Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

Reducing Obstetrician Barriers to Offering HIV Testing

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OEI-05-01-00260

OFFICE OF INSPECTOR GENERAL

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Memorandum

Date APR 11 2002

From George F. Grob
Deputy Inspector General
for Evaluation and Inspections

Subject OIG Final Report: "Reducing Obstetrician Barriers to Offering HIV Testing," OEI-05-01-00260

To Betty James Duke
Administrator
Health Resources and Services Administration

Attached is our final inspection report on barriers which obstetricians face in offering human immunodeficiency virus (HIV) testing to pregnant women and newborns. This report originated from the Ryan White CARE Act Amendments of 2000, which mandated that this study be conducted. The Secretary assigned responsibility for the study to the Health Resources and Services Administration, who then requested that the Office of Inspector General conduct it.

As part of the study, the Centers for Disease Control and Prevention estimated that in 2000, 80 to 110 HIV-infected infants were born to mothers who had not been diagnosed prior to birth. We found that obstetricians routinely offer HIV testing as part of their standard prenatal care. However, one third of them face barriers to doing so. These include language, late entry into prenatal care, and a perception that their patients are at low risk for HIV. Almost half of them also report significant barriers in offering testing during labor and delivery, such as lack of time for counseling and testing. Finally, obstetricians do not routinely test newborns for HIV, primarily because it is not their responsibility.

We make recommendations that the Health Resources and Services Administration collaborate with the Centers for Disease Control and Prevention, and the Centers for Medicare & Medicaid Services to address these problems. Many of them will depend on public/private partnerships for their implementation.

Would you please send us your action plan within 60 days. If you have any questions, please do not hesitate to call me or have your staff contact Elise Stein at (202) 619-2686.

Attachment

cc: Jeffrey P. Koplan, M.D.
Director
Centers for Disease Control and Prevention

Thomas A. Scully
Administrator
Centers for Medicare & Medicaid Services

EXECUTIVE SUMMARY

PURPOSE

Examine obstetrician barriers to offering HIV testing to pregnant women and newborns in order to reduce the incidence of perinatally transmitted HIV.

BACKGROUND

This report originated from the Ryan White CARE Act Amendments of 2000 which mandated that a study be conducted regarding perinatal HIV transmission. The Secretary assigned responsibility for the study to the Health Resources and Services Administration (HRSA), who then requested that the Office of Inspector General conduct the study.

Section 2628 of the law requests a study to determine "any barriers, including legal barriers, that prevent or discourage an obstetrician from making it a routine practice to offer pregnant women an HIV test and a routine practice to test newborn infants for HIV disease in circumstances in which the obstetrician does not know the HIV status of the mother." To accomplish this, we conducted a national survey of obstetricians, a survey of obstetrician State representatives, a survey of State HIV/AIDS directors and in-depth case studies in six high prevalence States. These surveys are limited to the issues laid out in the law. It is important to recognize, however, that these issues do not represent the full spectrum of services necessary to prevent perinatal transmission.

The mandate also requests "a determination of the number of newborn infants with HIV born in the United States with respect to whom the attending obstetrician for the birth did not know the HIV status of the mother." The Centers for Disease Control and Prevention (CDC) agreed with our request to provide the specified estimate. Finally, the law directs the Secretary to provide to Congress information regarding States' progress in fiscal year 2004.

REQUIRED ESTIMATE

In 2000, an estimated 80 to 110 HIV-infected infants were born to mothers who had not been diagnosed prior to birth

Of the 280-370 infants infected through perinatal transmission in 2000, the mother was not diagnosed with HIV until after the birth of the child in approximately 29 percent of the cases. Thus 80-110 HIV-infected infants were born to mothers who had not yet been diagnosed with HIV. If these women had been diagnosed and treated beginning in prenatal care, we estimate that the total number of HIV positive infants could be reduced by 70-90 infants, a decrease of 25 percent in the overall transmission of perinatal HIV.

BARRIERS AFFECTING OBSTETRICIANS

PRENATAL SETTING: Obstetricians routinely offer HIV testing as part of their standard prenatal practice; however, barriers affect approximately one-third of obstetricians

Ninety-three percent of obstetricians reported that they routinely offer HIV testing to their pregnant patients. However, 32 percent of all obstetricians, regardless of their testing practice, indicated ever facing a barrier that prevented them from offering an HIV test to a prenatal patient. Considering this, 66 percent of obstetricians reported both routinely testing and having never encountered a barrier. The top barrier, affecting 15 percent of obstetricians, was language. The next most frequently mentioned barriers were a patient's late entry into prenatal care and the physician's perception that their patient population is at low risk for HIV. The time involved in the pretest counseling and consent process were also mentioned as barriers by 5 percent of obstetricians.

LABOR AND DELIVERY SETTING: Significant barriers prevent almost half of obstetricians from routinely offering HIV testing during labor and delivery

Only 48 percent of obstetricans reported routinely offering HIV testing to women with unknown status during labor, and 17 percent reported never offering testing during labor. At least one barrier was reported by 44 percent of obstetricians: 36 percent reported barriers related to the HIV counseling and consent process, and about 20 percent reported barriers related to limitations in HIV testing technology to produce timely results.

NEWBORNS: Obstetricians do not routinely test newborns for HIV, primarily because it is not their responsibility

Ninety-three percent of obstetricians reported that HIV testing of newborns is the responsibility of the newborn's physician. Despite this fact, one-fifth of obstetricians report always recommending HIV testing for the newborn to the newborn's physician in cases where the mother's HIV status is unknown.

STATE EFFORTS: Almost all States report actions addressing obstetrician barriers to offering HIV testing to all pregnant women

Fifty States indicated that they have undertaken efforts to address barriers. While the extent of these efforts vary widely, they are primarily focused on provider education and training. Eighteen States indicated that they are engaged in monitoring and/or enforcement activities. A majority of States report that impacting private obstetrician testing practices is a major challenge, and about half of States report that competing priorities take precedence in their States.

RECOMMENDATIONS

The CDC Should Facilitate the Development of Administrative Tools and States Should Promote Administrative Tools to Make Prenatal HIV Testing Universally Routine

In order to encourage universal HIV screening of pregnant women, we recommend that the CDC and States develop administrative tools that ease the burden of the testing process and send a message that HIV screening is an expected part of prenatal care. These should include such things as prenatal forms that include HIV testing status and a simplified consent form that includes the minimum pretest information needed for informed consent. To assist in this effort, the CDC could develop model forms for the States to disseminate at the local level. States should work to have the model forms incorporated at the local level or ensure that HIV testing documentation on relevant medical charts is occurring.

The CDC and HRSA, in Collaboration with CMS, Should Facilitate Efforts to Expand the Capacity to Offer Linguistically Appropriate HIV Patient Education and Consent Materials

The CDC, HRSA and Centers for Medicare & Medicaid Services (CMS) should coordinate their efforts to provide linguistically appropriate, culturally sensitive patient education materials. Also, maintaining referral information on qualified national language banks and telephone translation services could help to alleviate language barriers to offering HIV testing.

The CDC Should Facilitate 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

The CDC should develop a model protocol for HIV testing of women with unknown HIV status at labor and delivery, encompassing counseling and consent during labor, technical capacity of hospital laboratories, and administrative handling of information on testing status. States should adopt and promote the CDC's labor and delivery protocols and assist institutions in incorporating them.

The CDC Should Encourage and Assist States to Appropriately Monitor HIV Testing of Pregnant Women

The CDC should assist States in developing monitoring systems that are appropriate to State and local needs. The monitoring currently being conducted in several States offers a continuum of potential monitoring models for the rest of the country. These range from requiring providers to report HIV testing to assessing missed opportunities to prevent future HIV infection.

The CDC, HRSA and States Should Promote Public/Private Partnerships to Design, Implement and Institutionalize Targeted Efforts to Remove Obstetrician Barriers

The CDC and HRSA should utilize public/private partnerships in implementing all the recommendations in this report by expanding current partnership projects. States should also strive to incorporate private partners in implementing all the recommendations in this report. The CDC and HRSA could promote public/private partnerships by writing collaborative language into their grant applications and program guidance, and by offering technical assistance regarding building and sustaining partnerships.

AGENCY COMMENTS

We received comments on our draft report from HRSA, CDC, CMS and American College Obstetricians and Gynecologists. Each organization indicated that the report presented useful information for shaping future efforts to increase the HIV testing rates of obstetricians and thereby reduce perinatal HIV transmission. Each organization also supported the substance of the recommendations. The CDC, however, expressed concern that they were called upon to take a leadership role, stating that their mission revolves around prevention rather than developing standards and guidelines for health care practice.

We recognize that CDC is not always in the position to direct outside groups and that in these cases their leadership comes in the form of support and influence. We have modified our recommendations accordingly by emphasizing CDC's ability to "facilitate" desirable actions and outcomes. By emphasizing CDC's role as facilitator, we reflect on their initial success in promoting HIV testing of pregnant women via official recommendations for testing and through their administration of the perinatal prevention grants. We believe that, as part of their prevention mission, CDC has a powerful role to play in facilitating and orchestrating further efforts to ensure that HIV testing is offered to all pregnant women.

We also recognize that the recommendations will require a broad array of resources beyond that which CDC alone can bring to bear. For this reason the recommendations are directed not at CDC alone, but CDC in collaboration with HRSA, CMS, and the States in public/private partnerships. We hope that all of the stakeholders mentioned, including private obstetricians, will actively collaborate with CDC to accomplish these recommendations.

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INTRODUCTION

PURPOSE

Examine obstetrician barriers to offering HIV testing to pregnant women and newborns in order to reduce the incidence of perinatally transmitted HIV.

BACKGROUND

This report originated from the Ryan White CARE Act Amendments of 2000 which mandated that a study be conducted to provide the following information:

1. For the most recent fiscal year for which the information is available, a determination of the number of newborn infants with HIV born in the United States with respect to whom the attending obstetrician for the birth did not know the HIV status of the mother.
2. A determination for each State of any barriers, including legal barriers, that prevent or discourage an obstetrician from making it a routine practice to offer pregnant women an HIV test and a routine practice to test newborn infants for HIV disease in circumstances in which the obstetrician does not know the HIV status of the mother of the infant.
3. Recommendations for each State for reducing the incidence of cases of the perinatal transmission of HIV, including recommendations on removing the barriers identified.[1]

The Secretary assigned responsibility for this study to the Health Resources and Services Administration, who then requested that the Office of Inspector General (OIG) conduct the study. The Secretary is also required to provide Congress with information regarding States' progress in fiscal year 2004.

In 1992, the annual incidence of perinatally-acquired AIDS peaked, and an estimated 907 HIV-infected children were born.[2] In 1994, the Pediatric AIDS Clinical Trial Group (PACTG) Protocol 076 demonstrated that by administering the drug zidovudine (ZDV) during pregnancy and during delivery intravenously, and later to the newborns, doctors could reduce by two-thirds the risk of perinatal HIV transmission. The PACTG 076 study found that without the drug treatment HIV-infected women faced a 25 percent risk of transmitting HIV to their infants, however with zidovudine the transmission rate fell to 8 percent. Subsequent studies using multiple treatment strategies have achieved transmission rates as low as 1-2 percent.[3]

The CDC Guidelines for HIV Counseling and Testing of Pregnant Women

In response to the success of the PACTG 076, the CDC, through the Department of Health and Human Services, Public Health Service (PHS) issued guidelines in 1995 recommending universal counseling and voluntary testing of all pregnant women and zidovudine treatment among those testing positive. The American College of Obstetricians and Gynecologists (ACOG), the American Academy of Pediatrics (AAP) and other professional associations endorsed these guidelines[4], and most States have adopted either policies or laws that reflect the essence of the PHS guidelines.[5]

In 1996, Congress commissioned the Institutes of Medicine (IOM) to conduct a study looking at further reducing perinatal HIV transmission.[6] In 1999, the IOM's report, *Reducing the Odds: Preventing Perinatal Transmission of HIV in the United States*, recommended the adoption of a national policy of universal HIV testing, with patient notification, as a routine component of prenatal care. This means that HIV testing would be conducted as one of the standard battery of prenatal tests, and that women would be informed of their right to refuse the test.

Recently, CDC responded to the IOM report by issuing revised guidelines for voluntary HIV screening of pregnant women. Although CDC did not adopt the IOM's central recommendation to include HIV testing with patient notification as part of the standard battery of prenatal testing, the revised CDC guidelines include simplification of the pretest process: CDC recommends that women receive the minimum information needed for consent to testing, and receive other HIV prevention education separate from the test. Differences from the original PHS guidelines include increased emphases on HIV testing as a routine component of prenatal care, on exploring and addressing reasons for test refusal, on testing and treatment at delivery for women with unknown HIV status, and on encouraging newborn testing if the mother's status remains unknown postpartum.[7]

HIV Testing During Prenatal Care

While there are multiple aspects related to the reduction of perinatal transmission, including accessing prenatal care, treatment acceptance and adherence to the medication regimen, an important aspect is being aware of HIV status in order to make informed decisions regarding treatment. The earlier the initiation of treatment, the lower the potential of passing HIV on to the child. Therefore, HIV testing during prenatal care is crucial for the best possible treatment outcomes.

According to Pregnancy Risk Assessment Monitoring System (PRAMS) data from 14 States, between 58 to 81 percent of mothers received HIV testing during pregnancy in 1997. Women were most likely to receive prenatal counseling and testing who were: African-American, covered under Medicaid, under 25 years of age, seen by public health care providers, and who had less than a high school education. About 71 percent of mothers in States with high seroprevalence recall being tested for HIV, compared to 58 percent of mothers in low seroprevalence States.[8]

The IOM study identified several barriers that prevented some health-care providers from offering HIV testing to all their pregnant patients.[9] Some providers believed they could predict which women were at risk for HIV. As a result, they selectively offered the test to those perceived to be at risk. In addition, some providers reported that HIV testing protocols, especially pretest counseling requirements, were too burdensome to follow for all their pregnant patients. Other studies have identified some additional barriers, including insufficient time, reimbursement issues, informing a pregnant woman she is HIV positive, patient refusal, treating an HIV positive patient, concern about offending the patient by offering the test, late entry into prenatal care and low priority of HIV testing.[10]

HIV Testing at Labor and Delivery

Studies have demonstrated that treatment at labor and delivery can reduce transmission risk by 50 percent among women who have not received prenatal treatment. Women who have not received any prenatal care may be able to benefit from last minute treatment during labor if their HIV status can be determined. Perinatal surveillance data from CDC indicates that 14 percent of HIV-infected women did not receive prenatal care.[11]

Because of the need to get HIV test results as quickly as possible in the labor/delivery setting, rapid and expedited HIV testing is receiving increasing attention. Currently, rapid testing is not in widespread use. In lieu of rapid testing, standard HIV tests can be expedited by using on-site laboratories and running the tests individually, instead of waiting to run them in batches.

There is one rapid test, the Abbott/Murex Single Use Diagnostic Systems (SUDS) HIV-1, currently approved by the Food and Drug Administration (FDA) for marketing and use in the United States. This test returned to production as of April 2001 after being voluntarily pulled from the market by the manufacturer in October 2000 when finished lots began failing certain control specifications. Other rapid HIV tests are currently being reviewed by the FDA for approval. In order to promote the commercial distribution of a new generation of rapid HIV tests, FDA has committed to assisting device manufacturers who wish to bring rapid tests to market and to prioritizing the review of rapid HIV test applications. Despite the priority placed on bringing new rapid tests to market expeditiously, it is impossible to determine when these new tests will be available and it may be years before reliable rapid tests are widely used.

HIV Testing of Newborns

The CDC recommends that a mother whose HIV status is unknown after delivery be informed that HIV testing is recommended for her newborn and could impact the child's health.[12] If newborns are identified as HIV-exposed,[13] CDC guidelines recommend treatment to prevent HIV transmission within 6 to 12 hours after birth and treatment within 4 to 6 weeks to prevent a common opportunistic infection that is often fatal. New York mandates HIV testing of all newborns and Connecticut mandates newborn testing for infants whose mother's HIV status is unknown.

Trends in Perinatal HIV Transmission

The annual incidence of perinatally-acquired AIDS increased steadily from 1984 to its peak of 907 in 1992.[14] This was followed by an 83 percent decline in perinatal AIDS cases from 1992 to 1999.[15] The CDC attributes most of this decline to successful implementation of PHS guidelines for HIV testing and treatment.[16] Births to HIV-infected women continue to decline, but do not fully explain the decline in rates of AIDS among infants. Rates of AIDS among infants declined 69 percent from 1992 to 1996 even though births to HIV positive women only declined by 17 percent.[17] It is difficult to estimate trends in perinatal HIV incidence because the Survey of Childbearing Women was discontinued and all States do not report perinatally HIV exposed infants with follow-up to ascertain infection status. While all States report AIDS cases to CDC, only 34 States and 2 territories report HIV cases.[18]

In the United States, approximately 6,000 to 7,000 HIV-infected women give birth each year.[19] Without intervention, a 25 percent mother-to-infant transmission rate would result in the birth of an estimated 1,000-2,000 HIV-infected infants annually in the United States.[20] By end of December of 2000, 1,611 children were reported to be living with HIV and an additional 2,703 children were reported to be living with AIDS.[21] Approximately 91 percent of all pediatric (under age 13) AIDS cases were attributed to perinatal transmission.[22] Through June 1998, the majority of the cumulative number of perinatally acquired AIDS cases were diagnosed in the Northeast (44 percent), followed by the South (36 percent).[23] In fact, New York, Florida, New Jersey and California accounted for 58 percent of all cases.[24]

The Health Resources and Services Administration

The HIV/AIDS Bureau within the Health Resources and Services Administration (HRSA) provides funding to States and other entities for the delivery of health care and support services to individuals and families affected by HIV disease through the Ryan White CARE Act programs. Most HRSA programs related to perinatal HIV transmission are funded through Title IV grants, which allocated $65 million in 2001 to State and local programs. These services include primary and specialty medical care, psychosocial services, and logistical support for women and their families affected by HIV as well as outreach and prevention to provide a continuum of care for at-risk populations.[25] Two other HRSA Bureaus, the Bureau of Health Professionals and the Bureau of Primary Health Care, administer programs that involve perinatal providers and underserved populations, respectively.

The Maternal and Child Health Bureau (MCHB) provides block grant funding to States' Maternal and Child Health (MCH) programs to promote and improve the health of mothers and children. In addition to block grants, MCHB funds special projects including a grant to the American College of Obstetricians and Gynecologists (ACOG) that was used to create Perinatal HIV Prevention "Provider Partnerships" between obstetricians and State health departments in two States. The MCHB also administers the

Healthy Start program in 94 sites to improve health care access and outcomes for women and infants by promoting healthy behaviors and combating the causes of infant mortality.

Current Projects of the Centers for Disease Control and Prevention

One of CDC's goals is to provide leadership in preventing and controlling HIV infection. The CDC pursues this goal through community, State, national, and international partnerships. The CDC's prevention efforts include support for State and local prevention activities, education programs, disease surveillance, and research designed to identify the most effective interventions to combat HIV. The CDC has established a supplemental funding program to specifically address perinatal HIV prevention through grants for the following several programs.[26]

Using HIV Perinatal Prevention Cooperative Agreements, CDC has awarded $6,300,000 annually since 1999 to 16 State and local health departments to reach pregnant women at high risk for HIV. The goals include ensuring that healthcare providers counsel pregnant women on HIV testing, making voluntary HIV testing available to pregnant women whenever and wherever they access the medical care system, ensuring that infected or at-risk women receive appropriate prenatal care and ensuring women and infants' access to appropriate prevention interventions and treatment services.

In 2000, 26 State and local health departments were funded at a total of $1,867,000 to conduct on-going enhanced surveillance of newborns who have been perinatally exposed or infected with HIV. Health departments collect extensive surveillance data about mother-infant pairs using a wide variety of medical records, birth and death certificates and laboratory reports. One of the goals of this project is to assist in evaluating perinatal prevention efforts. For example, some health departments are using the data gathered to examine "missed opportunities" in prevention in cases where a newborn was infected.

The CDC allocated $933,000 in 2000 in professional education and training grants to six grantees. Grants went to two organizations for MCH programs: CityMatCH, dedicated to improving maternal and child health in urban areas, and the Association of Maternal and Child Health Programs (AMCHP) who works with State public health MCH programs. The CityMatCH funding will support three "Urban Perinatal HIV Prevention Learning Clusters." The Urban Learning Clusters, teams of scientists, issue experts, policy-makers and practitioners, promote the translation of research and data into effective practice in urban communities with the highest rates of perinatal HIV. The funding to AMCHP will support eight State "Action Learning Labs." These working groups bring together cross-program teams of State health officials, obstetricians and other key players involved in the prevention of the perinatal transmission of HIV.

The other four organizations to which CDC awarded professional education and training grants include: ACOG, AAP, the National Pediatric and Family HIV Resource Center and the AIDS Alliance for Children, Youth & Families. These funds are used to educate health care providers about the importance of HIV counseling and testing and ways to prevent the transmission of perinatal HIV. Grants include provisions to evaluate

providers' knowledge, attitudes, and behaviors. In particular, ACOG used their funding to conduct a national survey of obstetricians, and disseminate prevention materials to obstetricians. Their survey revealed a reduction in barriers after broad distribution of their professional and patient materials on perinatal HIV.

In addition to the Congressional funding described above for perinatal HIV prevention activities, CDC also supports a number of research projects addressing perinatal HIV transmission. These include: 1) the Perinatal Guidelines Evaluation project, 2) the Perinatal AIDS Collaborative Transmission study, 3) the Pediatric Spectrum of Disease Project, and 4) the Mother-Infant Rapid Intervention At Delivery (MIRIAD).

The MIRIAD study explores HIV testing and treatment during labor and delivery for women whose testing status is unknown at delivery. This study explores voluntary HIV testing with informed consent during labor or soon after birth. The MIRIAD study will result in a protocol for HIV testing in the delivery setting that will be generalizable to non-research hospital settings. This 4 year study includes researchers in five metropolitan areas.

The Centers for Medicare & Medicaid Services

The Centers for Medicare & Medicaid Services (CMS) oversees the Medicaid program, which includes expanded eligibility for pregnant women (to at least 133% of the Federal Poverty Level) to ensure access to prenatal care. Medicaid serves over 50 percent of adults and 90 percent of children with AIDS.[27] Of the 18 million Medicaid-eligible women, CMS estimates that approximately 32,000 are HIV-infected and approximately 3,000 are HIV-infected and pregnant.[28]

The CMS developed the Maternal HIV Consumer Information Project (CIP) to increase patient and provider knowledge about prevention of perinatal HIV transmission. Specifically, CMS developed patient education brochures, posters and videos for States to use in order to promote the benefits of prenatal HIV testing and to raise awareness of Medicaid eligibility and coverage for prenatal care. The CMS initiated this project in 1995 as a demonstration project and has since expanded in some form to all States, the District of Columbia and Puerto Rico.

SCOPE

The scope of this evaluation is delineated in Section 213 of the Ryan White Reauthorization Act of 2000. This section of the law requests an evaluation to identify the barriers that may discourage or prevent an obstetrician from routinely offering HIV tests to all pregnant women and/or all newborns whose mother's HIV status is unknown. In accordance with this mandate, our study focused solely on obstetricians and did not attempt to identify barriers faced by other providers of obstetric care such as family physicians or certified nurse midwives. The ACOG estimates that non-obstetricians deliver 15 percent of all births, and that a greater, yet unknown, percentage of prenatal care is provided by family physicians and certified nurse midwives.[29] Also in keeping

with the specific mandate laid out in the law, our study focused only on barriers obstetricians face in *offering* HIV testing, as opposed to barriers that would prevent a test from actually occurring, such as women who do not access prenatal care at all, or women who refuse the HIV test.

Figure 1 provides one way to understand how this study fits into the larger scheme of preventing perinatal HIV transmission. The "cascade" outlines the events that lead to perinatal transmission. Each step is important to consider in overall efforts to maximally reduce perinatal transmission rates. This study focuses on women who are not offered HIV testing. Although this is only one event out of many that leads to a perinatal infection, it is an important step; research has shown that when testing and treatment are strongly recommended by providers, pregnant women are very unlikely to refuse.[30] Therefore, whether a woman is offered HIV testing is crucial toward halting this cascade of events. It is important to recognize, however, that the offering of HIV testing is only one of the many aspects in the cascade of services necessary to prevent perinatal transmission. Ultimately, to prevent HIV in children, preventing new HIV infections in women is an essential first step.

Figure 1

Cascade of Events Leading to the Number of Perinatally Infected Newborns

The proportion of women...

* who are HIV-infected
  * who become pregnant
    * who do not seek prenatal care,
      or ***who are not offered HIV testing*** *or* who refuse HIV testing
      * who are not offered treatment, *or* who refuse treatment
        * who do not complete treatment
          * whose child is infected despite treatment

Source: Based on figure from the Institutes of Medicine report, "Reducing the Odds"

METHODOLOGY

National Estimate of HIV-infected Infants Where Obstetrician Did Not Know Mother's Status

To address the request for a national estimate within the evaluation mandate, the Office of Inspector General requested that the Surveillance Branch of the Division of HIV/AIDS Prevention within the CDC, devise an appropriate estimate. In response to the OIG request, CDC has crafted an estimate that is very close to the legislative language. However, they cannot provide the exact figure requested. The mandate specifies an estimate of ". . . the number of newborn infants with HIV born in the United States with respect to whom the *attending obstetrician* for the birth did not know the HIV status of the mother." The CDC provided an estimate of the total number of HIV-infected infants

born in the United States for whom the mother's HIV status *was not diagnosed until after delivery*.

The CDC estimate diverges from the Congressional request since some of the elements of the request are not routinely collected through HIV surveillance or other evaluation efforts. First of all, information regarding whether or not an obstetrician was aware of their patient's HIV status during delivery is not available. Furthermore, any attempt to investigate this information would be unreliable. An obstetrician who was not aware of a woman's HIV status at delivery may never find out whether the woman or the newborn was later diagnosed with HIV. Secondly, although the mandate specifies obstetricians, routine HIV surveillance does not make distinctions among providers. Although national estimates exist indicating that 85 percent of all births are attended by obstetricians, these rates cannot be reliably applied to the tiny subset of births to women with unknown HIV status whose newborns are HIV infected. It is very likely that these deliveries share some qualities that would make them uncomparable to national figures.

This estimate is modeled from data collected from multiple sources including some but not all States, during variable time periods, with different biases and limitations. This amalgam represents the best data available. Since the cessation of the Survey of Childbearing Women in 1995,[31] there is no longer a single source of nationally representative data from which estimates of the number of HIV-infected infants born each year can be derived. Currently, only 34 States have instituted HIV reporting. Despite the many caveats, CDC feels that the figures represent a plausible range and are consistent with previously published CDC estimates. The full CDC methodology is included in Appendix D.

Obstetrician Barriers to HIV Testing of Pregnant Women and Newborns

To identify barriers that prevent or discourage obstetricians from HIV testing of pregnant women and/or newborns and to recommend actions to reduce testing barriers, our data collection focused first and foremost on the individual obstetrician perspective. Next we reviewed these issues from a State perspective by surveying the chairperson that heads each ACOG State organizational unit (District or Section) and State health department HIV/AIDS directors. Lastly, we conducted in-depth case studies in six States in order to fully understand the complexity of the existing barriers and to identify promising practices. All survey instruments included sections on barriers to offering testing during prenatal care, labor and delivery, and to newborns, and sections on solutions or efforts to address these barriers.

Beyond interviewing experts in six States, we solicited input from national experts with a wide range of perspectives, including representatives from AIDS Alliance for Children, Youth & Families, the Children's AIDS Fund, the National Minority AIDS Council, and the New York Assembly. We also solicited feedback on draft survey instruments from individual obstetrician volunteers, ACOG staff, National Association of State and Territorial AIDS Directors (NASTAD) staff and State HIV/AIDS directors from several States.

National obstetrician mail survey

For our national confidential survey of obstetricians, we obtained our sample from the membership list of the American College of Obstetricians and Gynecologists (ACOG) which represents 94.6 percent of all board certified obstetricians. Using surveillance data from the CDC, we stratified the list into low and high prevalence strata based on the county-level prevalence of women of child-bearing age living with AIDS. We defined the high prevalence stratum as counties with a rate greater than or equal to 4 cases of AIDS for every 1,000 women of child-bearing age. The ACOG was extremely helpful in our survey effort by allowing us to use ACOG membership information for our sample, promoting our survey to ACOG members and sharing ACOG research on obstetricians.

We randomly selected a sample of 1,200 ACOG members, 600 from each strata. Because the ACOG membership database does not distinguish those obstetrician-gynecologists who do not practice obstetrics, we oversampled to estimate for non-obstetrician respondents. We also over-sampled to account for an expected response rate of around 40 percent, based on previous surveys of obstetricians. We received 602 completed surveys, for a 50 percent response rate. We conducted a non-response analysis of 30 stratified randomly sampled non-respondents. Non-respondents did not vary from respondents in their test offering practices but did report some differences with specific barriers. See Appendix H for a more detailed explanation of the non-respondent analysis results.

Of our respondents, 475 surveys were from obstetricians and were used in the data for this study. This final sample size provides a confidence level of 90 percent with 4 percent precision for estimates. See Appendix E for the confidence intervals of selected point estimates. Table 1 illustrates the stratification of our sample and respondents.

Table 1
National Random Sample of Obstetricians

	High Prevalence Strata	Low Prevalence Strata	Totals
Population of ACOG OBGYNs[32]	15,953	16,208	32,161
Sample of ACOG OBGYNs	600	600	1,200
Excluded (not practicing obstetrics)	69	58	127
Total Obstetrician Respondents	224	251	475

We used several methods to analyze the survey data. We first calculated basic frequencies, weighted proportions and confidence intervals using the statistical package SUDAAN. Second, we ran chi-square tests to identify associations among key testing practice variables and barriers. Next, we used SUDAAN to conduct logistic regression analysis to identify predictors of key variables, including barriers to offering HIV testing

during prenatal care and labor and testing practices during labor. Predictor variables included specific practices and procedures, other barriers and demographic characteristics. Appendix F displays these models, including the odds ratios of significant predictors. We considered odds ratios to be significant if the p-value was less than 0.10.

State obstetrician representative fax survey

In order to gain a State-level perspective of the barriers obstetricians face and provide context for the national survey responses, we sent a fax survey to an obstetrician representative in each of the 50 States, the District of Columbia and Puerto Rico. For the purposes of this report, we will be referring to these 52 entities as "the States." In order to identify an obstetrician in each State, we worked with ACOG to approach the chairperson that heads each State Section or District. Chairpersons could complete the survey or refer it to another obstetrician in their State. For the purposes of this report, we will refer to obstetrician representatives as "ACOG representatives" although 10 surveys were from obstetricians referred by the ACOG Section/District chairperson for their State. We received responses from obstetricians representing 49 States (non-respondents were the District of Columbia, New Hampshire and Texas).

State HIV/AIDS directors fax survey

In order to understand State health department perspectives and efforts addressing perinatal HIV transmission, we faxed a survey to State HIV/AIDS directors. For this survey, we used the membership list from the National Association of State and Territorial AIDS Directors (NASTAD) for the most current contact information. We received responses from all States except Puerto Rico.

In-depth case studies of six States

We conducted case studies in order to provide a multi-layered picture of the barriers to testing and the context of those barriers, and to uncover potential causes and identify ways to reduce or remove barriers to testing. We selected a purposive sample of six States with a significant incidence of AIDS cases: New York, New Jersey, Florida, Texas, Georgia and California. These States represent 59 percent of total pediatric AIDS cases as of December 2000.[33] In fact, these six States are high incidence States across a variety of CDC HIV/AIDS indicators.[34]

In each of the selected States, we used non-probability sampling methods to select the most appropriate persons to interview. First, we purposively selected a core group of experts and stakeholders to represent a wide range of perspectives on the issue of obstetrician barriers to HIV testing. Key stakeholders included the State MCH director, State Medicaid representative, State and local health department HIV/AIDS program representatives and policy and front-line staff from at least one Title IV grantee. Interviews with these key stakeholders provide a level of consistency across case studies. Next, we employed a snowball technique to allow the stakeholders that we initially

identified to nominate additional experts to be included in our sample. This allowed us to develop a comprehensive list of State experts on the topic of obstetrician barriers to HIV testing.

In each State, we interviewed 15 to 25 experts or stakeholders. Experts included staff from Ryan White Title IV agencies, State and local health departments, social service agencies, and State Medicaid agencies. We also interviewed individual medical providers, case workers and, when possible, HIV-infected women who had either given birth or acted as peer counselors to other women. We have protected the anonymity of the HIV-infected women respondents by removing all personal identifiers from our records.

FINDINGS

In 2000, an estimated 80 to 110 HIV-infected infants were born to mothers who had not been diagnosed prior to birth

The CDC estimates that there were approximately 6,000 - 7,000 births to women living with HIV or AIDS in 2000. This is 0.15 percent of the almost 4 million live births in the United States for the same year. Based on a national extrapolation of available State-specific data, the births to women living with HIV/AIDS produced an estimated 280-370 HIV-infected infants. Thus, 4 to 6 percent of children born to HIV-infected women developed HIV themselves. This represents the overall transmission rate of perinatal HIV infections in 2000.

Focusing on the subset of infants infected through perinatal transmission is an important step in understanding the scope of this issue and in fulfilling the Congressional mandate to determine "the number of newborn infants with HIV born in the United States with respect to whom the attending obstetrician for the birth did not know the HIV status of the mother." The next step is to ascertain the extent to which these infections resulted from transmission despite treatment versus a lack of treatment due to inadequate or no prenatal care, absence or refusal of HIV testing, or the refusal of treatment. The Congressional mandate specifically focuses on the potential that lack of treatment could be due to the absence of testing. Consequently, that is the focus of the rest of this finding and the report.

Of the 280-370 HIV-positive infants infected through perinatal transmission in 2000, the CDC estimates that approximately 62 percent were born to mothers who were diagnosed with HIV prior to the birth. For another approximately 9 percent of HIV-infected infants, the mother's HIV diagnosis came during delivery. The mother was not diagnosed with HIV until after the birth of the child in approximately 29 percent of the cases, resulting in 80 to 110 HIV-infected infants born to mothers who had not yet been diagnosed with HIV. Appendix D contains a detailed description of the methodology used for deriving these estimates, which are based on transmission rates associated with initiating treatment at the time of diagnosis. Although timely treatment significantly reduces transmission rates, it does not eliminate the possibility of transmission. Table 2 provides the numbers and percentages of infected infants broken out by the mother's time of diagnosis.

Table 2
Time of Mother's HIV Diagnosis
for the Estimated 280-370 HIV-Infected Infants Born in 2000

	Estimated, Rounded Range of HIV-infected Newborns	Estimated Percent of HIV-infected Newborns
Infants Whose Mother was Diagnosed Prior to Birth	170-230	62%
Infants Whose Mother was Diagnosed During Delivery	20-40	9%
Infants Whose Mother was Diagnosed After Birth	80-110	29%
Rounded Totals[35]	280-370	100%

Source: Centers for Disease Control and Prevention

Assuming the time of the mother's diagnosis, as reported to the CDC from medical records,[36] is synonymous with obstetrician knowledge of HIV, and assuming all HIV-infected births were attended by obstetricians, then these newborn estimates represent the "number of newborn infants with HIV with respect to whom the attending obstetrician for the birth did not know the HIV status of the mother" that was specifically requested by Congress. Using these assumptions, 80 to 110 HIV-infected infants were delivered by an attending obstetrician with no knowledge of the mother's status.

As with any set of assumptions used to provide estimates, there are limitations. Most importantly, while it is likely and logical that the mother's diagnosis time is synonymous with obstetrician knowledge of HIV and the initiation of treatment, it is not certain. In some instances, the attending physician may not be the woman's prenatal caregiver or the woman may not have received prenatal care at all. Perinatal surveillance data from CDC indicates that 14 percent of HIV-infected women did not receive prenatal care.[37] In these cases, even if the woman was diagnosed prior to the birth, the attending obstetrician may be unaware of her testing history and her status. Further, it is unlikely that all of these births were attended by obstetricians. Although obstetricians preside over an estimated 85 percent of births nationally, it is uncertain whether this ratio applies to women with unknown HIV status who deliver HIV infected infants. It is likely that these deliveries share some qualities that would make them more likely to be attended by an obstetrician (i.e. hospitals might be more likely to assign obstetricians to women with potentially complicated deliveries such as women with substance abuse issues or no prenatal care).

Using the different rates for perinatal transmission based on treatment initiation, we can estimate the extent to which earlier diagnosis could prevent the infection of infants. If all of the HIV-infected infants whose mothers were diagnosed after the birth had been diagnosed and treated during labor or delivery, we estimate the total number of HIV-infected infants could be reduced by roughly 15 percent. This translates into preventing HIV infection in 50 to 65 infants in the year 2000. Assuming a more ideal scenario,

where all the HIV-infected infants whose mothers were diagnosed after the birth or at delivery had been diagnosed prior to the birth of the child, and adhered to treatment that was initiated in prenatal care, we estimate that the total number of HIV-infected infants in 2000 could have been reduced by 90 to110 infants. This represents a decrease in the number of HIV-infected infants by approximately 30 percent.

These scenarios clearly demonstrate the crucial impact early diagnosis and treatment can have. Despite the fact that over half of the HIV-infected newborns were born to mothers who were diagnosed prior to birth, the question of why some women remained undiagnosed until after the birth of their child remains. As previously stated, we examine only one possible answer to this critical question, that the women were not diagnosed because they were never offered an HIV test by their obstetrician or other health care provider. In particular, this report strives to determine what barriers might prevent or discourage *obstetricians* from routinely offering HIV testing to all pregnant women as well as suggesting solutions for removing those barriers.

Obstetricians routinely offer HIV testing as part of their standard prenatal practice; however, barriers affect approximately one-third of obstetricians.

Almost all obstetricans offer HIV testing during prenatal care, but other related procedures vary with AIDS prevalence

Obstetricians provided information on both their practices of offering testing to pregnant patients and on any barriers that have ever prevented them from offering an HIV test to a prenatal patient. Ninety-three percent of obstetricians reported that they routinely offer HIV testing to their pregnant patients.[38] However, some of the same obstetricians who reported routinely offering testing also acknowledged specific barriers that have prevented that practice on at least one occasion. A total of 66 percent of obstetricians reported both offering testing to all pregnant patients and having never been prevented from that practice by any barriers.

Obstetricians in both high and low prevalence counties showed similar standard practices of offering testing. This was also true across a number of other demographic variables, including urban versus rural practice setting, private versus public practice setting, private versus public insurance, gender and years since residency. However, obstetricians in high prevalence counties differ from those in low prevalence counties in other aspects of the testing process. Most importantly, logistic regression analysis indicated that obstetricians in high prevalence counties were less likely to be obstructed by any barriers to testing during prenatal care. There are also significant associations between prevalence rates and some testing practices. Obstetricians in high prevalence counties tended to "recommend" testing to pregnant women at low risk for HIV rather than just "offer" testing. Practicing in the high prevalence strata also related positively to documenting a woman's refusal of testing and re-offering testing at a subsequent prenatal appointment. Obstetricians in the high prevalence strata also recalled receiving educational materials or training from CDC

and from their State or local health departments significantly more often. Finally, more physicians in this strata than in the low prevalence strata reported knowledge of their State laws on HIV testing of pregnant women.

Barriers to offering HIV testing during prenatal care have affected one-third of obstetricians

Thirty-two percent of all obstetricians, regardless of their testing practice, have ever faced a barrier that has prevented them from offering an HIV test to a prenatal patient. The three most commonly reported barriers to offering HIV testing during prenatal care included language, a patient's late entry into prenatal care and an obstetrician's considering his or her patient population to be at low risk for HIV. These barriers each affected 13 to 15 percent of obstetricians. Pretest counseling being too time-consuming and the consent process being too time-consuming were the fourth and fifth most common barriers, respectively, but each were reported by only 5 percent of obstetricians. Table 3 lists the percentage of obstetricians who identified each barrier as having ever prevented them from offering an HIV test to a prenatal patient. Appendix A displays prenatal care barriers by State, as identified by the State HIV/AIDS directors and ACOG representatives.

Table 3
Barriers That Have Ever Been a Reason for
Not Offering an HIV Test to a Prenatal Patient

Barriers to Offering HIV Testing	Percentage of Obstetricians
Language barrier	15 %
Late entry into prenatal care	13 %
Patient population is at low risk	13 %
Pretest counseling too time consuming	5 %
Consent process too time consuming	5 %
Concern about offending patient	5 %
Inadequate reimbursement	2 %
It is not the standard of care in my hospital/clinic	1 %
Concern about informing a pregnant woman she is HIV-positive	1 %
Concern about treating an HIV-positive patient	1 %

Source: OIG national survey of obstetricians

Guidance on testing may help to alleviate barriers to offering testing. Logistic regression analysis showed that barriers were less likely to obstruct obstetricians whose workplace had written policies on HIV testing of pregnant women. Obstetricans who report receiving educational materials or training on perinatal HIV from CDC were also less likely to encounter any barriers to testing than obstetricians who do not report receiving such resources. Additionally, obstetricians who did not know their State's laws regarding HIV testing were more likely to report barriers than those familiar with State laws.

Language barriers constitute an exception to obstetricians' routine test offering

A language barrier, the most frequently reported barrier, has prevented 15 percent of obstetricians from offering HIV testing during prenatal care on at least one occasion. Language barriers affected the greatest number of obstetricians; however, finding language to be a barrier did not seem to dictate obstetricians' routine testing practice. Analysis using logistic regression supports this characterization. Among obstetricans facing any barriers, those obstetricians who routinely offer HIV testing to all pregnant patients were more likely to report a language barrier than those who only offer testing to some patients. Thus, it appears that a language barrier represents an exception to their routine practice. For these obstetricians, language constitutes a practical but formidable problem that arises occasionally. In qualitative interviews, some obstetricians and other health professionals have noted that a lack of multilingual patient education materials and consent forms and shortages of bilingual staff have exacerbated this barrier.

Although language constitutes the most commonly identified national barrier, it may not impact localities uniformly. Within States, obstetricians in suburban areas were less likely to report this barrier, although language barriers did occur in similar frequencies in urban and rural locations. Further, only 15 State HIV/AIDS directors identified this as a barrier in their State. However, States should not discount the potential for this barrier to impact their populations in the future, nor the possibility that it may already be occurring sporadically in their State. Data from an Urban Institute study indicates that certain States with historically small immigrant populations have recently experienced a rapid growth in immigration.[39]

A patient's late entry into prenatal care or lack of any prenatal care can prevent testing

Like a language barrier, a patient's late entry into prenatal care most often obstructs obstetricians who otherwise routinely offer testing. Logistic analysis again supported this characterization. Considering obstetricians with any barriers, the obstetricians who routinely offer testing to all prenatal patients were more likely to report the late entry into prenatal care as a barrier. For these obstetricians, a patient's late entry into care appears to disrupt their standard testing practice. Anecdotal evidence suggests that many women with late entry into prenatal care have multiple, immediate medical needs. These needs can interact with time constraints to make HIV testing more difficult. Some obstetricians may focus on competing clinical priorities at the expense of offering HIV testing. Forty-

three percent of State HIV/AIDS directors also agreed that presenting late in pregnancy for prenatal care is an ongoing barrier in their State.

However, several interviews with obstetricians and experts in high prevalence States offered a different perspective on a woman's late entry into prenatal care, arguing that late entry would increase the likelihood of test offering. They asserted that if a woman presents for prenatal care late in pregnancy, this signals a "high risk" pregnancy, which increases the priority the obstetrician places on HIV testing for her. One obstetrician summarized this perspective with the remark, "[Lack of prenatal care] is a red flag for most of us," increasing the likelihood of testing as opposed to acting as a barrier to it.

In addition to the potential difficulties that late entry into care may present, women who receive no prenatal care present an even greater barrier to timely HIV testing. Only a few State ACOG representatives agreed that late entry into prenatal care constituted a testing barrier. However, one quarter of ACOG respondents reported that "no prenatal care" prevents obstetricians from offering HIV testing. Forty-five percent of State HIV/AIDS directors also identified "no prenatal care" as a barrier. Our national survey of obstetricians did not include "no prenatal care" as a barrier since it is beyond the scope of obstetricians' prenatal practices.

For some obstetricians, the risk assessment barrier impedes routine offering of HIV testing

Although most of the medical community, including CDC, ACOG and IOM, has actively supported universal offering of HIV testing to all pregnant women, perceptions of patient risk still act as a barrier to testing for a subset of obstetricians. Nationally, 13 percent of obstetricians reported that they have not offered HIV testing because they considered their patient population at low risk. Similarly, 13 percent of State ACOG representatives felt that this was a barrier that prevented testing. A slightly higher percentage felt that risk assessments discouraged, but did not prevent testing. HIV/AIDS directors felt that the use of risk assessments among obstetricians posed a more serious barrier to HIV testing. Fifty-five percent of HIV/AIDS directors identified "the belief that only high risk patients should be tested for HIV" as a barrier, making it the barrier most often reported among HIV/AIDS directors.

An important difference emerged between the barrier of using risk assessments and the other top barriers. Although language and late entry barriers seem to operate as exceptions to the physician's routine practice, an obstetrician's risk assessments seem to partly determine routine testing practices. Unlike language and late entry barriers, there is demonstrated a negative relationship between risk assessment barriers and routine test offering practices. Considering obstetricians who reported any barriers, those who routinely offer HIV testing to all prenatal patients were less likely to identify the risk perception barriers than those who offer testing only to some prenatal patients.

Discussions with obstetricians and other experts have produced some ideas of why obstetricians may use risk-assessments despite the widespread promotion of universal

offering as the standard of care. Some respondents highlighted the fact that some obstetricians have never encountered an HIV-infected patient, and particularly in low prevalence areas, firmly believe that their patient population faces no risk of HIV. As one expert expressed, information on standards of care only takes you so far; a small proportion of physicians will disagree with those standards and only change their behavior if they face repercussions for not offering testing. Others addressed the "mixed messages" of HIV prevention. Epidemiologic research has tended to focus on identifying risk factors and subpopulations most affected by HIV. This emphasis on subpopulations may undermine the promotion of universal screening and may reinforce obstetrician perceptions that they do not need to test their patient populations. A final reason why obstetricians may still use risk assessments is due to State laws governing HIV counseling and testing procedures. For example, risk assessment language is included in perinatal testing laws in two States.

Though experts have characterized using risk assessments as one of the most difficult barriers to overcome, evidence suggests that institutional guidance can help to prevent obstetricians' reliance on them. Practicing in a workplace that has developed written policies regarding HIV testing of pregnant women predicted that an obstetrician would *not* indicate that using risk assessments obstructs testing. Also, almost three-fourths of obstetricians indicated that "making voluntary HIV testing of all pregnant women the standard of care in my hospital or clinic" would be helpful in assisting them to routinely offer HIV testing.

Our data indicates that the risk assessment barrier may underlie other barriers to offering testing, such as an obstetrician's concern about offending the patient. Most obstetricians who indicated that their concern about offending the patient prevented them from offering a test, have also been prevented by the perception that their patients are at low risk. Discussions with providers and experts support the theory that these two barriers can interact with one another. An obstetrician may presume both that the patient is at low risk for HIV and that she would be offended by an offer of testing. This physician may justify not offering the test to avoid the risk of offense since the physician does not feel the woman really needs the test anyway.

Pretest counseling and consent barriers discourage, but seldom prevent, offering testing

Despite the prominence of counseling and consent issues in previous research regarding prenatal testing barriers, including the IOM report which cited "lack of provider time and the legal requirements for counseling and informed consent" as barriers, a surprisingly small proportion of obstetricians indicated that these barriers have ever prevented them from offering an HIV test. Pretest counseling being too time-consuming and the consent process being too time-consuming each have obstructed testing for only 5 percent of obstetricians. These barriers ranked as the fourth and fifth most common of 10 barriers by both obstetricians and State HIV/AIDS directors.

Obstetricians and other health experts offered possible explanations for the perception of counseling and consent requirements as too time-consuming. The health care system often focuses incentives on treating many patients as quickly as possible, so even a brief discussion of HIV testing may impose a burden. However, experts have also asserted that these burdens may represent misperceptions of State requirements. Respondents suggested that some obstetricians believe that the pretest counseling and consent process requires up to 20 minutes to complete, but in reality it can take less than 5 minutes. According to our survey of State HIV/AIDS directors, only eight States require that pretest counseling be provided to all pregnant women and of those States, only five have specified the information that must be included in the counseling session. Twenty-one States indicated that they require written consent for HIV testing.

Pretest counseling and consent requirements may impose a burden that is bothersome but not prohibitive. Our survey of State ACOG representatives differed from the other two surveys by allowing the additional response that a barrier "discourages, but doesn't prevent testing." Sixty-nine percent of ACOG representatives assessed the pretest counseling barrier as one that discourages but does not prevent testing, and 63 percent indicated the same for the consent barrier. These barriers ranked as the first and second most common to discourage (but not prevent) testing. These State ACOG results also support the perspectives of some other respondents interviewed during field work. Many argued that the perception of counseling and consent as burdensome is more likely to compromise the quality of the counseling and informed consent than to prevent the offer of the test.

Significant barriers prevent almost half of obstetricians from routinely offering HIV testing during labor and delivery

Overall, offering HIV testing to all women in labor with unknown status is not standard practice

Standard practices vary widely between the prenatal care setting and the labor and delivery setting. Though almost all obstetricians reported routinely offering HIV testing to prenatal patients, only 48 percent of obstetricians routinely offer HIV testing (rapid, expedited or standard testing) to women of unknown HIV status during labor.[40] Some obstetricians who did report routinely offering testing to all women in labor with unknown status also indicated that a barrier had prevented that practice on at least one occasion. In total, 41 percent of obstetricians reported both routinely offering HIV testing during labor and having never been prevented from that practice by any barriers. A noteworthy minority of 17 percent never offer testing during labor and delivery. In contrast, only 1 percent of obstetricians reported never offering HIV testing to prenatal patients.

The AIDS prevalence rates impacted standard testing practices in the labor and delivery setting. According to logistic regression, obstetricians practicing in a high prevalence county were more likely to routinely offer testing during delivery. Obstetricians

practicing in a low prevalence county more commonly reported offering testing to women in labor with unknown status only sometimes. Obstetricians in low prevalence counties were also more likely to indicate that they faced barriers to testing during labor.

Guidance on HIV testing, particularly from an obstetrician's hospital, also impacted testing practices during labor. Logistic regression analysis identified that the receipt of educational information or training on perinatal HIV from one's hospital or from an educational course predicted that an obstetrician routinely offered testing during labor. Educational information from the hospital also decreased an obstetrician's likelihood of reporting any labor and delivery barriers. Interestingly, educational information from other sources did not demonstrate this effect.

The labor and delivery setting entails significant challenges to offering HIV testing

Compared to the prenatal care setting, testing barriers impacted many more obstetricians during labor and delivery. Approximately one-third of obstetricians reported any barriers to testing in the prenatal setting, but almost one-half faced challenges to offering HIV testing to women in labor with an unknown HIV status. Forty-four percent of obstetricians named at least one barrier that has ever prevented them from offering an HIV test to a woman in the labor and delivery setting. The most commonly reported barriers related to the process of conducting counseling and obtaining consent during labor, followed by limitations in the capacity to produce test results quickly. Some obstetricians also categorized the labor setting as being too late for preventive treatment. The following table lists the percentages of obstetricians identifying each barrier as having prevented them from offering testing during labor. Appendix A displays testing barriers during labor and delivery by State, as identified by the State HIV/AIDS directors and ACOG representatives.

Table 4

Barriers That Have Ever Been a Reason for Not Offering an HIV Test to a Patient During Labor and Delivery

Barriers to Offering HIV Testing	Percentage of Obstetricians
Process Barriers	
Insufficient time to counsel during labor	32 %
Too difficult to obtain consent during labor	28 %
Technology Barriers	
Test results take too long	19 %
Rapid or expedited HIV tests not available	18 %
Too late for preventive treatment	17 %
Too much emotional stress for patient	9 %
Hospital did not have antiretroviral drugs available for treatment	1 %

Source: OIG national survey of obstetricians

The HIV counseling and consent process during labor represented the most common source of barriers

The two most common barriers involved the process of offering HIV testing in the labor and delivery setting. Thirty-six percent of obstetricians reported that either "insufficient time to counsel" or "too difficult to obtain consent" or both of these barriers has ever prevented testing during labor. These two barriers were strongly associated, meaning that obstetricians who reported one barrier were likely to report the other.

Reporting insufficient time to counsel as a barrier is associated with whether or not an obstetrician has a set testing practice. Obstetricians who indicated that they "always" or "never" test during labor seem to be signaling a routine practice, whereas those that indicate "sometimes" appear to be testing on a more case-by-case basis. Considering obstetricians with any barriers during labor and delivery, obstetricians who appear to be deciding on a case-by-case basis whether to offer testing reported having insufficient time to counsel significantly more often than those who always offer or never offer testing. During interviews, some providers noted that obstetricians often operate under strict time constraints in the labor and delivery setting. For example, some women present in very advanced stages of labor with multiple immediate needs, which compete with the offering of HIV testing. On the other hand, obstetricians who indicated that they always test must also face similar time constraints, but have apparently managed to surmount them.

In addition to reducing the likelihood of facing barriers in general, institutional policies may also help to remedy this counseling barrier in particular. Obstetricians whose

workplaces had developed a written policy regarding HIV testing of pregnant women were less likely to report this barrier.

The difficulty of obtaining consent during labor and delivery is a barrier that impacts 28 percent of obstetricians. During discussions of the consent barrier, some health professionals described this difficulty as stemming from a doubt about a woman's capacity to consent to testing while under the influence of pain, emotional stress or medication during labor. Others did not encounter this doubt and compared the testing consent to women's consent to other medical procedures, such as a Cesarean section, under the same circumstances. Some respondents also voiced confidentiality concerns in situations where partners or family members accompany the woman into the delivery room.

Limitations in HIV testing technology present an insurmountable barrier for one-fifth of obstetricians

A limited capacity to process HIV tests quickly can prevent obstetricians from offering testing during labor. Slightly more than a fifth of obstetricians named either of two barriers related to testing technology as obstructions. Further, the obstetricians who do not routinely offer testing during labor and delivery were more likely to report either of these testing technology barriers. These barriers included "test results take too long" and "rapid or expedited HIV tests not available." State HIV/AIDS directors and ACOG representatives identified the unavailability of rapid or expedited tests more frequently than any other barrier during labor and delivery.

That 80 percent of obstetricians did not name these testing barriers was somewhat surprising in the context of discussions with other providers and experts. With the notable exception of New York, which mandates that HIV test results of mothers in labor and/or newborns be available within 48 hours, limitations in processing tests quickly featured prominently in many interviews discussing testing barriers during labor and delivery. During these discussions, many experts characterized the lack of expedited and rapid testing capacity as a formidable and widespread barrier. Over 40 percent of State HIV/AIDS directors also identified lack of rapid or expedited testing as an ongoing barrier in their States. This apparent divergence, between the obstetricians' responses and the State surveys and interviews implying a greater prevalence of this barrier, raises an issue that warrants further attention. An assessment of the extent to which hospitals in each State have developed the capacity to produce expedited or rapid HIV test results is an important foundation for increasing obstetricians' ability to intervene during labor and delivery.

Some obstetricians consider labor too late for preventive treatment, but interpretations of this barrier vary

Antiretroviral treatment initiated during delivery or within 12 hours of birth can reduce HIV transmission rates. However, 17 percent of obstetricians indicated that they have not offered an HIV test during labor because it was too late for preventive treatment. Two

explanations may explain the prevalence of this barrier. First, lack of rapid or expedited testing could prevent the obstetrician from ascertaining HIV status until after the window of intervention had passed.[41] Slightly more than half of the obstetricians who indicated that it was too late for preventive treatment also named at least one of the two testing technology barriers. Second, doctors may be unaware of prevention treatment options during labor and delivery. Approximately 7 percent of obstetricians reported "too late for preventive treatment" but did not report any barriers based on test results being delayed or on lack of antiretrovirals drugs for treatment. For these physicians, a lack of continuing education or educational materials on treatment options may account for this barrier. Finally, only one percent of obstetricians reported not testing due to a lack of antiretroviral drugs in their hospital, and so presumably, this condition was not a factor in perpetuating the "too late for preventive treatment" barrier.

Obstetricians do not routinely test newborns for HIV, primarily because it is not their responsibility

Ninety-three percent of obstetricians reported that testing is the responsibility of the newborn's physician. In fact, 90 percent indicated that they never perform HIV testing on newborns when the mother's status is unknown. Obstetricians reinforced this idea in the barriers they reported. Among obstetricians reporting any barriers to newborn testing, 90 percent said that they have not tested newborns either because they were not responsible for newborn testing or because they had recommended newborn testing to the newborn's physician.

Moreover, States have generally not assigned obstetricians the responsibility to test newborns when the mother's status is unknown. Only two States, New York and Connecticut, have enacted laws that mandate HIV testing of newborns born to mothers of unknown status. Neither State specifies that obstetricians must carry out this testing; instead, the laws hold the hospital accountable for developing protocols to ensure the testing of these infants.

While most professionals and State laws do not hold obstetricians responsible for newborn testing, a lack of communication between obstetricians and pediatricians, who are typically responsible for newborn testing, may act as a barrier to testing. Approximately one-fifth of obstetricians noted that a lack of communication with the newborn's physician has been problematic. Pediatricians whom we interviewed also noted the "fragility of the paper trail" that documents the mother's testing history. State confidentiality laws regarding the disclosure of HIV information may explain some of this difficulty. One pediatrician explained that when the mother's HIV status is not documented in the newborn's chart, some pediatricians assume that the mother tested negative. If the obstetrician had failed to offer an HIV test or had failed to document the mother's refusal of the test, the newborn's pediatrician would likely be unaware that the mother's status remained unknown.

Though obstetricians do not conduct newborn HIV testing for the most part, one-fourth of obstetricians do take some action related to newborn testing when the mother's status is unknown. Twenty-four percent of obstetricians reported that they always recommend to the mother that the newborn be tested for HIV. Also, twenty-two percent of obstetricians routinely recommend newborn testing to the newborn's pediatrician.

Almost all States report actions addressing obstetrician barriers to offering HIV testing to all pregnant women

Fifty of the 51 State respondents indicated that they had undertaken some measures to address barriers to counseling and testing all pregnant women, although the intensity and breadth vary tremendously. Fifteen States efforts include laws that mandate HIV testing or the offering of testing to all pregnant women. Appendix B provides additional information on State laws relating to perinatal HIV testing. Interviews with several HIV/AIDS experts suggest that there was a tremendous effort put forth right after the release of the 1995 PHS guidelines to disseminate information and train health care providers, but that efforts have diminished in recent years. However, most States are still engaged in some effort related to the topic. The majority of these States have multiple efforts underway focused on reducing the remaining barriers to offering HIV testing during pregnancy. Appendix C provides additional information on each State's efforts to reduce perinatal HIV testing barriers.

States' efforts are primarily focused on provider education and training, but these activities may not represent the most effective solutions to eliminate continuing barriers from an obstetrician perspective

Forty-five States reported at least one effort, and many States had multiple efforts, to educate providers regarding the necessity of providing HIV counseling and testing to all their pregnant patients. Education efforts took a variety of forms, but primarily consisted of the development and distribution of written materials and group training regarding prevention and treatment issues. Seventy-eight percent of States indicated that they disseminated State laws or policies regarding HIV testing of pregnant women through direct mailings to obstetricians. Training on testing and treatment has been offered by 19 States.

When asked for ideal solutions to improve obstetrician practices, States continue to focus on provider education. Of the 34 States offering opinions on the ideal solution to improve obstetrician practices, almost half wrote in provider education. In comparison, only 21 percent thought more research was the answer, while 18 percent focused on collaborative efforts.

In contrast, obstetricians do not seem to favor additional educational or training efforts as the most helpful solutions to promote their routine offering of testing. On a list of 10 possible solutions, obstetricians ranked continuing education courses on perinatal HIV as the 8th and training on HIV counseling as the 10th most helpful to them. The three

solutions that obstetricians indicated would be most helpful are: including testing in the standard battery of prenatal tests, making voluntary testing of all pregnant women the standard of care in their hospital/clinic and receiving patient education materials.

Furthermore, it appears that most obstetricians pay more attention to educational efforts by professional organizations and CDC than by the public health department. When asked about the educational materials on perinatal HIV that they received, 94 percent of all obstetricians remember receiving materials from ACOG, and 71 percent remember receiving materials from CDC. However, only 53 percent remember receiving materials from their State and local health departments. This is despite the fact that 90 percent of these obstetricians practice in States where the State health department indicated that they sent materials. During interviews, several obstetricians remarked that they pay less attention to public health letters than they do to technical bulletins. The reluctance to read information from State and local health departments could explain why one-third of obstetricians indicated that they were not familiar with State's laws or policies.

Collaboration efforts lack formal involvement by private providers

Forty-six State health departments indicated that they collaborated with private sector stakeholders to develop strategies to overcome the barriers to HIV counseling and testing. However, only 19 of these States indicated that their collaborative efforts formally included private providers or provider associations. Challenges to collaboration can lie in successfully engaging the private sector as partners. The ACOG representatives from 17 States felt their State health department has not tried to engage the private sector in addressing the issue of perinatal HIV transmission. Further, only 6 percent of State health departments indicated that collaboration with private partners would be an ideal way to improve obstetrician practices around perinatal HIV testing.

In interviews, HIV/AIDS experts expounded upon these issues. Respondents indicated that while specific task forces or working groups may be convened, truly integrating private providers into a State's response to this issue also presents a challenge. Sometimes the quality of the collaboration is questionable. For example, one State's task force includes several private obstetricians, however most are not actively involved in the group and rarely attend meetings.

In most States, efforts do not include monitoring compliance

While a few States are engaged in monitoring or enforcement activities, the majority of States do not have the means to ascertain whether obstetricians and other health care providers are complying with their laws or policies regarding HIV testing during pregnancy. In total, 12 States indicated that they have either monitoring and/or enforcement provisions in the law. Six additional State health departments indicated that they are engaged in activities to monitor obstetrician and/or hospital compliance.

Twenty-four States engage in research that provides valuable information; however, this does not perform a monitoring function. Several States have participated in issue-specific

research regarding obstetrician practices, which offers a picture of compliance at a specific point in time. On the other hand, epidemiological research and surveillance provides an on-going method for assessing overall provider compliance. However, with the exception of some enhanced perinatal surveillance projects in conjunction with the CDC, this research lacks the means to pinpoint categories of providers who do not offer HIV testing to all women.

States face challenges to changing obstetricians' testing practices

The number one challenge faced by 36 States is influencing the behavior of private obstetricians. Attempting to influence the attitudes and behavior of obstetricians is inherently difficult, as are all attempts to alter behavior patterns. This is made especially difficult by the gulf that often exists between the public health perspective and the private obstetrician provider perspective. For example, providing prevention messages and risk reduction education to pregnant women has public health value, but may compete for time with other clinic aspects of treating the individual. Further, many obstetricians do not support what one obstetrician called "HIV exceptionalism" in which HIV is treated differently from other public health issues due to social and political issues associated with the disease. Agreeing with this point of view, one obstetrician wrote, "HIV should be treated like a medical illness, not a social disease. We don't have to counsel to the same degree for gonorrhea and chlamydia testing."

Another challenge identified by the States also may make successfully persuading all obstetricians to universally test for HIV difficult. In 49 percent of the States, State health departments felt that competing priorities take precedence over the issue of perinatal transmission. This viewpoint is supported by ACOG State representatives, 43 percent of whom reported that perinatal transmission is "not an issue" or "other issues take precedence" on the State ACOG agenda. In many low prevalence States, the low ranking of this issue is not surprising and probably appropriate given the larger prevention issues facing the State. However, it certainly speaks to a general attitude in the State that may be shared by the obstetricians in that State. As one HIV/AIDS clinical director stated, "With the dramatic reduction in cases, people have become complacent and within the scheme of challenges, this issue now seems so small that it is hard to get people to focus."

RECOMMENDATIONS

Since the PHS guidelines recommending HIV counseling and testing for all pregnant women were instituted in 1995, testing rates have increased substantially.[42] In our survey, 93 percent of obstetricians reported routinely offering testing to all of their patients for HIV. The increase in testing rates, along with significant reductions in perinatal HIV incidence, testify to Federal, State and local efforts to implement universal HIV screening of pregnant women. However, there is more that could be done to reach the goal of ensuring that every pregnant women is offered an HIV test. One-third of obstetricians still face barriers to offering HIV testing in the prenatal setting, and almost one-half faced challenges to offering HIV testing to women with unknown HIV status during labor and delivery.

In general, reducing barriers to testing requires CDC and States to develop, disseminate and institutionalize at the local level the practical tools necessary to make HIV testing administratively routine. To be successful, these efforts must entail the involvement of the private sector as advisors in the developmental stage and as partners in the implementation stage. Achieving the highest possible testing rates also requires instituting a level of accountability that will modify the behavior of obstetricians for whom targeted training and new tools are not sufficiently motivating.

In offering specific recommendations to increase HIV testing, we have focused on increasing obstetrician testing of women rather than newborns. First and foremost, obstetricians do not define newborn testing as being within the scope of their duties. Further, early testing of the mother is the most effective way to reduce transmission rates and prevent the largest number of children from becoming HIV-infected. For this reason, increasing testing rates during prenatal care should be a priority. Finally, rapid and expedited testing promises the possibility of being able to reduce transmission rates through testing and treatment of the mother when she presents in the hospital to deliver. With this safety net in the labor and delivery setting, women with inadequate prenatal care can still benefit from testing and treatment.

While the legislative mandate requests recommendations for each State, we advocate that our recommendations be instituted in all States. In light of the fact that our findings are based on a nationally representative sample of obstetricians and supported by a variety of data sources, we feel that our general recommendations are appropriate for all States. In particular, we feel that the recommendations should be adopted regardless of prevalence level. First, there are very few States that do not contain high prevalence counties. Further, Congress mandated that our study explore the barriers that exist that might prevent or discourage obstetricians from offering HIV testing to *all* pregnant women and newborns whose status is unknown, with a goal to promote universal testing of pregnant women by obstetricians. In fact, our research has shown that obstetricians in low prevalence settings are more likely to face barriers to offering HIV testing. Finally, this disease is not static. Counties currently facing low prevalence may experience rising

incidence in the future and should not dismiss the need for ongoing efforts to reduce the obstetrician barriers to testing.

The legislative mandate also requires "the Secretary to collect information from the States describing the actions taken by the States toward meeting the recommendations specified for the States." Towards this assessment, we offer our recommendations as a national template that States may use to evaluate their efforts to increase HIV testing rates by obstetricians. Each State could benchmark their current status against our recommendations, taking into account current efforts that may already address aspects of our recommendations (Appendix C). This benchmarking exercise would lay the foundation for evaluating the progress States make fulfilling these recommendations over the next few years. How each State chooses to respond to these recommendations would depend not only on where their current efforts put them on the continuum, but also on their assessment of the most problematic obstetrician barriers to offering HIV testing to all pregnant women, outlined in Appendix A and B. While our recommendations only speak to overcoming obstetrician barriers per the scope of our study, States might wish to benchmark their status and push for achievement with respect to all prenatal care and obstetric providers.

How States respond and the resources they have available to implement these recommendations regarding testing rates will also be impacted by investments States may be making in other areas in the cascade of events that lead to perinatal transmission. Improving obstetrician testing rates is only one crucial step in the larger effort to reduce perinatally transmitted HIV. In a world of limited resources, tension exists between the implementation of solutions to achieve the intermediate goal of increasing testing and the ultimate goal of reducing perinatal transmission. When focusing on increasing HIV testing, all obstetricians, regardless of the HIV prevalence of their practice, should be targeted equally. When focusing on the range of efforts directed at reducing the incidence of perinatal transmission, concentrating disproportionately on those obstetricians practicing in high prevalence settings may have more impact. More broadly, in States with high testing rates, focusing prevention funding on preventing HIV infection among women of childbearing age may provide an effective means of reducing transmission. Given this tension, our recommendations have been purposely crafted to allow for State flexibility in their implementation.

The CDC Should Facilitating the Development of Administrative Tools and States Should Promote Administrative Tools to Make Prenatal HIV Testing Universally Routine

To have a significant impact on perinatal HIV transmission rates, we must ensure that all women are offered HIV testing, and treatment when positive, during prenatal care. To this end, we recommend that HIV testing during prenatal care become a part of the universal standard of care for pregnant women. This should be fully accepted and expected by the medical community, including institutions such as clinics, hospitals,

managed care organizations and Medicaid. Our data shows that 74 percent of obstetricians indicated that making voluntary testing the standard of care at their clinic or hospital would be helpful in removing testing barriers.

While prenatal HIV testing is a part of written office and clinic policies for almost half of obstetricians, the remaining providers and institutions should formally integrate this into their standard prenatal practice. Obstetricians with written office/clinic policies for prenatal HIV testing are significantly less likely to report barriers such as using risk assessments to determine testing. We offer some specific recommendations aimed at making HIV testing the universally practiced standard of care by incorporating HIV testing into routine practice and by streamlining the testing process.

The CDC should, working in partnership with national health care provider organizations, promote the documentation of HIV testing by facilitating the development of model administrative tools

One way to reinforce HIV testing of pregnant women as the practiced standard of care is for CDC to promote the documentation of HIV testing on all regular paperwork such as patient prenatal, labor and delivery charts, laboratory request slips and medical records forms. This sends a strong message that HIV testing is an expected part of prenatal care and can be seen as the practical extension of CDC's perinatal testing guidelines. It also serves as a constant reminder to perform testing. From our interviews, several respondents noted that obstetricians use prenatal charts like a checklist for the office visit. In fact, many obstetricians showed us that prenatal patient charts do not contain a space to document the mother's HIV status, let alone whether or not HIV counseling and testing were offered.

In order to promote the incorporation of HIV testing into expected practice, CDC should engage ACOG and other national health care provider organizations in a partnership to encourage the documentation of HIV testing on relevant records. It is crucial to include ACOG and other national health care provider organizations in any effort to impact obstetricians' professional practice. Our findings demonstrate that influencing private obstetrician behavior is a major challenge and obstetricians are more likely to remember materials sent by ACOG. To assist this effort to encourage documentation, the CDC, in partnership with ACOG, could develop and disseminate a variety of model administrative forms. The ACOG currently has prenatal chart forms for sale that include a space for HIV testing and disease status that could serve as the CDC model prenatal chart form. Models could also be gathered from prenatal screening protocols and administrative procedures employed by MCHB grantees.

Another administrative tool that, if adopted by institutions, could impact the standardization of testing into all prenatal care would be a dual patient education and consent form. Again, CDC, in conjunction with ACOG and other provider organizations, could promote the use of such a form by creating and disseminating a model form. This form could be based on the minimum information essential for pregnant women prior to HIV testing as outlined in the revised CDC guidelines. In the new guidelines, the

minimum pretest information is condensed to six very brief points that should easily fit on a single sheet of paper along with any other necessary consent information.

Some health care systems have already adopted a dual counseling and consent form. The New York State health department has created and distributed a standard HIV consent form to all healthcare providers. The consent form includes patient information on the HIV test, the benefits of testing (including prevention of perinatal transmission), State confidentiality and reporting requirements and other pertinent information. The patient and healthcare provider both sign the form, and this fulfills the State's pretest counseling and informed consent requirements. While no formal evaluation of the impact of this new form has been conducted, feedback from our respondents was extremely positive.

State health departments should ensure that HIV testing is documented to administratively reinforce testing and should streamline consent to reduce burden

States should actively work to ensure HIV testing documentation is incorporated as policy at the State and local levels, both within the public and private sectors. One way to promote documentation would be to disseminate and require the use of CDC developed model forms. On the other hand, many obstetricians and institutions may have forms designed specifically to fit their unique administrative procedures. In these cases, States may find it more practical to require the inclusion of HIV testing documentation on existing forms. Currently, 13 States require, by law or regulation, that the offer of HIV testing be documented. Fourteen more States recommend documentation as their policy.

States should also work to streamline their counseling and consent procedures along the lines of the minimum requirements laid out in the revised CDC guidelines. The guidelines separate HIV prevention education from prenatal test offering. They recommend providing the patient prior to the test minimum pretest information rather than more extensive pretest counseling, which can be offered at another time. As with earlier CDC guidelines, States should review their laws, regulations, policies and guidelines and modify them if needed in order to adopt the new streamlined pretest process outlined in the CDC guidelines or the model form provided by CDC. The Washington State Board of Health, for example, asked the public health department to undertake a review of existing regulations to determine if these rules present a barrier to implementation of HIV testing in pregnant women. Simplifying the State counseling and consent requirements reduces some of the administrative disincentives to offering testing to all pregnant women, including the time and burden many obstetricians associate with the pretest process.

In order for these tools to be effective, they must be implemented as policy at the local level in both public and private settings. Our findings demonstrated that obstetricians with written policy and procedures in place at their hospital or clinic were less likely to face barriers to universal prenatal testing. Incorporating these new tools into the written policies and practice standards of the private sector will require States to partner with institutions and provider associations. Another potential avenue would be to work with medical school residency programs and professional associations such as the American

Board of Obstetrics and Gynecology (ABOG) to incorporate streamlined HIV testing practices into medical education and training.

The CDC and HRSA, in Collaboration with CMS, Should Facilitate Efforts to Expand the Capacity to Offer Linguistically Appropriate HIV Patient Education and Consent Materials

Language barriers affected more obstetricians than any other barrier. Multilingual patient education materials and consent forms may ease the difficulty of limited verbal communication enough to ensure that pregnant women with limited English have the opportunity to make an informed decision about HIV testing. In fact, 53 percent of obstetricians reported that patient education materials would be helpful in reducing barriers to HIV testing.

Such efforts are in line with the Department of Health and Human Service's "Strategic Plan to Improve Access to HHS Programs and Activities by Limited English Proficient Persons." Among other goals, this strategic plan already calls upon all HHS agencies, including CDC, to assess language needs and capacity of all programs and activities and to provide oral language assistance services and written translations of vital documents. The Centers for Medicare & Medicaid Services has a similar goal in ensuring that Medicaid-covered pregnant women with limited English receive the opportunity to make an informed HIV testing decision.

The CDC and HRSA should collaborate with CMS to expand the language resources for perinatal HIV education and consent. Through the Maternal HIV Consumer Information Project (CIP), CMS has already developed and test marketed patient outreach and education materials on perinatal HIV prevention in 14 languages, including Spanish, Chinese, Russian, and Vietnamese.[43] Census data could be used to pinpoint other language needs. The CDC has partnered with ACOG in development of consent information and consent forms in Spanish. The CDC, HRSA and CMS should coordinate their efforts to achieve this similar goal so that they can maximize effectiveness and minimize duplication. The model pretest consent form, described in the previous recommendation, should be included in this multilingual effort.

Community-based organizations and other programs that provide services to HIV positive women as well as national provider organizations should be incorporated into this effort to expand language resources. National health care provider organizations could provide invaluable insight into language translation needs as well as offer advice on appropriate content and usable formats. Community-based organizations, with their unique community perspective, have the knowledge necessary to develop linguistically appropriate, culturally sensitive translations.

The CDC's National Prevention Information Network (NPIN), could provide the repository for these materials. The CDC's NPIN offers general HIV information in

several languages; however, the selection of languages for materials specific to pregnancy and perinatal transmission remains limited. Also, using the NPIN network to refer providers to qualified national language banks and telephone translation services could also help to alleviate language barriers to offering HIV testing. Again, collaborating with national health care provider organizations to promote new language resources would be the most effective way to disseminate the information.

The CDC Should Facilitate 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

Impacting transmission through prenatal HIV testing is only possible for women who receive prenatal care. While great strides have been made in making prenatal care available, there are pockets of women, including HIV-infected women, that are less likely than the general population to access adequate prenatal care. For women who do not access prenatal care, as well as women who did not get tested during prenatal care, rapid or expedited HIV testing in the labor and delivery setting provides a crucial safety net. Currently, almost half of obstetricians face challenges to offering HIV testing to women in labor with an unknown HIV status. The most commonly reported barriers related to the process of conducting counseling and obtaining consent during labor, followed by limitations in the capacity to produce test results quickly. In order to promote rapid or expedited HIV testing as the standard of care for women with unknown status during labor and delivery, we recommend that protocols be developed and instituted at the hospital level.

The CDC should facilitate the development of a model protocol for HIV testing of women with unknown HIV status at labor and delivery

Because the labor and delivery setting involves many challenges to rapid or expedited HIV testing, CDC should develop protocols for hospitals to routinize this process. This could be done in consultation with professional associations such as ACOG and other government agencies such as the Agency for Healthcare Research and Quality, the lead agency responsible for research on the functioning, quality and costs of the health care system. Our findings indicate that institutional policies for HIV testing of pregnant women positively influenced the likelihood of obstetricians routinely offering testing to women in labor with unknown status. They also minimized some of the barriers that prevent testing during labor.

The policies instituted in hospitals should encompass three main aspects in order to overcome the barriers this report identifies. First of all, they should develop appropriate counseling and consent procedures. Toward this end, CDC, in collaboration with ACOG, could promote the results, both interim and final, of their Mother Infant Rapid Intervention At Delivery (MIRIAD), which is evaluating innovative approaches to counseling and assessing the feasibility of obtaining informed consent.

Secondly, CDC should offer States the technical assistance to ensure that all hospitals build the capacity, both administratively and technically, to produce HIV test results within the window of effective intervention. This could be accomplished by utilizing the Single Use Diagnostic System for HIV-1 (SUDS), the only FDA approved rapid test. Some States, such as Louisiana and Connecticut, have conducted perinatal prevention programs to explore rapid testing during labor. Broader preparation for the general availability and greater reliability of these tests, at this point in time, ensures hospitals' ability to quickly integrate the latest medical advancements related to perinatal prevention. If hospitals are reluctant to use SUDS due to concern about the rate of false positives, they could opt for expedited testing, in which preliminary results of standard HIV tests are returned within a few hours. One State, New York, already requires by law that all hospitals produce the results of standard HIV tests conducted during labor within forty-eight hours. Other hospitals would likely need technical assistance in building the laboratory capacity to process standard tests quickly.

Finally, the labor and delivery protocols should include guidance regarding the administrative procedures necessary to ensure the confidential, written communication of the mother's testing status to the newborn's physician. A lack of documentation of the mother's HIV status in the newborn's chart can mislead a pediatrician to assume that the mother had tested negative for HIV when, in fact, she may not have been tested at all. This misinformation could then impact the pediatrician's subsequent recommendations for testing of the baby.

This provision will need to take into consideration current State laws on confidentiality. According to a review of State laws conducted by ACOG, 20 States currently have confidentiality statutes that would allow for the disclosure of the mother's HIV status to the newborn's physician. Half of these States' statutes directly reference the ability to disclose a mother's HIV status to the physician of her child. The rest of the States have confidentiality laws that either explicitly prohibit or appear to prohibit such an exchange of information.

The CDC, CMS and States should partner with hospital associations to encourage institutions to incorporate labor and delivery protocols for HIV testing based on the CDC model protocols

To achieve the effective implementation of these new labor and delivery protocols, CDC, CMS and States must work closely with hospitals and hospital associations. Ideally, the testing protocol would be incorporated into hospital's written standards for quality care. The CDC and CMS can lay the foundation for this effort by partnering with such entities as the American Hospital Association in order to promote the adoption of the protocol. Working with the Joint Commission on Accreditation of Healthcare Organizations to include a labor and delivery protocol for HIV testing in their accreditation process or including HIV testing at labor and delivery as a measure in the Health Plan Employer Data and Information Set (HEDIS) are other possible routes to encouraging hospitals to adopt the protocol.

The CDC Should Encourage and Assist States to Appropriately Monitor HIV Testing of Pregnant Women

As a final means to improve the testing behavior of health care providers, we recommend that CDC work with State health departments to establish monitoring mechanisms that track HIV testing during pregnancy by provider. Monitoring testing rates, in conjunction with appropriate feedback, has the potential to alter behavior in instances where knowledge alone has proved insufficient. Our data, as well as previous research, shows a discrepancy between what obstetricians know regarding the expected standard of care and their testing behavior, indicating that more education and training will not alter testing behavior for some obstetricians. Despite widespread knowledge that all pregnant women should be tested for HIV, 13 percent of obstetricians indicated that their assessment that their patients were at low risk has prevented them from testing.

The CDC should assist States in developing monitoring systems that are appropriate to State and local needs. This could be accomplished by providing the technical assistance, including model tools, to assist hospitals or practices learn how to monitor and review their testing rates. Current monitoring systems and laws in 14 States offer a continuum of potential monitoring models for the rest of the country. The CDC could promulgate best practices from these models.

At one end of the spectrum, Tennessee law requires that each health care provider report the total number of pregnant women tested for HIV and the total number of women who tested positive on a monthly basis to the public health department. The department is required to publish these figures for the entire State and for each county. Texas has developed a monitoring system that relies on hospitals rather than physicians. Hospitals record whether HIV testing has occurred and whether zidovudine was administered during pregnancy on every birth certificate. The State department is then responsible for compiling and utilizing this information. One advantage to a hospital-based solution is that it not only allows for the identification of those obstetric providers who are not testing during prenatal care, but could also assist in identifying those patients who were not tested or treated for reasons that are beyond the control of obstetricians. Other States have instituted methodologies such as random chart audits that do not require universal reporting by either physicians or hospitals. New York conducts periodic on-site reviews to determine compliance with the prenatal HIV counseling requirements as well as HIV test acceptance rates. They offer technical assistance based on their analysis of these medical record reviews.

Several other States have instituted the Pregnancy Risk Assessment Monitoring Systems (PRAMS) or enhanced perinatal surveillance, in collaboration with CDC. The PRAMS is a population-based surveillance system that collects information on maternal behaviors and experiences around the time of pregnancy. Enhanced perinatal surveillance only collects HIV testing information for HIV-infected women and thus can only be used to assess missed prevention opportunities. Michigan, for example, reviews cases at individual hospitals and practices where “missed opportunities” occurred and offers

assistance in revising policies to prevent future problems. While assessing missed opportunities would not monitor whether all doctors were offering testing to all of their patients, it may prove to be an acceptable compromise for low prevalence counties where investments in a broader monitoring effort may not be practical. Several of the monitoring systems profiled would be resource intensive to develop and maintain. Currently, low prevalence areas do not receive money for enhanced perinatal surveillance. This, and other resource issues, may limit the extensiveness of the monitoring systems they are able to develop.

The CDC, HRSA and States Should Pursue Public/Private Partnerships to Design, Implement and Institutionalize Targeted Efforts to Remove Obstetrician Barriers

Collaborating with the private sector is essential in order to overcome the communication barrier that often exists between prevention experts focused on public health issues and health care professionals working in the context of a private market. Although most States indicate that they have engaged private partners in various perinatal efforts, we believe that States could benefit from even greater collaboration. The number one challenge faced by 36 States is influencing the behavior of private obstetricians. Without on-going, active partnerships with private providers, States may be missing opportunities to provide private obstetricians with the information and tools necessary to overcome barriers, or may not be effectively reaching many practitioners. Professional organizations and private providers understand the best ways to reach and convince providers.

The CDC and HRSA should utilize public/private partnerships in implementing all the recommendations in this report by expanding current partnership projects

Both CDC and HRSA have established partnerships with national health care provider organizations and other stakeholder organizations aimed at accomplishing perinatal transmission objectives. As mentioned in the background, CDC funds programs aimed at reducing perinatal transmission through ACOG, AAP and others national organizations. The Maternal and Child Health Bureau (MCHB) of HRSA funded a program, administered by ACOG, designed to foster partnerships between State agencies and private obstetricians around the topic of perinatal transmission. These partnerships were established in two States. The MCHB also administers the Healthy Start program to mobilize strong coalitions of consumers, local and State governments, the private sector, schools, perinatal providers and neighborhood organizations to improve health care access and outcomes for women and infants. The Association of Maternal and Child Health Programs (AMCHP) has established eight State "Action Learning Labs" that bring together a coalition of public and private stakeholders to educate each other across State lines. We strongly support these efforts and recommend their expansion in order to most effectively implement the preceding recommendations. We have addressed the specifics of these partnerships in the appropriate recommendation.

The CDC should provide States with an impetus to include private providers in their efforts to overcome obstetrician barriers by including collaborative language in grants and guidance documents. This language could encourage the development, maintenance and reporting of collaborative partnerships. The HRSA should strengthen application guidance materials for all Ryan White CARE Act providers to come into compliance with all recommendations. Finally, CDC and HRSA should be prepared to assist grantees in their public/private partnerships when necessary by leveraging their national level partnerships.

States should incorporate private partners in implementing all recommendations in this report

State and local initiatives should strive to incorporate partners from the private sector in all efforts to address obstetrician barriers to offering HIV testing. As stated previously, the most efficacious implementation of our recommendations rests on the ability of States to implement and institutionalize them as policy and practice at the local level. Collaboration with private partners is necessary to make this happen. These private partners should be active participants in the design and implementation of prevention efforts. This could be done by incorporating partners such as obstetricians, representatives from clinics or hospitals or representatives from professional organizations such as ACOG, American Academy of Pediatricians (AAP), American Academy of Family Physicians (AAFP), American College of Nurse-Midwives (ACNM) or American Hospital Association (AHA) into ongoing or newly created task forces.

AGENCY COMMENTS

We received comments on our draft report from HRSA, CDC, CMS and ACOG. Each organization indicated that the report presented useful information for shaping future efforts to increase the HIV testing rates of obstetricians and thereby reduce perinatal HIV transmission. Each organization also supported the substance of the recommendations, although CDC expressed some reservations regarding their role in implementation. These reservations, as well as other issues of concern, are reviewed below. One concept all of the organizations endorsed was the collaborative nature of the recommendations. The ACOG in particular made note of the fact that the recommendations called for greater involvement of obstetricians, stating that "the public/private partnership strategy is one of the best available for identifying which barriers and implementing effective strategies that will influence obstetricians behavior."

While expressing support for the recommendations and a willingness to work towards their implementation in a collaborative fashion, the CDC expressed concern that they were called upon to take a leadership role rather than a supporting one. They indicated that they believe they can more effectively aid in the implementation of our recommendations in an advisory capacity, providing technical assistance in developing standards and guidelines.

We recognize that CDC is not always in the position to direct outside groups and that in these cases their leadership comes in the form of support and influence. We have modified our recommendations accordingly by emphasizing CDC's ability to "facilitate" desirable actions and outcomes. By emphasizing CDC's role as facilitator, we reflect on their initial success in promoting HIV testing of pregnant women via official recommendations for testing and through their administration of the perinatal prevention grants. We believe that, as part of their prevention mission, CDC has a powerful role to play in facilitating and orchestrating further efforts to ensure that HIV testing is offered to all pregnant women.

We also recognize that the recommendations put forth will require a broad array of resources to accomplish effectively, beyond that which CDC alone can bring to bear. For this reason, the recommendations were not directed solely to CDC, but rather to CDC in collaboration with HRSA, CMS, and the States. Within the text of the recommendations, we offer other potential partners such as ACOG and other professional organizations. It is our hope and expectation that all of the stakeholders mentioned will actively collaborate with CDC to accomplish our recommendations.

Both HRSA and ACOG shared concerns related to the scope of the report. Both organizations pointed out that by not including other providers of prenatal and obstetric care, such as family physicians and certified nurse midwives, our findings and recommendations may not have relevance to the larger issue of increasing testing rates. It is true that the scope of this report was limited to obstetricians and excluded other health

care providers. This limitation was based on the statutory language mandating this study. As such, this report only offers data regarding barriers to testing faced by obstetricians and recommendations on how to alter obstetrician practices. The extent to which these observations and recommendations are representative of the practices of other health care providers is unknown. However, obstetricians represent a major and important provider of health care in this arena. The ACOG estimates that 85 percent of deliveries are attended by an obstetrician and believes that a somewhat lesser, yet unknown, percentage of prenatal care is provided by obstetricians. While all providers of prenatal and obstetric care should be encouraged to universally offer HIV testing to pregnant women, improving the testing rates of obstetricians would certainly result in improving overall testing rates.

Finally, ACOG pointed out that some of the barriers faced by obstetricians are beyond obstetricians' control. For example, counseling and consent laws, the lack of rapid tests in the labor and delivery setting and State confidentiality laws all may act as barriers to HIV testing. This is certainly true, and our recommendations request States to review such impediments. Due to the matrix of institutional and practice barriers we have identified, our recommendations suggest that responsible Federal agencies, States and private provider associations work together toward their common goal of increasing testing rates and reduce perinatal transmission.

For a more detailed review of the comments provided by CDC, HRSA, CMS and ACOG, please refer to Appendix I. This Appendix contains the general comments from all four organizations. We also received technical comments which were considered carefully and incorporated into the report as appropriate.

APPENDIX A

Obstetrician Barriers Identified by State

Barriers to Offering HIV Testing *during Prenatal Care* that States have Identified

For each of the prenatal and labor and delivery barriers listed, State HIV/AIDS directors were asked, "Has this been identified as an ongoing barrier that prevents obstetricians in your State from offering an HIV test?" Respondents also indicated the sources through which barriers had been identified, which ranged from formal evaluations to focus groups to anecdotes. Because our question asked for identified barriers, the responses may not represent those barriers operating in the State as yet unidentified. Further, the responses have not been independently verified by the OIG.

	Pretest counseling requirements	Consent process requirements	Reimbursement issues	Unaware that universal counseling and voluntary testing is standard of care	Belief that only women at high risk should be tested for HIV	Concerns about treating an HIV+ patient	Desire not to offend or embarrass the woman	Concerns about informing a pregnant woman she is HIV+	Cultural or language barrier	Woman presents for prenatal care late in pregnancy	Woman presents in labor without prenatal care
AK											
AL*	●	●	●	●	●	●	●	●	●	●	●
AR										●	●
AZ					●		●			●	●
CA			●	●	●				●	●	●
CO				●						●	●
CT*										●	●
DC	●	●		●	●			●	●	●	●
DE*							● ■	■	■		
FL*				●	●	■	●	■	● ■	●	● ■
GA*	●	● ■	●		●	●		●	● ■	●	●
HI											
IA*			●		●		●	●	●		
ID*		■		●	●		●				
IL*	● ■	●	●		●		●	● ■	●	●	● ■
IN*					■		■				
KS*	■	■		■	■		■				■
KY											
LA*	●	● ■			●					●	●
MA	●	●							●	●	
MD*	●	●		● ■	● ■		■	■			
ME*	● ■	● ■			●						■
MI*	●	●		●	● ■		●		●	● ■	● ■
MN*				●	●		●				
MO											
MS											

Legend:

● = **State HIV/AIDS director** identified this as an ongoing barrier in the State

■ = **ACOG representative** with statewide perspective identified this as an ongoing barrier. Only includes the 25 State ACOG representatives that indicated a statewide perspective on barriers. These 25 States are identified with an asterisk (*).

Barriers to Offering HIV Testing *during Prenatal Care* that States have Identified, (cont.)

	Pretest counseling requirements	Consent process requirements	Reimbursement issues	Unaware that universal counseling and voluntary testing is standard of care	Belief that only women at high risk should be tested for HIV	Concerns about treating an HIV+ patient	Desire not to offend or embarrass the woman	Concerns about informing a pregnant woman she is HIV+	Cultural or language barrier	Woman presents for prenatal care late in pregnancy	Woman presents in labor without prenatal care
MT*		●			●		●				
NC*	●	●			●		●	●		●	
ND											
NE				●	●						
NH					●		●	●			●
NJ			●							●	●
NM*							●			●	●
NV*				● ■	■	■			■	■	■
NY*	●	●	●		● ■		●	●	●		
OH*	■	■	●								
OK			●		●						
OR	●	●	●		●		●		●	●	●
PA*	●	●							●		● ■
PR											
RI			●		●		●		●		
SC											
SD											
TN*			●		●		●		● ■	● ■	● ■
TX		●	●						●	●	●
UT	●	●		●	●					●	●
VA					●						●
VT											
WA*	●	●	●		●		●				
WI*	●	●			●				■	■	■
WV	●	●	●		●						
WY											

Legend:

● = **State HIV/AIDS director** identified this as an ongoing barrier in the State

■ = **ACOG representative** with statewide perspective identified this as an ongoing barrier. Only includes the 25 State ACOG representatives that indicated a statewide perspective on barriers. These 25 States are identified with an asterisk (*).

Barriers to Offering HIV Testing to Women of Unknown Status *during Labor* that States have Identified

	Test results take too long	Rapid or expedited tests not available	Too much emotional stress for the patient	Too difficult to obtain consent during labor	Insufficient time to counsel during labor	Too late for preventive treatment	Appropriate medication not available at hospital
AK							
AL*	●	● ■	●	●	●	●	●
AR							
AZ	●	●			●		
CA	●	●			●		
CO	●	●			●	●	●
CT*							
DC				●	●		
DE*	●	● ■					
FL*		● ■	● ■	● ■	● ■	■	●
GA*	●	●				●	
HI							
IA*		■		■	■	■	
ID*						■	
IL*	●	●	●	●	● ■	● ■	●
IN*							
KS*				■	■		
KY							
LA*	●	●					
MA		●	●				
MD*	●	● ■					
ME*	●	■		■	■		
MI*	●	●	●	●	●		
MN*							●
MO							
MS							

Legend:

● = **State HIV/AIDS director** identified this as an ongoing barrier in the State

■ = **ACOG representative** with **statewide** perspective identified this as an ongoing barrier. Only includes the 25 State ACOG representatives that indicated a statewide perspective on barriers. These 25 States are identified with an asterisk (*).

Barriers to Offering HIV Testing to Women of Unknown Status *during Labor* that States have Identified (cont.)

	Test results take too long	Rapid or expedited tests not available	Too much emotional stress for the patient	Too difficult to obstain consent during labor	Insufficient time to counsel during labor	Too late for preventive treatment	Appropriate medication not available at hospital
MT*		■					
NC*	●	●					
ND							
NE	●	●					
NH	●	●	●	●	●	●	●
NJ	●	●	●	●	●	●	
NM*		●					●
NV*			●	●	●		
NY*							
OH*					■		
OK							
OR	●	●			●		
PA*							
PR							
RI							
SC							●
SD							
TN*	●	● ■	●	●	●	● ■	●
TX	●	●					
UT							
VA		●			●		
VT							
WA*					■		
WI*	●				■		
WV							
WY							

Legend:

● = **State HIV/AIDS director** identified this as an ongoing barrier in the State

■ = **ACOG representative** with **statewide** perspective identified this as an ongoing barrier[1]

[1] Only includes the 25 State ACOG representatives that indicated a statewide perspective on barriers. These 25 States are identified with an asterisk (*).

APPENDIX B

State Laws, Regulations, and Policies

This chart represents information gathered through the OIG survey of State HIV/AIDS Directors. It has not been independently verified by the OIG and therefore is not intended as an exhaustive review of all State laws, regulations or policies on HIV counseling and testing of pregnant women. **Legend**: X= required; √ = recommended

	TESTING			PRETEST COUNSELING		CONSENT		DECLINATION OF TESTING		POST-TEST COUNSELING		NEWBORN TESTING
State	Routine with Right of Refusal	Voluntary, Informed Consent	Document Testing Offered	To all Pregnant Patients	State Prescribed Information	Written	Document in Chart	Written	Document in Chart	Provide Regardless of Results	State Prescribed Information	
AK		√										
AL		√	√	√	√	X				√	X	
AR	X		X	X	√		√			√	√	√
AZ		√				√	√		X			
CA		X	X		√		X			√	√	
CO										X		
CT		X	X	X	X	X	X	X	X	X	X	X
DC		√	√	√	√	√				√	√	
DE		X	X	X	X		X		X	X		
FL		X	X	X	√	√	X	X	X	√	√	
GA		√	√	X	√	X	X			√	√	
HI		√		√	√	√				√	√	
IA		√	√	√	√		√			X	X	
ID					√	X				√		
IL			√	X	X	X				√	X	

	TESTING			PRETEST COUNSELING		CONSENT		DECLINATION OF TESTING		POST-TEST COUNSELING		NEWBORN TESTING
State	Routine with Right of Refusal	Voluntary with Informed Consent	Document that Testing Offered	To all Pregnant Patients	State Prescribed Information	Written	Document in Chart	Written	Document in Chart	Provide Regardless of Results	State Prescribed Information	
IN		X	X	√					X			
KS		√		√	√	√				√	√	
KY		√				√	√				√	
LA		√			X	X	X			√	√	
MA		√		√	√	X				√		
MD		X				X				X	X	
ME		√		√		X				X		
MI[2]	X	√	X	X	X	X		X	X	X	X	
MN	√		√			√	√		√	√		
MO		√		√	X					X		
MS[3]	√	√	√	√					√	X		
MT		√		√	X	√	√			X	X	
NC		X		X	X					X	X	

2 Physicians and other licensed prenatal care providers must test pregnant patients at their initial appointment for venereal disease, HIV and hepatitis B, unless the provider believes that the tests are medically inadvisable or the woman refuses. Providers must still obtain written, informed consent for HIV testing using the Department of Health's prescribed form and provide the patient with a copy of the HIV information pamphlet developed by the Department of Health.

3 Specific informed consent for HIV testing is not required in Mississippi. However, the provider must inform the patient that the test is being conducted. The Mississippi Department of Health has a policy of counseling and offering voluntary HIV testing to all pregnant patients in its own clinics, and recommends that other providers do the same.

	TESTING			PRETEST COUNSELING		CONSENT		DECLINATION OF TESTING		POST-TEST COUNSELING		NEWBORN TESTING
State	Routine with Right of Refusal	Voluntary with Informed Consent	Document that Testing Offered	To all Pregnant Patients	State Prescribed Information	Written	Document in Chart	Written	Document in Chart	Provide Regardless of Results	State Prescribed Information	
ND		√		√		X			√			
NE		√		√	√	X						
NH		√	√	√			√		√	X		
NJ		X	X	X	X	X		X	X	X	X	
NM		√	√	√		√	X		√			
NV	√		√	√	√	√	√		√	√	√	√
NY		X	X	X	X	X			√	X	X	X
OH		√	√	√	√	√	√	√	√	√	√	
OK	√		√			X		√	√	√	√	
OR										√		
PA		√		√	√	X				X	X	
RI		X	X		X	X		X	X	√	√	
SC												
SD												
TN	X		X	X	X	X		X	X		X	
TX	X		X	X	X	X	X		X		X	
UT		√	√	√		√		√	√	√		
VA		X	X	X					X	X		
VT		√		√						√		√

	TESTING			PRETEST COUNSELING		CONSENT		DECLINATION OF TESTING		POST-TEST COUNSELING		NEWBORN TESTING
State	Routine with Right of Refusal	Voluntary with Informed Consent	Document that Testing Offered	To all Pregnant Patients	State Prescribed Information	Written	Document in Chart	Written	Document in Chart	Provide Regardless of Results	State Prescribed Information	
WA		√	√	X	X		√				X	
WI		√		√		X				√		
WV		√		√	X	X				X		
WY												

Source: OIG survey of State HIV/AIDS Directors

APPENDIX C

State Efforts to Address Obstetrician Barriers

This chart represents information gathered through the OIG survey of State HIV/AIDS Directors. The directors were asked to list "perinatal HIV prevention efforts that the State has undertaken to address *obstetrician* barriers to offering HIV tests to all pregnant women." This compendium has not been independently verified by the OIG and therefore is not intended as an exhaustive review of all States' efforts related to reducing obstetrician barriers to offering HIV testing.

State	Provider Education			Collaboration with Private Partners	Patient Education		Research		Outreach to high risk women	Established Referral Network	Hot-lines
	Training	Letters	Education Materials		Materials	Media Campaign	Epidemiology	Issue Specific			
AK	Ongoing	X	1999				1999				
AL		Ongoing			Ongoing						
AR		since 1996	1998 1999	X							
AZ		1996	1996 1998								
CA		X	1996-1998				1998-2000	1996 1999-2004			
CT	1999	1996	1996 1999	1999-2000				1998 2001			
DC	2000-2001	X		2000-present		2001		1999	1999-2001		
DE	2001	X									
FL	2000	1995				1996-1999 2000-2001		1999			
GA	Ongoing	X			since 2001			1997	since 2001		since 2001
HI		X		X							

State	Provider Education			Collaboration with Private Partners	Patient Education		Research		Outreach to high risk women	Established Referral Network	Hot-lines
	Training	Letters	Education Materials		Materials	Media Campaign	Epidemiology	Issue Specific			
IA		X									
IL	2000-2004	X	2001-2002	2000-2004				1998			
IN		X						1998-1999			
KS		X									
KY		X									
LA	since 2000	2001		X						2001	
MA		X	Ongoing				Ongoing	2000 2002			
MD	Ongoing	X	Ongoing			1999-2002					
ME	since 1997	X	2000	since 1999				1998 2001			
MI	since 1999	2001	1998	since 2000							
MN	1998-2001	2000	since 1999	X							
MO			1996	1996				1995 1998			
MS		1995	1995	1995							
MT		1995-1996	since 1999	X	1999-2000			1998			
NC		X		since 2001				2001			

State	Provider Education			Collaboration with Private Partners	Patient Education		Research		Outreach to high risk women	Established Referral Network	Hot-lines
	Training	Letters	Education Materials		Materials	Media Campaign	Epidemiology	Issue Specific			
ND		X			2001						
NE		1996	1996								
NH	1997-1999	1997		1997	1997						
NJ	since 1994	X	1997 since 1999	since 2000				1997			
NM	since 1996		since 1996	X	since 1996						since 1995
NV				participating in				1992 1999			
NY	Ongoing	Ongoing	Ongoing	X	Ongoing			1999	Ongoing	Ongoing	
OH	1998-1999	1996	1996							1999-2000	
OK	Ongoing	Ongoing	Ongoing								
OR	1998		1997					X			
PA	1997-2000		1999	Ongoing			2000	1999			
RI	2001	X									
SC		1996	2001	since 1995				1997 2000			
TN		X								since 1999	

State	Provider Education			Collaboration with Private Partners	Patient Education		Research		Outreach to high risk women	Established Referral Network	Hot-lines
	Training	Letters	Education Materials		Materials	Media Campaign	Epidemiology	Issue Specific			
TX	Ongoing	X	1996 2001	since 2001	ongoing		since 1998 1999-2000	1997 1997-1998			
UT	Ongoing	Annually	Ongoing					1999			
VA		X	2001	since 2001				1996 2002			
WA		X	1995 1997-2000	1993	1995			1995 2001-2002		1995	
WI	1996	1995 1999	1995 1998 2000	1995	since 1996			1993 1996			
WV	1998	X	1995 1997		1995 1997			1995			

Source: OIG survey of State HIV/AIDS Directors

Notes:

This chart represents 46 States. The missing States are: CO, ID, PR, SD, VT, WY. While CO, ID, SD and VT did indicate that they had formal collaborations with other governmental agencies regarding perinatal transmission, this chart only documents collaborations with private partners.

Education materials include such things as: State recommendations or guidance for counseling and testing, laminated cards with counseling tips, cost-benefit analysis, resource packets including such things as CDC guidelines and standard consent forms.

APPENDIX D

Methodology for National Estimate

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Centers for Disease Control
and Prevention (CDC)

Memorandum

December 7, 2001

Susan Otter
Program Analyst
Dept. of Health and Human Services
Office of Inspector General (OIG)
Office of Evaluation and Inspections
233 N. Michigan Ave., Suite 1390
Chicago, IL 60601

Reference: Estimates of the number of HIV-positive infants whose mothers were diagnosed after birth

Dear Ms. Otter:

The attached table provides the estimates of the number of HIV-positive infants born in the United States in 2000 as requested by your office for your study of the impact of the Ryan White Reauthorization Act of 2000. Your study will result in a report by the OIG entitled "Reducing Obstetrician Barriers to HIV Testing." As you are aware, since the cessation of the anonymous seroprevalence survey of births to HIV-positive mothers (i.e., the Survey of Childbearing Women (SCBW)), and because it is no longer possible to model HIV incidence from AIDS surveillance data due to the successful impact of antiretroviral treatments and prophylaxis for opportunistic illnesses in delaying progression to AIDS among HIV-positive children, there is no longer a single source of nationally representative data from which to derive estimates of the number of HIV-positive infants born each year.

To produce the estimates that you require, we have used the best available data. However, we caution that the data we used come from multiple sources, represent some but not all states, were collected during variable time periods, and have different biases and limitations. However, in cross-checking components of our estimates with prior estimates, we conclude that the data in the attached table represent a plausible range of the number of HIV-infected children born in 2000. For example, our modeled estimate of the number of HIV diagnoses in women of childbearing ages added to the estimated prevalence of AIDS in women of childbearing ages is consistent with previous published estimates of HIV prevalence in childbearing women ages from the SCBW. Also, the estimated percentage decline in perinatally-acquired HIV infections in our estimates is consistent with previously published declines in the number of perinatal AIDS cases, as would be expected. The lack of reports from all states of adult/adolescent women who have been diagnosed with HIV infection is the most critical deficit in our ability to model the estimated number of HIV-positive births. States that monitor perinatally-exposed and infected children and that report adults who have been diagnosed with HIV are able to conduct comprehensive epidemiologic follow up to obtain the data needed to evaluate the effectiveness

and impact of perinatal prevention efforts. Although many of the studies from which we derived parameter estimates were not designed to be nationally representative, the characteristics of the study populations are similar in many cases to the distributions by race/ethnicity, sex, and risk group of national AIDS surveillance data. We have made numerous such assumptions throughout the attached table in applying estimates from a few states to all states. Because the estimates in Table 1 do not represent actual counts of infants, we recommend presenting the estimates as a range. We cannot calculate precise confidence intervals, therefore, we present the range of estimates adjusted by +/- 10%, and rounded to the nearest ten.

A large number of additional data tables, with explanatory technical notes, from databases maintained in-house by the Surveillance Branch of the Division of HIV/AIDS Prevention were provided under separate cover to your staff. Our conclusions from all the data presented are that there have been enormous achievements in reducing perinatal transmission in the United States. The data also provide useful insights into the programmatic and surveillance efforts that are needed in order to further reduce perinatal HIV transmission. Reducing barriers to prenatal care, substance abuse prevention and treatment, the development of rapid testing and short-course treatment interventions in labor and delivery for mothers who do not access or receive prenatal care, increased offering of HIV testing in pregnancy, improving access to standard of care for pregnant mothers for treatment of their HIV disease, and clinical follow up of perinatally-exposed infants so they can receive prompt prophylaxis against opportunistic infections, diagnosis and treatment are needs that are highlighted by the attached estimates and accompanying data tables. Finally, comprehensive surveillance programs are needed in many more states in order to monitor the outcomes and impact of perinatal HIV prevention efforts.

We appreciate your interest in the HIV/AIDS surveillance data. If we can be of further assistance in the preparation of your report, please contact me at 404-639-2050.

Sincerely yours,

Patricia L. Fleming, PhD, MS
Chief, Surveillance Branch
Division of HIV/AIDS Prevention
National Center for HIV/STD/TB Prevention

cc: Robert S. Janssen
Eva Margolies-Seiler

Table 1. Estimate of the number of HIV-positive infants, by mother's knowledge of HIV status before, at, or after birth, United States, 2000

	Rate	Low estimate	Estimate	High Estimate
Modeled estimate of HIV+ women 13-44 diagnosed and living with HIV without AIDS in 2000 [1]			72,336	
Adjustment to estimate undiagnosed HIV+ women [2]		(Low 1.11) 80,293		(High 1.19) 86,080
Estimated births to HIV+ women 15-44 without AIDS (avg. 6 births per 100 PY) [3]		4,818		5,165
Estimated number of women 13-44 living with AIDS in 2000 [4]			49,238	
Estimated births to 46% women with immunologic AIDS (3.2 pregnancies per 100 PY) [5]		725	(=)	725
Estimated births to 54% women with clinical AIDS (2.0 pregnancies per 100 PY) [6]		532	(=)	532
Estimated total births [7]		6,075		6,422
Scenario I (Based on observed data)				
(Proportion) and number of births whose mothers were diagnosed:				
before birth	(.89)	5,407		5,716
at birth	(.05)	304		321
after birth [8]	(.06)	364		385
(Transmission rates (tm)) and number of HIV+ infants whose mothers were diagnosed:				
	tm rate			
before birth				
60% combination ARV	(.02)	65		69
40% ZDV 076	(.06)	130		137
at birth	(.10)	30		32
after birth [9]	(.25)	91		96
Total		316		334
Scenario I: Estimated HIV+ Infants [10]			**280-370**	
Estimated HIV+ Infants whose mothers were diagnosed after birth [9]		**80**		**110**

	Rate	Low Estimate	Estimate	High Estimate
Scenario II: Hypothetical data assuming mothers diagnosed after birth were diagnosed before birth				
(Proportion) and number of births whose mothers were diagnosed before birth (0.89 + 0.06) at birth	(.95) (.05)	5,771 304		6,101 321
(Transmission rates) and number of HIV+ infants whose mothers were diagnosed:				
before birth: 60% combination ARV 40% ZDV 076 at birth Total	(.02) (.06) (.10)	69 138 30 237		73 146 32 251
Scenario II: Estimated HIV+ infants [11]		210		280
Scenario III: Hypothetical data assuming all mothers were diagnosed before birth				
(Proportion) and number of births whose mothers were diagnosed before birth (.89+.05+.06)	(1.0)	6, 075		6,422
(Transmission rates) and number of HIV+ infants whose mothers were diagnosed:				
before birth: 60% combination ARV 40% ZDV 076 Total	(.02) (.06)	73 146 219		77 154 231
Scenario III: Estimated HIV+ infants [12]		**190**		**260**

Footnotes

(1) CDC unpublished data. Dr. Robert H. Byers developed a Poisson regression model to estimate the number of persons living with diagnosed HIV infection in the United States. The model is based on data from 25 states that conduct confidential (i.e. by patient name) HIV case reporting. Estimates of the number of prevalent diagnosed cases of HIV are derived from the relationship between AIDS incidence and deaths, taking into account race/ethnicity, risk, age, and a proxy variable for the age of the epidemic in each state. A parsimonious model was selected that obtained the best fit of observed cases to modeled estimates and the model was applied to non-HIV reporting states. The estimated total number of women (13-44) living with diagnosed HIV (without AIDS) in the United States was derived. An approximate 95% confidence interval for the estimate is from 71,809 to 72,865. These numbers do not represent actual counts of HIV-infected women because they are based on a model.

(2) Not all HIV-infected women are diagnosed with HIV in the 25 HIV reporting states that were the basis for the total U.S. estimates in (1) above. Thus, the estimate only represents a proportion of all women with HIV (without AIDS). We used two methods (high and low) to adjust the estimate in (1). In data from 7 states (Wortley et al., 2001), the number of mother-infant pairs that were diagnosed and reported to HIV/AIDS surveillance was 90% of the total number of births to HIV+ women in those states, as estimated from the anonymous Survey of Childbearing Women. This rate of completeness of reporting was used to obtain the factor for the low estimate (1/.9=1.11). Because these data only represented 7 states, we used an indirect method to obtain the factor for the high estimate. Assuming that the number of prevalent HIV cases in women 15-44 years from previously published estimates remained stable (Davis et al., 1998), we compared the estimated prevalence of HIV (without AIDS) for the U.S. (86,000 in 1994) to the estimated prevalence of diagnosed HIV (without AIDS) in 2000 (86,000/72,000=1.19).

(3) We used published data from Lee et al., 2000. The average number of births to HIV+ women (without AIDS) was 6 per 100 person years (PY). The data were derived from a population of positive compared to negative women receiving Medicaid in Maryland. Although not necessarily representative of all HIV+ women in the U.S., the study is unique in examining fertility of HIV+ women in the U.S. and the study population included mostly racial/ethnic minority women who account for the vast majority of AIDS cases in women in the U.S. The underlying assumption is that the age distribution and fertility of the study population is similar to that of all HIV+ U.S. women.

(4) Estimate is derived from national AIDS surveillance data and represents all women of childbearing age living with AIDS in the U.S. at the end of 2000. Data are adjusted for reporting delays. (CDC unpublished data)

(5) With increasing age, both fertility decreases and HIV disease progresses, which in itself is associated with decreased fertility. Fertility has generally been presumed to be low in women with AIDS. To estimate births to women with AIDS, we used unpublished CDC data from the Adult/adolescent Spectrum of Disease project (ASD) conducted in over 100 clinics in 11 U.S. cities. Data on HIV+ adults/adolescents are abstracted at 6 month intervals. We calculated the number of recorded pregnancies for women 15-44 per 100 person years of observation during 1994-1999. For women with AIDS, we divided our calculations into women with immunologic AIDS (representing 46% of women with AIDS and having 3.2 pregnancies per 100 person years (PY)) and,

(6) women with clinical AIDS (i.e. AIDS opportunistic illnesses; 54% of women with AIDS and having 2.0 pregnancies per 100 PY). ASD does not necessarily record pregnancy outcome such that the underlying assumption is that the pregnancies resulted in live births, which may slightly overestimate the number of live births to women with AIDS.

(7) The sum of (3), (5), and (6) for low and high estimates.

(8) In 7 states that conducted the Surveillance to Evaluate Prevention project (STEP), the proportion of mothers who were tested for HIV before their child's birth rose from 1993 through 1997 and then stabilized at an estimated 89% of all perinatally exposed infants who were diagnosed as indeterminate or infected and reported to surveillance; 5% of mothers were diagnosed at the time of labor and delivery, and 6% of mothers were found to be HIV positive after their child's birth. This assumes that mothers who are diagnosed before birth have the opportunity for all 3 arms of the 076 protocol (prenatal, intrapartum, neonatal); those diagnosed at birth have the opportunity for two arms; infants of those diagnosed after birth may receive one or no arms. (CDC unpublished data; Hammett et al., 2001)

(9) Because there is a lag between births to positive mothers and enough time to conduct follow up testing of the infant to determine infection status, and for reporting to health departments and then to CDC, we used unpublished CDC data on transmission rates for perinatally exposed infants reported from the 7 STEP states who were born during 1995 through 1997. Mothers who had an opportunity to receive all three arms of the Pediatric AIDS Clinical Trials Group (PACTG) protocol 076 (prenatal, intrapartum, neonatal) had an observed 6% transmission rate. Based on data from all HIV reporting states in 2000, we applied that transmission rate (i.e. 0.06) to 40% of the estimated number of infants born in 2000 whose mothers were diagnosed before birth. We applied a lower transmission rate (2% from recent unpublished data presented at national conferences from observational cohorts) to 60% of mothers who were diagnosed before birth. These mothers were receiving combination antiretroviral therapy which reduced transmission to rates substantially lower than those observed for the 076 protocol alone (8% in the PACTG 076 trial). The data from STEP states are more recent and may reflect additional factors associated with reductions in transmission, such as stage of maternal disease or mode of delivery, thus accounting for the observed 6% in these states versus 8% in the 076 trial. We applied a transmission rate of 0.1 to those mothers who were diagnosed at birth (intermediate between 6% and 14%, the range observed for infants who received two or one arm(s)). In the 7 STEP states, the observed transmission rate for all perinatally exposed infants diagnosed and reported for the baseline year 1993 (before 076 results) was approximately 20%. However, we applied the 25% reported for the placebo arm in the 076 trial to the 6% of births whose mothers were diagnosed after birth to produce a conservative (i.e. maximum) estimate of the number of infected infants born because their mothers were not tested at or before birth. The estimated range of the number of infants born whose mothers were not diagnosed before or at birth is from 91 to 96 infants. Because the parameter estimates in this exercise are derived from a variety of studies each of which may represent a small proportion of all HIV+ mothers in the U.S. , we adjusted our estimates to an approximate range of +/- 10% (82-106), and rounded up and down to the nearest ten, for an estimated range of 80 to 110.

(10) The sum of the estimates of positive births for all categories of timing of maternal diagnosis and transmission rates. As in (9), the calculated range of 316 to 334 is based on estimates that are not necessarily representative of all HIV+ U.S. mothers and we estimate that an approximate range is +/- 10% or 284 to 367, which, rounded to the nearest ten, is 280-370 HIV-positive infants born in 2000. The estimated proportion of all HIV+ infants born in 2000 that is attributable to mother's testing after birth ranges from 22% (80/370) to 39% (110/280). The peak number of live births to HIV+ women occurred in 1991. From the anonymous Survey of Childbearing Women, an estimated 7,040 births to HIV+ mothers occurred in that year, of which it is assumed that 1,760 were HIV+ infants based on a 25% transmission rate. The estimated range of 280 to 370 HIV+ infants born in 2000 represents a decline in perinatally acquired HIV infections of between 79% and 84%. This is consistent with the observed decline perinatally acquired AIDS cases. These cases peaked in 1992 and declined more than 80% through 2000.

(11) At OIG's request, we constructed two hypothetical scenarios. First, assuming that all mothers diagnosed after birth were diagnosed before birth and received treatment prenatally, the estimated

number of HIV-positive infants born in 2000 would be 237-251. After adjusting +/- 10% and rounding to the nearest ten, the estimated number of HIV-positive infants under this scenario is in the range 210-280.

(12) Second, assuming that all mothers diagnosed at or after birth were diagnosed before birth and received treatment prenatally, the estimated number of HIV-positive infants born in 2000 would be 219-231. After adjusting +/- 10% and rounding to the nearest ten, the estimated number of HIV-positive infants under this scenario is in the range 190-260.

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Lindegren, ML, R Byers, P Thomas, et al. Trends in perinatal transmission of HIV/AIDS in the United States. JAMA 1999;282:531-538.

Wortley PM, ML Lindegren, PL Fleming. Successful implementation of perinatal HIV prevention guidelines: a multistate surveillance evaluation. CDC MMWR 2001;50(No.RR-6):17-28.

Table 2. Summary * of Estimated transmission rates and numbers of HIV+ infants whose mothers were undiagnosed before, at, or after birth, United States, 2000

Diagnosed	Proportion Treated	Transmission	Low estimate of births	High estimate of births
Before birth	0.6 ARV	0.02	65	69
	0.4 ZDV 076	0.06	130	137
At birth		0.10	30	32
After birth		0.25	91	96
Total			316	334

* Derived from Table 1

**Estimated range after adjustment and rounding (see footnote 10): 316 x 0.9=284; round down to 280; 334 x 1.1=367

Table 3. Summary* of estimated ranges of HIV+ infants born in 2000 assuming three scenarios - 89%, 95% and 100% of mothers diagnosed before birth and treated prenatally, United States, 2000.

Proportion of mothers diagnosed before birth:	Adjusted estimated ranges of HIV+ infants
.89	280-370
.95	210-280
1.00	190-260

* Derived from Table 1

APPENDIX E

National Obstetrician Survey Instrument

1. Do you currently practice obstetrics?

☐ Yes ☐ No (If NO, please SKIP to Question 23)

2. In what State and zip code is the majority of your obstetrics practice located?

☐ State _____ Zip Code *(For the rest of this survey, please ONLY consider your practice in this particular location.)*

PRENATAL HIV COUNSELING AND TESTING

3. To how many of your pregnant patients do you offer HIV testing?

☐ None ☐ Some ☐ Most ☐ All

4. Which BEST describes your procedure for offering HIV testing to a pregnant patient? (Check ONE)

☐ Advise her that I will perform the test and that she has the right to refuse

☐ Offer to perform an HIV test but indicate that it is her choice

5. Which steps, if any, occur prior to you testing a pregnant woman for HIV? (Check ALL THAT APPLY)

☐ I (Obstetrician) discuss HIV and perinatal transmission with patient

☐ Other staff discusses HIV and perinatal transmission with patient

☐ Patient receives written information or a video on HIV

☐ Other (please specify)
_____

☐ Patient signs consent form to cover all prenatal tests

☐ Patient signs specific consent form for HIV test

☐ Patient gives verbal consent for HIV test

6. Which category BEST reflects your HIV testing practices with each of the following types of patients?

	Recommend against testing	Test only upon patient request	Offer testing	Recommend testing
Pregnant women at high risk for HIV	☐	☐	☐	☐
Pregnant women at low risk for HIV	☐	☐	☐	☐

7. What steps do you take if your pregnant patient refuses to consent to HIV testing?

Document refusal in the patient's medical record	No	Yes
Inquire as to the reason for refusal	No	Yes
Re-offer testing at a subsequent prenatal appointment	No	Yes
Other (please specify)_____	No	Yes

8. Does your office/clinic have a written policy regarding HIV counseling and testing of pregnant women?

No Yes

9. Are you familiar with your State's laws or policies regarding HIV testing of pregnant women?

No, I'm not familiar | Yes, I'm familiar | My State has no such laws or policies

PRENATAL HIV TESTING BARRIERS

For Questions 10 and 11, please consider only the time period prior to the onset of labor.

10. Please consider any instances in which you have NOT offered HIV testing to a pregnant patient. Has each of the following EVER been a reason that you have NOT offered an HIV test to a pregnant patient? If yes, HOW OFTEN has this prevented you from offering an HIV test?

	Has This Ever Prevented You from Offering an HIV Test?		Once or twice	Sometimes	Often	Always
Pretest counseling too time-consuming	No	Yes ➔				
Consent process too time-consuming	No	Yes ➔				
Patient is at low risk	No	Yes ➔				
Concern about offending patient	No	Yes ➔				
Late entry into prenatal care	No	Yes ➔				
Inadequate reimbursement	No	Yes ➔				
Concern about informing a pregnant woman she's HIV-positive	No	Yes ➔				
Concern about treating an HIV-positive patient	No	Yes ➔				
Language barrier	No	Yes ➔				
It is not the standard of care in my hospital/clinic	No	Yes ➔				

11. To what extent would each of the following help YOU, in your practice, to routinely offer HIV testing to all of your pregnant patients?

	Not Helpful	Somewhat Helpful	Very Helpful
Continuing education courses on perinatal HIV			
Training on HIV counseling			
Scripts for HIV counseling			
Reducing time involved in pretest counseling requirements			
Reducing time involved in consent requirements			
Designating a non-physician staff member to conduct HIV counseling and to obtain consent			
Making voluntary HIV testing of all pregnant women the standard of care in my hospital/clinic			
Inclusion of HIV test in standard prenatal testing battery			

Resource lists of HIV specialists and treatment hotlines	☐	☐	☐
Patient education materials	☐	☐	☐

HIV COUNSELING AND TESTING DURING LABOR AND DELIVERY

12. Do you offer HIV testing to women in labor with unknown HIV status?

☐ Never ☐ Sometimes ☐ Often ☐ Always

13. Please consider any instances in which a woman presented in labor with unknown HIV status. Has each of the following EVER been a reason that you have NOT offered an HIV test during labor? If yes, HOW OFTEN has this reason prevented you from offering an HIV test?

	Has This Ever Prevented You from Offering an HIV Test?		Once or twice	Sometimes	Often	Always
Test results take too long	☐ No	☐ Yes ➛	☐	☐	☐	☐
Rapid or expedited HIV tests not available	☐ No	☐ Yes ➛	☐	☐	☐	☐
Too much emotional stress for patient	☐ No	☐ Yes ➛	☐	☐	☐	☐
Insufficient time to counsel during labor	☐ No	☐ Yes ➛	☐	☐	☐	☐
Too difficult to obtain consent during labor	☐ No	☐ Yes ➛	☐	☐	☐	☐
Too late for preventive treatment	☐ No	☐ Yes ➛	☐	☐	☐	☐
Hospital did not have antiretroviral drugs available for treatment	☐ No	☐ Yes ➛	☐	☐	☐	☐

HIV TESTING OF NEWBORNS

14. What are your HIV testing practice(s) for newborns whose mother's HIV status is unknown?

Newborn testing is handled solely by newborn's physician	☐ Never	☐ Sometimes	☐ Often	☐ Always
I recommend testing to the newborn's physician	☐ Never	☐ Sometimes	☐ Often	☐ Always
I recommend newborn HIV testing to the mother	☐ Never	☐ Sometimes	☐ Often	☐ Always
I perform/order an HIV test for the newborn	☐ Never	☐ Sometimes	☐ Often	☐ Always
Other (please specify) _____				

15. Please consider newborns whose mother's HIV status is unknown. Has each of the following EVER been a reason that you have NOT tested such a newborn for HIV? If yes, HOW OFTEN has this reason prevented you from testing a newborn for HIV?

	Has This Ever Prevented You from Testing?		Once or twice	Sometimes	Often	Always
Recommended test to newborn's physician	☐ No	☐ Yes ➛	☐	☐	☐	☐
OB not responsible for newborn testing	☐ No	☐ Yes ➛	☐	☐	☐	☐
Lack of communication with newborn's physician	☐ No	☐ Yes ➛	☐	☐	☐	☐
Testing violates mother's privacy	☐ No	☐ Yes ➛	☐	☐	☐	☐
Parent(s) refused consent	☐ No	☐ Yes ➛	☐	☐	☐	☐
Patient(s) not likely to return for follow up	☐ No	☐ Yes ➛	☐	☐	☐	☐

16. Are you familiar with your State's laws or policies regarding HIV testing of newborns?

☐ No, I'm not familiar ☐ Yes, I'm familiar ☐ My State has no such laws or policies

ADDITIONAL INFORMATION AND SUGGESTIONS

17. Please describe any additional barriers to testing pregnant women and/or newborns for HIV.

18. Please offer any additional suggestions for reducing barriers to HIV testing of pregnant women and/or newborns?

BACKGROUND INFORMATION

19. Approximately what percentage of your practice is obstetrics? ☐ **%**

20. Have you ever provided care for an HIV-positive pregnant woman? ☐ Yes ☐ No

21. Have you received any educational materials or training on perinatal HIV from the following sources?

The American College of Obstetricians and Gynecologists (ACOG)	☐ Yes	☐ No
The Centers for Disease Control and Prevention (CDC)	☐ Yes	☐ No
Your State or local health department	☐ Yes	☐ No
Your hospital	☐ Yes	☐ No
Education course (outside your hospital)	☐ Yes	☐ No
Insurance company or managed care organization	☐ Yes	☐ No

22. About what percentage of your pregnant patients utilize each of the following insurance sources?

☐ % Private Insurance ☐ % Medicaid ☐ % Self-Pay/No Insurance ☐ % Other

23. Please provide the following demographic information.

a. Practice location:	☐ Urban	☐ Suburban	☐ Rural	☐ Military
b. Practice setting:	☐ Private, community	☐ Private, hospital	☐ Public, community	☐ Public, hospital
c. Gender:	☐ Female	☐ Male		
d. Years since completion of residency:	☐ Years			

APPENDIX F

Confidence Intervals for Selected Statistics

Statistic	Point Estimate	n	90 Percent Confidence Interval
Percent of obstetricians reporting the following testing practices:			
Routinely offer HIV testing to all prenatal patients	92.9%	475	90.9% to 94.8%
Routinely offer HIV testing to women of unknown status during labor	48.0%	464	44.2% to 51.8%
Never offer HIV testing to women of unknown status during labor	17.0%	464	14.2% to 19.9%
Newborn testing is the responsibility of the newborn's physician	93.4%	435	91.4% to 95.3%
Percent of obstetricians reporting that this barrier has ever prevented test offering *during prenatal care*:			
Language barrier	15.1%	458	12.3% to 17.8%
Late entry into prenatal care	13.3%	458	10.7% to 16.0%
Patient population is at low risk	13.1%	460	10.5% to 15.7%
Pretest counseling too time consuming	5.3%	457	3.5% to 7.0%
Consent process too time consuming	5.0%	457	3.4% to 6.7%
Concern about offending patient	4.6%	457	3.0% to 6.2%
Inadequate reimbursement	1.5%	458	0.6% to 2.5%
It is not the standard of care in my hospital/clinic	1.1%	452	0.3% to 1.9%
Concern about informing a pregnant woman she is HIV+	0.7%	457	0.0% to 1.7%
Concern about treating an HIV+ patient	0.7%	458	0.0% to 1.7%

Statistic	Point Estimate	n	90 Percent Confidence Interval
Percent of obstetricians reporting that this barrier has ever prevented test offering *during labor*:			
Insufficient time to counsel during labor	32.2%	451	28.6% to 35.8%
Too difficult to obtain consent during labor	28.2%	450	24.8% to 31.8%
Test results take too long	18.9%	451	15.9% to 21.9%
Rapid or expedited HIV tests not available	17.8%	451	14.8% to 20.7%
Too late for preventive treatment	17.7%	450	14.2% to 20.0%
Too much emotional stress for patient	8.9%	451	6.7% to 11.0%
Hospital did not have antiretroviral drugs available for treatment	1.1%	449	0.3% to 1.9%
Percent of obstetricians reporting the following sources of information on perinatal HIV:			
Received educational information or training from ACOG	93.6%	469	91.7% to 95.5%
Received educational information or training from CDC	71.2%	465	67.7% to 74.6%
Received educational information or training from their hospital	28.9%	463	25.4% to 32.3%
Received educational information or training from their State or local health department	53.0%	462	49.2% to 56.8%
Office/clinic has a written policy on HIV testing of pregnant women	45.9%	470	42.2% to 49.7%
Obstetrician is familiar with State laws or policies on HIV testing of pregnant women	61.5%	471	58.0% to 65.1%

APPENDIX G

Logistic Regression Models

We used logistic regression to identify predictors of several key variables. The following tables display the odds ratios for each of the significant predictors (at $p < 0.10$ level) in each of those logistic regressions. The non-significant variables are also listed below each table. In logistic regression, an odds ratio of 1 is considered neutral, an odds ratio greater than one is considered a positive relationship and anything less than one indicates a negative relationship. For example, obstetricians in the high prevalence strata are 1.73 times more likely not to face barriers in offering testing during prenatal care.

Logistic Regression Model 1: No Barriers during Prenatal Care

Predicting that none of the barriers on our survey have ever prevented an obstetrician from offering HIV testing during prenatal care.

Independent Variable	Odds Ratio	p-value
Positive Relationships:		
Obstetrician advises woman test will be performed but she can refuse	2.78	0.00
Obstetrician received information/training on perinatal HIV from CDC	2.05	0.01
Office/clinic has written policy on HIV testing of pregnant women	1.83	0.02
High prevalence strata	1.73	0.03
Negative Relationships:		
Obstetrician not familiar with State laws	0.35	0.00
Obstetrician received information/training on perinatal HIV from State/local health dept	0.57	0.04
Practice setting is in a hospital	0.59	0.05

Logistic Regression Model 2: No Language Barriers

Predicting an obstetrician will report that language has never been barrier to offering HIV testing during prenatal care. This model includes only the subset of obstetricians who reported at least one barrier to testing.

Independent Variable	Odds Ratio	p-value
Positive Relationships:		
Obstetrician practices in an suburban location (compared to urban or rural)	**2.17**	**0.05**
Obstetrician received information/training on perinatal HIV from State/local health dept	**1.93**	**0.09**
Negative Relationship:		
Obstetrician routinely offers testing to prenatal patients	**0.39**	**0.08**

Non-significant variables in model: obstetrician received information/training on perinatal HIV from CDC; strata; office/clinic has written policy on HIV testing; percentage of patients with no insurance; obstetrician provides patient with written materials or video on HIV prior to testing

Logistic Regression Model 3: No "Late Entry into Prenatal Care" Barriers

Predicting an obstetrician will report that late entry has never been a barrier to offering HIV testing during prenatal care. This model includes only the subset of obstetricians who reported at least one barrier to testing.

Independent Variable	Odds Ratio	p-value
Positive Relationships:		
Obstetrician practices in an urban location (compared to rural)	4.66	0.06
Obstetrician received information/training on perinatal HIV from their hospital	3.66	0.01
Obstetrician routinely offers testing to women in labor with unknown status	2.61	0.05
Percentage of patients with private insurance	1.01	0.03
Negative Relationship:		
Obstetrician routinely offers testing to prenatal patients	0.18	0.00

Non-significant variables in model: years since completion of residency; suburban practice location (compared to rural); strata

Logistic Regression Model 4: No Risk Assessment Barriers

Predicting an obstetrician will report that "patient population at low risk" has never been a barrier to offering HIV testing during prenatal care. This model includes only the subset of obstetricians who reported at least one barrier to testing.

Independent Variable	Odds Ratio	p-value
Positive Relationships:		
Obstetrician routinely offers testing to prenatal patients	6.93	0.02
Office/clinic has written policy on HIV testing	2.12	0.09
Years since completion of residency	1.06	0.03
Negative Relationships:		
Obstetrician reported "concern about offending patient" as a barrier	0.10	0.00
Percentage of patients with private insurance	0.98	0.02

Non-significant variables in model: suburban practice location (compared to rural); recommending testing (vs offering testing) to women at low risk for HIV

Logistic Regression Model 5: Not Routinely Offering Testing during Labor

Predicting that obstetrician does not routinely offer testing to women in labor with unknown HIV status.

Independent Variable	Odds Ratio	p-value
Positive Relationships:		
Obstetrician reported a risk assessment barrier during prenatal care	5.07	0.00
Obstetrician reported "late entry into prenatal care" as a barrier during prenatal care	2.84	0.01
Negative Relationships:		
Obstetrician advises woman test will be performed but she can refuse	0.25	0.00
Obstetrician received information/training on perinatal HIV from hospital	0.34	0.00
High prevalence strata	0.66	0.07
Obstetrician received information/training on perinatal HIV from a course (outside hospital)	0.67	0.08

Non-significant variables in model: percentage of practice that is obstetrics; obstetrician received information/training on perinatal HIV from CDC; obstetrician received information/training on perinatal HIV from State/local health dept

Logistic Regression Model 6: No Barriers during Labor

Predicting that none of the barriers on our survey have ever prevented an obstetrician from offering HIV testing to a woman of unknown status during labor.

Independent Variable	Odds Ratio	p-value
Positive Relationships:		
Obstetrician advises woman test will be performed but she can refuse	2.33	0.00
Obstetrician received information/training on perinatal HIV from hospital	2.24	0.00
High prevalence strata	1.50	0.07
Negative Relationships:		
Obstetrician reported a risk assessment barrier during prenatal care	0.31	0.00
Obstetrician has ever cared for an HIV+ pregnant patient	0.56	0.03
Obstetrician not familiar with State laws	0.61	0.03

Non-significant variables in model: years since completion of residency

APPENDIX H

Non-Response Analysis

A consideration in survey analysis is that the results may be biased if non-respondents are significantly different from respondents. To determine whether such differences exist in this survey, we attempted to contact 60 non-respondents (30 from each strata) by telephone to ask them key questions from our survey. We randomly selected the 60 non-respondents and 60 replacements (in case we could not complete the interviews of the original 60) using a program called Rat-stats. Our office placed at least three phone calls to each of the 60 non-respondents and then to each of the 60 replacement non-respondents. Ultimately, we completed surveys for 30 practicing obstetricians. Additionally, we spoke with six non-respondents who do not currently practice obstetrics.

Using the 30 completed surveys, we compared the two groups, respondents and non-respondents, with regards to demographics, testing patterns and prenatal barriers. We used chi-square tests of association to identify any significant differences between these two groups of obstetricians. We considered differences significant if $p < 0.10$. Table 1 displays the characteristics that did not differ significantly between non-respondents and respondents. Table 2 displays the significant differences between the two groups.

Non-respondents did not vary from respondents in their test offering practices. Almost all obstetricians reported routinely offering testing to prenatal patients, and chi-square tests of association showed no significant difference between the reported test offering practices of respondents and non-respondents. Non-respondents' test offering practices in the labor and delivery setting also showed no significant differences from the respondents' practices during labor.

Likewise, the non-respondents did not differ significantly from respondents in whether they reported any barriers to offering testing during prenatal care. Also, non-respondents did not differ significantly from respondents for two of the top barriers to prenatal test offering identified by our survey, "patient population is at low risk" and "late entry into prenatal care."

However, some other prenatal testing barriers did differ between the two groups. Notably, non-respondents reported language barriers less often than respondents did. This variation could suggest that a language barrier affects less than the 15 percent of the universe of obstetricians as reported by our survey respondents. Additionally, some barriers reported by a small percentage of respondents were not reported by any non-respondents, and therefore, demonstrated a significant difference between these groups.

Table 1: Variables showing NO Significant Difference between Respondents and Non-Respondents

Variable	p-value
whether ob routinely offers testing to all prenatal patients	0.310
whether ob offers testing "never," "sometimes/often" or "always" during labor	0.390
whether ob reported any barriers during prenatal care	0.166
whether ob reported risk assessment barrier during prenatal care	0.647
whether ob reported late entry into prenatal care as barrier	0.207
whether ob concern about how to treat HIV+ woman as prenatal barrier	0.418
whether ob reported "not standard of care in my hospital/clinic" as prenatal barrier	0.232
whether ob practices in urban, suburban, rural or military location	0.330
whether ob has ever cared for HIV+ pregnant patient	0.335

Table 2: Variables showing Significant Differences between Respondents and Non-Respondents

Variable	p-value	Respondents	Non-Respondents
ob reported language barrier during prenatal care	0.007	15%	3%
ob is female	0.006	48%	23%

APPENDIX I

Agency Comments

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

FEB 22 2002

TO: Janet Rehnquist
Inspector General, HHS

FROM: Director
Centers for Disease Control and Prevention

SUBJECT: OIG/OEI Draft Report on "Reducing Obstetrician Barriers to Offering HIV Testing" (OEI-05-01-00260)

The widespread implementation of the Public Health Service guidelines for universal counseling and testing and perinatal use of zidovudine (ZDV) has sharply reduced transmission risk and the number of perinatally-acquired HIV infections in the United States. Analysis of U.S. perinatal AIDS surveillance data reported through June 2000 indicated a sharp decline in the number of perinatal AIDS cases; this decline was temporally associated with increasing ZDV use among pregnant women aware of their HIV status. Despite these declines, cases of perinatal HIV transmission continue to occur, largely because of missed opportunities for prevention, particularly among women who lack prenatal care or who are not being offered voluntary HIV counseling and testing during pregnancy.

The Centers for Disease Control and Prevention (CDC) conducts surveillance and research studies on various aspects of the interventions necessary to maximally reduce perinatal HIV transmission. CDC collaborates with state and local health departments to provide funding for surveillance, research, and programs to implement activities that enhance efforts to prevent mother-to-child transmission. The focus of your report, "Reducing Obstetrician Barriers to Offering HIV Testing" (OEI-05-01-00260), is one important component of the Department's overall efforts in preventing perinatal HIV transmission. This report will serve as a useful tool. However, we are concerned about the recommendations focused on CDC assuming a lead role in developing standards and guidelines. More detailed comments are provided below; edits and suggested revisions are included in the attachment for your consideration.

Preventing perinatal HIV transmission has been achieved largely by promoting HIV testing and treatment in clinical care settings, such as when women present for prenatal care. CDC has a lead role in HIV prevention, but on the other hand has only a supporting role in the development of standards and guidelines for reducing barriers to maternal HIV testing and reducing new infant HIV infections. Organizations that have lead roles in establishing health care practice, setting standards for practice, and authorizing reimbursement for services are best suited to alter the behavior of providers, who offer HIV testing, and to increase acceptance of testing or test-seeking by women. We believe these agencies should also have the lead role in developing and

implementing the changes recommended in the Office of Inspector General's (OIG) report. One example is the American College of Obstetricians and Gynecologists' (ACOG) influence in affecting practice patterns to prevent HIV perinatal transmission. ACOG's role is highlighted in the OIG survey findings of physician attention to educational efforts by professional organizations and CDC. According to the report, 94 percent of all obstetricians remembered receiving materials on perinatal HIV from ACOG compared with 71 percent who remembered receiving materials from CDC. In addition, the vast majority of obstetric providers in the United States is represented by ACOG and tends to look to the organization for models of prenatal forms and educational materials.

The recommendation that CDC should develop administrative tools, such as model consent forms and pamphlets, to make prenatal HIV testing universally routine might appear duplicative of the efforts undertaken by ACOG. For example, ACOG has a prenatal record for HIV testing that includes tear-off patient information sheets in at least two languages. ACOG also recommended that if HIV testing is not done, then physicians should document the refusal in the medical chart. We believe that CDC can more effectively serve in an advisory capacity and provide technical assistance in developing standards and guidelines. We will carefully review the recommendations directed at CDC in the context of our mission, areas of primary responsibility, existing resources, and programs and activities. We will also identify ways to promote increased collaboration with federal agencies responsible for activities outside CDC's purview and to offer expertise, as well as data and information, to other public health partners concerning the activities of their primary responsibility.

We appreciated the opportunity to collaborate with your staff in the production of the report, and we are grateful for the opportunity to contribute data and information. If you have any questions regarding these comments, please contact Mr. Alvin Hall, Acting Director, Management Analysis and Services Office, or Mr. Joe Davis, IG/GAO Audit Liaison, at telephone (404) 498-1500.

Sincerely,

Jeffrey P. Koplan, M.D., M.P.H.
Director

Attachment

FEB -8 2002

TO: Inspector General

FROM: Acting Administrator

SUBJECT: Office of the Inspector General (OIG) Draft Report, "Reducing Obstetrician Barriers to Offering HIV Testing" (OEI-05-01-00260)

We appreciate the opportunity to respond to the above subject draft report. Attached are HRSA's comments

Staff questions may be referred to John Gallicchio on (301) 443-3099.

Betty James Duke

Attachment

Health Resources and Services Administration's Comments on the Office of Inspector General's Draft Report: "Reducing Obstetrician Barriers to Offering HIV Testing"
Code OEI-05-01-00260

General Comments

Thank you for the opportunity to provide comments on the draft Office of Inspector General (OIG) report entitled "Reducing Obstetrician Barriers to Offering HIV Testing" dated December 2001.

In a previous meeting between the OIG and Health Resources and Services Administration (HRSA), it was stated that approximately 85% of deliveries in the U.S. were assisted by obstetricians. Do we know the percentage of pregnancies in which the prenatal care is offered by obstetricians as opposed to family practice specialists, nurse midwives, etc? If one assumes that the proportion is lower, there are implications about the relevance of this study.

HRSA also questions whether the barriers are the same for obstetricians practicing in rural versus urban areas and whether presenting this information would be useful. If so, we suggest presenting information on the rural versus urban distribution of the 80-110 HIV-infected infants who were born to mothers who had not been diagnosed with HIV.

In addition, The American College of Obstetricians and Gynecologists (ACOG) and the AIDS Education and Training Centers (AETCs) have an important role to play in education of the obstetrical providers and HIV providers respectively.

HRSA agrees with the recommendations on page 30 to focus efforts on tool development to simplify and facilitate HIV counseling and testing for women with unknown HIV status at labor and delivery. This is an important group to reach. In fact, it should also be recommended that states continue if not enhance efforts to engage this population in prenatal care prior to the intrapartum period.

In several sections under Findings, the narrative discusses differences between three groups of obstetricians: those who routinely offer HIV testing; those who sometimes offer; and, those who never offer testing. The latter two groups are an important target audience for many of the recommendations in the report. Consequently, it would be very helpful to display a table that summarizes their barriers to HIV counseling and testing. Similarly, it would be helpful to display a table that summarized key findings and strategies from obstetricians who routinely offer HIV testing, that may be replicated in other groups.

The report aggregates findings from all states that submitted data. It would be useful to summarize regional differences in barriers to HIV counseling and

testing, as appropriate. This would assist DHHS Agencies to prioritize efforts as necessary.

OIG RECOMMENDATION:

The CDC and HRSA, in collaboration with CMS, Should Expand Efforts Aimed at Developing the Capacity to Offer Linguistically Appropriate HIV Patient Education and Consent Materials.

HRSA RESPONSE:

We concur with the recommendation. We are pleased that there is additional clarity in the report on how the Maternal and Child Health Bureau (MCHB) in the Health Resources and Services Administration (HRSA) and the Centers for Disease Control and Prevention (CDC) should work together on implementing the recommendations of the report.

OIG RECOMMENDATION:

The CDC, HRSA and States Should Promote Public/Private Partnerships to Design, Implement and Institutionalize Targeted Efforts to Remove Obstetrician.

HRSA RESPONSE:

We concur with the recommendation.

Technical Comments

Page iii: Under the second Recommendation, 1st line after CDC, add " HRSA, in collaboration with CMS."

Page iii, Third Recommendation: The CDC should facilitate 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. We suggest that OIG include AHRQ as another resource for collaboration on development of protocols

Page iii, second paragraph in plain font should read: "*The CDC,HRSA, and Centers for...*" HRSA was left out of this paragraph but it was included in the subheading.

Page iv, under the Recommendation, add this sentence to the end: "HRSA should strengthen application guidance materials for all Ryan White CARE Act providers to come into compliance with recommendations."

Page iv, first sentence should read: '*The CDC and HRSA should promote...*'

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: FEB - 4 2002

TO: Janet Rehnquist
Inspector General

FROM: Thomas A. Scully
Administrator

SUBJECT: Office of Inspector General Draft Report: *Reducing Obstetrician Barriers to Offering HIV Testing* (OEI-05-01-00260)

Thank you for the opportunity to review and comment on the above-referenced report.

The report does not contain any specific recommendations for the Centers for Medicare & Medicaid Services (CMS) as the lead agency. We concur with the recommendation that CMS work with states and the Centers for Disease Control and Prevention to urge hospitals and hospital associations, including the Joint Commission on Accreditation of Healthcare Organizations, to incorporate labor and delivery protocols for HIV testing into each hospital's written care standards.

Office of the Vice President
Practice Activities
Stanley Zinberg, MD, MS, FACOG
Telephone 202/863-2500
Fax 202/863-4909

January 30, 2002

Janet Rehnquist
HHS/Office of Inspector General
Room 5246 Cohen Building
330 Independence Avenue, SW
Washington, DC 20201

Dear Ms. Rehnquist:

The American College of Obstetricians and Gynecologists is pleased to be invited to review and comment on the Department of Health and Human Services' Office of Inspector General's draft inspection report, "Reducing Obstetrician Barriers to Offering HIV Testing." ACOG was happy to help develop and disseminate the survey instrument as well as reviewing the preliminary findings with DHHS OIG staff. We were pleased that Jan Chapin and Debra Hawks were asked to meet with DHHS OIG staff to provide comments on the attached draft. We also appreciate your many kind remarks in the report about ACOG's assistance in this survey.

For the past several years, ACOG has been involved in numerous activities to help reduce perinatal HIV transmission. This has involved policy setting and developing educational materials as well as administering federal grants from the Centers for Disease Control and the Maternal and Child Health Bureau (MCHB) to further aid obstetrician-gynecologists in reducing HIV transmission during pregnancy.

General Comments:

Overall, the DHHS OIG's report should provide a valuable reference to clinicians as well as policy makers on additional barriers to perinatal HIV testing. Of particular note is the DHHS OIG's finding that language poses a significant barrier. The recommendations are specific and targeted, which should facilitate implementation.

We are pleased with the positive approach that asked ob-gyns about the barriers they encounter as they attempt to counsel and test all pregnant women for HIV. We are also pleased about the recommendations that call for greater formal involvement of ob-gyns as partners in developing and implementing the solutions to the barriers that have been identified.

THE AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS • WOMEN'S HEALTH CARE PHYSICIANS
409 12TH STREET SW WASHINGTON DC 20024-2188
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202/638-5577

It is very important that the language used in the report is clear and consistent. This will avoid misinterpretation that can lead to unnecessary criticism. For example, when describing the estimate for the number of HIV-infected infants (page i, 11-12), two different terms are used and it is not clear if the report means those infants who are born HIV positive, which includes the infant who ultimately will not be infected, or if it means only those infants who are truly HIV-infected.

It is important to be clear at the beginning, and throughout the report at the appropriate places, that, although the legislation limited the scope of the study to obstetrician-gynecologists, both family physicians and Certified Nurse Midwives provide a significant (although unknown) quantity of private sector prenatal care. Further, in some public prenatal care programs, nurse practitioners may provide some care as well. It appears from the survey ACOG undertook in North Carolina that the certified nurse midwives were less likely than the other two groups of providers to provide routine testing during prenatal care.

The reference to "ACOG chairpersons" throughout the report should be changed to "ACOG Section/District chairpersons." Page 10, paragraph 1, line 1, change to "chairperson that heads each State Section or District."

Page 2--You may wish to cite the AAP/ACOG HIV policy statement, Joint Statement on Human Immunodeficiency Virus Screening" (May 1999) in paragraph 1 on page 2.

Page 3 – HIV testing at Labor and Delivery. This section makes it sound like rapid testing is easily available at all sites. According to information from the survey of ob-gyns that was undertaken for this report as well as reports that we have received from ob-gyns, this is definitely not the case, particularly in smaller community hospitals and rural areas. The significance of this barrier should not be underemphasized since it is one that CDC and FDA have some ability to influence by trying to expedite the development, approval and deployment of true rapid tests.

Page 4 – The MCHB cooperative Agreement with ACOG had as a focus over the last two years improving HIV counseling and testing for pregnant women. We were able to work directly in two states (NC and CT) and with the Association of Maternal and Child health Programs in seven additional states (contact Frances Varella at AMCHP for additional information). However, the MCHB has requested that ACOG focus this cooperative agreement on women's health rather than perinatal heath issues in the coming year. Without additional funding, it will be difficult to repeat the successes that both the individual state projects and the joint AMCHP projects have attained.

Page 5 – It would be helpful to list the years of each of the programs and projects described in this section. It is important to be clear about which were one-time projects and which are on-going activities.

APPENDIX J

Endnotes

1. Ryan White CARE Act Amendments of 2000, Pub. L. No. 106-345, Title II, Sec. 213 (2000).

2. Lindegren, M.L., et al (1999). Trends in Perinatal Transmission of HIV/AIDS in the United States. JAMA, 282, 531-538.

3. Mofenson L.M., Lambert J.S., Stiehm E.R., et al. (1999). Risk factors for perinatal transmission of human immunodeficiency virus type 1 in women treated with zidovudine. New England Journal of Medicine, 341, 385-93. Ioannidis J.P.A., Abrams E.J., Ammann A., et al. (2001). Perinatal transmission of human immunodeficiency virus type 1 by pregnant women with RNA viral loads less than 1,000 copies/ml. Journal of Infectious Disease, 183, 539-45. Garcia P.M., Kalish L.A., Pitt J., et al. (1999). Maternal levels of plasma human immunodeficiency virus type 1 RNA and the risk of perinatal transmission. New England Journal of Medicine, 341, 394-402.

4. American Academy of Pediatrics - American College of Obstetricians and Gynecologists Joint Statement on Human Immunodeficiency Virus Screening. (1999).

5. Stoto, M. A., Almario, D. A. & McCormick, M. C. (Eds.). (1999). Reducing the Odds: Preventing Perinatal Transmission of HIV in the United States. Washington, DC: National Academy Press.

6. Ryan White CARE Act Amendments of 1996, Pub. L. No. 104-146 (1996).

7. Centers for Disease Control and Prevention. (2001). Revised Recommendations for HIV Screening of Pregnant Women. Morbidity and Mortality Weekly Report, 50 (RR-19), 59-100.

8. Centers for Disease Control and Prevention. (1999). Prenatal Discussion of HIV Testing and Maternal HIV Testing — 14 States, 1996-1997. MMWR, 48(19), 401-404.

9. Stoto, M. A., Almario, D. A. & McCormick, M. C. (Eds.). (1999). Reducing the Odds: Preventing Perinatal Transmission of HIV in the United States. Washington, DC: National Academy Press.

10. Compiled from the following sources: American College of Obstetricians and Gynecologists (2000). [National Obstetrician Perinatal HIV Survey, and North Carolina Obstetrician Perinatal HIV Survey]. Unpublished raw data. Wilson, E. L., Hamm, R. H. & Kleier, K. M. (1998). Perinatal HIV Prevention: A Statewide Survey of Missouri Health Professionals About Critical Issues on Perinatal HIV Transmission. Missouri Epidemiologist, 20 (5), 1-6.

11. Centers for Disease Control and Prevention. (2001). Morbidity and Mortality Weekly Report, 50 (No. RR-6), 23.

12. Centers for Disease Control and Prevention. (2001). Revised Recommendations for HIV Screening of Pregnant Women. Morbidity and Mortality Weekly Report, 50 (No. RR-19), 59-100.

13. All infants born to HIV-infected mothers are HIV-exposed, but not all infants subsequently develop HIV .

14. Lindegren, M.L., et al (1999). Trends in Perinatal Transmission of HIV/AIDS in the United States. JAMA, 282, 531-538.

15. Centers for Disease Control and Prevention. (2000, December). HIV/AIDS Surveillance Report, 12 (No.2);36.

16. Compiled from: Centers for Disease Control and Prevention. (2001). Revised Recommendations for HIV Screening of Pregnant Women. MMWR, 50(No. RR-19), pp. 59-85. Lindgren, ML, et al. (1999). Trends in Perinatal Transmission of HIV/AIDS in the United States., JAMA, 282 (6), 531-538.

17. Lindgren, ML, et al. (1999). Trends in Perinatal Transmission of HIV/AIDS in the United States., JAMA, 282 (6), p. 531-538.

18. Centers for Disease Control and Prevention. (2000, December). HIV/AIDS Surveillance Report, 12 (2), 9.

19. Lindegren, ML, Steinberg, S, & Byers, RH (2000). Epidemiology of HIV/AIDS in Children, HIV/AIDS in Infants, Children, and Adolescents, 47(1).

20. Lindegren, ML, Steinberg, S, & Byers, RH (2000). Epidemiology of HIV/AIDS in Children, HIV/AIDS in Infants, Children, and Adolescents, 47(1).

21. Centers for Disease Control and Prevention. (2000). HIV/AIDS Surveillance Report, 12 (2), 7

22. Centers for Disease Control and Prevention. (2000). HIV/AIDS Surveillance Report, 12 (2), 14.

23. Lindgren, ML, et al. (1999). Trends in Perinatal Transmission of HIV/AIDS in the United States., JAMA, 282 (6), 531-538.

24. Ibid.

25. Health Resources Services Administration. (2001). Services for Children, Youth, Women, and Their Families (Title IV). (hab.hrsa.gov/care.html).

26. Centers for Disease Control and Prevention. Perinatal HIV Prevention Program. (www.cdc.gov/hiv/projects/perinatal/grantees.htm).

27. Centers for Medicare & Medicaid Services. (2001). Fact Sheet: Medicaid and AIDS and HIV. (www.hcfa.gov/medicaid/obs11.htm).

28. Centers for Medicare & Medicaid Services. Reducing HIV Transmission: The Maternal HIV Consumer Information Project. (www.hcfa.gov/hiv/subpg6.htm).

29. Centers for Disease Control and Prevention. (2000, January 10). Meeting to Discuss Epidemioology Branch Projects for the Program to Maximally Reduce Perinatal HIV Transmission: American College of Obstetricians and Gynecologists. (www.cdc.gov/hiv/projects/perinatal/summarymeeting.htm).

30. Royce, RA, et al. (2001). Barriers to Universal Prenatal HIV Testing in 4 US Locations in 1997, American Journal of Public Health, 91(5), 727-733.

31. The Survey of Childbearing Women's primary objective was to determine the prevalence of HIV infection among women delivering live infants in the United States and to provide information about the demographics, location, and seroprevalence trends of this population over time. The survey was based on anonymous HIV testing of leftover blood specimens collected on filter paper for routine newborn metabolic screening and on existing public health programs in all areas conducting the survey. The survey was halted in 1995 after debate as to whether the testing should be unblinded in order to locate and treat newborns and their mothers determined to have HIV.

32. The entire ACOG membership database contains 42,943 records. For the purposes of our sample selection a subset of Fellows, Junior Fellows in Practice, Junior Fellow Residents, Junior Fellow Resident/CREOG and Fellow Senior status was created. Also removed from the overall database were ACOG members whose prior mailings were returned due to a bad postal address, those members indicating that they never wish to receive mailings from ACOG and those members that indicated that they did not want their name published. This created a sampling frame of 32,161 obstetricians and gynecologists.

33. Centers for Disease Control and Prevention. (2000). HIV/AIDS Surveillance Report, 12 (2), Table 1.

34. Centers for Disease Control and Prevention. (2000). HIV/AIDS Surveillance Report, 12 (2), Table 1, Table 2, Figure 5.

35. Ranges do not sum precisely to 280-370 due to rounding of the individual estimates versus adding the estimates and then rounding the sum. All estimates are extrapolated from the CDC data. We adjusted CDC's high and low estimates by +/- 10 percent and rounded up and down to the nearest 10. This presentation of estimated, rounded ranges of HIV-infected newborns is consistent with CDC's presentation of the data. See Appendix D.

36. Using data from medical record reviews includes an inherent assumption that the earliest HIV testing date for the mother found in the medical records is in fact the earliest test. However, this might not be the case. The mother may have had testing out-of-state, anonymously or had testing at another facility. Also, physicians may simply not have indicated on the records that and HIV test was recommended or conducted.

37. Centers for Disease Control and Prevention. (2001). Morbidity and Mortality Weekly Report, 50 (No. RR-6), 23.

38. The survey question read, "To how many of your pregnant patients do you offer HIV testing?" and the response choices included "none," "some," "most," or "all." The obstetricians to whom this report refers to as "routinely" offering testing to pregnant women are those who indicated "all" to this question. It is noted, however, that some of the obstetricians who checked "all" also identified one or more barriers that have ever prevented them from offering an HIV test. We have interpreted this discrepancy by designating those who both checked "all" and indicated barriers as "routinely" offering testing but being subject to occasional exceptions to this standard practice.

39. Passel, J., & Zimmerman, W. (2001). Are Immigrants Leaving California? Settlement Patterns of Immigrants in the Late 1990's. Washington DC: Urban Institute. (http://www.urban.org/pdfs/are_immigrants_leaving_ca.pdf).

40. The survey question read, "Do you offer HIV testing to women in labor with unknown HIV status?" and the response choices included "never," "sometimes," "often" and "always." The obstetricians to whom this report refers to as "routinely" offering testing to women in labor with unknown status are those who indicated "always" to this question. It is noted, however, that some of the obstetricians who checked

"always" also identified one or more barriers that have ever prevented them from offering an HIV test during labor. We have interpreted this discrepancy by designating those who both checked "always" and indicated barriers as "routinely" offering testing but being subject to occasional exceptions to this standard practice.

41. There is still an argument for testing under these circumstances. First, the obstetrician may have time to suggest that the mother not breast-feed, a recommended preventive measure. Also, if the mother is HIV-infected, the CDC recommends initiating prophylactic treatment for the infant to protect against PCP, the most common cause of death for perinatally-infected babies.

42. Stoto, M. A., Almario, D. A. & McCormick, M. C. (Eds.). (1999). Reducing the Odds: Preventing Perinatal Transmission of HIV in the United States. Washington, DC: National Academy Press.

43. The fourteen languages are: English, Spanish, Bosnian, Chinese, French, Haitian Creole, Hmong, Japanese, Khmer, Korean, Portugese, Russian, Vietnamese and Yupik.

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