of HIV/AIDS Prevention, National Center for HIV, STD, and TB Prevention, CDC.

**Editorial Note:** Prenatal HIV testing affords the best opportunity for the prevention of perinatal HIV transmission. On the basis of clinical trial data, perinatal HIV-transmission rates among HIV-infected women who begin antiretroviral treatment during pregnancy are as low as ≤2% (6), compared with 12%–13% early transmission rates among women who do not begin preventive treatment until labor and delivery or after birth (7) and 25% among women who receive no preventive treatment (8).
Among the three prenatal HIV testing approaches assessed in this report, opt-out voluntary testing and the mandatory testing of newborns appear to be associated with the highest testing rates. On the basis of the chart-review methodology, prenatal testing rates were higher in Tennessee, which uses the opt-out approach, than rates in states using the opt-in approach and similar to rates achieved with mandatory newborn testing in New York during the same time period. A similar trend was observed among Canadian provinces. In New York and Connecticut, mandatory HIV testing of newborns was associated with increases in prenatal testing rates. On the basis of PRAMS data, three of seven states using the opt-in approach achieved lower prenatal HIV-testing rates than states using the opt-out or mandatory newborn testing approaches.

Increases in prenatal HIV-testing rates were noted in states that shifted from an opt-in approach to either an opt-out or mandatory newborn testing approach and were probably associated with a greater likelihood that women were offered HIV testing during prenatal care. Data from the Perinatal Guidelines Project indicated that the majority of women will accept HIV testing if it is recommended by their health-care provider. Perinatal HIV experts and professional organizations have advocated streamlining prenatal HIV pre-test counseling and consent procedures to reduce barriers to the offer of testing by health-care providers.

The findings in this report are subject to at least seven limitations. First, testing results for each strategy are for all women, and the proportion of HIV-positive women who accepted testing under each strategy is not known. Second, among women who did not receive prenatal testing, the proportion of women who were not tested because they did not seek prenatal care is unknown. Third, among women who did not receive prenatal testing, the proportion of women who were tested at labor and delivery or whose infants were tested at birth is not known. Fourth, maternal self-reported data from

### TABLE 1. Number of medical charts reviewed and percentage of charts with a documented prenatal HIV test for pregnant women, by testing approach and area — Active Bacterial Core Surveillance/Emerging Infections Program Network, eight states, 1998–1999

<table>
<thead>
<tr>
<th>State</th>
<th>Testing approach</th>
<th>No. charts reviewed</th>
<th>% with HIV test* (95% CI†)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tennessee (five counties)</td>
<td>Opt-out§</td>
<td>623</td>
<td>85% (82.1%–88.5%)</td>
</tr>
<tr>
<td>New York (seven counties in the Rochester area)</td>
<td>Mandatory newborn testing§ without expedited testing requirement** Mandatory newborn testing; results returned within 48 hours††</td>
<td>438</td>
<td>52% (47.3%–57.1%)</td>
</tr>
<tr>
<td>Connecticut</td>
<td>Opt-in§§</td>
<td>668</td>
<td>31% (27.0%–34.3%)</td>
</tr>
<tr>
<td>Maryland</td>
<td>Opt-in</td>
<td>665</td>
<td>69% (65.4%–72.8%)</td>
</tr>
<tr>
<td>Georgia (20 counties in the Atlanta area)</td>
<td>Opt-in</td>
<td>866</td>
<td>66% (61.8%–69.6%)</td>
</tr>
<tr>
<td>Minnesota (seven counties in the Minneapolis/St. Paul area)</td>
<td>Opt-in</td>
<td>605</td>
<td>62% (57.5%–65.8%)</td>
</tr>
<tr>
<td>California (three counties in the San Francisco area)</td>
<td>Opt-in</td>
<td>575</td>
<td>39% (34.5%–42.4%)</td>
</tr>
<tr>
<td>Oregon (three counties in the Portland area)</td>
<td>Opt-in</td>
<td>498</td>
<td>25% (21.5%–29.1%)</td>
</tr>
</tbody>
</table>

* Percentages are weighted to reflect all live-born infants and account for sample weights and design.
† Confidence interval.
§ Pregnant women are informed that a human immunodeficiency virus (HIV) test is being conducted as a standard part of prenatal care and that they may refuse it.
¶ Infants are tested for HIV antibodies if the mother was not tested during prenatal care or at delivery. Mother’s consent is not required. Neither Connecticut nor New York have data on numbers of newborn infants tested under these laws.
** Policy in effect until August 1999.
†† Policy in effect beginning August 1999.
§§ Pregnant women are required to consent specifically to an HIV test.
¶¶ Policy in effect beginning October 1999.

### TABLE 2. Number of women delivering and percentage receiving prenatal HIV testing, by testing approach, year, and province — Canada, 1999–2001

<table>
<thead>
<tr>
<th>Province</th>
<th>Year</th>
<th>Testing approach</th>
<th>No. (%)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alberta</td>
<td>2000</td>
<td>Opt-out†</td>
<td>37,963 (98)</td>
</tr>
<tr>
<td>Newfoundland and Labrador</td>
<td>2001</td>
<td>Opt-out</td>
<td>4,770 (94)</td>
</tr>
<tr>
<td>Quebec</td>
<td>1999</td>
<td>Opt-in§</td>
<td>73,781 (83)</td>
</tr>
<tr>
<td>British Columbia</td>
<td>1999</td>
<td>Opt-in</td>
<td>41,739 (80)</td>
</tr>
<tr>
<td>Ontario</td>
<td>2001</td>
<td>Opt-in</td>
<td>129,758 (54)</td>
</tr>
</tbody>
</table>

* Canadian prenatal human immunodeficiency virus (HIV) testing rates are based on all live-born infants in each province for the year.
† Pregnant women are informed that an HIV test is being conducted as a standard part of prenatal care and that they may refuse it.
§ Pregnant women are required to consent specifically to an HIV test.
PRAMS collected 2–6 months after delivery might be subject to recall bias. Fifth, PRAMS data do not indicate whether a prenatal-care provider was aware of the woman’s HIV status. Sixth, among the women interviewed in PRAMS, up to 16% (in Arkansas) indicated they did not know if they had been tested. Finally, chart abstraction can document only prenatal HIV testing recorded in maternal medical records; without such documentation, clinicians might not be aware of the need to offer effective perinatal interventions to infected women and their HIV-exposed infants.

This report emphasizes the need for better data to assess perinatal HIV testing rates in the United States. Ongoing, randomized reviews of prenatal, labor/delivery, and pediatric charts, with a sampling framework ensuring that the sample is representative of the population of women delivering, might provide the most valid approach to assessing a state’s progress on perinatal HIV testing and prevention. CDC is working with states with high HIV prevalence rates among women of childbearing age and high numbers of pediatric AIDS cases to ensure standardized monitoring of prenatal testing rates. The data suggest that jurisdictions that use an opt-in approach and that have low prenatal HIV-testing rates should reevaluate their approach.

**References**

1. CDC. Revised recommendations for HIV screening of pregnant women. MMWR 2001;50(No. RR-19).

**Influenza Outbreak — Madagascar, July–August 2002**

In mid-July 2002, Madagascar health authorities were notified of a substantial number of deaths attributed to acute respiratory illness (ARI) in the village of Sahafata (population: 2,160), located in the rural highlands of Fianarantsoa Province, southeastern Madagascar (Figure 1). This region is approximately 450 km (280 miles) south of the capital Antananarivo. The Madagascar Ministry of Health (MOH) and the Institut Pasteur, Madagascar (IPM) initiated an investigation, which found an attack rate of 70% for ARI, with 27 deaths in Sahafata. Pharyngeal swab specimens were collected from ill persons for viral culture. Of the four influenza A viruses that were isolated at IPM, two were identified...
Rapid HIV Antibody Testing During Labor and Delivery for Women of Unknown HIV Status

A Practical Guide and Model Protocol
Rapid HIV-1 Antibody Testing During Labor and Delivery for Women of Unknown HIV Status

A Practical Guide and Model Protocol

January 30, 2004

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**Introduction**

Effective interventions are available to reduce the rate of perinatal HIV transmission when women are identified as HIV infected early in pregnancy. Pregnant women who are HIV infected but who do not receive prenatal care or do not receive an HIV test during prenatal care are not identified as HIV infected and therefore miss opportunities to reduce the risk of transmission to their infants and to receive life-saving treatments for themselves. With the implementation of screening programs using rapid HIV testing in labor and delivery settings, women with unknown HIV test results during prenatal care (results not documented in the prenatal medical record) can learn their HIV status quickly and receive short-course antiretroviral (ARV) prophylaxis to dramatically reduce the risk of transmitting HIV to their infants. The Centers for Disease Control and Prevention (CDC) recommends routine rapid HIV testing using an opt-out approach for women in labor whose HIV status is unknown (see Dear Colleague Letter, Appendix A).

As a result of a congressional mandate contained in the Ryan White CARE Act Amendments of 2000 that a study should be conducted of perinatal HIV transmission in the United States, the Office of the Inspector General (OIG) issued a 2002 report entitled “Reducing Obstetrician Barriers to HIV Testing.” One of the recommendations in the report is that “CDC should facilitate the development and states’ implementation of protocols for HIV testing during labor and delivery in order to promote testing in this setting as the standard of care.” Implementing rapid testing and short-course ARV prophylaxis in labor and delivery settings is feasible, but as is true when implementing any new screening program and clinical intervention, there are challenges. CDC has established a working group of 10 persons with expertise in obstetrics, pediatrics, public health practice, nursing, health education and training, blood screening and laboratory science, epidemiology, and rapid HIV testing technology to develop this model protocol for rapid HIV screening for women in labor. The working group represents academic institutions and university hospitals, a peer advocacy and support organization for women living with HIV infection, state and federal health agencies, as well as an internationally recognized HIV training and education organization. Each member of the group brings diverse experiences with rapid HIV testing to this document. The committee recognizes that as rapid HIV testing is more routinely implemented in labor and delivery settings, more knowledge will be gained. This guide will therefore be maintained as a “living document” and will be regularly updated and maintained on the CDC Web sites; it can be viewed on the perinatal HIV prevention site (www.cdc.gov/hiv/projects/perinatal/) and the rapid HIV testing site (www.cdc.gov/hiv/rapid_testing).
I. Background on Rapid Testing During Labor and Delivery

Tremendous medical and public health achievements have been made in the prevention of mother-to-child transmission (MTCT) of HIV-1. The risk for infant infection has been reduced from approximately 25% to less than 2% by the use of currently recommended prenatal ARV and obstetric interventions for a woman who is aware of her HIV infection early in pregnancy.

Ideally, all women should be screened for HIV before delivery, during an initial prenatal care visit so that potent combination antiretroviral treatment can be given to women who are HIV-infected. However, according to the CDC, approximately 40% of the mothers of the estimated 280–370 HIV-infected infants born in 2000 were not known to have HIV infection before delivery. It is critical to greatly reduce these missed opportunities for identifying HIV-infected pregnant women during the prenatal period, when the most effective interventions can be delivered.

According to clinical trial data, ARV prophylaxis, even when begun during labor and delivery and then given to the neonate, can reduce MTCT of HIV as much as 50%. To maximize this benefit, it is of utmost importance to obtain HIV test results for women in labor as soon as possible. Timely rapid HIV test results may allow providers to avoid some common obstetric practices that may increase the risk of transmission (e.g., artificial rupture of membranes, amniocentesis, or sampling of blood from the fetus’s scalp), and they can also advise the mother not to breastfeed.

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 allow test results to be available in 20 minutes or less. Results from the OraQuick Rapid HIV-1 Antibody Test (OraSure Technologies, Inc., Bethlehem, Pennsylvania) can be read within 20–40 minutes, and results from the Reveal Rapid HIV-1 Antibody Test (MedMira Laboratories, Inc., Halifax, Nova Scotia) can be read in approximately 5–10 minutes after test procedures are begun. Findings from the CDC-sponsored Mother-Infant Rapid Intervention at Delivery (MIRIAD) study indicate that offering voluntary HIV testing during labor is feasible in obstetric settings and that the OraQuick Rapid HIV-1 Antibody Test, used on whole blood specimens, delivers accurate and timely test results.

The purpose of this document is to offer guidance and practical tips to clinicians, laboratorians, hospital administrators, and policymakers who are planning and implementing a program for HIV rapid testing during labor and delivery for women of unknown HIV status and to provide the general structure of a model rapid HIV testing protocol that can be adapted by staff at facilities that seek to implement rapid testing during labor and delivery. For additional background on perinatal HIV prevention, see References, Other Suggested Reading, and Resources.
II. Planning and Implementing a Rapid HIV Testing Program for Women in Labor: Points to Consider in Preparing to Develop a Rapid HIV Testing Protocol

A. Location of Testing: in the Laboratory or in the Labor and Delivery Unit?
The U.S. Food and Drug Administration (FDA) recently approved a 1-step rapid HIV test that can be performed with whole blood either in the laboratory or at the point of care, that is, in the labor and delivery unit. With this test, it is possible to obtain results in as little as 20 minutes from the time the specimen is collected. In practice, based on data from the MIRIAD study at 1 site, median turn-around time for test results was 45 minutes in hospitals where testing was performed in the labor and delivery unit, and 3 1/2 hours when specimens were sent to the laboratory.

Deciding where to conduct rapid HIV testing depends on a number of factors, including logistics in the labor and delivery unit, availability of trained staff, the capacity of the laboratory to consistently convey rapid HIV test results quickly (optimally in less than 60 minutes), and the Clinical Laboratory Improvement Act (CLIA) categorization of the test device. The OraQuick Rapid HIV-1 Antibody Test is designated by CLIA as waived and can be performed in the labor and delivery unit; the Reveal Rapid HIV-1 Antibody Test is designated under CLIA as moderate-complexity and must therefore be performed in a laboratory.

Point-of-care testing requires training and continual supervision to ensure competent and proficient testing. This requirement can pose a challenge, especially if staff turnover is high. When rapid testing is performed in the laboratory, attaining consistently prompt results requires the availability of 24-hour staff responsive to the urgent need for immediate HIV test results. Choosing the location for rapid testing may be best accomplished after a needs assessment during labor and delivery and consultation with the hospital’s point-of-care testing committee. (See section IV for the training essentials for point-of-care testing.) The College of American Pathologists Commission on Laboratory Accreditation has published a point-of-care testing checklist, which is used as part of its accreditation process. The checklist, which may help to guide the point-of-care testing process in labor and delivery settings, is available at www.cap.org/apps/docs/laboratory_accreditation/checklists/checklistftp.html.

B. Interpretation of Test Results: What Does a Positive Rapid HIV Test Result Mean?
The accuracy of diagnostic tests is expressed in terms of sensitivity and specificity, as well as the positive and negative predictive value of the test result. No test is both 100% sensitive (no false-negative test results) and 100% specific (no false-positive test results). Screening tests are designed to be highly sensitive to ensure that no infected person is missed. The price for this high sensitivity is a slightly reduced specificity, that is, some women who are not infected with HIV will have false-positive HIV screening test results. In addition, the positive predictive value of a test depends on the prevalence of the condition in the group being screened. In a setting where prevalence is high, a positive result from a screening test is much more likely to reflect the person’s true status than is a positive result in an area of low prevalence, where a higher percentage of positive results will be false-positives. In all settings, a positive rapid HIV test result is a preliminary positive result that requires confirmation.
Provisions, therefore, must be made to confirm all preliminary positive rapid HIV test results, as soon as possible, with a supplemental test such as the Western blot or immunofluorescent assay (IFA). However, such testing can take several days or more and does not satisfy the need for timely HIV test results for women in labor. Thus, even in optimal rapid testing programs, some women who are not infected will receive ARV prophylaxis on the basis of a false-positive result from a rapid HIV test. The seriousness of the psychological effect of such a result is self-evident. However, a short course of the ARV prophylaxis currently recommended by the US Public Health Service has no known long-term safety effects for women and infants who are not infected.\textsuperscript{11} Observational studies and clinical trials have shown that when ARV prophylaxis is administered during labor or within the first 12 hours after birth, the risk of perinatal HIV transmission is reduced from 25\% to 9\%–13\%\textsuperscript{2-6}. In addition, diagnosing HIV infection during labor and delivery provides a window of opportunity to offer infected women referral and treatment for their own care.

C. Importance of System to Ensure Labor Staff Access to Prenatal HIV Test Results

Experience at several hospitals has shown that HIV testing has often been done during the prenatal period but that results have not been available to labor and delivery staff. The lack of access to prenatal test results thus leads to unnecessary rapid testing and increases the potential for false-positive results and unnecessary ARV prophylaxis. During planning for the implementation of a protocol for rapid testing during labor, it is critical to ensure that all results of HIV testing during pregnancy are documented in the woman’s prenatal record and readily available to labor and delivery staff. Ensuring the availability of prenatal results may require coordination with other antenatal health care facilities to make sure that the pregnant woman signs a medical release and that her prenatal records are routinely and promptly transferred to the delivery facility before the woman’s due date.

D. Choosing the Type of Rapid HIV Testing to Use

Four rapid tests approved by the U.S. Food and Drug Administration (FDA) can provide rapid results during labor and delivery: the OraQuick Rapid HIV-1 Antibody Test (OraSure Technologies, Inc., Bethlehem, Pennsylvania), the Reveal Rapid HIV-1 Antibody Test (MedMira Laboratories, Inc., Halifax, Nova Scotia), the Uni-Gold Recombigen HIV Test (Trinity Biotech Plc., Co Wicklow, Ireland) and the Murex-SUDS-Single Use Diagnostic System HIV-1 Antibody Test (Abbott Laboratories, Abbott Park, Illinois). The SUDS test is no longer available because manufacture was discontinued in 2003.

When selecting a rapid HIV test for use during labor and delivery, it is important to consider the accuracy of the test and the location within the institution at which testing will be performed. Tests that require serum or plasma (i.e., Reveal and SUDS) are more suitable for use in the laboratory because of the need to centrifuge the blood specimen, whereas tests that can be performed with whole blood (e.g., OraQuick, Uni-Gold) without specimen processing are more easily performed in the labor and delivery unit. The sensitivities and specificities, according to clinical licensure data submitted to the FDA, are shown in Table 1.
Because HIV prevalence among pregnant women is low in many parts of the United States, a test with high specificity will minimize the number of false-positive results. Comparisons of the positive predictive values of several FDA-approved HIV-1 antibody tests in populations with differing HIV prevalence rates are shown in Table 2.

Table 1. FDA-approved Test Performance, by Specimen Type*

<table>
<thead>
<tr>
<th>Test</th>
<th>Specimen Type</th>
<th>Sensitivity, % (95% C.I.)</th>
<th>Specificity, % (95% C.I.)</th>
<th>CLIA complexity</th>
</tr>
</thead>
<tbody>
<tr>
<td>OraQuick</td>
<td>Whole blood**</td>
<td>99.6 (98.5-99.9)</td>
<td>100 (99.7-100)</td>
<td>Waived</td>
</tr>
<tr>
<td></td>
<td>Serum</td>
<td>99.9 (98.5-99.9)</td>
<td>100 (99.7-100)</td>
<td>Moderate</td>
</tr>
<tr>
<td></td>
<td>Plasma</td>
<td>99.9 (98.5-99.9)</td>
<td>100 (99.7-100)</td>
<td>Moderate</td>
</tr>
<tr>
<td></td>
<td>Oral Fluid</td>
<td>99.9 (98.5-99.9)</td>
<td>100 (99.7-100)</td>
<td>Moderate</td>
</tr>
<tr>
<td>Reveal</td>
<td>Whole blood</td>
<td>99.8 (99.0-99.9)</td>
<td>99.1 (98.8-99.4)</td>
<td>Moderate</td>
</tr>
<tr>
<td></td>
<td>Serum</td>
<td>99.8 (99.0-99.9)</td>
<td>99.1 (98.8-99.4)</td>
<td>Moderate</td>
</tr>
<tr>
<td></td>
<td>Plasma</td>
<td>99.8 (99.0-99.9)</td>
<td>99.1 (98.8-99.4)</td>
<td>Moderate</td>
</tr>
<tr>
<td>Uni-Gold</td>
<td>Whole blood^</td>
<td>100 (99.5-100)</td>
<td>99.7 (99.0-100)</td>
<td>Moderate</td>
</tr>
<tr>
<td></td>
<td>Serum</td>
<td>100 (99.5-100)</td>
<td>99.8 (99.3-100)</td>
<td>Moderate</td>
</tr>
<tr>
<td></td>
<td>Plasma</td>
<td>100 (99.5-100)</td>
<td>99.8 (99.3-100)</td>
<td>Moderate</td>
</tr>
<tr>
<td>SUDS</td>
<td>Whole blood</td>
<td>99.9 (—)</td>
<td>99.6 (—)</td>
<td>Moderate</td>
</tr>
<tr>
<td></td>
<td>Serum</td>
<td>99.9 (—)</td>
<td>99.6 (—)</td>
<td>Moderate</td>
</tr>
<tr>
<td></td>
<td>Plasma</td>
<td>99.9 (—)</td>
<td>99.6 (—)</td>
<td>Moderate</td>
</tr>
</tbody>
</table>

* Data from FDA summary basis of approval
** Fingerstick and venipuncture
^ Venipuncture only

Note: SUDS has not been available since August 2003.

Estimated Positive Predictive Value, %

<table>
<thead>
<tr>
<th>HIV Prevalence, %</th>
<th>OraQuick (blood)</th>
<th>Reveal (serum)</th>
<th>Uni-Gold (blood)</th>
<th>Single EIA</th>
<th>SUDS (serum)</th>
</tr>
</thead>
<tbody>
<tr>
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<td>60</td>
<td>38</td>
</tr>
<tr>
<td>0.1</td>
<td>100</td>
<td>10</td>
<td>25</td>
<td>33</td>
<td>18</td>
</tr>
</tbody>
</table>

*Based on point estimate for specificity from FDA summary basis of approval. In practice, the specificity and actual PPV may differ from these estimates.

Note. Trade names are for identification purposes only and do not imply endorsement by the US Department of Health and Human Services or the Centers for Disease Control and Prevention. EIA, enzyme immunoassay; SUDS, Single Use Diagnostic System.

Based on the specificity observed in clinical licensure trials, the number of false-positive results would be substantially fewer with OraQuick than with either a single enzyme immunoassay, Uni-Gold or the Reveal rapid test. In fifteen hospitals participating in the MIRIAD study, the prevalence of HIV ranged from 0.3% to 3% among women with unknown HIV status who consented to HIV testing in labor and delivery.
E. Training Labor and Delivery Staff in Rapid Testing

Whether or not point-of-care testing is performed, labor and delivery staff will be called upon to provide women in labor whose HIV status is unknown with information on the availability of rapid HIV testing and perinatal HIV prevention and also to inform them that they will be tested unless they decline. (See section IV. for training essentials for persons performing the test.)

III. Key Elements of a Model Protocol for Rapid Testing during Labor and Delivery

A. Determining Eligibility for Rapid HIV Testing

The prenatal records of all women presenting to the labor and delivery unit should be reviewed for documentation of an HIV test result during the current pregnancy. Any woman without documentation of an HIV test result during the current pregnancy should be routinely screened for HIV by the use of a rapid HIV test and an opt-out approach (see section III. C). Including a standing order (e.g., “provide routine rapid HIV testing if there is no documentation of prenatal HIV test results unless the woman declines”) as part of the admission orders for women in labor may also save valuable time. Clinicians may use an opt-out approach to rapid HIV testing to re-screen women with documented negative HIV test results during the current pregnancy if there are indications that the woman is at continued risk for HIV infection (e.g., a history of sexually transmitted diseases [STDs], exchange of sex for money or drugs, multiple sex partners during the current pregnancy, use of illicit drugs, sex partner[s] known to be HIV-positive or at high risk, or signs and symptoms of seroconversion). This approach is similar to that used for syphilis screening, in which retesting for syphilis during the third trimester and again at delivery is recommended for pregnant women at high risk.13 Some states mandate syphilis screening at delivery for all pregnant women. Routine universal retesting for HIV by the use of an opt-out approach should be considered in health care facilities in areas with high HIV seroprevalence among women of childbearing age.14

B. Ensuring Confidentiality of Pregnant Women

Protecting the confidentiality of the pregnant woman who receives HIV testing during labor is required both by ethical standards and legal requirements. However, in the busy and complex labor and delivery unit, maintaining confidentiality requires that staff members be knowledgeable and vigilant. The following are practical tips to help protect the confidentiality of women who receive rapid HIV testing during labor and delivery:

- Discuss HIV testing when the woman is alone and feels safe to answer honestly: spouses, partners, and other family members may not know her sexual, reproductive or HIV testing history and this information should not be disclosed to them.
- Set up services as part of the rapid testing protocol to make available a professional interpreter, rather than family members, to protect the confidentiality of women who do not speak English.
- Ask the woman in labor ahead of time whom, if anyone, she would like present when the results of the HIV test are provided. Confidentiality should be maintained when giving results, and only the persons the woman has indicated should be present when the test results are provided.
- Ensure confidentiality when discussing ARV prophylaxis if the test result is positive.
- Label intravenous ARV medications in a way that protects confidentiality.
• Develop and implement procedures to ensure the confidentiality of HIV test results received in the labor and delivery unit. Some hospitals maintain a logbook in which to record the following information: the patient’s medical record number, date and time that the HIV test is done in the unit or sent to the laboratory, date and time the test results are received, and notation that the test results have been documented in the chart or communicated to the postpartum unit if the patient has given birth and been transferred. The system should both maintain confidentiality and ensure that results are communicated promptly to clinical staff.

C. Suggested Approaches to Routine Rapid HIV Testing during Labor and Delivery for Women of Unknown HIV Status: Considerations in Implementing the Opt-out Approach

CDC recommends routine rapid HIV testing for women in labor whose HIV status is unknown (women with no documentation of a prenatal HIV test in their medical records) unless they decline testing, that is, unless they opt out (Appendix A, CDC, Dear Colleague Letter, April 22, 2003; also available at: http://www.cdc.gov/hiv/PROJECTS/perinatal/2003/letter.htm). CDC also recognizes that regulations, laws, and policies regarding the HIV screening of pregnant women and neonates are not standardized throughout US states and territories. Health care providers and other hospital staff developing a rapid testing protocol for their facility should be familiar with, and adhere to, state and local laws, regulations, and policies concerning the HIV screening of pregnant women and neonates. They should document in the medical chart the results of all tests, both the rapid and the confirmatory. If a woman in labor and of unknown HIV status refuses rapid HIV screening, her refusal should likewise be noted in the medical chart.

The following information should be given to a woman in labor whose HIV status is unknown so that she has sufficient information to make an informed decision about screening:

1. She should be informed that the HIV virus can be transmitted from a mother to her infant during pregnancy, during labor and delivery, and through breastfeeding and that effective interventions during labor and after birth can substantially reduce the risk that her baby will become infected.
2. She should be informed that rapid HIV testing will be done routinely to help protect her infant’s health unless she declines testing.
3. She should be informed that a negative rapid HIV test result means that she is most probably not HIV infected, but that the test cannot detect very recent infection or recent exposure. A positive rapid test result is preliminary and a confirmatory test will need to be done.
4. She will be offered medicines right away for both her and her baby to reduce the chance that her baby will become infected. If the confirmatory test is also positive, she will be offered medical care for her own health.

All efforts should be made to determine a mother’s HIV status as soon as possible during labor. If the mother’s HIV status remains unknown at delivery, she or the infant or both should have rapid HIV testing as soon as possible postpartum. Some states mandate HIV screening of the neonate in this circumstance; however no states mandate screening of mothers.

Providing information about HIV infection to women in labor whose HIV status is unknown and routinely conducting rapid HIV testing are challenging, but the obstacles can generally be overcome with a thoughtful and systematic approach.
CDC recommends routine rapid HIV testing by the use of an opt-out approach, in which women are informed that HIV testing will be routinely done if her HIV status is unknown during labor and delivery but that she may decline testing (Appendix A,CDC, Dear Colleague Letter, April 22, 2003, available also at: http://www.cdc.gov/hiv/PROJECTS/perinatal/2003/letter.htm). (For an example of a script for an opt-out approach, see Appendix B.) Recognizing that some jurisdictions may still require written, signed informed consent for HIV testing, a sample written informed consent document (opt-in; also included in Appendix B) may be useful during the transition to routine HIV testing during labor and delivery.

The François-Xavier Bagnoud Center (FXBC), of the University of Medicine and Dentistry of New Jersey is an internationally recognized organization dedicated to improving the lives families infected and affected by HIV infection. FXBC has developed a formula for offering routine rapid testing. (For an adaptation of this formula, see Appendix C, which incorporates both the content that must be covered and the process still required by some state laws.)

D. Currently Approved Rapid HIV Test Kits

Two of the 4 rapid HIV antibody tests currently approved by the FDA are available for clinical use: the OraQuick Rapid HIV-1 Antibody Test and the Reveal HIV-1 Antibody Test. The Uni-Gold Recombigen HIV Test is expected to become available shortly. The availability of rapid HIV tests will change as new devices are developed and approved by the FDA and marketed by manufacturers. Information on the availability of rapid HIV tests is routinely updated on the CDC Web site, at www.cdc.gov/hiv/rapid_testing/ and is also available on the FDA Web site, at http://www.fda.gov/cber/products/testkits.htm. The manufacturer’s instructions for rapid HIV tests should be strictly followed.15,16

E. Interpreting Preliminary and Confirmatory Testing Results

Test results from rapid HIV tests are interpreted the same as other HIV screening test results.

- A negative result from a single test is considered negative. However, if the person being tested may have been exposed to HIV within the past 3 months, a repeat test at a later time is recommended because the rapid antibody test may not show very recent infection.
- A positive (or reactive) result from a rapid HIV test is considered a preliminary positive and must be followed up with a confirmatory test, either a Western blot or an immunofluorescence assay (IFA). Confirmatory testing should be done as soon as possible.
- When the results of a rapid test and a confirmatory test are discrepant, both the rapid and confirmatory test should be repeated, and consultation with an infectious disease specialist is recommended.

F. Providing Results

When the rapid HIV test is discussed, the woman should be told how soon to expect the results. Usually, test results will be available before delivery and are given to the woman during labor, at which time she is asked to consent to antiretroviral prophylaxis if the preliminary result is positive. A woman may state that she doesn’t want to be told the result of the rapid HIV test until after the baby’s birth. In such an instance, consent for the initiation of prophylaxis should be obtained when testing is discussed. If possible, the clinician who discussed the HIV test should give the results.
Privacy during the discussion of test results is essential to ensure confidentiality. The woman’s physical comfort should be assessed and monitored while she is being given test results.

**Providing NEGATIVE rapid HIV test results**

If the rapid test result is negative, no further medical intervention is necessary. The woman should be told that she is most likely not infected with HIV but that the test may not show recent infection. The clinician should ask whether she is concerned about any recent specific risk of exposure; if she is concerned, the clinician should recommend retesting after 3 months if indicated. More extensive HIV counseling should be set up for her during the postpartum period, and she should be told of these arrangements.

**Providing POSITIVE rapid HIV test results**

If the rapid HIV test result is positive, the clinician should tell the woman that she is likely to have HIV infection and that the baby may be exposed to HIV. She should be assured that a second test is being done right away to confirm the rapid test result but that the results will not likely be available before delivery. The clinician should explain that the rapid test result is preliminary and that false-positive results are possible but that it would be best to start ARV prophylaxis as soon as possible to reduce the risk of HIV transmission to the baby. The medication regimen that will be offered to the woman and her baby should be explained, including the known effects and possible adverse effects, and she should be given the opportunity to ask questions before accepting it. She should also be told to postpone breastfeeding until the confirmatory results are available because she should not breastfeed if she is HIV infected. The clinician should explain that all ARV prophylaxis will be stopped if the confirmatory test result is negative.

Preliminary results may not be available before delivery if labor is rapid or the woman is admitted to the unit late in labor. If the preliminary HIV test result is positive, ARV prophylaxis for the neonate should be initiated as soon as possible. (See Section G, for information on peripartum clinical management, scenario 4)

If the confirmatory HIV test result is positive, antiretroviral prophylaxis for the infant, to help prevent perinatal transmission, will be continued.

If the rapid HIV test result is positive, complicated and sensitive information needs to be explained privately to the woman during labor, a very vulnerable time. The clinician should allow time for questions and assure her that with her permission, every measure will be taken to reduce the infant’s risk of acquiring HIV. She should also be reassured that effective treatment is available to help keep her healthy while she is raising her child.

In some settings, the results of the confirmatory Western blot or IFA will be available after the mother and her infant are discharged from the hospital. As part of discharge planning, the woman should be informed of the importance of returning to discuss her confirmatory test result so that both she and her infant can receive appropriate medical care. A system for contacting women who miss appointments to receive their confirmatory test results is important, especially for women who did not receive prenatal care. Involving family members or other support persons in discharge planning
can be helpful if the woman agrees to their participation and has disclosed her rapid HIV test results to them.

**G. Peripartum Clinical Management of Women with Positive Rapid HIV Test Results**

The US Public Health Service Perinatal HIV Guidelines Working Group publishes Recommendations for Use of Antiretroviral Drugs in Pregnant HIV-1–Infected Women for Maternal Health and to Reduce Perinatal HIV-1 Transmission in the United States. The recommendations are available as a living document (frequently updated) at [www.aidsinfo.nih.gov/guidelines/](http://www.aidsinfo.nih.gov/guidelines/). Given the potential complexity of the clinical management decisions, it is strongly encouraged that local protocols for peripartum intervention for women whose HIV infection is diagnosed during labor be developed in consultation with HIV/infectious disease experts.

The current recommendations (version dated November 26, 2003) present 4 clinical scenarios and ARV treatment recommendations to reduce perinatal transmission. Scenarios 3 and 4 (summarized in the following sections) apply to women who arrive in a labor and delivery with undocumented HIV status and who have positive rapid HIV test results. In initiating rapid HIV testing and treatment protocols, hospital staff should access [www.aidsinfo.nih.gov/guidelines/](http://www.aidsinfo.nih.gov/guidelines/) to ensure that they follow the most recently updated recommendations. When hospital policy is being developed, input from clinicians with expertise in perinatal HIV management is encouraged.

**HIV-infected women in labor with no prior treatment**

(The following is a summary of scenario 3 from the USPHS guidelines.)

Several effective ARV treatment regimens are available, including (1) zidovudine (ZDV) monotherapy, (2) ZDV plus lamivudine (3TC), (3) nevirapine (NVP) monotherapy, and (4) ZDV plus NVP. Dosing is described in Table 3.

<table>
<thead>
<tr>
<th>Medication(s)</th>
<th>Woman</th>
<th>Neonate</th>
</tr>
</thead>
<tbody>
<tr>
<td>ZDV</td>
<td>Intrapartum IV ZDV (loading dose [2 mg/kg for 1 hour, followed by</td>
<td>ZDV syrup (2 mg/kg) orally every 6 hours for 6 weeks, beginning 8–12</td>
</tr>
<tr>
<td></td>
<td>continuous infusion [1 mg/kg/hr] until delivery)</td>
<td>hours after birth</td>
</tr>
<tr>
<td>ZDV + 3TC</td>
<td>ZDV (600mg) po and 3TC (150 mg) orally at onset of labor, followed</td>
<td>ZDV syrup (4 mg/kg) and 3TC (2 mg/kg) orally every 12 hours for 7 days</td>
</tr>
<tr>
<td></td>
<td>by ZDV (300 mg) orally every 3 hours and 3TC (150 mg) orally every 12</td>
<td></td>
</tr>
<tr>
<td></td>
<td>12 hours until delivery</td>
<td></td>
</tr>
<tr>
<td>NVP</td>
<td>Single dose of NVP (200 mg) orally at onset of labor&lt;sup&gt;a&lt;/sup&gt;</td>
<td>Single dose of NVP 2 mg/kg</td>
</tr>
<tr>
<td>NVP+ZDV</td>
<td>Intrapartum IV ZDV (loading dose [2 mg/kg for 1 hour, followed by</td>
<td>ZDV syrup (2 mg/kg) orally every 6 hours for 6 weeks, beginning 8–12</td>
</tr>
<tr>
<td></td>
<td>[1 mg/kg/hr.] until delivery) and single dose of NVP (200 mg) orally</td>
<td>hrs after birth and single dose of NVP (2 mg/kg) orally 48–72 hours</td>
</tr>
<tr>
<td></td>
<td>at onset of labor&lt;sup&gt;a&lt;/sup&gt;</td>
<td>after birth</td>
</tr>
</tbody>
</table>

*Note.* IV, intravenous; ZDV, zidovudine; 3TC, lamivudine; NVP, nevirapine.

<sup>a</sup> ZDV dosing for infants of <35 weeks gestation at birth is 1.5 mg/kg/dose orally, every 12 hours, increasing to every 8 hours at 2 weeks of age if >30 weeks gestation at birth or at 4 weeks of age if <30 weeks gestation at birth.<sup>17</sup>

<sup>b</sup> If the mother received NVP less than 1 hour before delivery, the neonate should be given 2 mg/kg of oral NVP as soon as possible after birth and again at 48–72 hours.
During the immediate postpartum period, the woman should have appropriate assessments (e.g., CD4+ count and HIV-1 RNA copy number) to determine whether ARV treatment is recommended for her own health.

A description of recommended intrapartum and postpartum treatment regimens for women identified in labor (USPHS guidelines, scenario 3) is available at [www.aidsinfo.nih.gov/guidelines/](http://www.aidsinfo.nih.gov/guidelines/) and includes data on transmission and the advantages and disadvantages of each regimen. The selection of a specific abbreviated ARV prophylaxis regimen may be based on the resources of the institution or the facility and an individualized clinical assessment of the patient. Clinicians should also weigh the potential for future NVP resistance when considering treatment options.

**Infants born to mothers who have received no antiretroviral therapy during pregnancy or intrapartum** (Summary of scenario 4 of the USPHS guidelines)

- The 6-week neonatal ZDV component of the ZDV chemoprophylactic regimen should be discussed with the mother and recommended for the neonate.
- ZDV for the neonate should be initiated as soon as possible after birth—preferably within 6–12 hours.
- Some clinicians may choose to use ZDV in combination with other antiretroviral drugs, particularly if the mother is known or suspected to have ZDV-resistant virus. However, the efficacy of this approach for the prevention of transmission is unknown, and appropriate dosages for neonates are incompletely defined.
- During the immediate postpartum period, the woman should undergo appropriate assessments (e.g., CD4+ count and HIV-1 RNA copy number) to determine whether ARV treatment is required for her health. The neonate should undergo early diagnostic testing so that if the neonate is HIV infected, treatment can be initiated as soon as possible.

**Note:** Discussion of treatment options and recommendations should not be coercive, and the final decision about the use of ARV prophylaxis is the mother’s. The selection of a specific, abbreviated course of ARV prophylaxis may be based on the resources and policies of the institution or the facility, as well as an individualized clinical assessment of the patient.

**Intrapartum care**

If labor progresses and membranes are intact, artificial rupture of membranes and invasive monitoring should be avoided. Labor should be managed with spontaneous rupture of membranes (SROM). Episiotomy should be avoided if clinically appropriate. Breastfeeding should also be avoided.

**Cesarean section**

Women diagnosed with HIV infection through rapid testing at the time of presentation for delivery will frequently present in active labor and/or with ruptured membranes. In such circumstances, information regarding maternal viral load will likely not be available to guide the management of delivery. Data are insufficient to indicate whether cesarean section (C-section) will add any benefit in reducing the risk of MTCT. In the only published randomized controlled trial of c-section in HIV-infected women, rates of perinatal HIV transmission between mother-infant pairs with emergency C-section (after active labor or rupture of membranes) and mother-infant pairs with vaginal delivery did not differ. However, for women whose HIV infection was diagnosed late in pregnancy and who have no evidence of labor or rupture of membranes but who have clinical indications for delivery (e.g. preeclampsia, vaginal bleeding, fetal heart rate abnormalities, intrauterine growth retardation,
oligohydramnios), c-section may help to prevent HIV transmission. Management in such circumstances should be individualized, and accepted principles should be taken into consideration:

1. The greatest benefit in preventing transmission is associated with cesarean delivery performed before the rupture of membranes or to the onset of labor in conjunction with the administration of ARV prophylaxis.

2. ARV prophylaxis should be administered to the woman before cesarean delivery whenever possible (ideally, 2–4 hours).

A more comprehensive discussion of the role of C-section in the prevention of perinatal HIV transmission is available in the U.S. 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 (www.aidsinfo.nih.gov/guidelines/).

**Neonatal care**

- The neonate should be bathed promptly after birth and before injections (e.g., vaccines or vitamin K).
- A baseline complete blood count (CBC) with differential AND serum chemistries should be performed before initiating ARV prophylaxis. A CBC should be repeated at 6 and 12 weeks of age.
- Polymerase chain reaction (PCR) testing for HIV-1 should be done at birth (before 48 hours of age) and repeated at ages 1–2 months and 3–6 months. Additional testing at 14 days of age might allow the early detection of infection.20

*HIV-exposed infants should be evaluated by, or in consultation with, a specialist in HIV infection in pediatric patients. Regular updates of the Guidelines for the Use of Antiretroviral Agents in Pediatric HIV Infection are available at www.aidsinfo.nih.gov/guidelines.

**H. Communication with Pediatricians**

It is crucial that the obstetric provider communicate with the pediatric provider when a neonate has been exposed to HIV. The medical care of an HIV-exposed infant is different than that of an infant who has not been exposed to HIV. In some states, regulations ensure that the obstetric provider’s communication of the mother’s HIV status to the pediatric provider is not considered a breach of confidentiality.

**I. Referral for Follow-up of HIV-infected Mother and HIV-exposed Infant**

Both mother and infant need to be referred for ongoing care to providers with experience and expertise in HIV care. Services for families affected by HIV infection are available in many communities through Title IV or Title III of the Ryan White CARE Act. HIV-infected mothers who are just learning their HIV status or who have not been in care need a thorough evaluation of their immune and clinical status and assessment of their need for ARV treatment or other care. Infants need diagnostic testing and clinical monitoring to determine their HIV status. All infants exposed to HIV should be placed on an antibiotic for prophylaxis against *Pneumocystis carinii* pneumonia (PCP) at 6 weeks of age, and should continue to receive it until it has been confirmed that they are not infected with HIV.20 Families need access to case management and psychosocial support services, ideally through a comprehensive, family-centered HIV program. In some communities, a case manager from the family HIV care program will visit the mother in the hospital if notified of the referral.
Before discharge, the mother should be educated about the ARV prophylaxis and why it is important that the infant complete the full course of medication. Teaching should emphasize that (1) the infant must complete the ARV prophylaxis, (2) the infant should begin taking antibiotic prophylaxis for PCP at 6 weeks of age, (3) the infant will need further testing during the first few months of life to determine HIV status, and (4) the mother should return to receive confirmatory HIV test results (if not received before discharge). If the mother has disclosed her HIV status to a family member or other support person, it is beneficial to involve the support person in instructions about the necessary follow-up care of both mother and infant.

J. Reporting HIV/AIDS

If Western blot or IFA test results confirm HIV infection, the facility must follow all applicable local and state requirements regarding the reporting of HIV infection or AIDS. If personnel are uncertain about the HIV/AIDS reporting requirements in their area, they should contact their state health department HIV/AIDS surveillance unit.

IV. Management Considerations in Developing and Implementing a Facility-based Rapid HIV Testing Protocol for Women in Labor: Preparation and Training

A. Key Players

Training is essential when introducing a new procedure to labor and delivery care. The entire patient care team should be educated about rapid HIV testing during labor. The hospital laboratory staff should be involved in developing and maintaining a quality assurance program.

B. Training of Labor and Delivery Staff--Rapid HIV Testing for Women in Labor

It is essential to provide ongoing training for labor and delivery staff in providing information about HIV infection and rapid testing for women in labor whose HIV status is unknown. Without such training, many nurses, obstetricians, nurse-midwives, residents, and house staff may not have up-to-date information about perinatal HIV transmission or the experience, comfort, or skill to use sensitivity when providing women with accurate information about rapid HIV testing or to perform rapid HIV testing during labor and delivery.

Who should be trained

Training in rapid HIV testing and intrapartum or neonatal ARV prophylaxis to reduce perinatal HIV transmission should be available for all staff who provide care for pregnant women, women in labor, and neonates. These staff members include obstetricians, residents and house staff, family practice physicians, nurse-midwives, labor and delivery nurses, perinatal nurse educators and managers, nurse practitioners, pediatricians, and infection control practitioners.

In nonteaching hospitals, the labor and delivery nurse is the person most likely to assess the woman’s medical record for documentation of HIV testing and to provide the woman with information about rapid HIV testing. In teaching hospitals, medical residents, house staff, obstetricians, or nurse-
midwives are most likely to have the responsibility for offering rapid testing. However, the labor and delivery nurse plays an important role in admission assessment, patient teaching, and support.

**Content**
The training should include the following:

- The failure of risk-based HIV testing to identify HIV-infected pregnant women
- Local, regional, and national HIV/AIDS statistics for women
- CDC guidelines for HIV testing for women in labor
- Factors that influence perinatal HIV transmission
- Interventions to reduce transmission during labor and postpartum
- Short-course ARV prophylaxis for mother and infant
- Strategies to ensure confidentiality
- Approaches to providing information during labor
- Methods for interpreting rapid test results
- Local referrals and follow-up care for the HIV-infected woman and her infant

Training in ARV prophylaxis should include the options for preventing MTCT, strategies for ensuring the availability of medication, specifics of medication administration for mother and infant, and teaching and follow-up for mother and infant.

**Teaching strategies and methods for staff:** Didactic or independent learning (computer-based or Web-based) works well for HIV statistics, factors that influence perinatal transmission, current research, treatment to reduce perinatal transmission, and specifics about the rapid test.

**Case-study discussion** in small groups can be the best approach for skill building and problem solving and for exploring attitudes. One or two cases can be discussed in approximately 30 minutes.

**Role-playing** can be used separately or with case-study discussion to practice discussions about rapid testing of the mother during labor or rapid testing of the infant during the postpartum period. One session of role-playing can usually be completed and discussed in 30?–45 minutes.

**Opportunities to provide training**
The busy labor and delivery suite does not offer many opportunities for formal in-service training. Thought is needed to present content and make it available at times that are convenient for obstetric staff and providers. Motivation for learning can be increased if CME (continuing medical education) credit and nursing CE (continuing education) contact hours are provided.

In the fall of 2003, CDC funded the Health Research Education Trust, the research and education affiliate of the American Hospital Association ([www.hret.org](http://www.hret.org)) and the François-Xavier Bagnoud Center ([www.fxbcenter.org](http://www.fxbcenter.org)) to develop model policies, tools, and training materials to assist hospitals and birthing centers implement rapid HIV testing programs in labor and delivery units.
C. Training Essentials for Persons Performing Point-of-Care Rapid HIV Testing

The OraQuick rapid HIV test is used as an illustration of a test that can be performed in the labor and delivery unit. The laboratory, medical, or nursing staff may lead the training session. Including the following suggested points will allow trainees to:

- Review the OraQuick package insert along with the facility’s standard operating procedure.
- View the OraQuick rapid HIV antibody testing video.
- Observe a demonstration of setting up the OraQuick Rapid HIV Antibody Test.
- Perform a panel of 5 known specimens and obtain 100% accuracy.
- Take a competency test on the OraQuick rapid HIV test 100% accuracy or counseling documented for incorrect answers.

The following points should be emphasized as part of training staff to carry out rapid HIV testing:

- Handle requests for rapid HIV testing stat.
- Verify that appropriate positive and negative controls have been performed on the lot number in use and match expected results before setting up a patient’s specimen. 
- Read the OraQuick Test 20 minutes after setup. Do not exceed 40 minutes. A timer can be clipped onto one’s uniform to ensure that the test is read within time limit.
- Report results as soon as possible (no longer than 60 minutes after receipt of specimen).
- Document all rapid HIV test results and inform the patient’s health care provider according to protocol.
- Refer all specimens that test preliminary positive to the appropriate laboratory for confirmatory testing.

In October 2003, CDC began to offer a training course called Fundamentals of HIV Testing Using the OraQuick Rapid HIV-1 Antibody Test in various locations throughout the United States. Information about the training and a regularly updated list of the cities can be found at http://www.cdc.gov/hiv/rapid_testing/. In early 2004, CDC will partner with the François-Xavier Bagnoud Center to offer regional training specific to perinatal HIV prevention, with emphasis on rapid HIV testing in labor and delivery settings. In addition, to assist with local training, OraSure, for example, offers a short training video about performing the OraQuick HIV-1 antibody test.

D. Ensuring Staff Proficiency and Competency to Carry Out Rapid HIV Testing in Labor and Delivery Settings

Implementation of a rapid HIV testing program is essential to effect the quick (no longer than 60 minutes) turnaround time of results, which is needed to offer timely prophylaxis to women in labor whose HIV status is undocumented but whose specimens are reactive (positive) to the rapid HIV test. All laboratories and testing sites must adhere to the minimum requirements of the Clinical Laboratory Improvement Act of 1988 (CLIA88). Because of the critical clinical implications of this test result, it is of the utmost importance to ensure accurate testing and the reporting of all results. CDC has developed quality assurance guidelines for performing rapid HIV testing, which are available at www.cdc.gov/hiv/rapid_testing/.
The keys to successful performance of rapid HIV testing and reporting are:

- Clear and concise procedures
- Training of personnel
- Verification of competence of personnel
- Proper performance of quality control procedures
- Recognition of when the testing does not comply with procedures

In a laboratory, these duties would be managed by a Quality Control or Quality Assurance Compliance Officer. In a point-of-care testing (POCT) setting, it is important to establish a POCT coordinator (typically a laboratorian) who is responsible for training, quality control, and quality assurance issues.

One way to assess the capacity of the laboratory or testing site to accurately test and report rapid HIV results is through proficiency testing, “an external program in which samples are periodically sent... for analysis.” The results from the individual participants are compared to the expected values. Each site receives a graded individualized report and a summary report showing their performance and the performance of all the participants. Proficiency testing is desirable, even for the CLIA-waived OraQuick test, because the decision to administer ARV prophylaxis will be based initially on a single, preliminary positive result. CLIA-certified laboratories and testing sites are required to participate in a proficiency testing program that is approved by the Center for Medicare and Medicaid Services for any test that is not certified by CLIA as waived (e.g., Reveal).

Another mechanism for ensuring the accuracy of test results is continued competency testing of personnel. Competency testing refers to the periodic evaluation of a person’s ability to “perform a test and use the testing device.” CLIA88 requires each person who is authorized to perform rapid HIV testing that has not been waived by CLIA (e.g., Reveal) and report results to perform competency testing semiannually the first year and at least annually thereafter. Competency testing can take many forms, including performance of the test on known specimens, direct observation, a written examination on the test, and a Web-based competency test. Although this testing is not explicitly required for CLIA-waived tests (e.g., OraQuick), it is recommended to ensure competency, and it is desirable because the decision to administer ARV prophylaxis will be based on 1 preliminary positive result of a rapid HIV test.

For testing done in the labor and delivery unit, the POCT coordinator would keep records of all training and competency verification of personnel, quality control, patient testing, and proficiency testing.

V. Conclusion

Until all HIV-infected pregnant women are tested for HIV infection during prenatal care, the promise of the findings of AIDS Clinical Trials Group Protocol 076, the first study to demonstrate the efficacy of an ARV medication (i.e., AZT) to substantially reduce perinatal HIV transmission, and the findings of other important perinatal HIV prevention studies—that perinatal HIV transmission can largely be prevented and virtually eliminated—cannot be realized. Although efforts are in place to improve access to prenatal care, prenatal HIV testing, and ARV prophylaxis, opportunities to prevent perinatal HIV transmission continue to be missed, and infants acquire HIV infection. The routine use
of rapid HIV testing and medical interventions in labor and delivery settings provides a final opportunity to reduce the effect of those missed opportunities for prevention. It is recommended that hospitals adopt a policy of routine rapid HIV testing by using an opt-out approach for women whose HIV status is unknown when presenting to the labor and delivery. It is recognized that implementing rapid testing programs in labor and delivery settings poses challenges. However, clinicians in labor and delivery settings frequently make complex medical decisions, implement emergency life-saving interventions, and discuss sensitive and difficult personal information with patients. This document is intended to assist clinicians by adding another important tool to their repertoire of clinical screening and HIV prevention interventions.

For inquiries or comments, e-mail Margaret A. Lampe, RN, MPH (mlampe@cdc.gov).

Acknowledgments

The working group thanks Drs. Ida Onorato, Marc Bulterys, Harold Jaffe, Alan Greenberg, Patrick Sullivan, Mr. Kevin Delaney, Ms. Marie Morgan, Ms. Thena Durham and Ms. Susan Danner at CDC, Ms. Yolanda Olszewski at the CORE Center in Chicago, Illinois, and Dr. Patricia Garcia at Northwestern University for their thoughtful review and contributions. The working group also thanks the women who have participated in the focus groups, pilots, research studies, and rapid testing programs that have taught many lessons and demonstrated the acceptability, feasibility, and effectiveness of rapid HIV testing during labor and delivery. The knowledge gained from, and the working group’s experiences with, these projects were helpful in formulating our approach to this document.
References, Suggested Reading, and Resources

References


**Suggested Reading**


**Resources**


Includes current CDC perinatal HIV prevention programs, current CDC recommendations and studies on perinatal HIV prevention in the United States, and notices and summaries of national meetings of CDC perinatal HIV prevention grantees.


Includes frequently asked questions about rapid HIV testing, official CDC and FDA releases, and studies on rapid tests.
Women and Children with HIV Web site of François-Xavier Bagnoud Center (University of Medicine and Dentistry of New Jersey) and Center for HIV Information (University of California San Francisco). Available at: http://www.womenchildrenhiv.org/.

Includes clinical information, training resources, and best-practice recommendations regarding perinatal HIV prevention and pediatric HIV infection. Resources for U.S. and international settings.


Includes fact sheets, data sets, summary slides, a searchable database of clinical trials, a resource directory, and a physician network for expert discussion on treatment. Additionally, members will be able to participate in confidential and secure discussion boards; read about real people living with, and successfully managing, HIV; download advocacy tools; and receive a regular e-mail newsletter highlighting the most up-to-date information about women and HIV infection.
Appendix A

Letter from Dr. Julie Louise Gerberding, Director
Centers for Disease Control and Prevention

and

Dr. Harold W. Jaffee, Director
National Center for HIV, STD, and TB Prevention
Dear Colleague:

The prevention of perinatal HIV transmission requires routine HIV screening of all pregnant women and the use of appropriate antiretroviral and obstetrical interventions that begin during pregnancy. Together, these actions can reduce the rate of mother-to-child HIV transmission to 2 percent or lower. Recently, new data have emerged indicating that higher testing rates are associated with testing strategies that routinely incorporate HIV tests in the standard battery of tests for all pregnant women. In light of this information, the Centers for Disease Control and Prevention (CDC) recommends that HIV testing be a routine screening procedure. CDC also recommends implementing rapid HIV testing in postnatal settings for infants of women not tested prenatally. Considering the potential for preventing transmission, no child should be born in this country whose HIV status, or whose mother’s status, is unknown.

CDC published data on recent prenatal HIV testing rates in the United States and Canada in the *Morbidity and Mortality Weekly Report (MMWR,)* of November 15, 2002. This study examined HIV prenatal testing rates associated with three different prenatal testing approaches from data gathered from 16 states and 5 Canadian provinces. A brief description of the testing approaches and data findings follows:

1. **“Opt-in”:** Pregnant women receive pre-HIV test counseling and must specifically consent to an HIV antibody test, usually in writing. This is the most common prenatal HIV testing approach in the United States. Among eight states using the “opt-in” approach where data were collected from medical records for 1998—1999, testing rates ranged from 25 percent to 69 percent. Canadian testing rates in three “opt-in” provinces ranged from 54 percent to 83 percent.

2. **“Opt-out”:** Pregnant women are notified that an HIV test will be routinely included in the standard battery of prenatal tests for all pregnant women, but they can decline HIV testing. Currently, Arkansas, Michigan, Tennessee, and Texas have adopted some version of this approach. In Tennessee, where this approach was used, a testing rate of 85 percent was reported. Two Canadian provinces using this approach showed a testing rate of 98 percent and 94 percent.

3. **Mandatory newborn screening:** If the mother’s HIV status is unknown at delivery, newborns are tested for maternal HIV-antibody, with or without the mother’s consent. Results must be available within 48 hours of testing. Connecticut and New York have implemented these approaches (in combination with an opt-in approach for pregnant women). In these two states, data indicate that prenatal testing rates rose from 52 percent to 83 percent in a seven-county area of New York, and from 31 percent to 81 percent in Connecticut, during the periods just before and just after implementation of mandatory newborn testing. In 2001, New York reported a statewide prenatal HIV testing rate of 93 percent based on newborn metabolic screening of all live births.
Prenatal HIV Screening

Based on information presented in the MMWR, the available data indicate that both “opt-out” prenatal maternal screening and mandatory newborn screening achieve higher maternal screening rates than “opt-in” prenatal screening. Accordingly, CDC recommends that clinicians routinely screen all pregnant women for HIV infection, using an “opt-out” approach, and that jurisdictions with statutory barriers to such routine prenatal screening consider revising them.

Newborn HIV Screening

In addition, CDC encourages clinicians to test for HIV any newborn whose mother’s HIV status is unknown. Jurisdictions should consider whether a mandatory screening policy for these infants is the best way to achieve such routine screening. Data demonstrate that detection of HIV infection during pregnancy through HIV testing of all pregnant women affords the best opportunity to deliver interventions when they are most efficacious. When intervention does not begin until the intrapartum or neonatal periods, 9 percent to 13 percent transmission rates are achievable based on clinical trial and observational data. Recent experience from the CDC funded Mother-Infant Rapid Intervention at Delivery (MIRIAD) study indicates that HIV rapid testing of women can be done during labor, and that antiretroviral interventions can be quickly delivered to HIV-infected mothers and their infants. Therefore, for those women whose HIV status is unknown at labor, CDC recommends routine, rapid testing. When the mother’s HIV status is unknown prior to the onset of labor and rapid HIV testing is not done during labor, CDC recommends rapid testing of the infant immediately post-partum, so that antiretroviral prophylaxis can be offered to HIV-exposed infants.

The federal Food and Drug Administration has approved three rapid HIV test kits (SUDS Oraquick and Reveal which can be used at delivery. When rapid test results are positive, antiretroviral interventions can be offered to the mother intrapartum and to her infant based on the preliminary results. Confirmatory testing should occur as soon as possible after delivery.

Sincerely,

Julie Louise Gerberding, M.D., M.P.H.
Director

Harold W. Jaffe, M.D.
Director
National Center for HIV, STD, and TB Prevention
References

1 CDC. Revised recommendations for HIV screening of pregnant women. MMWR 2001; 50(RR-19):59-86.
6 CDC. Notice to readers: Approval of new rapid test for HIV antibodies. MMWR 2002; 51:1051-2.
Appendix B

Providing Information to Women in Labor with Unknown HIV Status Regarding Routine, Rapid HIV-1 Antibody Testing (Using an OPT-OUT Approach)

and

Sample Consent for Rapid HIV-1 Antibody Testing in Labor and Delivery Settings for Women with Unknown HIV Status (Using an OPT-IN Approach)
Providing Information to Women in Labor with Unknown HIV Status
Regarding Routine, Rapid HIV-1 Antibody Testing
(Using an OPT-OUT Approach)

Eligibility

Pregnant women in labor and delivery settings who have no documentation of HIV testing on prenatal record or no history of prenatal care.

How to Use This Script:

- The script is meant to be a guide to help you inform women in labor.
  Background information/instructions are in regular type, words you can use are in italics – [italics are hard to read – suggest reworking – perhaps putting them in quotation marks.].
- It is important to show empathy while you are talking with the laboring woman – through your body language and/or through holding her hand /touch.
- Tell the woman she should signal you when a contraction is happening, so you can pause until it is over.
- Pause to verify understanding. Adjust your terminology as needed.
- Tell the woman that the discussion about HIV testing will be kept confidential.

Before discussing HIV testing, ensure that the woman is between contractions, that she is fairly comfortable, and that she is alone (no family member or significant other is present in the room, or within hearing). Tell her that you are going to talk to her about HIV testing, and ask if she wants her partner or family member to be present.

Introduction

You can begin the discussion in the following way:

We recommend HIV testing to all women in labor for whom we don’t have records of an HIV test result during pregnancy. We do this because so much can be done to protect the babies of women living with HIV, and to help women live a healthier, longer life. We have no record that you had an HIV test during this pregnancy.

I have three things I am going to talk to you about:

- A special HIV/AIDS test
- Why this test is important for you and your baby, AND
- What happens when the test result comes back

A special HIV/AIDS test

- It is important for you and your baby that you have a “rapid” HIV test. HIV is the virus that causes AIDS
- This test can give us results quickly
- It is a blood test that we do for all women in labor without results from a prenatal HIV test unless they decline to have the test.
Why the test is important
- Human Immunodeficiency Virus (HIV) is the virus that causes AIDS
- HIV is a serious illness that can affect a woman’s health and her baby’s health.
- One of the ways HIV is spread is by unprotected sex. Therefore, all pregnant women may be at risk for HIV infection.
- HIV can be passed from a mother to her baby during pregnancy, at delivery, and through breastfeeding.
- If you have HIV infection, rapid testing will allow you to get medication during labor and delivery to reduce the risk of passing HIV to your baby.
- Your baby will receive the same medication after birth.
- Without treatment, the chance the baby will be infected is about 25%, or 1 in 4 babies.
- We know if women are given medication during labor and delivery and their babies get the medication right after birth, we can reduce the risk of HIV transmission to about 10%, or about 1 in 10 babies.

What happens when the rapid test result comes back?
- You will receive a preliminary result about an hour after your blood is drawn.
- If the rapid HIV test is negative, no further testing is needed at this time. It is most likely that you do not have HIV. However, the test may not show very recent infection.
- If the rapid test is negative it is OK to breast feed your baby.

If the rapid HIV test is positive
- You likely have HIV infection and your baby may have been exposed to HIV
- The test is a screening test that provides a preliminary result and a false-positive result can happen.
- We always do a second test to confirm rapid tests that are positive
- To be safe, it is best to start medicines to help prevent transmission of HIV to your baby, while we wait for the confirmatory test result
- Experts recommend several medicines to reduce chance your baby will get HIV. One is called AZT and it is given through your IV fluids into your vein. The other is a pill called nevirapine.
- Your doctor will decide which medicines will be best for you and your baby and will discuss them with you before starting them.
- After your baby is born, he/she will start taking AZT syrup.
- These medicines have been studied for in pregnant women and newborns and there have been no serious side effects.
- Side effects that may occur with AZT are: vomiting, headache, feeling tired, anemia (low red blood cell numbers), decreased number of white blood cells, that fight infection, loss of appetite, heartburn, trouble sleeping. Side effects of nevirapine can be skin reactions or problems with the liver.
- You should wait until we have the results of the confirmatory test before you start breastfeeding

If the confirmatory test is negative
- You and your baby will immediately be taken off any medication that was started

If the test is confirmed as positive
- All medication that was started to help prevent HIV transmission will continue.
- If treatment is started, a doctor or nurse will discuss again any consequences of taking the medication.
- Your baby will need more testing for HIV infection.
- You will be referred to a physician for your own medical care—there are also medications to help keep you healthy longer. You will also be referred to a health care provider who will take care of your baby’s medical needs.
- HIV test results are confidential. There are laws to protect people with HIV from discrimination.
Conduct rapid HIV testing and document the result clearly in the medical record.

If the woman declines HIV testing, probe for her reasons and help her address her concerns. If she still declines testing, document her refusal clearly in the medical record and communicate to her baby’s pediatrician that her HIV status is unknown.
Sample Consent for Rapid HIV-1 Antibody Testing in Labor and Delivery Settings for Women with Unknown HIV Status (Using an OPT-IN Approach)

This is a sample consent form (OPT-IN) from the Francois Xavier Bagnoud Center for use in New Jersey. Recognizing that a number of jurisdictions may still require written, signed informed consent for HIV testing (an OPT-IN approach), this sample informed consent document may be useful during the transition to a more routine (OPT-OUT) approach to HIV testing in labor and delivery.

Introduction

New Jersey law mandates that all pregnant women be counseled about HIV infection and be offered the HIV/AIDS test. In our hospital, we follow this recommendation because so much can be done to protect the baby.

I have four things I am going to talk to you about
- A special HIV/AIDS test
- Why this test is important for you and your baby
- How HIV is transmitted
- What happens when the test result comes back

A special HIV/AIDS test
- It is important for you and your baby that we offer you what is called a “rapid” HIV test. Human Immunodeficiency Virus (HIV) is the virus that causes AIDS.
- This test can give us results quickly.
- It is a blood test. It is voluntary, and your consent is required before the test can be done.

Why the test is important
- HIV can be passed from a mother to her baby during pregnancy, at delivery, and through breastfeeding.
- If you have HIV infection, rapid testing will allow you to get medication during labor and delivery to reduce the risk of passing HIV to your baby.
- Your baby will receive the same medication after birth.
- Without treatment, the chance the baby will be infected is about 25%, or 1 in 4 babies.
- We know if women are given medication during labor and delivery and their babies get the medication right after birth, we can reduce the risk of HIV transmission to about 10%, or about 1 in 10 babies.

What is HIV and how is it transmitted?
- HIV is the virus that causes AIDS.
- HIV is a **serious** illness that can affect a woman’s health and her baby’s health.
- One of the ways HIV is spread is by unprotected sexual intercourse. Therefore, **all** pregnant women may be at risk for HIV infection.
- HIV can be passed from a mother to her baby during pregnancy, at delivery, and through breastfeeding.

**What happens when the rapid test result comes back?**
- You will receive a **preliminary** result about an hour after your blood is drawn.
- If the rapid HIV test is **negative**, no further testing is needed at this time. It **most likely means** that you do not have HIV. However, the test may **not** show recent infection.
- If the rapid test is negative it is OK to breast feed your baby.

**If the rapid HIV test is positive**
- You **likely** have HIV infection and your baby **may** have been exposed to HIV.
- The test is a **screening** test that provides a preliminary result. A false-positive result can happen.
- We always do a second test to confirm rapid tests that are positive.
- **But if your test result is positive, it is be best** to start treatment to help prevent transmission of HIV to your baby, while we wait for the confirmatory test result.
- We will need your permission to start medications if the preliminary test is positive.
- Experts recommend several medicines to reduce the chance your baby will get HIV. One is called AZT. We give it to you in your IV fluids through your vein. The other is a pill called nevirapine.
- Your doctor will decide which medicines will be best for you and your baby.
- After your baby is born, he/she will start taking AZT syrup.
- These medicines have been studied in pregnant women and newborns and there have been no serious side effects.
- Side effects that may occur with AZT are vomiting, headache, feeling tired, anemia (low red blood cell numbers), decreased number of white blood cells that fight infection, loss of appetite, heartburn, trouble sleeping. Side effects of nevirapine can be skin reactions or problems with the liver.
- You should **wait** until we have the results of the confirmatory test before you start breastfeeding.

**If the confirmatory test is negative**
- *You and your baby will immediately be taken off any medication that was started.*
If the test is confirmed as positive

- All medication that was started to help prevent HIV transmission will continue.
- If treatment is started, a doctor or nurse will discuss with you again any consequences of taking the medication.
- Your baby will need more testing for HIV infection.
- You will be referred to a physician for your on-going medical care. You will also be referred to a health care provider who will take care of your baby’s medical needs.
- HIV test results are confidential. There are laws to protect the rights of people with HIV and prevent discrimination.

Sample Informed Consent Form

Please sign your name below once you have read (or have had explained to you) and understand:

1. Antiretroviral medication may reduce the risk of HIV transmission to my baby and this medication will be started if my preliminary HIV test result is positive.
2. A positive preliminary test will be confirmed with additional testing.
3. Refusing to be tested will not jeopardize my ongoing care or services.
4. I have been given written information about everything told to me.

☐ I consent to be tested for HIV infection using a rapid test

☐ If my preliminary HIV test is positive, I consent to have antiretroviral medication started during labor and for my baby after birth

☐ I decline to have rapid HIV testing at this time.

Name_________________________________________    Signature__________________________________________

(PRINT)

Date__________________________________________    Witness____________________________________________

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Appendix C

The François-Xavier Bagnoud Center’s Formula for Offering Routine, Rapid HIV Testing to Women in Labor with Unknown HIV Status
The François-Xavier Bagnoud Center’s Formula for Offering Routine, Rapid HIV Testing to Women in Labor with Unknown HIV Status

(Based on the mnemonic “C³R³”)

The three Cs represent confidentiality, comfort, and consent. The three Rs are reasons for the rapid test, results, and “Rx” for treatment, or medications to reduce mother to child transmission.

C³

- **Confidentiality**: It is important to reassure the woman that the discussion about HIV testing will be kept confidential and that the information will not be shared with her partner or family without her permission.
- **Comfort**: The clinician should assess the woman’s stage of labor, comfort level, and need for analgesics. Providers need to show empathy while presenting information about rapid HIV testing. The content covered should be short and to the point and should be explained between contractions. The clinician should ask the woman to signal for a pause when a contraction is starting. The clinician should always consider the woman’s language and culture and, as needed, must adjust the terminology used. The clinician should make sure that the woman being counseled understands the content being covered by checking after each point is made and before beginning the next point to be sure she understands.
- **Consent** for testing and for antiretroviral treatment, if needed, in labor: Regulations, laws, and policies about HIV testing of pregnant women vary from state to state. Providers need to know and need to follow the laws and policies of their state. The minimum content that should be included in educating a pregnant woman about HIV rapid testing during labor is detailed next under *Reasons to test*.

R³

**Reasons to test**: The woman should be informed of the important reasons to get an HIV test during labor, and the crucial opportunity to prevent possible transmission of the virus to her unborn baby should be emphasized:

- HIV is the virus that causes AIDS. One of the ways HIV is spread is by unprotected sexual intercourse. Therefore, all pregnant women are at risk for HIV infection.
- A woman could be at risk for HIV and not know that she is at risk.
- The HIV virus can be passed from a mother to her baby during pregnancy, at delivery, and through breastfeeding.
- Learning that a woman has an HIV infection while she is still in labor gives her a crucial opportunity to reduce the risk of transmitting HIV to her infant; and, just as importantly, having this knowledge also ensures that both she and her baby receive the care and the treatment they need.
- HIV testing is recommended for all pregnant women. Hospital/national policy (and/or state law) recommends HIV testing for all women in labor with unknown HIV status.
- Unless the woman refuses to be tested, our hospital routinely does rapid HIV testing for all women in labor who don’t already have an HIV test result in their medical record.

**Results**

- If she is tested for HIV during labor, a woman should be told when she will receive her test results.
- A negative HIV test result means a woman almost certainly does not have HIV infection at this time. A positive HIV test result means a woman likely has HIV infection even if she is feeling well. Further testing will be done after she delivers to confirm if she has HIV infection.
- A woman should be asked who she wants to be present when she receives her rapid HIV test result.

**Rx – Medications**

- Medications can reduce the risk of transmission of HIV to the baby. Without medication, the chance the baby will be infected is about 25%—or about 1 baby in 4 births could be infected with HIV. With the medications given to the woman during labor and to the newborn, the risk of HIV transmission can be reduced to about 10— or to about 1 baby out of 10 births.
- If a woman is found to have HIV infection, treatment is available to help keep her well.
- Any medication will be stopped if the confirmatory HIV test result is negative.
Appendix D

Boxed Case Studies:

Development of a Statewide Standard of Care: The New Jersey Experience

and

A Review of the Implementation of Perinatal HIV Rapid Testing
Medical Center Of Louisiana, New Orleans
New Jersey is a high prevalence state for HIV disease, ranked fifth in the country in cumulative reported AIDS cases, third in the country in cumulative reported pediatric AIDS cases, and first in the country in the proportion of women among reported cumulative AIDS cases. Ninety-four percent of the pediatric AIDS and HIV cases are attributed to perinatal transmission.

The approach taken by the New Jersey Department of Health and Senior Services (NJDHSS) was to conduct a needs assessment to determine the major missed opportunity to reduce vertical transmission, develop a the standard of care in collaboration with stakeholders with consensus facilitated by meeting with stakeholders individually (i.e. meetings with the obstetrical society), dissemination of information, and evaluation of implementation and effectiveness.

**Needs Assessment**

The need for a statewide standard of care for women who present in labor with the delivery team unaware of her HIV status was determined based on several factors. These include
1) A review of missed opportunities that indicated that currently the major barrier to maximal reduction of vertical HIV transmission in New Jersey is women who present in labor with unknown HIV status;
2) Advances in HIV diagnostic testing technology and medical management that led to recent national recommendations that women who present in labor with unknown HIV status should receive counseling, be offered rapid HIV diagnostic testing, and, if HIV positive, be offered short course therapy;
3) Results of a study that was conducted in the highest risk areas in New Jersey that determined that none of the hospitals providing obstetrical care had policies, procedures, or laboratory capability to provide counseling and offer rapid testing and short course therapy; and
4) Meetings with two ad hoc advisory committees of stakeholders.

**Working with Stakeholders**

- Two ad hoc advisory committees were developed and met to 1) determine if a statewide approach was appropriate and 2) to develop the prototype policy and algorithm that facilities providing obstetrical care could implement for women who present in labor with unknown HIV serostatus.

- One ad hoc advisory committee consisted of stakeholders responsible for writing and implementing the Standard of Care. This ad hoc advisory committee included representatives from the New Jersey Department of Health and Senior Services (Division of AIDS Prevention and Control and the Division of Family Health Services), obstetricians, pediatricians, Title IV providers, the New Jersey Family-Centered HIV Care Network, case managers, social workers, consumers, maternal and child health consortia, infection control professionals, the Academy of Medicine of New Jersey, the AIDS Education and Training Center, and Medicaid. This committee met three times. The unanimous decision was that a statewide Standard of Care was the best approach to take in New Jersey. The committee felt that the NJDHSS should be the lead on developing, disseminating, and evaluating the Standard of Care. In the fall of 2001, the NJDHSS approved the draft of the Standard of Care for Women Who Present in Labor With Unknown HIV Status, which was written with the ad hoc advisory committee.
• The second ad hoc advisory committee consisted of stakeholders responsible for facilitating implementation of the Standard of Care. This ad hoc advisory committee included representatives from the New Jersey Department of Health and Senior Services (Division of AIDS Prevention and Control and the Division of Family Health Services), the Medical Society of New Jersey, all three hospital associations in New Jersey, the Infectious Diseases Society of New Jersey, the New Jersey Association of Osteopathic Physicians and Surgeons, New Jersey Section of the American College of Obstetrics and Gynecology, the New Jersey Obstetrical and Gynecology Society, the New Jersey Section of the American Academy of Pediatrics, the New Jersey Academy of Family Physicians, pediatric and obstetrical providers with a high-volume client load. This committee met once and provided written comments on the draft Standard of Care. They concurred with the other committee that NJDHSS should take the lead on developing, disseminating, and evaluating the Standard of Care. The unanimous decision was that a statewide Standard of Care was the best approach to take in New Jersey.

• Individual meetings were held with some key organizations such as the New Jersey Obstetrical and Gynecology Society, the Infectious Diseases Society of New Jersey, Medicaid, the NJDHSS Laboratory Task Force, and the Association for Professionals in Infection Control and Epidemiology.

• A one-on-one meeting was held with a high-volume facility in a high-prevalence area to help ascertain the potential barriers to implementing a statewide Standard of Care.

• Support for the statewide Standard of Care was obtained from the Governor’s Advisory Council on AIDS.

Identification and Overcoming Barriers
Several barriers were encountered in implementation of the standard of care. The first barrier was that the advisory committee members did not have enough information on rapid testing. To overcome this obstacle, a half-day continuing medical education conference with a didactic lecture on rapid testing by Dr. Bernard Branson from CDC and case studies of women who presented in labor with unknown HIV status preceded the advisory committee meeting. The committee then felt that they had enough information on rapid testing to proceed with development of the standard of care.

The second barrier was that providers were uncertain about the content of counseling for women in labor. To overcome this, a template counseling session was developed with assistance from focus groups composed of postpartum women. The template counseling session was disseminated statewide through five train-the-train sessions conducted in collaboration with all the local maternal-child health consortia.

The third barrier identified was that hospital laboratory directors were under the misimpression that preliminary positive rapid or expedited test results could not be given to the providers and patients. To overcome this, a fact sheet on rapid testing was sent to each hospital with other information related to the standard of care, information was provided in a series of lectures given statewide, and an article was published in New Jersey Medicine.

The fourth barrier was that some hospitals requested a template policy to use. This was provided to them.
Dissemination of the Statewide Standard of Care
A multimedia comprehensive approach is underway to disseminate the Standard of Care. This consists of free Internet-based continuing medical education (available at www.acadmed.org), publication of articles in New Jersey Medicine, publication of articles in AIDSLine, a laminated pocket card for providers, poster presentations, train-the-trainer sessions, and continuing medical education lectures statewide. A mailing was sent to the chair of pediatrics, the chair of obstetrics, the laboratory director, the infection control professional, the chief executive officer, the medical director, the head nurse for labor and delivery, the executive committee, the vice-president of risk management, and the emergency room director of each hospital. The information packet included a cover letter from the Deputy Commissioner, the Standard of Care, the laboratory alert, the laboratory algorithm, and information on continuing medical education and train-the-trainer sessions.

Evaluation
Evaluation will be conducted to look at process measures and outcome measures.
- Repeat the hospital survey to determine if the Standard of Care has been incorporated into hospital policies and procedures and identify barriers to its implementation
- Retrospective medical record review to evaluate the implementation and effectiveness of the Standard of Care
- Continuous evaluation of efforts to reduce vertical transmission through surveillance, survey for childbearing women, and special studies.

Funding
Funding to develop, disseminate, and evaluate the Standard of Care came from state and federal funds. These funds allowed NJDHSS to contract with the National Pediatric and Family HIV Resource Center to help develop the counseling session, conduct the train-the-trainer sessions, provide three of the continuing medical education programs, and evaluate the implementation and effectiveness of the Standard of Care.
This is a summary of the initial clinical experience with the SUDS assay, for obstetric rapid testing, at the Medical Center of Louisiana.

In October of 1998, the Medical Center of Louisiana, New Orleans (formerly Charity Hospital), initiated rapid HIV-1 screening for obstetric patients admitted to the labor and delivery unit without prior documentation of HIV status. This program was approved by the Hospital Executive Committee and was established in conjunction with the use of rapid screening for employee occupational exposures. The program was developed by the hospital’s Infection Control Division to address disease prevention and health care delivery needs of a subgroup of obstetric patients shown to have a two- to threefold greater HIV seroprevalence as compared with patients receiving obstetric prenatal care in the hospital’s clinics. As a standard of care, all obstetric patients presenting to the labor and delivery unit with an undocumented HIV serostatus are offered voluntary HIV testing. Patients at risk for delivery prior to the completion of conventional HIV testing were offered initial screening with the FDA-licensed Single-Use Diagnostic System Test (SUDS), a rapid enzyme-linked immunosorbent assay (EIA). Patient acceptance of HIV testing was documented with written informed consent based on hospital policy and standards of care and in accordance with State guidelines for HIV testing at public facilities. Request for SUDS testing are submitted via the computer laboratory entry system. Patients consenting for screening were tested concurrently with a conventional HIV EIA and the SUDS HIV-1 rapid assay. SUDS assay determinations were conducted in the hospital blood bank laboratory service. This laboratory resource was selected based on the presence of adequate technical staff on a 24-hour basis. A confirmatory Western blot was used to document a true positive HIV result. The results of the SUDS test are reported electronically via the computerized laboratory inquiry system and are read out as SUDS reactive or non-reactive, and patients are informed of their SUDS test result by their treating physician.

Patients with a positive SUDS test result were counseled by their treating physician about the implications of the presumptive HIV positive status and were counseled about options for intervention to reduce vertical transmission of HIV. Laboring patients were administered peripartum antiretroviral prophylaxis consistent with the Public Health Service (PHS) guidelines. Infants delivered to mothers with positive SUDS tests were considered HIV exposed and initiated postpartum antiretroviral prophylaxis consistent with the PHS guidelines. When conventional HIV test results were discordant with the SUDS test and failed to confirm infection, the newborn prophylaxis was discontinued. All mothers with a confirmed HIV infection and their HIV-exposed infants were referred for HIV primary care follow-up at time of hospital discharge. The results of all obstetric patients who underwent both conventional and rapid HIV testing were recorded in the Office of Hospital of Infection Control’s database.

Initial laboratory implementation and training was accomplished over several months. Blood bank technologists participated in a half-day “hands on” training session conducted by a SUDS vendor representative. Validation testing was conducted on site at the Medical Center of Louisiana, New Orleans Blood Bank Laboratory. The validation laboratory protocol required running 100
“unknown” serum samples with positive and negative controls. Compliance with accreditation guidelines required an evaluation of the new testing program with a proficiency testing survey. Subscription to the Wisconsin State Lab of Hygiene HIV Survey for HIV-1/2, formerly the Health Care Financing Administration (now called Centers for Medicare and Medicaid Services) approved and vendor recommended, was acquired to meet these requirements. The initial implementation cost of the hospital program for SUDS testing was approximately $2,000.

An examination of the Hospital’s perinatal HIV rapid testing program through the first 12 months demonstrated a SUDS test performance with a sensitivity and specificity of 100% and 99.2%, and positive and negative predictive value of 79% and 100%, respectively. The overall seroprevalence in the tested population was 2.9%. The positive predictive value of the SUDS assay was highest among laboring women with inadequate prenatal care and an undocumented HIV status, which represented the highest seroprevalence group (>5%).

An evaluation of the initial clinical experience with perinatal HIV rapid testing demonstrated that nearly 20% of the HIV exposed births at the facility were identified through rapid testing. The majority of these mothers had inadequate or absent prenatal care. All SUDS positive laboring mothers with a subsequent confirmed positive HIV status had evidence of advance labor or rupture of membranes at admission. All of these mothers had inadequate prenatal care. Of note upon review of medical records, it was determined that as many as 50% these mothers had evidence of a positive HIV test prior to the current pregnancy, but did not disclose their HIV status to their treating physician at time of presentation. Intrapartum antiretroviral prophylaxis was successfully initiated in the majority of these mothers, and newborn prophylaxis was initiated for all infants prior to hospital discharge. All infants entered HIV primary care follow-up post hospital discharge. A preliminary assessment of a small number of HIV-exposed infants identified with HIV rapid testing demonstrated significantly reduced transmission rate in contrast to that expected among HIV-exposed infants without peripartum antiretroviral prophylaxis.

This medical center’s experience highlights the capacity to effectively develop and implement targeted strategies for perinatal HIV rapid testing in a high-seroprevalence, obstetric population, and the potential impact of similar public health measures/interventions to reduce mother-to-child HIV transmission among childbearing women with an undocumented HIV status and poor prenatal care.
NOTICE: The project that is the subject of this report was approved by the Governing Board of the National Research Council, whose members are drawn from the councils of the National Academy of Sciences, the National Academy of Engineering, and the Institute of Medicine. The members of the committee responsible for the report were chosen for their special competences and with regard for appropriate balance.

The Institute of Medicine was chartered in 1970 by the National Academy of Sciences to enlist distinguished members of the appropriate professions in the examination of policy matters pertaining to the health of the public. In this, the Institute acts under the Academy’s 1863 congressional charter responsibility to be an adviser to the federal government and its own initiative in identifying issues of medical care, research, and education. Dr. Kenneth I. Shine is president of the Institute of Medicine.

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The serpent has been a symbol of long life, healing, and knowledge among almost all cultures and religions since the beginning of recorded history. The image adopted as a logotype by the Institute of Medicine is based on a relief carving from ancient Greece, now held by the Staatliche Museen in Berlin.

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Preface

The 1994 results of the AIDS Clinical Trials Group protocol number 076 (ACTG 076)--showing that the transmission of HIV from mothers to their children could be substantially reduced through the use of zidovudine (ZDV) by the mother during pregnancy and labor and in the newborn--represented one of the most important successes in the fight against AIDS. These findings led government agencies and professional organizations to propose and implement recommendations calling for counseling and testing all pregnant women for HIV, mostly on a voluntary basis. And as indicated in this report, this approach has been substantially successful. Yet despite the progress, more children than necessary continue to be born with HIV infection.

In response to a congressional mandate to "conduct an evaluation of the extent to which State efforts have been effective in reducing the perinatal transmission of the human immunodeficiency virus, and an analysis of the existing barriers to the further reduction in such transmission," this report addresses ways to increase prenatal testing, improve therapy for HIV-infected women and children, and generally reduce perinatal HIV infections. The report also considers the ethical and public health issues associated with screening policies as prevention tools, and their implications for prevention and treatment opportunities for women and infants.

The committee recognizes that screening and treating pregnant women is but one strategy among many to prevent perinatal transmission of HIV. The Institute of Medicine (IOM) has dealt with many issues in the primary prevention of HIV, as referenced in this report. The committee also emphasizes the connection between substance abuse and HIV infection in women as a factor in the perinatal transmission of HIV. More specific recommendations about the prevention and treatment of substance abuse are beyond the scope of this report. Likewise, one strategy for reducing perinatal transmission is to reduce the number of HIV-infected women who become pregnant unintentionally. The consequences and prevention of unintended pregnancy have also been examined recently by the IOM (IOM, 1995b). However, improved planning of pregnancy among HIV-infected women assumes that women know their HIV status. For many women, especially low income women, pregnancy may be a major opportunity for contact with the health care system. Thus access to care, the potential for ready implementation of screening along with other prenatal testing, and the availability of therapy to improve the outcomes of both mothers and infants in the face of HIV infection, all have led the committee to focus on this episode of care.

There are three additional issues related to HIV testing and perinatal transmission that are outside the committee's charge, and hence not dealt with in this report, except as they relate to preventing perinatal transmission. First, mandatory newborn testing, which is the law in New York State (see Appendixes C and L), and which could be the result of the
Ryan White Comprehensive AIDS Resources Emergency (CARE) Act Amendments of 1996, has limited utility in preventing perinatal transmission of HIV. While there may be some benefits to the HIV-infected children that would otherwise not be identified (as discussed in Chapter 4), the public health goals behind newborn testing can be better served by improved efforts to prevent transmission, as outlined in this report.

Second, perinatal transmission of HIV is a major concern in many developing countries that do not have the resources to implement the ACTG 076 regimen. To address this, there have been efforts to test less expensive approaches through randomized trials in the affected countries, and these trials have been criticized on ethical grounds (Lurie and Wolfe, 1997). Because this issue is outside the committee's charge, which relates to preventing perinatal transmission in the United States, the committee has not addressed this issue.

Third, a number of states have recently instituted a policy of named HIV reporting, and others are considering doing the same. Although this approach has important surveillance benefits, it has been criticized on human rights grounds (Gostin et al., 1997; ACLU, 1997). Since it is not clear that instituting this policy has any impact on women's willingness to be tested as a routine part of prenatal care, the committee takes no position on named HIV reporting.

To carry out this report, the Institute of Medicine established a committee of 13 individuals, with expertise in pediatrics, obstetrics and gynecology, preventive medicine, women's health, and other relevant medical specialties; social and behavioral sciences; public health practice; epidemiology; program evaluation; health services research; bioethics; and public health law. In keeping with IOM policies, the committee members were chosen to encompass a variety of different perspective and areas of expertise on the issues. The committee met on five occasions between December 1997 and June 1998, sponsored two workshops, conducted five site visits, and commissioned a series of papers, as described in Chapter 1.

The committee was aided in its work by a liaison panel of 19 individuals representing federal agencies, professional organizations, and other groups interested and knowledgeable about perinatal transmission of HIV. The liaison panel members and their affiliations are listed after the committee members on pages v and vi. The liaison panel members participated in the first committee meeting and two workshops, contributed information to the committee, and had an opportunity to review and comment on the workshop summaries and site visit reports. The liaison panel members did not, however, contribute to or review the committee's conclusions and recommendations. The committee is very grateful for the information and ideas that the liaison panel members contributed to this project.

This report has been reviewed in draft form by individuals chosen for their diverse perspectives and technical expertise, in accordance with procedures approved by the National Research Council's (NRC) Report Review committee. The purpose of this independent review is to provide candid and critical comments that will assist the
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Marie C. McCormick
Chair
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One of the most promising victories in the battle against AIDS was the finding, in 1994, that administration of the antiretroviral drug zidovudine (known as ZDV, and previously as AZT) during pregnancy and childbirth could reduce the chance that the child of an HIV-positive mother would be infected by about two-thirds (Connor et al., 1994). The "ACTG 076 results," referring to the AIDS Clinical Trials Group protocol number 76, quickly led the Public Health Service (PHS) to develop guidelines about counseling and testing of pregnant women for HIV infection (CDC, 1995b).

The 1995 PHS guidelines called for counseling all pregnant women about the risk of AIDS, the benefits of HIV testing, and voluntary testing. The approach was endorsed by the American College of Obstetricians and Gynecologists, the American Academy of Pediatrics, and other professional groups. The essence of the PHS guidelines also has been adopted by most states, either by policy or by legislation. Medical practice has changed in line with these recommendations, with an increasing proportion of women tested for HIV during prenatal care. As a result of these and other changes, there has been a substantial reduction--approximately 43% from a peak in 1992 to 1996--in the number of newborns diagnosed with AIDS. A reduction of this magnitude in only a few years certainly represents great progress, yet it is far less than the ACTG 076 findings can offer.
Two years after the publication of the ACTG 076 findings, Congress addressed perinatal transmission issues in the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act Amendments of 1996 (P.L. 104-146). Depending on a determination by the Secretary of Health and Human Services about these practices, Ryan White CARE Act formula funds to the states could become contingent upon mandatory HIV testing of newborns.

P.L. 104-146 also calls on the Institute of Medicine (IOM) to "conduct an evaluation of the extent to which State efforts have been effective in reducing the perinatal transmission of the human immunodeficiency virus, and an analysis of the existing barriers to the further reduction in such transmission." In its analysis, the committee has found it helpful to consider a chain of factors affecting perinatal transmission, as illustrated in Figure 1.

The proportion of women . . .

* who are HIV-infected
* who become pregnant
* who do not seek prenatal care
* who are not offered HIV testing
* who refuse HIV testing
* who are not offered the ACTG 076 regimen
* who refuse the ACTG 076 regimen
* who do not complete the ACTG 076 regimen
* whose child is infected despite treatment

FIGURE 1 Chain of events leading to an HIV-infected child.

PUBLIC HEALTH SCREENING PROGRAMS

Disease screening is one of the most basic tools of modern public health and preventive medicine. As screening programs have been implemented over the years, a substantial body of experience has been gained. In practice, when screening is conducted
in contexts of gender inequality, racial discrimination, sexual taboos, and poverty, these conditions shape the attitudes and beliefs of health system and public health decision makers as well as patients, including those who have lost confidence that the health care system will treat them fairly. Thus, if screening programs are poorly conceived, organized, or implemented, they may lead to interventions of questionable merit and enhance the vulnerability of groups and individuals. Through the experience with public health screening programs, a series of characteristics of well-organized public health screening programs has evolved (Wilson and Jungner, 1968).

The committee's summary of the relevant characteristics is as follows:

1. The goals of the screening program should be clearly specified and shown to be achievable.
2. The natural history of the condition should be adequately understood, and treatment or intervention for those found positive widely accepted by the scientific and medical community, with evidence that early intervention improves health outcomes.
3. The screening test or measurement should distinguish those individuals who are likely to have the condition from those who are unlikely to have it.
4. There should be adequate facilities for diagnosis and resources for treatment for all who are found to have the condition, as well as agreement as to who will treat them.
5. The test and possible interventions should be acceptable to the affected population.

**DESCRIPTIVE EPIDEMIOLOGY OF THE PERINATAL TRANSMISSION OF HIV**

In 1997, women accounted for 21% of AIDS cases in adults, and the proportion of all cases that are among females continues to grow. At least two-thirds of AIDS in women can be attributed to injection drug use either directly or through sex with drug users. Although a subset of women with HIV have injected drugs or have had sex with a known injection drug user, an increasing proportion of women have become infected through sexual activity with men whose risk behaviors were unknown to them. AIDS is more prevalent in African-American and Hispanic women, in women in the Northeast and the South, and in women in large cities. Approximately 6,000 to 7,000 HIV-infected women give birth every year. Trend data show a relatively steady national rate of HIV prevalence in childbearing women between 1989 and 1994, the last year for which data are available.

Perinatal transmission accounted for at least 432 AIDS cases in the United States in 1997. The number of perinatally acquired AIDS cases rose rapidly in the late 1980s and early 1990s, peaked around 1992, and subsequently declined by approximately 43% by 1996. Such data on perinatal AIDS cases reflect the number of children born with HIV infection in previous years, and more recent data are not available because of reporting delays. Changes in the number of perinatal AIDS cases, therefore, are not direct estimates of the impact of prevention activities on perinatal transmission of HIV.
Pediatrics AIDS cases are concentrated in eastern states, and especially in the New York metropolitan area. In 1996, three states alone—New York, New Jersey, and Florida—reported 330 cases. This represents 49% of the diagnosed cases, even though only 15% of children are born in those states (CDC, 1996b; Ventura et al., 1998). In contrast to the concentration of perinatal AIDS cases in the Northeast, they are far less common in most geographical areas. In 1997, 39 states had fewer than ten perinatally transmitted AIDS cases (CDC, 1997c).

NATURAL HISTORY, DETECTION, AND TREATMENT OF HIV INFECTION IN PREGNANT WOMEN AND NEWBORNS

Perinatal transmission can occur antepartum (during pregnancy), intrapartum (during labor and delivery), and postpartum (after birth), but most mother-to-infant transmission appears to occur intrapartum. The ACTG 076 protocol showed that antiretroviral therapy could reduce perinatal transmission to 8% in some populations (Connor et al., 1994), and subsequent studies have suggested that rates of 5% or lower are possible.

To maximize prevention efforts, women must be identified as HIV-infected as early as possible during pregnancy. Early diagnosis of HIV infection allows the mother to institute effective antiretroviral therapy for her own health. This treatment is also capable of significantly reducing perinatal transmission. HIV-infected pregnant women can also be referred to appropriate psychological, social, legal, and substance abuse services. Babies born to HIV-positive mothers can be started on ZDV within hours of birth, as in the ACTG 076 regimen. Mothers who know they are HIV-positive can be counseled not to breast-feed their infants.

In terms of preventing perinatal transmission, newborn HIV testing has fewer benefits than maternal testing. When maternal serostatus is unknown, however, newborn HIV testing permits early identification and evaluation of exposed infants, allows for initiation of *Pneumocystis carinii* pneumonia (PCP) prophylaxis in the first months of life to prevent life-threatening bouts of PCP infection, may prevent transmission through breast-feeding or in future pregnancies, and could lead to mothers being treated for their own infection.

THE CONTEXT OF SERVICES FOR WOMEN AND CHILDREN AFFECTED BY HIV/AIDS

Women and children in the United States, including those at risk for or with HIV/AIDS, receive their health care from a variety of sources. Their care is financed by a mixture of public and/or private insurance and public funds. Its content and quality are influenced by public and professional organizations. Its oversight and regulation are achieved through a combination of national, state, and local authorities. Major modifications in Medicaid and welfare programs, the increasing number of uninsured, and the growing presence of managed care in both the public and the private sectors, are having a significant impact on the health care system, affecting not only the availability of quality services, but access to those services as well.
The federal government, with support from state and sometimes local governments, as well as foundations, charitable agencies, and other groups, has established special programs to provide HIV- and AIDS-related care to women and children. All states and territories have an AIDS program funded by the Centers for Disease Control and Prevention (CDC) and Health Resources and Services Administration (HRSA). Moreover, an array of federal, state, and local laws, regulations, policies, institutions, and financing mechanisms shapes the services in any given locality and determines who has access to those services.

The complex patterns of medical care, financing mechanisms, program authority, and organizations that influence care make it difficult to institute uniform policies for reducing perinatal HIV transmission. In addition, the multiple lines of funding responsibility and accountability have made it extremely difficult to educate providers and convince them of the necessity of testing all pregnant women, as called for in the PHS counseling and testing guidelines (CDC, 1995b).

The resulting structure of the health care system presents a number of barriers to the treatment of HIV-positive women, which include--using the prevention chain as a framework--

- financial and access barriers that may discourage women from seeking prenatal care,
- time constraints that may discourage physicians from counseling pregnant patients about the importance of testing,
- prenatal care sites that may not have the staff to overcome the language and cultural barriers that may cause women to refuse testing, and
- financial and logistical problems that may make testing and treatment difficult.

IMPLEMENTATION AND IMPACT OF THE PUBLIC HEALTH SERVICE COUNSELING AND TESTING GUIDELINES

Since the publication of the ACTG 076 findings in 1994, there has been a concerted national effort to bring the benefits of HIV testing and appropriate treatment to as many women and children as possible. Reviewing the results of these efforts, the committee must make a qualified response to its congressional charge to assess "the extent to which state efforts have been effective in reducing the perinatal transmission of HIV." The committee interprets this charge to include the efforts of national as well as state and local health agencies, and professional organizations at both levels. The data reviewed indicate that, on the whole,

1. there have been substantial public and private efforts to implement the PHS recommendations,
2. prenatal care providers are more likely now than in the past to counsel their patients about HIV and the benefits of ZDV and to offer and recommend HIV tests,
3. women are more likely to accept HIV testing and ZDV if indicated, and
4. there has been a large reduction in perinatally transmitted cases of AIDS.

The number of children born with HIV, however, continues to be far above what is potentially achievable, so much more remains to be done. There is substantial variability from state to state in the way that the PHS guidelines have been implemented, but no evidence to suggest that any particular approach is more successful than others in preventing perinatal HIV.

**RECOMMENDATIONS**

**Universal HIV Testing, with Patient Notification, as a Routine Component of Prenatal Care**

To meet the goal that all pregnant women be tested for HIV as early in pregnancy as possible, and those who are positive remain in care so that they can receive optimal treatment for themselves and their children, the committee's central recommendation is for the adoption of a national policy of universal HIV testing, with patient notification, as a routine component of prenatal care.

There are two key elements to the committee's recommendation. The first is that HIV screening should be *routine with notification*. This means that the test for HIV would be integrated into the standard battery of prenatal tests and women would be informed that the HIV test is being conducted and of their right to refuse it. This element addresses the doctor—patient relationship, and can reduce barriers to patient acceptance of HIV testing. Most importantly, this approach preserves the right of the woman to refuse the test. If it is followed, women would not have to deal with the burden of disclosing personal risks or potential stereotyping; the test would simply be a part of prenatal care that is the same for everyone. Routine testing will also reduce burdens on providers such as the need for costly extensive pretest counseling and having discussions about personal risks that many providers think are embarrassing. A policy of routine testing might also help to reduce physicians' risk of liability to women and children, where providers incorrectly guess that a woman is not at risk for HIV infection.

The second key element to the recommendation is that screening should be *universal*, meaning that it applies to all pregnant women, regardless of their risk factors and of prevalence rates where they live. The benefit of universal screening is that it ameliorates the stigma associated with being "singled out" for testing, and it overcomes the problem that many HIV-infected women are missed when a risk-based or prevalence-based testing strategy is employed (Barbacci et al., 1991).

Making prenatal HIV testing universal also has broad social implications. First, if incorporated into standard prenatal testing procedures, the costs of universal HIV screening are low, and the benefits are high. Assuming that the marginal cost of adding an ELISA test to the current prenatal panel is $3 per woman and the prevalence of HIV in pregnant women is 2 per 10,000, the committee's calculations in Appendix K show that the cost of routine prenatal testing is $15,600 per HIV-positive woman found. Even if the
Cost of the test is $5 and the prevalence 1 per 10,000, the cost per case found is $51,100. Taken in the context of the cost of caring for an HIV-infected child, even though not all women found to be HIV-positive will benefit, these figures indicate the clear benefits of routine prenatal HIV testing.

Second, universal screening is the only way to deal with possible geographic shifts in the epidemiology of perinatal transmission. Although perinatal AIDS cases are currently concentrated in eastern states, particularly New York, New Jersey, and Florida, there have been shifts in the prevalence of HIV in pregnant women, including an increase in the South in the early 1990s. Changes in the regional demographics of drug use can also lead to changes in the distribution of HIV infection in pregnant women. Given the uncertainty of these trends, the committee considered universal testing the most prudent method to reduce perinatal transmission despite possible regional fluctuations.

Third, it would help to reduce stigmatization of groups by calling attention to a communicable disease that does not have inherent geographic barriers or a genetic predisposition. Focusing on the communicable disease aspect may allow national education programs that would otherwise be difficult, discouraging infected individuals from hiding themselves and thus not benefiting from care, and discouraging a "blame the victim" mentality.

Incorporating Universal, Routine HIV Testing into Prenatal Care

The following changes in health systems and public policy are needed by state health departments, health systems, and professional organizations to bring about the major change called for in the committee's central recommendation. The committee believes it is also important that these approaches be evaluated carefully, and that successful models be disseminated widely in the professional community.

Education of Prenatal Care Providers

One way to achieve the goal of universal HIV testing in prenatal care is for federal, state, and local health agencies, professional organizations, regional perinatal HIV research and treatment centers, AIDS Health Education Centers, and health plans to increase efforts to educate prenatal care providers about the value of testing in pregnancy. In particular,

The committee recommends that health departments, professional organizations, medical specialty boards, regional perinatal HIV centers, and health plans increase their emphasis on education of prenatal care providers about the value of universal HIV testing and about avenues of referral for patients who test positive.

Improved Provider Practices
A variety of specific clinical policies facilitate HIV testing, such as inclusion of HIV tests in the standard prenatal test panel and no longer requiring counseling as a prerequisite for HIV testing. In particular,

The committee recommends that professional organizations update their clinical practice guidelines to facilitate universal HIV testing, with patient notification, as a routine component of prenatal care.

In addition to their direct influence on clinical practices, guidelines of this sort issued by professional organizations have an important role to play in determining the standard of care.

In addition,

The committee recommends that all health care plans and providers develop, adopt, and evaluate clinical policies to facilitate universal prenatal HIV testing.

Clinical policies to implement the committee's recommendation for universal, routine testing with patient notification might include, for example, the inclusion of an HIV test on the checklist of clinical tests for which blood is drawn at the first prenatal visit, standing orders, and procedures to ensure that positive test results are delivered in a timely and appropriate way.

Performance Measures and Contract Language

Health care plans and providers increasingly are being held accountable for the services they provide through performance indicators in such areas as cost, quality of care, and patient satisfaction. In order to take advantage of this approach,

The committee recommends that health care plans and providers adopt performance measures for a policy of universal HIV testing, with patient notification, as a routine component of prenatal care.

To implement this recommendation, groups that develop performance measures, such as the National Committee for Quality Assurance (NCQA), should develop and adopt specific performance indicators for prenatal testing. Given the committee's emphasis on universal HIV testing as a routine component of prenatal care, the proportion of women in prenatal care actually tested would be an appropriate performance measure. Health care plans must, however, ensure patient confidentiality and guard against coercive testing when patients refuse to be tested.

Another approach to integrating public health goals and clinical practice is the development of contract language for managed care plans. In particular,
The committee recommends that health care purchasers adopt contract language supporting a policy of universal HIV testing, with patient notification, as a routine component of prenatal care.

If universal HIV testing with patient notification is to become a routine component of prenatal care, contracts should not allow health insurers to deny benefits under "pre-existing conditions" or similar clauses based on the client's HIV status.

**Improving Coordination of Care and Access to High-Quality HIV Treatment**

Prenatal HIV testing can achieve its full value only if women who are found to be positive receive high-quality prenatal, intrapartum, and postnatal care for themselves and their children. Thus,

The committee recommends efforts to improve coordination of care and access to high-quality HIV interventions and treatment for HIV-positive pregnant women.

Without linkage to specialty care for HIV-positive women, the committee's recommended policy of universal HIV testing, with patient notification, as a routine component of prenatal care would violate one of the fundamental criteria for public health screening programs, that is, there should be adequate facilities for diagnosis and resources for treatment for all who are found to have the condition, as well as agreement as to who will treat them.

**Addressing Concerns about HIV Testing and Treatment**

To enhance acceptance of HIV prenatal testing as a routine component of prenatal care, providers should understand the constellation of reasons why some pregnant women refuse HIV testing. Thus,

The committee encourages the development of outreach and education programs to address pregnant women's concerns about HIV testing and treatment.

**Resources and Infrastructure**

Development and dissemination of policy goals will not, in and of themselves, achieve universal testing and optimal treatment--a comprehensive infrastructure is needed. Maintaining this infrastructure requires federal funding, a regional approach, and an ongoing surveillance program.

**Federal Funding**

Successful perinatal HIV centers consistently rely upon federal funding for research and for services through HRSA's Ryan White program to maintain the infrastructure they need to succeed. The efforts called for in the earlier recommendations in this chapter will require similar or higher levels of investment. Thus,
The committee recommends that federal funding for state and local efforts to prevent perinatal transmission, including both prenatal testing and care of HIV-infected women, be maintained.

The administration and Congress should examine current budgets thoroughly for adequacy, particularly in light of the expanded programs recommended by the committee. Maintaining current program levels is the minimum requirement. The Ryan White CARE Act Amendments of 1996 (section 2625), for instance, authorized $10 million per year in grants to the states to carry out a series of outreach and other activities that would assist in making HIV counseling and testing available to pregnant women. Congress, however, never appropriated funds for this purpose. Doing so now would go a long way toward building the infrastructure needed to lower perinatal transmission rates.

As discussed in Chapter 1, The Ryan White CARE Act Amendments of 1996 set up a decision-making process that could result in states losing significant amounts of AIDS funding unless they demonstrate substantial increases in prenatal HIV testing or a substantial decrease in HIV transmission rates, or institute mandatory newborn testing. If the national goal is to prevent HIV transmission from mothers to children, the federal government should support prenatal testing and other state-based prevention efforts. The Ryan White CARE Act Amendments of 1996, paradoxically, could actually undermine them.

Regional Approach

HRSA currently funds a system of "HIV Programs for Children, Youth, Women and Families" through Title IV of the Ryan White CARE Act. Federal research funds in these and other centers also provide for both direct care and an infrastructure to support it. Many of these programs serve as de facto regional centers for specialized treatment of HIV-infected women and affected children, and to a lesser extent, for coordination of prevention activities. There is, however, no coordinated, regional approach. Thus,

The committee recommends that a regional system of perinatal HIV prevention and treatment centers be established.

The regional centers would help to assure optimal HIV care for all pregnant women and newborns, directly to those referred to the centers, and indirectly by working with primary care physicians who retain responsibility for the medical care of HIV-infected women. Moving beyond current practices, the regional centers would also help to develop and implement strategies to improve HIV testing in prenatal care, as discussed above.

Defining the organization, funding, and operations of the recommended regional approach is beyond the scope of this report. To advance this plan, HRSA's Bureau of HIV/AIDS and its Maternal and Child Health Bureau, which together have authority and funding to deal with prenatal care and HIV treatment, should convene a national working group to implement this regional approach. The members of the working group should
include representatives of CDC for their prevention authority, National Institutes of Health (NIH) because many of the existing centers receive significant research funding, and Health Care Financing Administration (HCFA) because of its oversight of Medicaid. State and local health authorities, representatives of managed care organizations, and representatives of the prenatal care providers should also be involved.

**Surveillance**

Surveillance systems are needed to support policy development and program evaluation regarding perinatal transmission of HIV. Thus, in order to support the previous recommendation about performance measures, and to generally guide prevention efforts,

The committee recommends that federal, state, and local public health agencies maintain appropriate surveillance data on HIV-infected women and children as an essential component of national efforts to prevent perinatal transmission of HIV.

The universal testing approach that the committee recommends, as well as the call for health plan performance measures, should facilitate the development of appropriate public health surveillance systems.

**Other Approaches to Preventing Perinatal HIV Transmission**

Although the committee's charge was focused on prenatal HIV testing and appropriate care, other ways to prevent perinatal transmission of HIV should also be considered. In particular, the committee calls attention to the following areas.

**Primary Prevention of HIV Infection**

Since perinatal transmission begins with infected mothers and their partners, primary prevention of HIV can contribute markedly to preventing perinatal transmission by lowering the number of HIV-infected women and their male partners. There are many established approaches to primary prevention: HIV/AIDS education programs, behavioral interventions, partner notification, treatment and prevention of sexually transmitted diseases, and community programs. Beyond more general HIV prevention efforts, prevention and treatment programs targeting drug users appear to be especially vital for preventing perinatal HIV transmission.

**Averting Unintended Pregnancy and Childbearing Among HIV-Infected Women**

Pregnancies that are intended--consciously and clearly desired--at the time of conception are in the best interest of the mother and the child (IOM, 1995b). If a woman is infected with HIV, unintended pregnancy and childbearing clearly have special significance. For these reasons, preconception counseling represents an important opportunity to identify HIV-infected women who are considering pregnancy. Some women who know they are HIV-infected choose to become pregnant, especially now that
the ACTG 076 regimen is available, but others become pregnant unintentionally. More women learn their HIV status through the course of their pregnancy. Nevertheless, improved knowledge of the consequences of unintended pregnancy (including HIV transmission) and the ways to avoid it, as well as access to contraception, can help to ensure that all pregnancies are intended (IOM, 1995b), and this would reduce, to some extent, the number of children born with HIV infection. The committee does not want to restrict reproductive choice (Faden et al., 1991), but notes that interventions for such women who choose to terminate unintended pregnancies can also be beneficial in reducing the number of children born with HIV infection.

**Increasing Utilization of Prenatal Care**

Roughly 15% of HIV-infected pregnant women, many of whom are drug users, receive no prenatal care. Efforts to increase the proportion of women, especially drug users, who receive prenatal care should therefore be a high priority. *Prenatal Care: Reaching Mothers, Reaching Infants* (IOM, 1988) recommends activities to (1) remove financial barriers to care; (2) make certain that basic system capacity is adequate for women; (3) improve the policies and practices that shape prenatal services at the delivery site; and (4) increase public information and education about prenatal care.

**Enhanced HIV Prevention in Correctional Settings**

Correctional settings--prisons and jails--offer a unique opportunity for prevention activities targeted to hard-to-reach women at risk for, or already infected with, HIV. The prevalence of HIV infection among incarcerated women is far higher than in the community at large: 4% of female state prison inmates nationwide are known to be HIV-positive; in nine states the proportion exceeds 10%. Women are more likely than men to be incarcerated for drug-related offenses, so female inmates are more likely than male inmates to be infected or at risk for HIV infection. Many interventions could be introduced in correctional settings either for primary prevention of HIV transmission or, particularly, for prevention of perinatal transmission among HIV-infected pregnant women. Interventions should focus on HIV testing and treatment, drug testing and treatment, prenatal care, and efforts to ensure continuity of care for HIV-positive patients who leave the correctional setting.

**Development of Rapid HIV Tests**

Because reporting of conventional HIV tests takes about one to two weeks, an accurate rapid test, with results available in hours, might have applications in prenatal, labor, and delivery settings to prevent perinatal transmission in some groups of patients. Women and newborns identified with a rapid test late in pregnancy or intrapartum could receive the intrapartum or postpartum component of the ACTG 076 regimen, respectively. In the prenatal setting, a rapid test might be especially valuable for women who are unlikely to return for test results. According to the committee's site visits and workshops, these women are more likely to be adolescents, drug users, undocumented immigrants, and/or homeless. In the labor and delivery setting, a rapid test might be
valuable for women who have not been tested previously or have not received prenatal care. The prevalence of HIV infection is elevated in women who have not received prenatal care, and the labor and delivery setting offers the last opportunity to interrupt HIV transmission through administration of intrapartum therapy and advice to avoid breast-feeding. Since this is not an ideal time to obtain consent to testing and to discuss the implications of a positive result, program design and implementation would need to address these issues.

CONCLUSIONS

If the promise of the ACTG 076 findings, that perinatal transmission of HIV can largely be prevented, is to be fulfilled, the United States needs to adopt a goal that all pregnant women be tested for HIV, and those who are positive remain in care so they can receive optimal treatment for themselves and their children. In order to meet this goal, the United States should adopt a national policy of universal HIV testing, with patient notification, as a routine component of prenatal care. Adopting this policy will require the establishment of, and resources for, a comprehensive infrastructure. This infrastructure must include (1) education of prenatal care providers; (2) the development and implementation of practice guidelines and the implementation of clinical policies: (3) the development and adoption of performance measures and Medicaid managed care contract language for prenatal HIV testing; (4) efforts to improve coordination of care and access to high-quality HIV treatment; (5) interventions to overcome pregnant women's concerns about HIV testing and treatment; (6) and efforts to increase utilization of prenatal care, as described above.