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A Missed Opportunity for U.S. Perinatal Human Immunodeficiency Virus Elimination:

Pre-exposure Prophylaxis During Pregnancy

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Abstract

OBJECTIVE—To estimate the proportion of women at increased risk of sexual human immunodeficiency virus (HIV) acquisition during pregnancy in a high HIV incidence urban setting to identify those who may be eligible for pre-exposure prophylaxis.

METHODS—We conducted a retrospective cohort study of women who received prenatal care at a large academic center in 2012. Univariable analyses and multiple logistic regression models were built to identify correlates for pre-exposure prophylaxis eligibility.

RESULTS—Among 1,637 pregnant women, mean age was 27.6 years (SD 6.3), 59.7% were African American, and 56.0% were single. Based on the Centers for Disease Control and Prevention's guidelines, more than 10% of women were at increased risk for HIV acquisition during pregnancy and eligible for pre-exposure prophylaxis. Younger [adjusted odds ratio (OR) 0.9/1-year increase, 95% CI 0.8–0.9], single (adjusted OR 2.4, 95% CI 1.2–4.8), African American women (adjusted OR 3.3, 95% CI 1.6–6.7) with higher parity (adjusted OR 1.3/one-child increase, 95% CI 1.1–1.5), and who smoked regularly during pregnancy (adjusted OR 1.8, 95% CI 1.0–3.0) had greater odds of being eligible for pre-exposure prophylaxis at any time during pregnancy.

CONCLUSIONS—Pregnancy is a vulnerable period during which some heterosexual women in urban settings have a high risk for HIV acquisition and stand to benefit from pre-exposure prophylaxis.

Elimination of perinatal human immunodeficiency virus (HIV) in the United States has been a goal set by the Centers for Disease Control and Prevention (CDC) since 2012.¹ Although significant declines have occurred, the recent estimate of perinatal HIV transmission is still 1.75 times the elimination goal of 1 per 100,000 live births.² Incident HIV infection during pregnancy and breastfeeding is associated with the highest perinatal HIV transmission risk.^{3–5} Biological and behavioral evidence about the increased risk for HIV during pregnancy

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remains conflicting,⁶ but studies show that women at risk for HIV have increased vulnerability during pregnancy.^{7,8}

Few HIV prevention strategies besides HIV testing have been incorporated into routine U.S.-based antenatal care. Repeat HIV testing in the third trimester for at-risk women is recommended; however, in one observational study conducted in the same setting as the present study, less than one third of pregnant women were retested for HIV despite living in a high prevalence area.⁹ Little is done in counseling pregnant women about their risk for HIV,¹⁰ a risk that is increased in high burden areas.¹¹ Despite safety data of effective biomedical interventions like HIV pre-exposure prophylaxis in pregnancy and breastfeeding,^{12–14} most U.S.-based pre-exposure prophylaxis awareness campaigns have not included at-risk pregnant women. The only U.S. Food and Drug Administration–approved form of pre-exposure prophylaxis is a daily oral fixed-dose combination of tenofovir disoproxil fumarate and emtricitabine for all people at substantial risk of acquiring HIV.¹⁵ Pre-exposure prophylaxis decreases HIV acquisition by 61% (95% CI 40–75%) among women with 75% adherence to daily dosing.¹⁶ Furthermore, a recent U.S. study showed that at-risk women frequently chose to use pre-exposure prophylaxis if offered during the periconceptional period or pregnancy.¹⁷

The continued, albeit decreased, HIV perinatal transmission cases reflect the need for targeted HIV prevention strategies to reach the elimination goal. However, studies targeting pregnant U.S. women at risk for HIV as potential pre-exposure prophylaxis candidates are lacking.¹⁸ The primary objective of this study was to estimate the proportion of U.S.-based pregnant women living in a high HIV incident area who were eligible for pre-exposure prophylaxis during pregnancy and identify associated correlates for eligibility.

MATERIALS AND METHODS

All women who delivered at the Johns Hopkins Hospital in Baltimore, Maryland, in 2012 were included in this retrospective cohort study. Women were excluded if they were living with HIV at the time of the first antenatal care visit, underwent elective termination of pregnancy, transferred prenatal care from an outside clinic, or did not have prenatal care records available. The Johns Hopkins University School of Medicine institutional review board approved the study.

Data were abstracted by doctoral-level clinicians and a postdoctoral trainee from the electronic medical record using a standardized data collection sheet with double data entry. At the first antenatal care visit, a skilled nurse systematically collected demographic information; insurance, medical, sexual, and social history; completed an HIV risk assessment; and performed routine prenatal blood tests and urine toxicology screening. At the second antenatal care visit, a health care provider confirmed the medical, sexual, and psychosocial history and performed a pelvic examination that included gonorrhea and chlamydia testing. Repeat testing for gonorrhea and chlamydia occurred if women reported genitourinary symptoms, during routine screening at 35–37 weeks of gestation, or both.

Pre-exposure prophylaxis eligibility was defined using the CDC's guidance for pre-exposure prophylaxis use based on the most common risk factors for HIV acquisition: HIV-negative heterosexual women with an HIV-positive partner, bacterial sexually transmitted infection (STI), a high number of sex partners, inconsistent or no condom use, practicing commercial sex work, or living in a high prevalence area or network.¹⁹ The primary outcome (ie, pre-exposure prophylaxis eligibility during pregnancy) was defined, on the basis of risk factors included in the CDC's guidance, as women with an HIV-positive partner or women with any positive gonorrhea or chlamydia test or diagnoses of genital herpes, syphilis, or trichomoniasis.²⁰ Because of the study's location in Baltimore, all participants were living in the metropolitan area with the third highest HIV incidence in the United States²¹ and incidence rates of chlamydia, gonorrhea, and syphilis 2.5- to threefold higher than the national rates during the study year.²² The study therefore assessed factors other than location to determine the risk of HIV acquisition and pre-exposure prophylaxis eligibility. The secondary outcomes were pre-exposure prophylaxis eligibility at the first antenatal care visit and negative change in pre-exposure prophylaxis eligibility during pregnancy, for example, those who were considered ineligible for pre-exposure prophylaxis at the first antenatal care visit but acquired a new risk factor during the course of pregnancy. Specifically, change in pre-exposure prophylaxis eligibility was defined as an incident STI over the course of pregnancy and was examined among the subpopulation of women who were not eligible for pre-exposure prophylaxis at the first antenatal care visit. Incident STI cases included women who 1) initially tested negative for gonorrhea or chlamydia at the first antenatal care visit but tested positive at a later date or 2) reported genitourinary symptoms and were subsequently diagnosed with trichomoniasis or genital herpes after the first antenatal care visit. Correlates included age, parity, race, marital status, education level, insurance status, histories of mental illness, substance use, prior STIs, smoking status during pregnancy, and gestational age at the first antenatal care visit.

For the univariable analysis, Student *t* test or Wilcoxon rank-sum test (nonnormal distributions) were used to compare continuous variables and χ^2 or Fisher exact tests were used for categorical variables. Multiple logistic regression models were used to identify correlates associated with pre-exposure prophylaxis eligibility. Results were reported as adjusted odds ratio (OR) with 95% CI. Statistical significance was defined by two-sided $P < .05$. Variables were included using forward and backward regressions and the most adequate models were selected on the basis of the Akaike information criteria to avoid overfitting, Hosmer-Lemeshow goodness-of-fit test, C-statistic, and mean variance inflation factor. Missing data were handled using listwise deletion because at most, they represented 1.5% of observations for the insurance status variable. Data analyses were performed with Stata 13.1.

RESULTS

Among the 1988 women who gave birth at the Johns Hopkins Hospital during the study year, we excluded 351 from our analysis: 36 living with HIV, 14 who underwent elective termination of pregnancy, 274 who transferred care from an outside clinic, and 27 who did not have prenatal care were excluded from the study. Thus, 1,637 women were included in this analysis of whom 10.1% (165) were eligible for pre-exposure prophylaxis at any time during pregnancy (Table 1). Three of these women (0.6%) reported having an HIV-positive

partner and 163 (34.5%) were diagnosed with an STI during pregnancy. Compared with women ineligible for pre-exposure prophylaxis, these pre-exposure prophylaxis-eligible women were significantly more likely to be younger, African American, single or never married, and have less than a high school diploma (Table 1). Compared with women ineligible for pre-exposure prophylaxis, these pre-exposure prophylaxis-eligible women were also more likely to report prior STIs, substance abuse, and regularly smoking during pregnancy (Table 1). Pre-exposure prophylaxis-eligible women entered into antenatal care at a median gestational age of 13.6 weeks and 86.1% had public insurance. There were no statistically significant differences between women eligible for pre-exposure prophylaxis and those who were not in terms of parity or history of mental illness.

In the multivariable analysis, women eligible for pre-exposure prophylaxis at any time in pregnancy had smaller odds of being older (adjusted OR 0.9/1-year increase, 95% CI 0.8–0.9) and greater odds of having higher parity (adjusted OR 1.3/one-child increase, 95% CI 1.1–1.5), being African American (adjusted OR 3.3, 95% CI 1.6–6.7), single (adjusted OR 2.4, 95% CI 1.2–4.8), and smoking during pregnancy (adjusted OR 1.8, 95% CI 1.0–3.0) than women who were not eligible for pre-exposure prophylaxis (Table 2). However, education level, insurance type, history of mental illness, substance use, prior STIs, and gestational age at the first antenatal care visit did not differ significantly between women based on their pre-exposure prophylaxis eligibility at any time in pregnancy.

We sought to determine which pregnant woman might be eligible for pre-exposure prophylaxis at the first antenatal care visit. Among the 1,637 participants, 122 women (7.5%) were eligible for pre-exposure prophylaxis at their first antenatal care visit; two had HIV-positive partners, 119 were diagnosed with an STI at that first visit, and one woman had an HIV-positive partner and was diagnosed with an STI. These women were significantly more likely to be younger, African American, single, have greater parity, have public insurance, and have less than a high school diploma compared with women who were not pre-exposure prophylaxis-eligible (Table 1). Women eligible for pre-exposure prophylaxis at their first antenatal care visit were also significantly more likely to have a history of substance abuse and STIs and to report smoking regularly during their pregnancy compared with women who were not eligible. They also had greater gestational age at their first antenatal care visit. History of mental illness was not significantly associated with pre-exposure prophylaxis eligibility at the first antenatal care visit in the univariable analysis.

After adjusting for all correlates, women who were eligible for pre-exposure prophylaxis at their first antenatal care visit had smaller odds of being older (adjusted OR 0.9/1-year increase, 95% CI 0.8–0.9) and greater odds of having a higher parity (adjusted OR 1.2/one-child increase, 95% CI 1.0–1.5), being African American (adjusted OR 4.3, 95% CI 1.8–10.1), and smoking regularly during pregnancy (adjusted OR 2.1, 95% CI 1.2–3.6) compared with women not eligible for pre-exposure prophylaxis (Table 2). However, marital status, education level, insurance type, history of mental illness, substance use, prior STIs, and gestational age at the first antenatal care visit did not differ between women based on their pre-exposure prophylaxis eligibility at their first antenatal care visit.

We sought to determine whether a pregnant woman's risk for HIV acquisition changed during pregnancy. Of the pregnant women who were initially ineligible for pre-exposure prophylaxis at the first antenatal care visit (n=1,515), 44 women (2.7%) had an incident STI and thus became eligible for pre-exposure prophylaxis. Compared with women who did not become eligible for pre-exposure prophylaxis during pregnancy, newly eligible women were significantly more likely to be younger, African American, single, and not to have graduated from high school (Appendix 1, available online at <http://links.lww.com/AOG/A990>). Most had public insurance. History of mental illness, substance use, STIs, parity, and gestational age at the first antenatal care visit were not significantly different between the two groups in the univariable analysis.

Age was the only covariate that remained statistically significant for change in pre-exposure prophylaxis eligibility during pregnancy in the multivariable analysis. Older women (adjusted OR 0.8/1-year increase, 95% CI 0.7–0.9) had smaller odds of becoming eligible for pre-exposure prophylaxis during pregnancy compared with younger women (Appendix 2, available online at <http://links.lww.com/AOG/A990>).

DISCUSSION

Among this sample of urban pregnant women, 10% were eligible for pre-exposure prophylaxis; independent correlates for pre-exposure prophylaxis eligibility included young age, multiparity, African American race, being single, and smoking status. These demographic factors—and by extension risk factors for HIV acquisition—can be used to target subpopulations with HIV prevention messages. Pregnant women are more likely to believe their main sexual partner is monogamous compared with nonpregnant women^{23,24} and may not be aware of their male partner's HIV status or risk behaviors such as injection drug use and having sex with men, yet less than 30% of pregnant women use condoms during sexual intercourse²⁵ and safe sex practices may be even further limited for pregnant women who experience intimate partner violence.²⁶

After examining HIV risk by timing of antenatal care clinical encounters, we found that a little more than 7% were eligible for pre-exposure prophylaxis during the first antenatal care visit, and 3% who were initially ineligible became eligible during antenatal care. After adjustment for correlates, the risk factors for pre-exposure prophylaxis eligibility were similar (age, race, and parity) with the exception of marital status comparing women eligible for pre-exposure prophylaxis at intake and at any time in pregnancy. Only younger age was found to be significantly associated with a negative change in pre-exposure prophylaxis eligibility. This change in risk is of particular importance given the high risk of perinatal HIV transmission after seroconversion during pregnancy.⁶ This change in women's HIV risk also challenges the notion of static risk profiles in favor of fluid ones and pinpoints the importance of repeated risk assessment. Addressing HIV risk solely at intake would not reach all patients. In high prevalence areas, each health care encounter should include an HIV risk assessment, and clinicians can initiate or at least raise awareness of pre-exposure prophylaxis.

Preventive HIV biomedical interventions are underused during pregnancy. The CDC estimated that 0.6% or 468,000 heterosexual women in the United States had an indication for pre-exposure prophylaxis on the basis of risky sexual behaviors,¹⁸ but no study has estimated that proportion among pregnant women. However, differences in target populations may make comparison with this study focusing on pregnancy difficult. Estimates of the number of U.S. perinatal HIV cases during 2010–2013 showed that 56.4% of maternal HIV diagnoses occurred during pregnancy or postpartum.² Although there were no data on timing of seroconversion, some of these perinatal transmission cases potentially could have been prevented through enhanced HIV counseling and testing for at-risk pregnant women and offering pre-exposure prophylaxis. Two U.S. medical centers identified only 27 women in or around pregnancy who chose to use pre-exposure prophylaxis (67% acceptance) over 5 years¹⁷; however, our study estimates that 10% of urban pregnant women would be pre-exposure prophylaxis-eligible.

Given at-risk women's high uptake of pre-exposure prophylaxis during pregnancy,¹⁷ health care providers should identify those with the highest risk to address this gap. Data suggest that pre-exposure prophylaxis is safe in pregnancy and breastfeeding²⁷; the Antiretroviral Pregnancy Registry finds no increased risk of birth defects from pre-exposure prophylaxis exposure²⁸; a substudy of women who became pregnant while on pre-exposure prophylaxis found no difference in pregnancy loss, preterm birth, birth defects, or 1-year growth anomalies²⁹; and a pharmacokinetic study found that pre-exposure prophylaxis was undetectable or negligible in breastfed infants' serum.¹³ These safety data should encourage health care providers to discuss and perhaps offer pre-exposure prophylaxis and other HIV prevention strategies during pregnancy with at-risk women who stand to reap tremendous benefits.

The study has several limitations. As a chart review from a single institution's obstetric population without a prospective design, some data elements (eg, condom use, number of sexual partners) were not collected, which might have identified additional pre-exposure prophylaxis-eligible women, making this study's findings conservative. However, condom use has been found to be an inaccurate measure that is susceptible to social desirability bias.^{30,31} Next, generalizability is limited given the primarily urban African American women engaged in antenatal care in a high HIV incidence setting. However, recent data show that the majority of perinatal HIV transmission occurs among African American patients living in specific locations.² Hence, HIV prevention interventions should target populations most at risk.

In summary, this study underscores missed opportunities for HIV prevention throughout pregnancy. Determining which women are most at risk for HIV is necessary to target prevention messaging and interventions to ultimately eliminate perinatal transmission. The study highlights additional demographic factors that may be used to identify pre-exposure prophylaxis-eligible pregnant women in addition to CDC guidelines. It is critical to gain a better understanding of the role of these preventive interventions among pregnant women when the consequences of acute HIV can be devastating for not only the mother, but also the unborn child. Given these high stakes, additional demonstration projects in U.S. prenatal

care delivery settings are needed to further assess risk of HIV acquisition and eligibility for pre-exposure prophylaxis among pregnant women.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Table 1

Sample Distribution for Selected Covariates by Pre-exposure Prophylaxis Eligibility at Any Time in Pregnancy and at the First Antenatal Care Visit

Covariate	All Women	PrEP Eligibility at Any Time in Pregnancy			PrEP Eligibility at 1st ANC Visit		
		No	Yes	P	No	Yes	P
Total	1,637 (100)	1,472 (89.9)	165 (10.1)		1,515 (92.6)	122 (7.5)	
Age (y)	27.56±6.25	28.11±6.13	22.65±5.03	<.001	27.92±6.17	23.12±5.49	<.001
Parity	1 (0–2)	1 (0–2)	1 (0–2)	.21	1 (0–2)	1 (0–2)	.05
Race							
African American	977 (59.7)	822 (55.8)	155 (93.9)	<.001	862 (56.9)	115 (94.3)	<.001
White	508 (31.0)	499 (33.9)	9 (5.5)		502 (33.1)	6 (4.9)	
Hispanic	22 (1.3)	21 (1.4)	1 (0.6)		22 (1.5)	0 (0.0)	
Asian and other	130 (7.9)	130 (8.8)	0 (0.0)		129 (8.5)	1 (0.8)	
Marital status							
Single or never married	908 (55.5)	756 (51.4)	152 (92.1)	<.001	798 (52.7)	110 (90.2)	<.001
Married	701 (42.8)	689 (46.8)	12 (7.3)		690 (45.5)	11 (9.0)	
Separated, divorced, or widowed	28 (1.7)	27 (1.8)	1 (0.6)		27 (1.8)	1 (0.8)	
Education							
Less than high school graduate	317 (19.4)	249 (16.9)	68 (41.2)	<.001	262 (17.3)	55 (45.1)	<.001
High school diploma	465 (28.4)	394 (26.8)	71 (43.0)		418 (27.6)	47 (38.5)	
Less than 4 y in college	270 (16.5)	249 (16.9)	21 (12.7)		256 (16.9)	14 (11.5)	
Bachelor and postgraduate	575 (35.1)	571 (38.8)	4 (2.4)		570 (37.6)	5 (4.1)	
Private insurance	731 (44.7)	710 (48.2)	21 (12.7)	<.001	713 (47.1)	18 (14.8)	<.001
History of mental illness	262 (16.0)	235 (16.0)	27 (16.4)	.89	243 (16.0)	19 (15.6)	.89
History of substance use	244 (14.9)	210 (14.3)	34 (20.6)	.03	216 (14.3)	28 (23.0)	.009
Smoking regularly in pregnancy	156 (9.5)	129 (8.8)	27 (16.4)	<.001	132 (8.7)	24 (19.7)	<.001
History of any STI	563 (34.4)	482 (32.7)	81 (49.1)	<.001	501 (33.1)	62 (50.8)	<.001
GA at first ANC median (wk)	10.9 (8.4–17.7)	10.6 (8.3–17.1)	13.6 (9.6–21.3)	<.001	10.7 (8.4–17.1)	15.5 (9.7–22.4)	<.001

PrEP, pre-exposure prophylaxis; ANC, antenatal care; STI, sexually transmitted infection; GA, gestational age.

Data are n (%), mean ± SD, or median (interquartile range) unless otherwise specified.

Missing values were handled using listwise deletion [10 (0.6%) for education, 25 (1.5%) for insurance, 2 (0.12%) for GA at first ANC].

Bold indicates $P < .05$.

Table 2

Unadjusted and Adjusted Odds Ratios for Logistic Regressions of Pre-exposure Prophylaxis Eligibility at Any Time in Pregnancy and at the First Antenatal Care Visit on Selected Covariates

Covariate	PrEP Eligibility at Any Time in Pregnancy			PrEP Eligibility at First ANC Visit		
	uOR (95% CI)	P	aOR* (95% CI)	uOR (95% CI)	P	aOR† (95% CI)
Age (change/1-y increase)	0.8 (0.8–0.9)	<.001	0.9 (0.8–0.9)	0.9 (0.8–0.9)	<.001	0.9 (0.8–0.9)
Parity (change/1-child increase)	1.1 (1.0–1.2)	.21	1.3 (1.1–1.5)	1.1 (1.0–1.3)	.04	1.2 (1.0–1.5)
African American (referent: white, Hispanic, Asian, other other)	12.3 (6.4–23.4)	<.001	3.3 (1.6–6.7)	12.5 (5.8–26.9)	<.001	4.3 (1.8–10.1)
Single (referent: married, separated, divorced, or widowed)	11.1 (6.2–19.7)	<.001	2.4 (1.2–4.8)	8.2 (4.5–15.1)	<.001	1.9 (0.9–3.9)
Less than high school education (referent: high school diploma or higher education)	0.3 (0.2–0.4)	<.001	0.9 (0.6–1.4)	0.3 (0.2–0.4)	<.001	0.7 (0.5–1.1)
Private insurance (referent: public insurance)	0.2 (0.1–0.3)	<.001	0.7 (0.4–1.2)	0.2 (0.1–0.3)	<.001	0.9 (0.5–1.7)
History of mental illness (referent: no history of mental illness)	1.0 (0.7–1.6)	.89		1.0 (0.6–1.6)	.89	
History of substance use (referent: no history of substance use)	1.6 (1.0–2.3)	.03		1.8 (1.2–2.8)	.01	
Smoking regularly in pregnancy (referent: no smoking in pregnancy)	2.0 (1.3–3.2)	.002	1.8 (1.0–3.0)	2.6 (1.6–4.2)	<.001	2.1 (1.2–3.6)
History of any STI (referent: no history of STI)	2.0 (1.4–2.7)	<.001	0.9 (0.6–1.3)	2.1 (1.4–3.0)	<.001	1.0 (0.6–1.4)
GA at first ANC (change/1-wk increase in GA)	1.0 (1.0–1.1)	.003	1.0 (1.0–1.0)	1.0 (1.0–1.1)	.001	1.0 (1.0–1.0)

PrEP, pre-exposure prophylaxis; ANC, antenatal care; uOR, unadjusted odds ratio; aOR, adjusted odds ratio; STI, sexually transmitted infections; GA, gestational age.

Hosmer-Lemeshow goodness-of-fit *P* value: model 1: 0.81, model 2: 0.85; C-statistic: model 1: 0.81, model 2: 0.80; mean variance inflation factor: model 1: 1.54, model 2: 1.54.

Bold indicates *P* < .05.

* Adjusted for age, parity, African American race, single marital status, private insurance, history of STIs, smoking in pregnancy, and GA at first ANC, on the basis of the smallest Akaike information criteria: 870.6.

† Adjusted for age, parity, African American race, single marital status, private insurance, history of STIs, smoking in pregnancy, and GA at first ANC, on the basis of the smallest Akaike information criteria: 734.6.