OBSTETRICS

Perinatal HIV testing and diagnosis in Illinois after implementation of the Perinatal Rapid Testing Initiative

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OBJECTIVE: The objective of the study was to assess whether implementation of a statewide initiative was associated with changes in perinatal human immunodeficiency virus (HIV) testing practices.

STUDY DESIGN: This was an observational cohort study of all 1,141,799 women who delivered in Illinois birthing hospitals over a 7 year period after the introduction of the Perinatal Rapid Testing Implementation in Illinois (PRTII) initiative. Changes in the frequencies of HIV status documentation, rapid test utilization, and newborns discharged with unknown HIV status were assessed.

RESULTS: The comparison of annual data from 2005 to 2011 demonstrated a 63% decrease in women with undocumented HIV status (11.7% vs 4.3%, $P < .001$), a 98% decrease in women with unknown status who did not receive rapid testing (29.6% vs 0.5%, $P < .001$), and a greater than 99% decrease in newborns with undocumented status at discharge (2.74% vs 0.01%, $P < .001$).

CONCLUSION: This statewide initiative resulted in a significant and sustained increase in the frequency of maternal-baby pairs who were discharged from the hospital with documented HIV status.

Key words: human immunodeficiency virus, perinatal transmission, rapid testing

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The risk of perinatal transmission of human immunodeficiency virus (HIV) among women who are infected with HIV and who receive no prophylactic interventions ranges from 15% to 40% but can be decreased to 1–2% with the use of widely available interventions in well-resourced settings.[1-4] Even in women not identified as HIV positive until they present in labor, the administration of antiretroviral treatment can reduce transmission by as much as 62%.[5] Because the timely identification of HIV-infected parturients is critical to reducing perinatal infection, in 2006 the Centers for Disease Control and Prevention began to recommend universal screening in pregnant women unless they decline (ie, opt-out screening).[6] Nevertheless, and as recently as 2008, 4% of HIV-infected pregnant women were not known to be positive at the time of delivery.[7]

In August 2003, Illinois passed the Perinatal HIV Prevention Act (Public Law 95-702). This act mandated the following: (1) counseling about and screening for HIV in all pregnant women as early in prenatal care as possible, (2) documentation of HIV test results in prenatal, labor and delivery and newborn medical records, and (3) offering rapid HIV testing to pregnant women presenting in labor without documented HIV status. No increase in hospital reimbursement accompanied this legislation and providers are not penalized for noncompliance with the law. Six months after the act was passed, only 72% of women who presented to Illinois birthing hospitals had their HIV status documented, and only 38% of hospitals reported routine rapid HIV testing on

★ EDITORS' CHOICE ★

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The Perinatal Rapid Testing Implementation in Illinois (PRTII) initiative was originally supported through a grant from the Illinois Department of Public Health. Collaborating institutions include the Illinois Department of Public Heath, the State of Illinois Perinatal HIV Taskforce, State of Illinois Regionalized Perinatal Network Administrators, the Midwest AIDS Training and Education Center, the Pediatric AIDS Chicago Prevention Initiative, the Hektoen Institute, the Ruth M. Rothstein CORE Center, and Northwestern University.

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labor and delivery for women with an undocumented status.[8]

In 2004, the Illinois Department of Public Health funded the Perinatal Rapid Testing Implementation in Illinois (PRTII) initiative to operationalize the policy changes stipulated in the law and achieve complete and effective implementation of rapid testing. This initiative was modeled on the experience of the Mother-Infant Rapid Intervention at Delivery (MIRIAD) study, a multicenter study that offered voluntary rapid HIV testing on labor and delivery units.[9] First, we conducted a statewide needs assessment surveying hospitals, conducting focus groups, and piloting implementation strategies to identify potential barriers to compliance. Second, 4 regional networks, each with a designated coordinator, were created to facilitate regional- and hospital-specific training that included the development of an implementation tool kit consisting of a manual, counseling flip chart, and templates of policies and consent forms. Third, a 24 hour a day, 7 day a week Illinois Perinatal Hotline was created to provide immediate assistance to hospitals caring for a woman with a positive rapid test by offering clinical management consultation, referral services, and case management services. The final component of the PRTII initiative involved ongoing surveillance and tracking of outcomes in a database linked to the Illinois Department of Public Health. The PRTII initiative started in 2004, and all Illinois birthing hospitals had implemented the protocol by September 2005.

The Perinatal HIV Prevention Act was revised in June 2006 to require testing of all neonates born to HIV-undocumented mothers within the first 12 hours postnatally. Fourteen other states have similarly passed legislation that requires HIV testing in pregnancy, 6 of which also mandate newborn testing if maternal status is undocumented.[10] There are 2 reports that associate the initiation of a state mandate with lower mother-to-child HIV transmission rates.[11,12] However, the quantitative changes in testing practices that led to this decrease were not fully described. Thus, there remains little information about the impact of state-initiated policies on clinical practice.

To understand whether the Illinois legislative mandates were associated with a change in clinical practice, this study was performed to investigate changes in perinatal HIV testing and in HIV status documentation among pregnant women in Illinois after the implementation of PRTII. We hypothesized that, after implementation, there would be progressive increases in both routine and rapid maternal testing for HIV and a decrease in the number of newborns tested after delivery. The sustainability of the intervention was also assessed.

Materials and Methods

The Illinois Perinatal HIV Prevention Act mandates that state birthing hospitals report monthly on the number of women who present with known HIV status, the number of pregnant women and newborn infants who undergo rapid HIV testing, and the number of preliminary and confirmatory positive test results. PRTII staff provided training to all 132 birthing hospitals in the state to collect and submit these data to the perinatal HIV database maintained by PRTII staff and supported by the Illinois Department of Public Health. The brand of rapid HIV test varied by birthing hospital.

A retrospective, population-based study was performed to analyze data submitted to this statewide database from January 2005 to December 2011. Data were collected from birthing hospitals (Figure 1) regarding the total number of women who delivered (Figure 1, box a) and the number who presented with documented (Figure 1, box b) and undocumented (Figure 1, box c) HIV status. A woman was considered to have undocumented status if she had not been tested in the current pregnancy or if her test result could not be confirmed by available prenatal records. Among women who had undocumented HIV status, the number who received rapid testing prior to delivery (Figure 1, box d) or immediately postpartum (Figure 1, box e) was ascertained (excluding women diagnosed with a fetal demise), as was the number of newborns who received rapid testing because maternal rapid testing was not performed (Figure 1, box f).

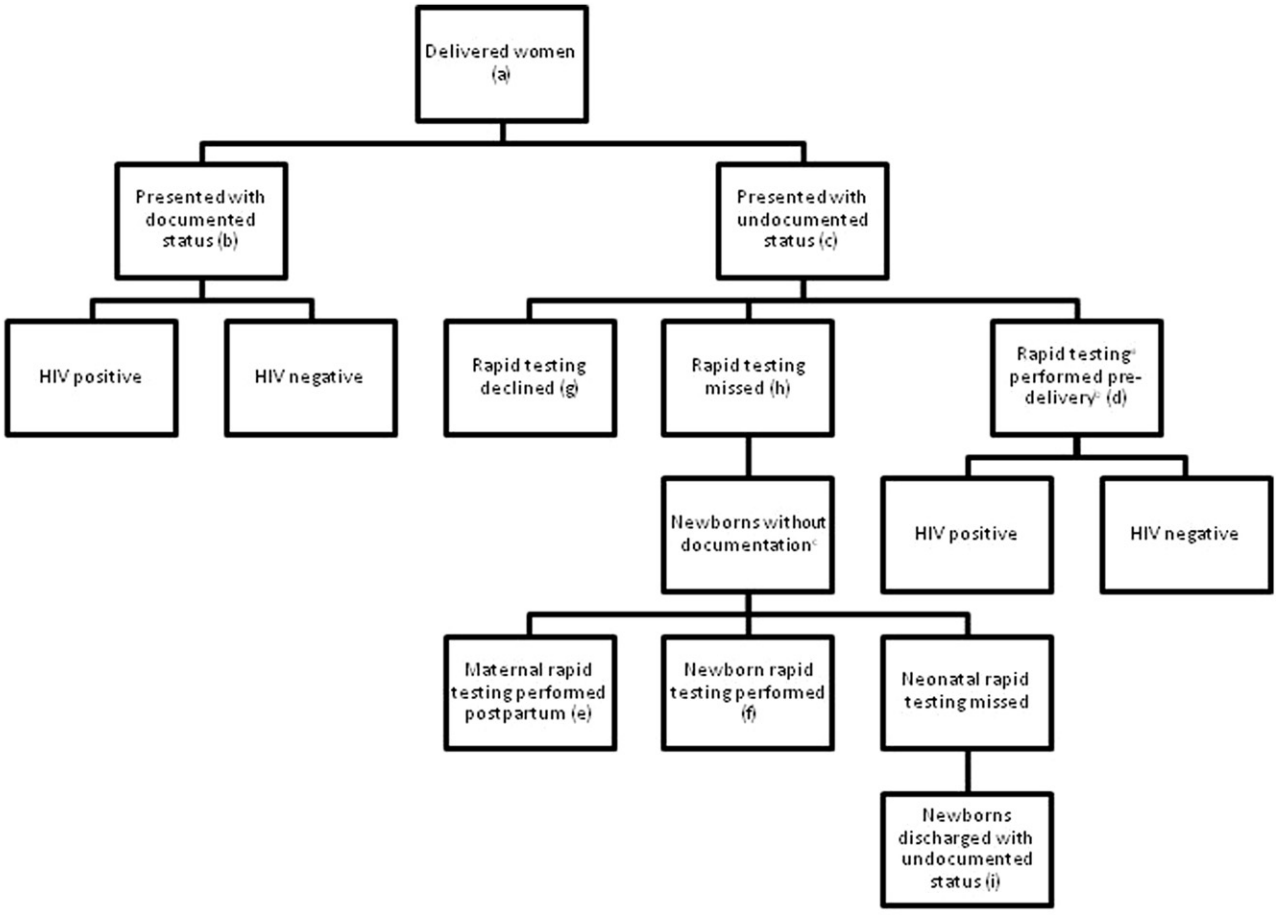
The number of newborns eligible for rapid testing included multiple gestations and those who were transported to the hospital after delivery but did not have documented maternal HIV status. Pregnant women with undocumented status at delivery who did not have rapid testing were categorized as declined (Figure 1, box g) if they were offered testing but refused or as missed (Figure 1, box h) if they were not offered the rapid testing prior to delivery (whether because of a clinical oversight or because their duration in the labor and delivery suite because of a precipitous delivery was too short to allow the rapid test). Women were identified as HIV positive if the confirmatory Western blot test also was positive. Finally, the number of newborns discharged from the hospital with an undocumented status was also determined (Figure 1, box i).

All data were stratified by quarter of each calendar year. Trends in frequency across years were assessed using χ^2 for trend, whereas comparisons of proportions were done with χ^2 analysis. Relative risks and 95% confidence intervals were calculated as appropriate. A value of $P < .05$ was used to define statistical significance, and all tests were 2 tailed. All analyses were performed with Minitab 13 (Minitab, Inc, State College, PA) and EpiInfo 7 (Centers for Disease Control and Prevention, Atlanta, GA). Prior to initiation, this study was approved by the Northwestern University Institutional Review Board.

Results

During the 7 year study period, 1,141,799 women delivered in the 132 birthing hospitals in Illinois. The Table presents data for these women, stratified by year, with regard to the testing they received and their HIV serostatus. Of these women, 72,344 (6.3%) presented to a hospital with undocumented HIV status. This frequency was highest during the first year of the study period and declined 63% over the study period (11.7%

FIGURE 1
Algorithm of perinatal HIV testing information submitted by Illinois birthing hospitals



[a] Rapid HIV test brands used were OraQuick Rapid HIV-1/2 Antibody Test (OraSure Technologies Inc, Bethlehem, PA), Reveal Rapid HIV-1 Antibody Test (MedMira Laboratories Inc, Halifax, Nova Scotia), Uni-Gold Recombigen HIV Test (Trinity Biotech PLC, Bray, Ireland), and Multispot HIV-1/HIV-2 Rapid Test (Bio-Rad Laboratories, Redmond, WA). Test brand varied by hospital.
[b] Excludes fetal demises
[c] Includes multiple gestations and transports

HIV, human immunodeficiency virus.

Wong. Illinois perinatal HIV testing. Am J Obstet Gynecol 2012.

in 2005 to 4.3% in 2011, $P < .001$). The proportion of women with unknown status who did not receive rapid testing also significantly declined from 29.6% to 0.5% ($P < .001$), a 98% reduction. This decline was due to decreases in both the proportion of women who declined testing (27.0% to 0.3%, $P < .001$) and the proportion of women in whom rapid testing was missed (2.7% to 0.2%, $P < .001$).

After accounting for the number of women with unknown HIV serostatus who declined or missed testing, multiple gestations, newborns who were transported, and women who had experienced a fetal demise, there were 6415 newborns whose mothers had undocumented serostatus. The rate of rapid testing of these newborns who were eligible for rapid testing increased over the study period from 5.9% to 67% ($P < .001$).

Cumulatively, 65,863 women or newborns who were eligible (91%) underwent rapid testing, a rate that significantly increased from 71.6% to 99.8% over the study period ($P < .001$). Of the rapid tests performed, 65,099 (98.7%) occurred prior to delivery. The number of newborns discharged from the hospital after delivery without documented HIV status decreased by 99%, from 3886 (2.74%) in 2005 to 8 (0.01%) in 2011 ($P < .001$).

Figure 2 illustrates the quarterly changes in the documentation of HIV status upon presentation to labor and delivery and rapid testing utilization. More than 99% of the total decline in undocumented status at the time of discharge occurred over the first 2 years of the study period. Both a decrease in the number of women with undocumented status (76% decline) and an increase in the use of rapid testing (99% increase)

TABLE
Documentation of HIV status and utilization of HIV rapid testing in the perinatal setting[a]

Variable	2005	2006	2007	2008	2009	2010	2011	Total
Total deliveries	141,773	175,230	175,160	171,473	160,050	159,483	155,355	1,141,799
Undocumented HIV status at presentation, n (%)[b]	16,575 (11.7)	12,902 (7.4)	10,672 (6.1)	9502 (5.5)	8557 (5.4)	7356 (4.6)	6878 (4.3)	72,344 (6.3)
Rapid testing not performed, n (%)[b,c]	4909 (29.6)	1932 (15.0)	179 (1.7)	105 (1.1)	93 (1.1)	48 (0.7)	36 (0.5)	7302 (10.1)
Declined, n (%)[b,c]	4470 (27.0)	1845 (14.3)	110 (1.0)	65 (0.7)	61 (0.7)	32 (0.4)	19 (0.3)	6602 (9.1)
Missed, n (%)[b,c]	439 (2.6)	87 (0.7)	69 (0.7)	40 (0.4)	32 (0.4)	16 (0.2)	17 (0.2)	700 (1.0)
Rapid testing performed, n (%)[b,c]	11,867 (71.6)	11,161 (86.5)	10,621 (99.5)	9478 (99.8)	8532 (99.7)	7341 (99.8)	6863 (99.8)	65,863 (91.0)
Maternal, before delivery[b]	11,625	10,970	10,493	9397	8464	7308	6842	65,099
Maternal, after delivery	0	16	22	14	10	0	5	67
Neonatal[b]	242	175	106	67	58	33	16	697
Preliminary positive rapid test, n (%)[c]	31 (0.19)	26 (0.20)	23 (0.22)	14 (0.15)	22 (0.26)	8 (0.11)	18 (0.26)	142 (0.20)
Confirmed positive rapid test, n (%)[c]	23 (0.14)	14 (0.11)	21 (0.20)	10 (0.11)	18 (0.21)	5 (0.07)	13 (0.19)	104 (0.14)
Documented HIV positive at presentation, n (%)[d]	131 (0.10)	132 (0.08)	140 (0.09)	132 (0.08)	157 (0.10)	127 (0.08)	130 (0.09)	949 (0.64)
Neonatal unknown HIV status at discharge, n (%)[b]	3886 (2.74)	1732 (0.99)	42 (0.02)	26 (0.02)	19 (0.01)	14 (0.01)	8 (0.01)	5727 (0.50)

HIV, human immunodeficiency virus.

[a] Numbers may not add up to the total because of fetal demises, multiple gestations, or maternal and newborn transports. Data from 2005 during process of implementation is incomplete; [b] $P < .001$, χ^2 test for trend; [c] Percentages reflect proportion of patients who presented with undocumented HIV status and were thus eligible for rapid testing; [d] Percentages reflect proportion of patients who presented with documented HIV status.

Wong. Illinois perinatal HIV testing. Am J Obstet Gynecol 2012.

accounted for this improvement. Patient acceptance of rapid testing changed dramatically and contributed to the overall increase in maternal rapid testing during these 2 years (99% decrease in women who declined rapid HIV testing). In addition, fewer undocumented women were missed prior to delivery (83% decrease). Of note, a large majority of the increase in newborns who were undergoing rapid testing occurred after the passage of the 2006 amendment. The proportion of eligible newborns undergoing rapid testing increased from 3.3% before the amendment to 85.5% by 6 months after the passage of the amendment.

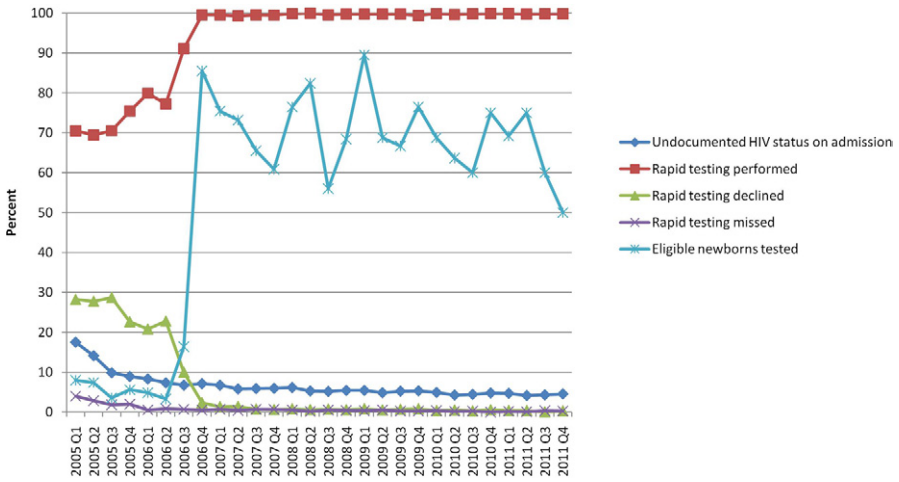
With regard to serostatus results, 949 of the 1,069,455 women who presented with known HIV status were positive, yielding a seropositive rate of 0.09%. One hundred forty-two of the 65,863 women who presented with undocumented HIV status and then underwent rapid testing had a positive result, of which 104 (73%) were confirmed by Western blot. This seropositive rate of 0.16% was significantly higher than the 0.09% frequency found in the women who had documented status at hospital admission (relative risk, 1.78; 95% confidence interval, 1.45–2.19; $P < .001$). Thus, of the 1053 women with known HIV seropositive status, 10% were identified by testing upon admission for delivery.

Comment

The implementation of a statewide initiative in Illinois to maximize opportunities to identify HIV positive pregnant women and reduce perinatal HIV transmission was highly successful and sustained. Within 7 years, HIV testing during the prenatal period and rapid HIV testing of women and neonates during their delivery hospitalization increased to such a degree that almost 100% of newborns left the hospital with a known HIV status.

Women may present to labor and delivery without documented HIV serostatus because they did not receive prenatal care, testing was not performed during their prenatal care (because of a lack of offer or patient refusal), or HIV test results were not confirmed because of the unavailability of medical records.[13] By having a rapid HIV test with high sensitivity and specificity available on labor and delivery units, a population of women with a preliminary positive test can be identified and receive intrapartum treatment and other potential changes in obstetric care (eg, avoidance of scalp electrodes, possible cesarean delivery) to decrease the risk of perinatal transmission. Indeed, after the implementation of this initiative, almost all rapid testing was performed prior to delivery of the infant, which allows timely intervention to decrease the risk of perinatal transmission. Even when testing was not done prior to delivery, it was almost always performed in either the mother or neonate (in whom maternal antibodies to HIV would be present) prior to discharge, allowing the possibility, in the case of seropositivity, of appro-

FIGURE 2
Testing practices after implementation of PRTII initiative



Percent of undocumented HIV status at presentation reflects the proportion of patients who presented to labor and delivery in labor without documented HIV status. Percent of rapid testing performed reflects the proportion of women and newborns who underwent rapid testing because of undocumented maternal HIV status at presentation. Percent of rapid testing declined reflects the proportion of patients with undocumented HIV status who declined predelivery or postdelivery rapid testing. Percent of eligible newborns tested reflects newborns eligible for rapid testing because of unknown maternal HIV status, including multiple gestations and transports.

HIV, human immunodeficiency virus; *PRTII*, Perinatal Rapid Testing Implementation in Illinois.

Wong. Illinois perinatal HIV testing. Am J Obstet Gynecol 2012.

priate neonatal antiretroviral therapy as well as the needed clinical follow-up after discharge.

The consistent year-to-year improvement in the frequency of prenatal testing and rapid testing after the implementation of the initiative supports the efficacy of the PRTII program. Prior to implementation, few hospitals (38%) had initiated any rapid testing. After regional- and hospital-specific training was performed to assist birthing centers with compliance with the law and ensure proper medical treatment, 100% of hospitals used rapid testing. Although the primary objective of mandated reporting by Illinois law was to optimize treatment and follow-up to decrease perinatal HIV transmission, it also permitted the collection of data for the surveillance of progress and the identification of areas for quality improvement. These data show that the vast majority of change occurred within the first 2 years after PRTII was established, but improvements in testing rates continued with each subsequent year, demonstrating sustainability of the initiative and the value of continued efforts at quality improvement.

Over the time period, there was a significant decrease in the number of women who had undocumented status at the time of labor, indicating not only provider compliance in the outpatient setting with the mandate of offering screening for HIV during routine prenatal care but also patient acceptance of that offer. By making the offer of HIV testing routine and required, stigma associated with testing for HIV, both from the perspective of the provider and of the patient, may have been reduced.

Of the women who had an undocumented status at presentation, significantly fewer declined the offer of rapid testing on labor and delivery, particularly after the amendment to the mandate in 2006. Fewer patients who were eligible for rapid testing were missed by labor and delivery providers, and a greater proportion of those who had rapid testing had that testing performed prior to delivery, indicating improvement in the systems for identification and testing of patients that Illinois hospitals put into place.[6] This improvement is a testament to the importance of hospital-specific policies and protocols and supports the concept, documented among hospitals in New Jersey, that regulatory issues and organizational requirements are among the greatest barriers to point-of-care rapid HIV testing in labor and delivery units.[14]

Nevertheless, even after the statewide implementation, there were still some women who missed rapid testing prior to delivery because of lack of prenatal care and precipitous birth. This possibility, combined with the finding that the transmission rate among those tested at the time of birth or postpartum is 15.5% compared with 1.6% for those tested during the antenatal period,[13] further emphasizes the importance of ascertaining HIV status, ideally, in the antenatal period. Fortunately, even when HIV serostatus is undocumented at admission to labor and delivery, our data demonstrate that rapid testing can be offered reliably and will be almost universally accepted by women. The MIRIAD study similarly found that rapid testing was well accepted, with 85% of women undergoing testing when offered.[15]

Our findings support those of Birkhead et al,[12] who assessed the change in the frequency of perinatal HIV transmission in New York state over a 20 year period during which policies and activities aimed at decreasing perinatal transmission were implemented. These investigators reported a significant increase in the rate of prenatal testing after the initiation of regulations that required rapid testing on labor and delivery for women with undocumented HIV status. As a result, there was a decrease in the proportion of women with undocumented status from 14% in 1999 to 3% in 2008. The Illinois policy aimed at altering intrapartum testing similarly had an upstream effect by improving antenatal testing practices.

Our analysis also demonstrated that the seroprevalence of HIV in the population of women who presented without a documented status was significantly higher than that in the population with a

documented status (0.16% vs 0.09%, respectively). The population of women presenting without HIV test results, which includes women without prenatal care, represents a population at higher risk of being infected with HIV.[11] Because of this higher seroprevalence, rapid testing has a greater positive predictive value and therefore even more utility in this population of women. However, the seroprevalence in our population was lower than the rate of 0.7% in the MIRIAD study, and correspondingly, our rapid HIV test false-positive rate of 27% is higher than the 10% reported in MIRIAD.[9,15]

One limitation of this study is that the data were derived from a public health surveillance database, which was not primarily a research tool. Nevertheless, these data underwent quality audits, and inconsistencies were reconciled on a monthly basis. They are similar to the vital statistics gathered by the Illinois Department of Public Health.[16] The only exception is data from 2005, which represent the early implementation process of PRTII, in which a 21% discrepancy in the number of deliveries exists. Such consistency overall should provide confidence in the accuracy of the results. These data are from a single state, and it is uncertain whether the results are generalizable to all municipalities. Yet because Illinois is a large state with many types of birthing hospitals (eg, community and academic) in a variety of settings (eg, urban and rural), and this study included more than 1 million women, we believe it is likely that such favorable results are replicable in other states.

Mandatory testing, particularly when done rapidly in a compressed time setting, is not without negative consequences. In addition to the bioethical and legal issues raised by such policies, the use of any test will yield false-positive results at a rate that is dependent on seroprevalence in the population. In the perinatal setting, the possibility of a false-positive rapid test means that unnecessary treatment, as well as emotional distress, may be caused to a patient while confirmation with a Western blot or immunofluorescence assay is obtained. However, these risks are likely outweighed by the potential benefit of reduced risk of perinatal HIV transmission and the enhanced ability to establish the foundation for long-term care for women.

In summary, implementation of rapid testing for HIV on labor and delivery was associated with a significant improvement, to almost 100%, in the proportion of newborns who were discharged from Illinois hospitals with a known HIV status. A statewide program that creates a safety net of prevention by using rapid HIV testing can be an effective stop-gap measure to ensure identification of all HIV-exposed fetuses/neonates. Such a program is not only achievable but is also a sustainable method that substantially reduces perinatal HIV transmission. ■

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