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Sustainability of Statewide Rapid HIV Testing in Labor and Delivery

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Abstract

The objective was to assess sustainability of a statewide program of HIV rapid testing (RT) for pregnant women presenting for delivery with unknown HIV status. This is a population-based retrospective cohort study of women delivered in Illinois hospitals (2012–15). Deidentified data on RT metrics from state-mandated surveillance reports were compared using descriptive statistics and non-parametric tests of trend. Over 95% of the 608,408 women delivered had documented HIV status at presentation. The rate of undocumented HIV status rose from 4.19 to 4.75% ($p < 0.001$). However, overall 99.60% of women with undocumented status appropriately received RT and the proportion who did not receive RT declined ($p = 0.003$). The number of neonates discharged with unknown HIV status declined ($p = 0.011$). RT identified 23 new HIV diagnoses,

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Compliance with Ethical Standards

Conflicts of interest The authors report no conflicts of interest.

Ethical Approval This article does not contain any studies with human participants or animals performed by any of the authors.

representing 4.62% of maternal HIV diagnoses. In conclusion, statewide perinatal HIV RT resulted in nearly 100% of Illinois mother-infant dyads with known HIV status. Sustained RT completion represents an important prevention safety net.

Keywords

Human immunodeficiency virus; HIV testing; Mother-to-child transmission; Perinatal transmission; Public health policy; Rapid testing

Introduction

Elimination of perinatal transmission of HIV is an ambitious but achievable public health goal in the United States [1, 2]. Without any intervention, the risk of perinatal transmission of HIV is approximately 15–25% [1, 3, 4], yet with early identification, combined maternal and neonatal antiretroviral therapy, and evidence-based delivery and infant feeding strategies, this risk can be reduced to < 1% in high-resource settings [1, 3–6]. Key to this risk reduction is the identification of maternal HIV status so prevention strategies can be employed [6–10]. Yet, cases of transmission continue to occur, with a reported 3.7% perinatal transmission rate from 2009 to 2013 in the U.S. and Puerto Rico and 86 cases of perinatally-acquired HIV diagnosed among children in the U.S. in 2015 [11, 12]. These cases are often related to lack of or delayed identification of maternal HIV infection [13–15]. Such failures may occur when a woman is not tested for HIV during her antenatal care or when she has not presented for prenatal care [10, 16, 17]. Thus, although early identification of HIV is essential to deploying optimal antenatal prevention strategies, identification of all opportunities for intervention throughout pregnancy and delivery is critical to elimination of perinatal HIV transmission [10, 18].

In 1999, the current standard of universal opt-out HIV testing for all pregnant women was recommended by the Institute of Medicine, the American College of Obstetricians and Gynecologists, and the American Academy of Pediatrics [7, 19, 20]. In Illinois, the 2003 Perinatal HIV Prevention Act (Public Law 95-702) mandated counseling about HIV testing early in pregnancy, documentation of HIV test results in maternal and newborn records, and performance of opt-out rapid HIV testing for women presenting to obstetrical units with an unknown HIV status [21]. Providers and hospitals initially failed to achieve testing goals, and thus, in 2004, the Illinois Department of Public Health (IDPH) funded the Perinatal Rapid Testing Implementation in Illinois (PRTII) initiative, a joint effort between multiple collaborating institutions and task forces [22]. PRTII operationalized the legal mandate for testing by providing local resources to hospitals and providers [22, 23]. In 2006, an amendment to the Illinois Perinatal HIV Prevention Act mandated funding and use of a perinatal HIV hotline to report positive rapid tests, performance of neonatal testing if maternal HIV status was unknown, and development of a hospital reporting system for monthly aggregate statistics [24]. Subsequent to the initiation of PRTII, our group demonstrated that rapid testing metrics improved dramatically, with over 95% of women presenting with a known HIV status and a decline in the number of neonates discharged with an unknown HIV status [23].

PRTII formally ended in 2012. However, the legislative mandate to perform rapid testing continues. This report examines whether rapid testing performance on Illinois parturients was maintained despite the absence of the ongoing in-hospital support provided by PRTII. We designed this study to assess the extent to which Illinois providers of obstetrical care have remained adherent to rapid testing laws and program procedures since 2012. We hypothesized that, over time, adherence to rapid testing would decay and more missed opportunities for testing would occur.

Materials and Methods

Program Background

PRTII performed hospital-based, nurse-focused training on rapid testing from 2004 to 2005. In this training process, PRTII staff met with hospital stakeholders (including physician, nursing, pharmacy, legal, risk management, and other teams), discussed plans for initiation of rapid testing, and solicited local strengths and barriers. PRTII staff assisted hospitals to revise internal protocols, develop order sets, and train personnel. Several 30-minute training sessions (conducted for all shifts) were performed at each hospital and a central resource library, including didactic information, flow sheets, competency checklists, presentations, and other educational materials, was made available. Multiple other tools were also created, such as provider counseling scripts and prepared packets of forms for providers to complete in the event of a positive test. Through this multi-step training process, with local participation and PRTII support, 100% of Illinois hospitals had begun offering rapid testing to parturients and their newborns with an undocumented HIV status by the end of 2005. After the 2006 Perinatal HIV Prevention Act amendment [24], PRTII began receiving reports on the number of pregnant women presenting to obstetrical units with known versus unknown HIV status, the number of pregnant women who underwent rapid testing (and the number who were missed or declined), the number of neonates who underwent rapid testing (and the number who were missed or refused), and the number of preliminary and confirmed positive tests. All hospitals in Illinois belong to one of 10 regionalized perinatal networks and the Perinatal Network Administrators coordinate the HIV reporting process for each hospital in their network.

Subsequently, from 2006 to 2011, PRTII functioned as a publicly-funded program with ongoing local, in-hospital support. PRTII established a feedback process which provided performance data to each reporting hospital and offered in-hospital assistance with process improvement measures. Regional coordinators provided intensive, local support such as staff training, protocol review, reporting support, critical incident debriefings, and assistance with individual hospital barriers to testing and quality issues. When PRTII ended in 2012, this publicly funded system was replaced by a public-private partnership with centralized monitoring and reporting responsibilities through the Pediatric AIDS Chicago Prevention Initiative (PACPI). PACPI offers statewide support for monthly data reporting and quality assurance but the local support for each hospital ended. PACPI staff monitor for completeness, timeliness, and accuracy of reports and work with the Perinatal Network Administrators as needed. Through this process, PACPI has been successful at obtaining

100% of reports from all birthing hospitals for every month since January 2006 [25]. In 2015, for example, 115 birthing hospitals (100% in the state) reported data.

All instances of missed testing opportunities are closely examined to determine whether these were isolated exceptional circumstances or systematic errors leading to missed cases. Data on missed opportunities are maintained in a centralized database supported by the IDPH. All hospital-level reports of data and any missed testing opportunities are confidential, shared only with IDPH and the Perinatal Network Administrators who support quality initiatives. On a routine basis, data are reviewed for quality improvement and are provided back to the local hospitals. Hospitals are informed of their compliance rates and of IDPH-identified areas for improvement. Additionally, hospitals are supported by the 24/7 Illinois Perinatal HIV Hotline, which serves as a clinical and social services resource and maintains a website (www.hivpregnancyhotline.org) with updated resources and forms.

Study Methods

This is a retrospective, population-based analysis of Illinois births reported to PACPI from 2012 to 2015. Data from the 2005–2011 period, prior to the end of PRTII, have been reported by our group previously [23]. For this analysis, data were collected from Illinois hospitals using the closed system and feedback loop described above. Data included de-identified statistics on documentation of HIV status, testing performance, and missed opportunities for testing mother–infant dyads prior to discharge from birthing hospitals. An example of the annual flow diagram of testing metrics is shown in the Supplemental File. This study was exempt from IRB review at Northwestern University.

A woman was considered to have an undocumented HIV status upon presentation to labor and delivery if she had not been tested in the current pregnancy or if her HIV test could not be identified in her prenatal records. Among women with undocumented HIV status, the number who received rapid HIV testing prior to delivery was ascertained. Of those who received testing, the proportions of negative tests and preliminary positive tests were determined. Of the preliminary positive tests, the proportion of true positives was reported, yielding the seropositive rate from rapid testing. The seropositive rate from women with known positive status prior to presentation was additionally reported. The specific HIV testing platform varied by hospital and perinatal network.

Of women who required (i.e., undocumented HIV status on presentation) but did not receive rapid testing, women were categorized as either missed or declined. Missed testing were those in whom testing was not performed due to clinical oversight or because delivery was too rapid to allow performance of a rapid test while on labor and delivery. Women were considered to have declined if they were offered testing but refused. Excluding fetal demises, the number of newborns without documentation was then reported. The number of newborns eligible for rapid testing included those who were transported to the hospital after delivery without documented maternal HIV status. If a woman with a multi-fetal gestation required but did not receive rapid testing, each newborn was considered eligible. Of the eligible neonates (i.e. maternal testing was not performed when indicated), the total numbers of newborns who underwent rapid testing, missed a test, or whose parents refused rapid testing were recorded. Refusal of neonatal testing was permissible only for religious reasons.

All data were aggregated by calendar year. Descriptive statistics were utilized to report each outcome. Changes in frequency across years were determined using the nonparametric test of trend across ordered groups [26, 27]. Tests were two-tailed and significance was set at $p < 0.05$. Data were analyzed using Microsoft Excel v15.0 (Microsoft, Redmond, WA) and Stata v13.0 (StataCorp, College Station, TX).

Results

From 2012 to 2015, 608,408 women were reported to PACPI as having delivered in Illinois hospitals (Table 1). During this time period, the rate of an undocumented HIV status at presentation rose from 4.19% in 2012 to 4.75% in 2015 ($p < 0.001$), demonstrating a gradual decline in the proportion of women with documentation of HIV testing prior to presentation to labor and delivery. However, overall, 99.60% women with an undocumented status appropriately received rapid testing; the proportion of women who did not receive indicated rapid testing declined from 2012 to 2015 ($p = 0.003$). Of women who failed to receive indicated rapid testing, overall, 47.3% declined and 53.7% were missed. The proportion not performed due to patient decline decreased ($p = 0.003$) whereas the proportion not performed because they were missed increased ($p = 0.008$) from 2012 to 2015. Ultimately, the number of neonates discharged with unknown HIV status declined ($p = 0.011$) from 2012 to 2015.

From 2012 to 2015, among mother–infant dyads who had rapid testing performed, overall 99.85% ($N = 27,059$) were performed on the mother before birth. The proportion of women whose rapid tests were performed before birth rose from 99.74% in 2012 to 99.89% in 2015 ($p = 0.008$). Consistent with the improvement in performance of antenatal maternal rapid testing, the proportion of rapid tests performed on neonates declined from 0.20% in 2012 to 0.07% in 2015 ($p = 0.019$).

Of the rapid tests performed from 2012 to 2015, 0.12% ($N = 32$) were preliminarily positive (Table 2). Twenty-three (71.88%) of the preliminarily positive rapid tests represented a true positive test. The incidence of true positive rapid tests remained stable from 2012 to 2015 ($p = 0.388$), with an overall seropositive rate from rapid testing of 0.08%. Comparably, the statewide proportion of pregnant women with documented HIV positive status at presentation was 0.08% and also remained stable over time ($p = 0.270$). Combining the rapid testing true positive results ($N = 23$) with previously known HIV positive women ($N = 475$), the cumulative estimated HIV seroprevalence among Illinois pregnant women was 0.08%. Of the 498 pregnant women presenting for delivery who were known to be or found to be HIV positive in this time period, 4.62% were identified via rapid testing upon delivery admission, a decline from the 9.88% identified by rapid testing in the 2006–2011 period [23].

Discussion

HIV testing for pregnant women and neonates with unknown HIV status at delivery is an important and sustainable process key to preventing maternal to child transmission of HIV. Now, 10 years after the original implementation of PRTII, and 4 years after the end of the

formal PRTII program, the Illinois HIV testing process and infrastructure continues to be a relevant and critical safety net. During this time period, the proportion of women with undocumented HIV status who appropriately received rapid testing for themselves or their neonates remained high, and these tests successfully identified women with previously unknown HIV diagnoses. Such findings demonstrate that even with major programmatic and funding transitions, continued attention to process and reporting can maintain the sustainability of a successful program. These findings affirm the importance of ongoing public and private funding for this critical Illinois public health program and provide a model for similar programmatic initiatives in other states.

The implementation of rapid HIV testing on parturients lacking a documented HIV status has been investigated in other settings in the United States. Similar to the Illinois data, New York state experienced improvements in uptake of rapid HIV testing on labor and delivery for women with unknown status after the implementation of a multilevel approach to prevention of perinatal transmission HIV testing [28]. In Houston, Texas, after implementation of hospital-based interventions to improve uptake of rapid HIV testing on labor and delivery, investigators identified significant increases in performance of rapid testing, to nearly 100% of eligible parturients by 1 year after program initiation [29]. In contrast, work by Gaur et al. reported low uptake of intrapartum rapid testing in the early years after a statewide recommendation for rapid HIV testing of women with undocumented status in labor [30]. Notably, their initiative was not supported by provider education nor any systematic support, likely contributing to the lack of an identified benefit. Such studies suggest that in the absence of intensive public health initiatives, U.S. providers remain suboptimal with regard to rapid HIV testing in the perinatal setting, as has also been demonstrated in the context of general HIV testing [31]. Prior work on physician barriers to HIV testing include: insufficient physician knowledge; lack of patient continuity; discomfort regarding initiating HIV counseling; concern about making patients uncomfortable; desire for patients to initiate the testing request; concerns about reimbursement or competing priorities; and other systems-based, intrapersonal, and interpersonal barriers [31–33]. Such barriers may also extend to rapid testing in the perinatal setting and should be investigated.

Our findings demonstrate room for improvement in the antenatal setting, as the proportion of women presenting with an undocumented HIV status increased over the study period. While the proportion of women with undocumented status remained less than 5%, the rise in frequency of undocumented status represents an alarming trend. It remains unclear why this trend has occurred, particularly with the expansion of electronic medical records. Specifically, it is unknown whether testing was not performed in the antenatal setting or whether testing was performed but results were not communicated to the delivery hospital. There were no changes in legislation or professional society guidelines regarding antenatal testing during this time period, thus it is unlikely that this decline in antepartum testing was directly related to programmatic changes. However, it is possible that the loss of hospital-based support for intrapartum rapid testing had downstream effects on the antenatal outpatient setting. While the total number of failed testing opportunities was small, clearly there is an ongoing need for enhanced support for antenatal HIV testing, as the antenatal period offers many more opportunities for efforts to prevent perinatal transmission than care initiated in the intrapartum period. Additionally, although it is reassuring that hospitals are

appropriately testing over 99% of undocumented women on presentation, the proportion of eligible women whose failure to receive testing was due to being missed rose over the study period, while correspondingly the proportion due to patient declination decreased. Although the overall rate of failed testing opportunities was low and improved over time, it is unclear why, at the conclusion of the study period, the majority of these were due to being missed. One may speculate, for example, that growing public awareness of HIV testing prompted fewer declinations, leading to a greater proportion being due to missed opportunities. This finding warrants further attention as an additional potential downstream effect of programmatic support changes.

Our data represent a unique opportunity to assess a statewide public health policy that has undergone significant evolution in its mandates, funding and practice over the last decade. We believe the reason the perinatal HIV testing process in Illinois is so comprehensive and successful is because of the highly regulated data reporting system, which instills accountability at each hospital and each perinatal network. Such a process not only ensures high-quality data, but also constitutes an ongoing closed loop system for feedback to each hospital, regardless of size, location, HIV experience, or individual protocols. This process ensures that each hospital understands the implications of their HIV testing statistics and allows for real-time changes to be made in testing practices. A pattern of missed or declined opportunities for testing directly feeds back to enhanced nursing education and structural support for improved testing adherence via the critical involvement of the Perinatal Network Administrator. However, additional work is required to understand the costs of this public health infrastructure. While rapid HIV testing for women presenting in labor without prenatal care has been modeled to prevent HIV infections and save costs [34], the costs associated with this statewide infrastructure have not been studied. Strategies to implement the Illinois approach in a less resource intensive manner, such as virtual training sessions supported by state public health systems or promotion of the 24/7 Illinois Perinatal HIV Hotline website training materials, deserve further exploration.

A major strength to this analysis is the use of a large, highly quality-controlled, centralized database for data storage and evaluation. Based on 2012 and 2013 IDPH Provisional Tabulations for birth statistics, PACPI captured 97.0% of births in Illinois, with the difference potentially reflecting home births and non-live births not captured by the monthly data reporting process [35]. Moreover, the comprehensive data validation process ensures that all testing scenarios and births are accounted for and all positive reports are accurate. However, there are several limitations to consider. Data were derived from a public health surveillance database maintained as a part of the Illinois public health infrastructure, rather than a research-focused database. Similar to the vital statistics gathered on the state and national level, such databases are subject to the possibility of discrepancies in numbers of deliveries, although the extensive quality audits described above demonstrated such discrepancies to be rare. Further, due to the use of de-identified data, we are unable to report on demographic or other local level data that may be helpful to determine areas to target to achieve 100% adherence to testing. Similarly, we are unable to report on potential duplicates of maternal patients, such as women who may present with undocumented status in different pregnancies during the study period. Further work with local data is also required to

understand how these findings regarding rapid testing translate to the performance of maternal and neonatal interventions to reduce transmission risk.

Conclusions

Despite changes in public health infrastructure, statewide perinatal HIV rapid testing in women with an undocumented HIV status resulted in sustained performance of nearly 100% of Illinois mother–infant dyads having known HIV status on discharge. The continued identification of HIV diagnoses via rapid testing affirms the necessity of this statewide intervention as a safety net. However, enhanced efforts are needed to support providers in performing antenatal HIV testing, as the late identification of HIV in the intrapartum setting, while better than no identification, represents a critical loss of opportunity for prevention of transmission. In summary, these findings demonstrate HIV testing can be performed in the critical perinatal time period and that such testing practices can be sustained. This statewide program is thus a model for development and maintenance of an effective HIV safety net to move one step closer towards perinatal HIV elimination.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Table 1

Documentation of antenatal HIV status and utilization of HIV rapid testing in the perinatal setting from 2012 to 2015

	2012	2013	2014	2015	Total	<i>p</i> value
Total deliveries	153,663	150,818	152,440	151,487	608,408	–
Undocumented HIV status at presentation	6443 (4.19%)	6399 (4.24%)	7169 (4.70%)	7197 (4.75%)	27,208 (4.47%)	<0.001
RT not performed ^a	37 (0.57%)	32 (0.50%)	23 (0.32%)	20 (0.28%)	112 (0.41%)	0.003
Declined ^b	23 (62.16%)	15 (46.88%)	10 (43.48%)	5 (25.00%)	53 (47.32%)	0.003
Missed ^c	14 (37.84%)	17 (53.13%)	13 (56.52%)	15 (75.00%)	59 (52.68%)	0.008
Unknown mother–baby HIV status at discharge ^d	9 (0.006%)	8 (0.005%)	7 (0.005%)	8 (0.005%)	32 (0.005%)	0.011

Data displayed as N (%)

RT rapid testing, *HIV* human immunodeficiency virus^aProportion of women who did not have rapid testing, out of all women with undocumented status (i.e., for whom testing was indicated)^bProportion of women whose testing was declined, out of all who did not have indicated rapid testing^cProportion of women whose testing was missed, out of all who did not have indicated rapid testing^dProportion of mother–baby dyads with unknown status at discharge, out of all reported deliveries in Illinois

Table 2

Results of antenatal and intrapartum HIV testing in Illinois from 2012 to 2015

	2012	2013	2014	2015	Total	<i>p</i> value
Antenatal HIV testing						
Documented HIV positive ^a	128 (0.09%)	108 (0.07%)	115 (0.08%)	124 (0.09%)	475 (0.08%)	0.270
Intrapartum rapid HIV testing						
Preliminary positive RT ^b	6 (0.09%)	6 (0.09%)	3 (0.04%)	17 (0.24%)	32 (0.12%)	0.024
True positive RT ^c	6 (0.09%)	5 (0.08%)	3 (0.04%)	9 (0.13%)	23 (0.08%)	0.388

Data displayed as N (%)

RT:rapid testing, HIV/human immunodeficiency virus

^aProportion of women with known HIV positive status, of all deliveries in Illinois with documented status prior to presentation

^bProportion of preliminary positive results on either the mother or neonate, of all rapid tests performed

^cProportion of true positive results on either the mother or neonate, of all rapid tests performed