Third-trimester repeat HIV testing: it is time we make it universal

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Since the 1990s, perinatal transmission of HIV has decreased substantially, largely as a result of improved detection secondary to routine HIV screening in pregnancy and the use of antiretroviral therapy. However, despite reductions in HIV transmission, elimination of perinatal transmission, defined as an incidence of perinatal HIV infection of <1 per 100,000 live births and a transmission rate of <1%, remains elusive. An estimated 80% of perinatal transmissions occur after 36 weeks' gestation, which highlights the importance of diagnosis and treatment of maternal HIV infection before the highest-risk period for perinatal transmission. With timely identification of seroconversion, intrapartum and neonatal interventions can lower the risk of perinatal transmission from 25% to 10%, substantially reducing perinatal transmission events. The American College of Obstetricians and Gynecologists and the Centers for Disease Control and Prevention recommend that routine HIV testing be performed in all pregnancies, as early in the prenatal course as possible. Third-trimester repeat testing is only recommended for individuals known to be at high risk of acquiring HIV ie, those who are incarcerated; who reside in jurisdictions with elevated HIV incidence; who are receiving care in facilities that have an HIV incidence in pregnant women > 1 per 1000 per year; or have signs or symptoms of acute HIV).. However, among reproductive-age women, heterosexual intercourse is the most common mode of HIV transmission, and the risk of HIV seroconversion is greater during pregnancy than outside of pregnancy. Furthermore, state statutes for HIV testing in pregnancy are largely lacking. In this clinical opinion, we reviewed the evidence in support of universal third-trimester repeat HIV testing in pregnancy using a successful state-mandated testing program in Illinois. In addition, we provided clinical recommendations to further reduce missed perinatal transmission cases by implementing universal third-trimester repeat testing, obtaining hospital buy-in, monitoring testing adherence, bridging communications across multidisciplinary teams, and engaging clinicians in advocacy work.

Key words: advocacy, HIV testing, neonatal HIV, perinatal HIV transmission, prenatal HIV testing, universal HIV testing

Introduction

HIV infection affects the lives of 1.1 million Americans. In 2018, approximately 38,000 people were newly diagnosed with HIV in the United States, and 19% of whom were female.[1] As many as 65% of women with a new HIV diagnosis are of reproductive age, with heterosexual intercourse being the most common mode of transmission.[1] It is estimated that 1 in 9 women living with HIV is unaware of their diagnosis,[2] leading to missed opportunities for engagement in healthcare, antiretroviral therapy, and prevention of transmission.

Perinatal transmission of HIV has decreased substantially since its peak in 1991, largely because of the increased detection secondary to routine HIV screening in pregnancy and the use of antiretroviral therapy.[3] These interventions, along with intrapartum and postpartum measures, have reduced perinatal HIV transmission rates from 25% to 30% to <2% in the United States.[4,5]

However, HIV seroconversion in pregnancy is one of the greatest risk factors of perinatal transmission, because of increased viremia associated with incident infection.[6] Although the lowest risk of transmission occurs when HIV is diagnosed before pregnancy and viral suppression is sustained throughout gestation, significant reductions in perinatal transmission are possible even with late antepartum or intrapartum diagnosis. Estimates suggest that 50% of perinatal transmission events occur between 36 weeks' gestation and delivery, with an additional 30% occurring in the intrapartum period.[7] However, the ability to reduce the risk of perinatal transmission hinges on knowledge of HIV status. Therefore, even diagnosis in a labor unit setting, with subsequent intravenous antiretroviral therapy administration, can reduce the risk of perinatal transmission from 25% to 10%.[8] In addition, when administered in conjunction with prelabor cesarean delivery and immediate neonatal presumptive HIV treatment, the risk can decrease even further. Unfortunately, in approximately 25% of infants born with HIV in the United States, maternal HIV was not diagnosed until the postpartum period.[9]

Current Screening Guidelines

Timely identification and treatment of HIV in pregnancy are critical to the

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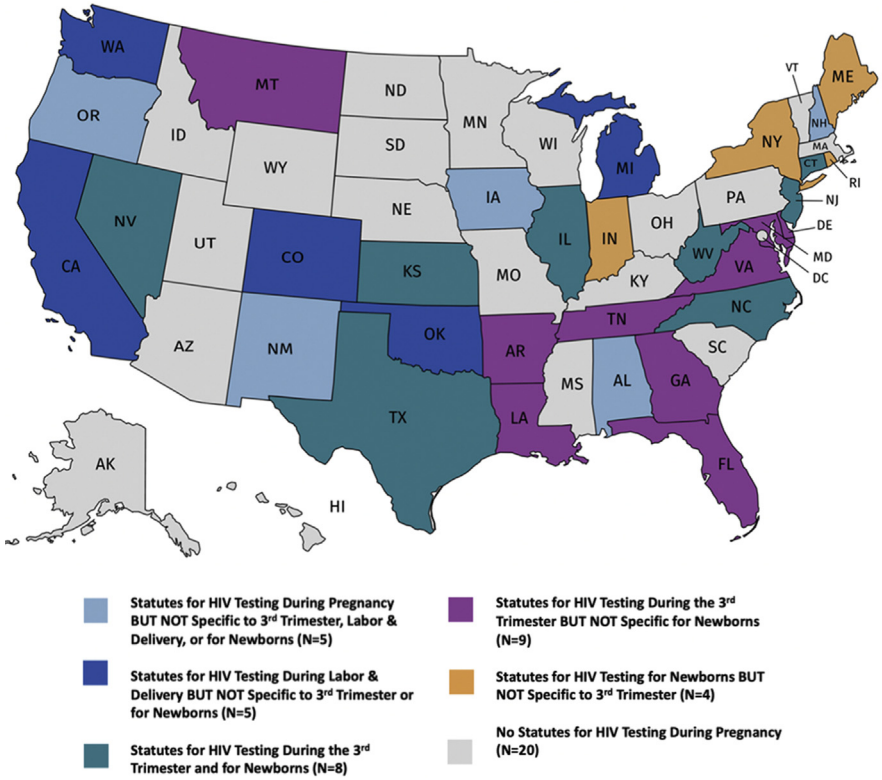
FIGURE
CDC map of statutes for HIV testing in pregnancy



Adapted from the Centers for Disease Control and Prevention.[12]

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elimination of perinatal transmission. The Centers for Disease Control and Prevention (CDC), the American College of Obstetricians and Gynecologists (ACOG), and the World Health Organization (WHO) have published guidelines for antenatal testing. The CDC and ACOG recommend that HIV testing be performed using the opt-out approach as early in pregnancy as possible. In addition, they recommend repeat testing in the third trimester (preferably between 28 and 32 weeks' gestation) for individuals at high risk of acquiring HIV, including those who are incarcerated; who reside in jurisdictions with elevated HIV incidence; who are receiving care in facilities that have an HIV incidence in pregnant women > 1 per 1000 per year; or have signs or symptoms of acute HIV.[10] In addition, they recommend rapid testing in labor units for patients without a previous HIV test in pregnancy.[10] Similarly, the WHO recommends HIV testing as a routine part of prenatal care.[11] The WHO only recommends repeat testing in the third trimester of pregnancy or on admission to labor units for patients living in high-burden or high-incidence areas.[11]

Despite these recommendations, 20 states do not have any statutes for HIV testing in pregnancy (Figure).[12] 4 states (Indiana, Maine, New York, and Rhode Island) lack statutes for testing in pregnancy but hold statutes for newborn testing; while, 5 states (Alabama, Iowa, New Hampshire, New Mexico, and Oregon) have statutes for testing during pregnancy but not in third-trimester or intrapartum period or for newborns.[12] Only 8 states require testing in the third trimester of pregnancy and in newborns.[12] Furthermore, 1 of the 8—Illinois—mandated HIV testing during pregnancy in 2003, and in 2018, universal third-trimester testing was added to the statute.[13] This law was implemented because of Illinois' experience with perinatal transmission, in which diagnoses were delayed until childhood secondary to the absence of repeat testing in pregnancy after an initial negative test. Simultaneously, there were several cases of seroconversion that were identified, in which prompt therapy in the third trimester of pregnancy contributed to the prevention of perinatal transmission. Thus, based on the Illinois experience, we aim to discuss the benefits of standard third-trimester HIV testing in pregnancy.

Importance of Testing

Rapid identification and treatment of new diagnoses of HIV in pregnancy are essential to the elimination of perinatal transmission. Between 2008 and 2012, the CDC reported that 23% of perinatal HIV transmissions were secondary to undiagnosed maternal infection.[14] Within that period, the CDC also estimated that 1.7% of births to pregnant individuals living with HIV were cases of HIV seroconversion during the pregnancy.[15]

Seroconversion is of particular concern as this has been found to increase the risk of perinatal transmission.[16] In acute HIV infection, patients experience viremia that may last several weeks,[17,18] and in addition to having high plasma viral loads, genital secretion viral loads rise.[19] Maternal plasma viral load is directly proportional to the risk of perinatal transmission.[20] Furthermore, several observational studies have shown that seroconversion during pregnancy contributes substantially to perinatal HIV transmission.[21,22] Based on these studies, the identification of maternal seroconversion may provide a crucial opportunity to eliminate perinatal transmission.

Illinois' Successful Testing Program

Illinois is 1 of 8 states with statutes in place for third-trimester and newborn testing. In 2003, Illinois passed the Perinatal HIV Prevention Act (Public Law 95-702), which mandated patients

be counseled about HIV testing in pregnancy and have documentation of HIV testing in all prenatal and newborn records.[23] For patients presenting to labor units without a documented HIV status, the Act mandated that providers offer a rapid test on admission. Moreover, 1 year later, funding became available through an initiative supported by the Illinois Department of Public Health to operationalize the policy and improve the implementation of rapid testing in labor units throughout the state.[24] This initiative, the Perinatal Rapid Testing Implementation in Illinois (PRTII), supported the previous year's Act through the allocation of resources for a comprehensive and coordinated statewide implementation plan and ongoing technical assistance to hospitals. Simultaneously, the 24/7 Illinois Perinatal HIV Hotline was established to provide support for hospitals conducting perinatal rapid testing. The Hotline provides clinical consultation in maternal-fetal medicine and pediatric and adult infectious disease specialists, including linkage to care and support services.

In 2006, an amendment was passed further mandating the continued existence of the Hotline, reporting of all positive perinatal rapid tests to the Hotline to ensure access to expert medical advice and case management, and mandatory neonatal HIV testing in situations in which maternal HIV status was unknown at delivery. In addition, the amendment mandated the development of a central reporting and monitoring system for monthly hospital testing statistics.[25] As a result of the mandate and PRTII funding, in subsequent years, over 95% of pregnant patients presenting to labor units had a documented HIV test.[24] Following expiration of PRTII funding, rapid HIV testing secondary to undocumented status in pregnancy continued at over 99%.[26] These findings demonstrated that despite discontinuation of funding, statewide HIV testing performance continued, maintaining public health efforts to prevent perinatal HIV transmission.

Subsequent internal epidemiologic data collected by the Hotline found that seroconversion during pregnancy was a contributor to perinatal transmission cases in the state.[27] To decrease seroconversion-related perinatal transmission, an additional amendment to the Act was passed (Public Act 100-0265) in 2017, mandating repeat opt-out HIV testing in the third trimester of pregnancy (after 27 weeks' gestation), rapid HIV testing in labor units for patients admitted without a documented third-trimester test, and mandatory testing for neonates born to patients without a negative HIV test from the third trimester of pregnancy.[13]

The Illinois testing mandate, state-supported comprehensive implementation initiative, and ongoing central reporting system and Hotline serve as an example of a successful statewide public health intervention. Yee et al[26] postulated that the success of the Illinois program was a product of the highly regulated data reporting system in place that imparted a sense of responsibility and accountability at each medical facility.

Cost-Effectiveness

HIV is unique in that the risk of transmission is low compared with other perinatal diseases, which raises the question: is universal third-trimester testing cost-effective? Based on multiple analyses, it seems so. Ishikawa et al[28] modeled the cost of universal HIV testing in pregnancy across 4 countries with low and high HIV prevalence. They found that even in low prevalence settings, universal testing in pregnancy was cost-effective. In addition, Sansom et al[29] performed a cost-effectiveness analysis to model outcomes associated with third-trimester testing and found that, in areas with HIV incidence of >1.2 per 1000 person years, third-trimester testing would result in net savings. Similarly, Scott et al[30] performed a cost-effectiveness analysis to model outcomes associated with universal rapid testing in labor units in high-incidence and high prevalence populations. They concluded that in areas with a cumulative HIV incidence in pregnancy > 0.2 per 1000 per year, universal rapid screening would be cost-effective.[30] Although the aforementioned studies do not evaluate the cost-effectiveness of universal third-trimester testing across low-incidence settings, we hypothesize that universal third-trimester testing could potentially be cost-effective even in these settings; however, the cost-benefit may vary by area of HIV seroprevalence.

Barriers to Uptake

Despite current HIV testing statutes across several states and the clear benefits of universal third-trimester testing, repeat testing is inconsistent even in high-incidence areas. Szlachta-McGinn et al[31] evaluated the adherence to CDC and ACOG guidelines for repeat testing in a high-incidence, tertiary care academic medical center in Florida. Florida is a state with mandated HIV screening as early as possible in the pregnancy and during the third trimester of pregnancy. In the absence of third-trimester HIV screening, testing on admission for delivery is required.[32] They found that among 1090 pregnant patients, 91.7% underwent HIV screening in the first or second trimester of pregnancy, whereas only 82.2% underwent repeat testing in the third trimester of pregnancy. Among those lacking third-trimester testing, only 89.3% eventually received a rapid test on labor and delivery.[31] Although few patients were missed, each missed test represents a potential failure to prevent perinatal transmission.

Similarly, Liao et al[33] conducted a retrospective cohort study of all individuals delivering at an urban academic center in Baltimore, another high-incidence city. They found that among 1632 patients, 98% of whom received prenatal care, only 28% received a repeat test after 26 weeks' gestation.[33] Among the patients without a third-trimester test, 5% were tested during their delivery hospitalization, either before delivery or before postpartum discharge. The authors evaluated patient and provider characteristics associated with repeat testing and postulated that inadequate retesting uptake in their hospital system was related to both parties' risk perceptions.[33]

TABLE
Recommendations for implementing third-trimester HIV testing and decreasing perinatal transmission

1. Universal third-trimester testing	• Retest all pregnant women for HIV, regardless of perceived risk, between 27 and 36 wk gestation • Consider incorporating third-trimester HIV screening as part of a panel with other third-trimester laboratory results
2. Hospital policy	• Develop a clinic, department, or hospital wide protocol for third-trimester testing • Consider incorporating implementation science principles to develop and maintain protocols
3. Monitoring testing adherence	• Collect and maintain data regarding third-trimester testing adherence; third-trimester testing missed opportunities; and clinical outcomes associated with missed testing
4. Clinical team involvement and advocacy	• Encourage medical assistants, nurses, and other clinical staff to take part in assessing medical records for missing third-trimester tests and recommending testing at clinical visits • Consider training for clinical nursing teams that incorporates third-trimester and labor and delivery testing • Encourage clinicians to engage in local and state advocacy to improve testing in their clinical settings

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Recommendations

Efforts to prevent perinatal transmission of HIV have expanded tremendously over the last 3 decades. However, despite a dramatic decline in perinatal infections, ongoing work is still needed to eliminate perinatal transmission. Although the use of antepartum, intrapartum, and neonatal antiretroviral therapies has contributed significantly to the decrease in perinatal transmission, unidentified maternal HIV infection remains a barrier to elimination. Based on the experience of several states and specifically the Illinois testing program, we believe the following clinical recommendations are required to reach the goal of elimination of perinatal HIV transmission (Table).

Recommendation Number 1: Universal Repeat Testing

We recommend universal testing of all pregnant patients in the third trimester of pregnancy, ideally before 36 weeks' gestation, rather than testing based on perceived risk. Studies have confirmed that provider perception of patient risk of HIV seroconversion is often a driving force in offering repeat testing.[34,35] Risk-based testing strategies are commonly inconsistent because of incorrectly perceived low-risk status, often as a result of providers not adequately assessing risk or patients not voluntarily disclosing risk factors; the inadequacies of risk-based testing in obstetrics have been demonstrated for many perinatal conditions. For example, Boudova et al[36] examined hepatitis C virus (HCV) screening practices in pregnancy at a major medical center in Maryland. They found that among patients with any risk factor for HCV infection, approximately 64% were not tested. In addition, 10% of pregnant patients with a positive HCV test had no risk factors.[36] Furthermore, despite heterosexual intercourse being the most frequent mode of HIV transmission among reproductive-age women,[1] most individuals with heterosexually transmitted HIV consider themselves to be at low risk.[37]

Transitioning to universal repeat testing in the third trimester of pregnancy would reduce inaccurate risk assessments and remove the stigma associated with repeat testing. At our institution, universal repeat testing is performed at the same prenatal visit as the gestational diabetes mellitus or third-trimester anemia screen. HIV testing can be added to a laboratory panel so that it routinizes the process, to the benefit of both patients and providers.

Recommendation Number 2: Hospital Policy

Paramount to the successful implementation of universal third-trimester testing is hospital buy-in and clinical flow integration. We recommend the evaluation of current hospital policies and administrative support and the development of hospital or department protocols and frameworks to improve testing. This may be achieved using an implementation process known as the "Expert Recommendations for Implementing Change" (ERIC).[38] ERIC involves an evidence-based approach to implementation science in which multiple stages are used sequentially to develop the best strategy for specific goals and situations.[38,39]

Another aspect of a successful implementation strategy is buy-in from hospital leadership. Rucker et al[40] conducted a retrospective study in which routine HIV testing was evaluated at 3 Chicago hospitals with varying levels of institutional support via the "Frontlines of Communities in the United States" (FOCUS) program.[41] The FOCUS program partners with medical facilities to identify the best practices to overcome implementation barriers to routine HIV screening. It focuses on 4 pillars to improve routine screening: testing integration into the clinical flow, electronic medical record modification, systemic policy change, and training with feedback and quality improvement.[41] In Rucker's study, the presence of all 4 pillars at 2 of 3 hospital sites facilitated increased HIV screening. In contrast, the hospital that tested the least number of patients relied heavily on providers offering screening, limited executive buy-in, and an electronic medical record that did not facilitate consent as part of the standard workflow.[40] Although we recognize that the incorporation of all 4 pillars is not feasible in all clinical

settings, we propose that, at a minimum, the development of a clinical protocol incorporating third-trimester repeat testing can greatly increase the consistency of testing.

Recommendation Number 3: Monitoring Adherence to Testing

Based on our experiences in Illinois, we believe that clinical facilities should collect and maintain data regarding successful and missed opportunities for third-trimester testing and clinical outcomes. Monthly hospital reports are a mainstay of Illinois' perinatal HIV safety net, and the information obtained through the central reporting system and the Hotline were fundamental in recognizing that seroconversion in pregnancy was contributing to perinatal transmission. In addition, through ongoing monitoring of testing frequency, clinicians and public health specialists can rapidly identify barriers to testing and implement changes on a local level.

Recommendation Number 4: Advocacy and Multiple Stakeholders

Lastly, clinicians must feel empowered to take on broader advocacy roles on the local and state government level and to ask for changes from local public health departments that may aid in increasing testing. We recommend that clinicians become involved with the process of advocating for legislation that mandates third-trimester testing, because even in the absence of funded programming, state laws have been shown to improve testing.[42] In addition, we recognize that the legislation of clinical care is not often recommended. While we recognize in the setting of HIV, stigma and implicit bias contribute to testing disparities. In our experience, legislation partnered with implementation support resolved these disparities and promoted universal repeat screening.[24,26]

Moreover, we call on nurses and other members of the healthcare team to become involved in the testing process. In Illinois, nurses have played a critical role in the successful execution of testing in obstetrical triage units and in intrapartum admission. In addition, in outpatient settings, nurses and medical assistants are the first points of contact during clinical visits; they spend a significant amount of time reviewing records and alert the team to outstanding laboratory results. Therefore, they are a key component of a safety net for patients who lack testing. Engaging nurses and other health professionals to champion HIV testing is an important aspect of developing effective teams for improving third-trimester testing.

Conclusion

Eliminating perinatal transmission of HIV—defined as an incidence of perinatal HIV infection of <1 per 100,000 live births and a transmission rate of <1%[43]—is a feasible goal. However, timely identification and treatment of maternal infection are fundamental to achieving this goal. Illinois' experience with state-mandated HIV testing in pregnancy, initial implementation program funding, and an ongoing statewide hotline that provides guidance to clinicians and tracks data are all essential in the efforts to eliminate perinatal HIV. We believe that there is important additional work to be done: improved surveillance on maternal seroconversions and perinatal HIV infections because seroconversions are critical areas of future focus. Given the importance of this cause, we call on clinicians and local public health experts to evaluate their current testing practices and consider the most appropriate ways to optimize and standardize universal third-trimester testing. We propose that small changes, even at the clinic level, will play a considerable role in reducing perinatal HIV transmission, ultimately making the elimination of perinatal HIV transmission a reality. ■

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