DEPARTMENT OF HEALTH & HUMAN SERVICES

Indian Health Service
California Area Office

GPRA Bulletin 05-02

SUBJECT: Prenatal HIV Screening Indicator

DATE: July 20, 2005

To: Executive Directors

CC: Site Mangers, Clinical Directors, GPRA Coordinators

Prenatal HIV testing is a new GPRA indicator in 2005. When we recently took a look at the aggregated third quarter results for California sites, we noticed that many sites had no tests recorded, although all but three sites did have patients who are pregnant.

We believe that more HIV testing is being done than this report shows and suspect that the reason that many sites have no HIV tests recorded is that the local taxonomy for this indicator has not been populated. We are enclosing a spreadsheet with California Prenatal Testing results for your review. If you believe that your results do not accurately reflect the level of testing of your patients, we suggest that your IT support check the taxonomy associated with this indicator and make sure that all the laboratory codes that your site uses have been entered. Directions for performing the taxonomy check and set up appear in the CRS user manual, version 5.1, dated June, 2005. Once the taxonomy is entered, the CRS software will begin to count the HIV tests that have been completed and entered into RPMS.

For your information and reference, we are also attaching a document on Prenatal HIV screening and consent procedures that was prepared in May, 2005. Section 4 of this document addresses the overall issue of GPRA reporting for this indicator. The rest of the document includes information about HIV and Prenatal Screening, as well as an extensive discussion of HIV consent and screening procedures.

Please contact Steven.Lopez@ihs.gov or Cynthia.Perez@ihs.gov if you have questions about setting up local taxonomies. Please contact amy.patterson@ihs.gov if you have questions about other information in the Prenatal HIV Screening and Consent Procedures document.

LaMerle Fridley
Associate Director, OPH

Prenatal HIV Screening and Consent Procedures at the Indian Health Service

May 2005

Contact Information:

Theresa Cullen (OIT-Tucson)
Theresa.Cullen@ihs.gov

Amy Patterson (CAO)
Amy.Patterson@ihs.gov

Table of Contents

I. HIV Transmission and Prenatal Screening 3

II. Best Practices Benchmarks 5

III. FAQ 7

IV: GPRA Reporting of Prenatal HIV Screening 12

V. Resources 13

I. HIV Transmission and Prenatal Screening

The HIV/AIDS epidemic represents a growing threat to American women of childbearing age. In 1992, women made up 14% of adults and adolescents living with AIDS; by the end of 2003, they made up 22%. In 2001, HIV infection was the 6th leading cause of death among women aged 25-34 years, and the 4th leading cause of death among women aged 35-44.[1] Although the rate of HIV infection has stabilized among adult women since 2000, women accounted for 27% of all new HIV and AIDS diagnoses among adults and adolescents in 2003. From 1999 through 2003, the estimated number of AIDS cases increased 15% among women and 1% among men.[2]

HIV infections in newborn children are one potential consequence of higher HIV infection rates among women of childbearing age. In 2003, the CDC reported that 92% of HIV and AIDS cases in children and virtually all new HIV infections in children in the United States were the result of perinatal transmission of HIV.[3] In the year 2000, the CDC estimated that 280-370 infants contracted HIV from their mothers in the United States.[4] The CDC estimates that over 8,700 children have contracted HIV through perinatal transmission cumulatively through the year 2003.[5]

In 1994, Zidovudine (ZDV) was found to reduce perinatal transmission of HIV infection, and the US Public Health Service published guidelines regarding the use of ZDV and routine testing and counseling of HIV positive pregnant women. These guidelines have been effective in reducing rates of HIV in newborns. Studies have shown transmission rates of less than 2% among HIV infected mothers who started antiretroviral treatment during pregnancy; those who did not begin treatment until labor or after birth had transmission rates of 12-13%.[6] By contrast, studies have shown that infants whose mothers receive no preventative treatment contract HIV at a rate of 25%.[7] The CDC believes routine prenatal HIV testing of all pregnant women is the best way to avoid transmission of HIV from mother to infant.[8]

---

[1] CDC Fact Sheet: *HIV/AIDS Among Women.* (2004) http://www.cdc.gov/hiv/pubs/facts/women.pdf
[2] CDC. *HIV/AIDS Surveillance Report,* 2003 (Vol. 15). Atlanta: US Department of Health and Human Services, Centers for Disease Control and Prevention; 2004 http://www.cdc.gov/hiv/stats/hasrlink.htm
[3] CDC. *HIV/AIDS Surveillance Report,* 2003 (Vol. 15). Atlanta: US Department of Health and Human Services, Centers for Disease Control and Prevention; 2004 http://www.cdc.gov/hiv/stats/hasrlink.htm
[4] CDC. Revised Recommendations for HIV Screening of Pregnant Women: Perinatal Counseling and Guidelines Consultation MMWR Recommendations and Reports 11/9/01;50(RR19);59-86. http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5019a2.htm
[5] CDC. *HIV/AIDS Surveillance Report,* 2003 (Vol. 15). Atlanta: US Department of Health and Human Services, Centers for Disease Control and Prevention; 2004 http://www.cdc.gov/hiv/stats/hasrlink.htm
[6] CDC. HIV Testing Among Pregnant Women—United States and Canada, 1998-2001 *MMWR: Morbidity and Mortality Weekly Report*. 2002. November 15/51(45);1013-1016.
[7] Connor EM, Sperling RS, Gelber R, et al. Reduction of maternal-infant transmission of human immunodeficiency virus type 1 with zidovudine treatment. *New England Journal of Medicine.* 1994;331:1173-80.
[8] CDC. US Public Health Service recommendations for human-immunodeficiency virus counseling and voluntary testing for pregnant women. *MMWR Recommendations and Reports*. 1995 Jul 7;44(RR-7):1-15.

Although ZDV can reduce perinatal transmission below 2%, HIV testing of all pregnant women is critical in identifying women who will need treatment during pregnancy. In 2000, 1 in 8 HIV-infected women did not receive prenatal care, and 1 in 9 was not tested for HIV before birth.[9] Since 1995, the CDC has recommended that all pregnant women be tested for HIV, and if found to be infected, offered treatment. In 2001 it updated its recommendations to "emphasize HIV testing as a routine part of prenatal care and strengthen the recommendation that all pregnant women be tested for HIV; recommend simplifying the testing process so that pretest counseling is not a barrier to testing; [and] increase the flexibility of the consent process to allow for various types of informed consent."[10]

In 2002, the CDC published information on HIV testing rates in the US and Canada. Specifically, it compared two types of testing approaches, "opt-in" testing, where pregnant women must agree to getting an HIV test, usually in writing, and "opt-out" testing, where pregnant women are told that an HIV test will be included in the standard group of prenatal tests and that they may decline the test. Unless they decline, they receive an HIV test.

In eight states using the opt-in approach in 1998-1999, testing rates ranged from 25% to 69%. However, in Tennessee, which used an opt-out approach, the testing rate was 85%. The CDC concluded from this study, and other information on prenatal HIV testing, that more women are tested with the opt-out approach, and that the opt-out approach can increase the number of HIV-infected women who are offered treatment, and reduce HIV transmission to infants during birth.[11]

---

[9] CDC. Enhanced Perinatal Surveillance—United States, 1999–2001. Atlanta: US Department of Health and Human Services, Centers for Disease Control and Prevention; 2004. Special Surveillance Report 4. http://www.cdc.gov/hiv/STATS/SpecialReport10-7.pdf

[10] CDC. Revised Recommendations for HIV Screening of Pregnant Women: Perinatal Counseling and Guidelines Consultation MMWR Recommendations and Reports 11/9/01;50(RR19);59-86. http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5019a2.htm

[11] CDC Fact Sheet: Reducing HIV Transmission from Mother to Child: An Opt-Out Approach to HIV Screening. 2004. http://www.cdc.gov/hiv/projects/perinatal/materials/OptOut.pdf

II. Best Practices Benchmarks

The Indian Health Service uses the Institute of Medicine (IOM), Public Health Service (PHS), Centers for Disease Control (CDC) and the American College of Obstetricians and Gynecologists (ACOG) as best practice benchmarks. Each group has called for standards that minimize barriers to universal screening for HIV in pregnancy.

IOM

The IOM recommends universal HIV testing, with patient notification, as a routine component of prenatal care. "Routine notification" is defined by the IOM to mean that HIV tests are included in the standard battery of prenatal tests and that women are informed that an HIV test is being conducted and that they have a right to refuse it.[12]

CDC

The CDC's Revised Recommendations for HIV Screening of Pregnant Women:

- "Emphasize HIV testing as a routine part of prenatal care and strengthen the recommendation that all pregnant women be tested for HIV;
- Recommend simplifying the testing process so that pretest counseling is not a barrier to testing;
- Increase the flexibility of the consent process to allow for various types of informed consent;
- Recommend that providers explore and address reasons for refusal of testing, and;
- Emphasize HIV testing and treatment at the time of labor and delivery for women who have not received prenatal testing and chemoprophylaxis."[13]

---

[12] "New report calls for universal testing of pregnant women." Institute of Medicine. WORLD. 1998 Nov;(No 91):2-3. The AAP and ACOG endorsed this recommendation: American Academy of Pediatrics, American College of Obstetricians and Gynecologists. Human Immunodeficiency virus screening (RE 9916); Joint statement of the American Academy of Pediatrics and the American College of Obstetricians and Gynecologists. Pediatrics 1999;104(1):128.

[13] CDC. Revised Recommendations for HIV Screening of Pregnant Women: Perinatal Counseling and Guidelines Consultation MMWR Recommendations and Reports 11/9/01;50(RR19);59-86. http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5019a2.htm

ACOG

"Early identification and treatment of all pregnant women with human immunodeficiency virus (HIV) is the best way to prevent neonatal 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 (i.e. opt-out approach). Repeat testing in the third trimester and rapid HIV testing at labor and delivery are additional strategies to further reduce the rate of perinatal HIV transmission. 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."[14]

---

[14] ACOG committee opinion number 304, November 2004. Prenatal and perinatal human immunodeficiency virus testing: expanded recommendations. ACOG Committee on Obstetric Practice. Obstetrics and Gynecology 2004 Nov;104(5 Pt 1):1119-24.

III. FAQ

The following section provides guidelines on putting the CDC, IOM and ACOG recommendations into practice.

1) What are the best-practice benchmarks on HIV screening during pregnancy?

The Indian Health Service uses the Institute of Medicine (IOM), American College of Obstetricians and Gynecologists (ACOG) and Centers for Disease Control (CDC) as best practice benchmarks. Each group has called for policies that minimize barriers to universal screening for HIV in pregnancy. Universal HIV screening significantly decreases perinatal HIV transmission. Through universal screening, practitioners can save infant lives and improve maternal health status.

The IOM, ACOG, and the CDC recommend universal HIV testing during pregnancy, with patient notification, as a routine component of prenatal care. The CDC emphasizes that practitioners should simplify the testing process so that pretest counseling is not a barrier to testing, and allow for various types of informed consent. ACOG specifically recommends following an “opt-out” prenatal HIV testing approach. HIV tests are included in the standard battery of prenatal tests and women are informed that an HIV test is being conducted and that they have a right to refuse it.

The “opt-out” screening recommendation, which is further explained below, maximizes HIV screening rates.

2) What is opt-out screening?

Opt out also means that the patient will be screened unless she specifically “opts out”, or declines screening. In other words, all pregnant patients are screened for HIV, unless the patient specifically refuses HIV screening.

The idea behind “opt-out” testing is to remove barriers to what constitutes life-saving therapy for fetuses.

Most Indian health centers that have successfully implemented “opt out” have done so by informing the patient during her initial prenatal appointment that she will be screened as a course of her routine care. They also provide information on HIV as part of their prenatal teaching content.

Opt-out screening must include prenatal HIV education for patients. This information accompanies the standard compliment of prenatal teaching content. Opt-out screening requires that the patient be informed about HIV and its dire consequences.

3) What steps must be followed in opt-out screening?

According to the CDC, there are three steps for health-care providers must follow in the opt-out approach:

1) Tell all pregnant women that an HIV test will be performed as part of the standard group of tests for pregnant women.

2) Tell them that they may decline this test.

3) Give them information about how to prevent HIV transmission during pregnancy and about treatment for pregnant women who are HIV positive.[15]

Counseling is a key component of opt-out testing. More information on HIV counseling can be found below.

4) When should pregnant patients be screened for HIV?

According to the CDC, health-care providers should “perform HIV testing in consenting women as early as possible during pregnancy to promote informed and timely therapeutic decisions.”

Initial screening should occur at the first prenatal visit.

Subsequent screening should be repeated in high risk groups and upon admission to labor and delivery, if screening has not occurred previously. According to the CDC, “expedited testing by either rapid return of results from standard testing or use of rapid testing (with confirmation by a second licensed test when available) is recommended for these women.”

Retesting is also recommended in certain situations. According to the CDC, “retesting in the third trimester, preferably before 36 weeks of gestation, is recommended for women known to be at high risk for acquiring HIV (e.g., those who have a history of sexually transmitted diseases [STDs], who exchange sex for money or drugs, who have multiple sex partners during pregnancy, who use illicit drugs, who have sex partner[s] known to be HIV-positive or at high risk, and who have signs and symptoms of seroconversion). Routine universal retesting in the third trimester may be considered in health-care facilities with high HIV seroprevalence among women of childbearing age.”[16]

---

[15] CDC Fact Sheet: Reducing HIV Transmission from Mother to Child: An Opt-Out Approach to HIV Screening. 2004. http://www.cdc.gov/hiv/projects/perinatal/materials/OptOut.pdf

[16] CDC. Revised Recommendations for HIV Screening of Pregnant Women: Perinatal Counseling and Guidelines Consultation MMWR Recommendations and Reports 11/9/01;50(RR19);59-86. http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5019a2.htm

5) Does the IHS require a specific consent form for opt-out HIV testing for pregnant patients?

No. There is no requirement for a *separate* signed consent form for HIV testing.

Chapter 13 of the IHS Manual does not require additional separate written IHS consent for HIV screening in pregnancy.

Also, the IHS no longer requires providers to use the two-sided HIV Screening form (IHS-509, 8/93).

However, some states have separate requirements. This is important if you use a state lab for free HIV tests, so check your local state laws. If you use a separate reference lab, it may not be as much of an issue.

If local or statewide requirements place any barriers to universal screening for HIV in pregnancy, then those requirements should be modified as soon as possible to remove any barriers to life saving care in pregnancy.

Please note that this guidance applies only to HIV testing during pregnancy.

6) Then how do we document "informed consent" with opt-out screening?

If your initial prenatal teaching covers HIV education, as outlined by CDC, ACOG, and the IOM, **and** you tell your patients that you intend to screen them unless they choose to "opt out", then the patient's initial acceptance of routine care at your facility will meet the best practice recommendations for informed consent.

Consent for HIV screening can be part of "bundled consent" as long as HIV screening is discussed with the patient. Obtaining consent should not slow down the prenatal clinic or act as a barrier to clinical HIV screening in any way, either real or perceived.

The CDC emphasizes that "information regarding consent can be presented orally or in writing and should use language the client understands …documentation of informed consent should be in writing, preferably with the client's signature."

The CDC also states that "information regarding consent may be presented separately from or combined with other consent procedures for health services (e.g., as part of a package of tests or care for certain conditions). However, if consent for HIV testing is combined with consent for other tests or procedures, the inclusion of HIV testing should be specifically discussed with the client."[17]

---

[17] CDC. Revised Recommendations for HIV Screening of Pregnant Women: Perinatal Counseling and Guidelines Consultation MMWR Recommendations and Reports 11/9/01;50(RR19);59-86. http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5019a2.htm

Many centers have successfully used this system since the CDC came out with its revised guidelines in 2001. Often the rate of HIV initial screening at those facilities is very high (>95%).

7) Can opt-out HIV testing be part of routine care for non-pregnant patients?

No. Opt-out testing HIV testing can be used only as part of routine prenatal care.

8) What specific information needs to be provided to pregnant patients about HIV?

Information regarding HIV and assessment of risks for HIV infection (i.e. risk screening) should be provided to all pregnant women as part of routine health education.

A nurse or primary provider can tell patients: "included in your packet of consents is a request to do an HIV test, which explained the risk and benefits. What questions do you have? Would you like to talk more about behaviors you may have or had that put you at risk?"

Pregnant women found to have behaviors that place them at high risk for acquiring HIV infection or who want more intensive client-centered HIV prevention counseling should be provided with or referred to HIV risk-reduction services.

The CDC has specific guidelines for what information to provide:

"Before HIV testing, health-care providers should provide the following minimum information. Although a face-to-face counseling session is ideal, other methods can be used (e.g., brochure, pamphlet, or video) if they are culturally and linguistically appropriate.

- HIV is the virus that causes AIDS. HIV is spread through unprotected sexual contact and injection-drug use.

- Approximately 25% of HIV-infected pregnant women who are not treated during pregnancy can transmit HIV to their infants during pregnancy, during labor and delivery, or through breast-feeding.

- A woman might be at risk for HIV infection and not know it, even if she has had only one sex partner.

- Effective interventions (e.g., highly active combination antiretrovirals) for HIV-infected pregnant women can protect their infants from acquiring HIV and can prolong the survival and improve the health of these mothers and their children.

- For these reasons, HIV testing is recommended for all pregnant women.

- Services are available to help women reduce their risk for HIV and to provide medical care and other assistance to those who are infected.

- Women who decline testing will not be denied care for themselves or their infants."[18]

9) What about women who decline or refuse HIV screening?

The CDC makes it clear that any woman who declines testing should not be denied care or tested without her knowledge.

"Women who refuse testing should not be coerced into testing, denied care for themselves or their infants, or threatened with loss of custody of their infants or other negative consequences."

The CDC recommends discussing and addressing the reasons for refusal of testing. These might include: lack of awareness of risk or fear of the disease, partner violence, potential stigma, or discrimination. Such a discussion "could promote health education and trust-building and allow some women to accept testing at a later date."

The CDC also advises that "women who refuse testing because of a previous history of a negative HIV test should be informed of the importance of retesting during pregnancy. All logistical reasons for not testing (e.g., scheduling) should be addressed as well." Some women who initially refuse testing may accept at a later date if their concerns are addressed. Others may refuse confidential testing but might be willing to obtain anonymous testing. Women who choose anonymous testing should be informed that "no documentation of the results will be recorded in the medical chart, and their providers might have to retest them, potentially delaying provision of antiretoviral drugs for therapy or perinatal prophylaxis." Finally, the CDC advises that "some women will continue to refuse testing, and their decisions should be respected." [19]

[18] CDC. Revised Recommendations for HIV Screening of Pregnant Women: Perinatal Counseling and Guidelines Consultation MMWR Recommendations and Reports 11/9/01;50(RR19);59-86. http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5019a2.htm
[19] CDC. Revised Recommendations for HIV Screening of Pregnant Women: Perinatal Counseling and Guidelines Consultation MMWR Recommendations and Reports 11/9/01;50(RR19);59-86. http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5019a2.htm

IV: GPRA Reporting of Prenatal HIV Screening

To be included for the GPRA measure, facilities should ensure the HIV test for all pregnant female patients is documented by one of the following five methods:

1. As a lab test (e.g. HIV screening) either in the RPMS Lab package or in PCC. The facility must also ensure the test is included in the facility's site-defined lab taxonomy BGP HIV TEST TAX in CRS.

2. If the patient refused the lab test, the provider should write "Refused HIV test" in POV section of the PCC form. This may be documented with the REF mnemonic in PCC. After typing "REF" in PCC data entry, the name of the lab test and the date the test was refused must also be entered.

3. As a CPT code, if the information came from a Super Bill or if the test was paid for by Contract Health Services. The CPT codes CRS counts for this measure are:

- 86689 HTLV or HIV antibody, confirmatory test
- 86701 HIV-1
- 86702 HIV-2
- 86703 HIV-1 and HIV-2, single assay
- 87390 HIV-1
- 87391 HIV-2

4. In the Laboratory package as a LOINC code. There are 100 codes that CRS counts for this measure.

5. In PCC as a historical (event) Lab record, if the patient had the test performed at a facility other than the facility where she normally receives care. These records may be entered in PCC by using the HLAB mnemonic, entering the date the test the test was performed, selecting the name of the lab test (e.g. HIV screening), and entering the results of the test.

V. Resources

IHS Maternal Child Health FAQ:
http://www.ihs.gov/MedicalPrograms/MCH/M/documents/HIVscreen21305.doc

IHS Women's Health HIV web page:
http://www.ihs.gov/MedicalPrograms/MCH/W/WHhiv.asp

Chapter 13: MCH – Indian Health Manual, current volume:
http://www.ihs.gov/PublicInfo/Publications/IHSManual/Part3/pt3chapt13/pt3chpt13.htm

Revised (2001) CDC guidelines for HIV screening of pregnant women:
http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5019a2.htm

ACOG (2004) recommendations for prenatal HIV screening:

For ACOG members:
http://www.acog.org/publications/committee_opinions/co304.cfm

For Non-ACOG members:
http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=pubmed&dopt=Abstract&list_uids=15516421

HHS General AIDS information
http://www.aidsinfo.nih.gov/

HIV Testing Among Pregnant Women, US and Canada, 1998-2001 (MMWR)
http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5145a1.htm

CDC HIV/AIDS Surveillance Report, 2002 (HIV increasing in women)
http://www.cdc.gov/hiv/stats/hasr1402.htm

CDC web page on Rapid HIV testing:
http://www.cdc.gov/hiv/rapid_testing/