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## Venue-Based Recruitment of Women at Elevated Risk for HIV: An HIV Prevention Trials Network Study

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### Abstract

**Background:** The challenge of identifying and recruiting U.S. women at elevated risk for HIV acquisition impedes prevention studies and services. HIV Prevention Trials Network (HPTN) 064 was a U.S. multisite, longitudinal cohort study designed to estimate HIV incidence among women living in communities with prevalent HIV and poverty. Venue-based sampling (VBS) methodologies and participant and venue characteristics are described.

**Methods:** Eligible women were recruited from 10 U.S. communities with prevalent HIV and poverty using VBS. Participant eligibility criteria included age 18–44 years, residing in a designated census tract/zip code, and self-report of at least one high-risk personal and/or male sexual partner characteristic associated with HIV acquisition (e.g., incarceration history). Ethnography was conducted to finalize recruitment areas and venues.

**Results:** Eight thousand twenty-nine women were screened and 2,099 women were enrolled (88% black, median age 29 years) over 14 months. The majority of participants were recruited from outdoor venues (58%), retail spaces (18%), and social service organizations (13%). The proportion of women recruited per venue category varied by site. Most participants (73%) had both individual and partner characteristics that qualified them for the study; 14% were eligible based on partner risk only.

**Conclusion:** VBS is a feasible and effective approach to rapidly recruit a population of women at enhanced risk for HIV in the United States. Such a recruitment approach is needed in order to engage women most at risk and requires strong community engagement.

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## Introduction

THE BURDEN of acquired immune deficiency syndrome (AIDS) in women in the United States has grown substantially over the past 30 years, rising from 8% of all newly diagnosed AIDS cases in 1983 to more than 23% in 2010.<sup>1,2</sup> In 2010, one in five new human immunodeficiency virus (HIV) infections in the United States were among women; 84% of those infections were acquired through heterosexual transmission.<sup>2</sup> Significant racial disparities exist for newly reported cases among women. In 2010, the rate of new HIV infections (per 100,000 for the general female adult and adolescent population) among black/African American women was nearly 20 times as high as white females and approximately four times as high as the rate for Hispanic/Latino females.<sup>3</sup>

Identifying women at greatest risk of HIV acquisition in the United States has been a challenge, particularly when targeting such women for HIV clinical trials,<sup>4</sup> as well as prevention research requiring HIV endpoints.<sup>5-7</sup> Women most at risk for HIV in the United States may be less likely to enroll in research, due in part to restrictive eligibility criteria, researcher bias that certain individuals may be more difficult to retain, cultural and language barriers, childcare responsibilities, a lack of trust on the part of the potential study participants, or structural barriers such as access to transportation.<sup>4,8-14</sup>

Specific individual-level behaviors, such as substance misuse and sex exchange, have been associated with sexually transmitted infections (STIs) and HIV.<sup>15-18</sup> As a result, many studies have focused on individual-level behaviors when defining study eligibility criteria. There is a growing appreciation, however, that larger social and structural factors, including neighborhood environment, shape HIV risk. Place characteristics, such as rates of poverty, violent crime, incarceration, and male to female sex ratios are thought to be powerful drivers of sexual behaviors and HIV/STI risk, particularly among U.S. black adults.<sup>19-25</sup>

Past studies have used a variety of approaches to recruiting high risk women into prospective HIV cohort studies in the United States, such as peer referrals, self-referrals (e.g., flyers), and clinic-based recruitment.<sup>6,9,26-29</sup> Methodologies that recruit participants from community settings may be a particularly promising approach to finding women at elevated risk of HIV and to engage them in the research process. One such approach is venue-based sampling (VBS). VBS is a sampling strategy used to find hard-to-reach populations and has been used to sample persons who attend venues within locally defined geographic areas.<sup>30</sup> Based on the application of time-space sampling, VBS has been used previously to obtain large, diverse samples from previously underrepresented populations.<sup>30-34</sup> The most notable use of venue-based sampling of women in the United States context was the Centers for Disease Control and Prevention National HIV Behavioral Surveillance Heterosexual Cycle (NHBS-HET) pilot study from 2006-2007, which was designed to identify the behavioral and social factors which place heterosexuals at risk for HIV; half of the sites were randomized to VBS recruitment.<sup>33,35</sup>

Although a number of studies have used venue-based recruitment, little is known about which venues are most fruitful for identifying and recruiting women at high-risk of HIV in the United States. Studies that have described demographic and behavioral characteristics of adults by enrollment venue were heavily weighted toward locales that may not be as relevant for

studies recruiting women only, such as sex establishments, bars and clubs, and men's shelters.<sup>36,37</sup> A comparison of recruitment venues for at risk adolescent girls and young men who have sex with men (YMSM) determined that young women were more likely to be recruited from neighborhood-based or commercial venues than YMSM.<sup>38</sup> Thus, recruitment efforts of women at elevated risk of HIV in the United States may be enhanced by an understanding of what venue types yield the most participants and the behavioral attributes of these participants.

The HIV Prevention Trials Network (HPTN 064) identified women at increased risk for HIV acquisition using VBS as a recruitment strategy. We describe the recruitment process used in HPTN 064 and explore associations between venue category and participant attributes of women enrolled.

## Materials and Methods

### *Study communities*

HPTN 064 was a multisite, longitudinal cohort study designed to estimate the HIV incidence among women living in communities with prevalent HIV and poverty and to determine the feasibility of recruiting women using venue-based sampling based on predefined eligibility criteria for location, individual, and partner characteristics associated with high risk for HIV acquisition. The targeted sample size for each site was 200 women. This target could be exceeded by up to 5%. Although the original recruitment target period was 6 months from approval for the initiation of site recruitment activities, a subsequent Scientific Review Committee recommendation and protocol amendment increased the length of recruitment at some sites.<sup>17</sup> Participants were enrolled between May 2009 and August 2010 from one of 10 study communities, across six geographic areas. These communities included The Bronx and Harlem (New York City, New York), North and South Newark (Newark, New Jersey), Washington (District of Columbia), Baltimore (Maryland), Durham and Raleigh (North Carolina), and Atlanta and Atlanta/Decatur (Georgia). A certificate of confidentiality was obtained for the study and research sites obtained local institutional review board (IRB) approval before initiation of study activities. Women were followed for 6 or 12 months, depending on date of enrollment, and were compensated for in-person visits (i.e., enrollment and follow-up) and phone locator update calls. The amount of compensation varied by site and was approved by local IRBs (ranging from 35 to 50 dollars for in-person study visits and 10 to 15 dollars for locator-update phone calls). The study design has been described in detail elsewhere.<sup>17,39</sup>

### *Recruitment areas: study census tract/zip code selection*

Recruitment areas were defined by census tracts (and for New York only, zip codes) with high prevalences of both HIV and poverty. Census tracts on average contain 4,000 persons and are typically homogeneous with respect to population characteristics, economic status, and living conditions.<sup>40</sup> In 2000, zip codes in New York City contained an average of 8,785 persons aged 18 and older. A list of eligible census tracts (zip codes for New York City) for study inclusion was generated between November 2008 and August 2009. Eligible study census tracts/zip codes were areas with high prevalence of HIV and poverty as defined based on the

NHBS-HET pilot methodology, which in 2006–2007 combined U.S. Census poverty data with state health department HIV prevalence data using a standardized algorithm,<sup>33</sup> within reasonable travel time of clinical research site (e.g., within 2 hours), and had sufficient population density to facilitate rapid recruitment. HIV prevalence was generated from the most recently available data, which in 2008–2009 was from 2007 HIV cases rates (2006 for North and South Newark); percent living below poverty was established using 2000 U.S. Census data on population size and poverty rate (2005 estimates for Georgia). Census tracts in the top 30th percentile of poverty and with more than 25% of inhabitants living below the U.S. federal poverty threshold were assigned a combined “score.” Higher ranked scores denoted tracts with greater levels of HIV and poverty relative to the surrounding tracts.

Study staff conducted an ethnographic review of the top 30th percentile of the ranked census tracts/zip codes generated using the standardized algorithm described above to confirm the ranked tracts were high poverty areas, to determine whether the study areas had experienced notable changes in community characteristics since the 2000 census (e.g., gentrification, consisted of primarily commercial nonresidential areas), and to identify recruitment venues. Each site developed a tailored approach to conducting ethnography based on consultation with local experts and community advisory boards (CABs). Ethnographic data collection activities included, walking and driving through potential tracts (e.g., “windshield tours”), informal communication with community partners, advisory boards, residents, and business owners, and in some cases, brief interviews and focus groups with women and other key informants. Census tracts determined to be largely nonresidential or visibly gentrified were removed from the eligible census tract/zip code list. Through this process, each site generated a final list of census tracts/zip codes that was then used to determine residence eligibility for participants (residential sampling frame). Women residing in a census tract outside of the sampling frame were considered ineligible for the study. A range of 8% to 30% of tracts in each community were ultimately classified as eligible census tracts.

*Participant eligibility criteria*

Study participants were self-identified women aged 18–44 years who reported unprotected vaginal or anal sex with a man in the past 6 months and who resided within the study census tracts/zip codes as described above, and who reported at least one additional personal risk (e.g., substance use) and/or male partner characteristic (e.g., history of incarceration) associated with greater risk of HIV acquisition, as outlined in Table 1. Women were excluded from participating if they reported a history of previous positive results on an HIV test, current HIV prevention trial enrollment, current or past participation in an HIV vaccine trial, or anticipated absence for more than two consecutive months during follow-up. Eligibility criteria were collected through staff-administered questionnaires. Subsequent behavioral measures (e.g., anal sex, concurrency) were collected at baseline and follow-up using an audio computer-assisted survey instrument (ACASI).<sup>17</sup>

*Venue identification*

Participants were recruited using VBS. Eligible venues were located in the highest ranking census tracts/zip codes as

TABLE 1. STUDY ELIGIBILITY CRITERIA

*All eligible women met the following criteria:*

- Self-identify as a woman (transgendered women eligible)
- 18 to 44 years of age, inclusive on the date of screening
- Willing to receive HIV test results
- Reside in designated census tract or, for New York City only, zip code
- Unprotected (e.g., without a condom) vaginal and/or anal sex with a man during the prior 6 months

*AND at least one of the following reported by participant:*

Personal history of any of the following in the prior 6 months:<sup>a</sup>

- Illicit injected and/or noninjected drug use (e.g., heroin, cocaine, crack cocaine, methamphetamine, and/or prescription drugs used outside the oversight of a medical professional)<sup>b</sup>
- Alcohol dependence<sup>c</sup>
- Binge drinking<sup>d</sup>
- Incarceration for more than 24 hours (jail or prison)<sup>a</sup>
- Gonorrhea, chlamydia, trichomonas, or syphilis
- Exchange of sex for commodities (e.g., drugs, money, shelter, or other commodities)

Male sexual partner with any of the following in the prior 6 months:<sup>a</sup>

- Self-reported use of illicit injected or noninjected drugs (e.g., heroin, cocaine, crack cocaine, methamphetamine, and/or prescription drugs used outside the oversight of a medical professional)<sup>b</sup>
- Incarceration for more than 24 hours (jail or prison)<sup>a</sup>
- Gonorrhea, chlamydia, trichomonas, or syphilis
- HIV seropositive diagnosis (ever)
- Binge drinking<sup>d</sup>
- Alcohol dependence<sup>c</sup>

*Exclusion criteria*

Women were excluded from participating if they reported any of the following:

- A history of previous positive results on an HIV test
- Current HIV prevention trial enrollment
- Current or past participation in an HIV vaccine trial
- Anticipated absence for more than two consecutive months during follow-up

<sup>a</sup>Within the prior 6 months, with the exception of incarceration, which was within the prior 5 years.

<sup>b</sup>Participants whose only illicit drug use is marijuana did not meet the illicit drug use eligibility criteria.

<sup>c</sup>Defined as a CAGE<sup>56</sup> score  $\geq 2$ .

<sup>d</sup>Defined as four or more drinks at one time (e.g., during the morning, afternoon, or evening) for women and five or more drinks for men.

CAGE, cut down, annoyed, guilty, eye-opener.

defined above or within proximity of the identified census tracts/zip codes and deemed likely to be frequented by women living in the eligible census tracts. Research staff used ethnography (as described above) and community consultation to enumerate a list of all potential venues (e.g., beauty salons, library, grocery, and liquor stores) in or near the study tracts and to assess the age range, gender, and number of individuals typically attending the venue. Venues were



determined to be inappropriate for recruitment if (1) they were frequented predominantly by men; (2) a minority of women not meeting the age eligibility criteria were likely to attend the venue (e.g., majority under 18); (3) it would be impossible logistically to screen potential participants for confidentiality or safety reasons; or (4) venue owner(s) refused to allow the project staff access to venue attendees.

For each eligible venue, site ethnographers documented the high traffic days and times (e.g., weekdays from 1–5 pm). Each venue daytime period (VDT) was enumerated and collectively made up the list of potential recruitment venue time slots (e.g., each VDT had a distinct enumeration). A total of 13 venue categories and corresponding definitions were included on the study enrollment form. These categories were based on existing NHBS-HET cycle categories.

### Recruitment

Random-number generators were used to select VDTs from the enumerated venue list and to construct monthly sampling frames. Alternative venues for each primary recruitment venue were also randomly selected to ensure that backup venues were available in the event that the primary venue proved unsuccessful (e.g., inclement weather, lack of participants for screening).

A systematic process was used at each venue to recruit potential participants. Prior to initiation of screening activities, study staff identified a catchment area within the venue with high pedestrian traffic; any woman crossing into this region was approached either sequentially or systematically (e.g., every fourth woman) for screening in the order in which they “crossed the line” into the catchment area. This decision was made *a priori* based on the availability of staff and the amount of foot traffic at the venue. All staff were knowledgeable of the boundaries of this region; however, in an attempt to avoid participant self-selection, this region was “invisible” to potential study participants. Study screening and enrollment activities took place at locations that assured adequate confidentiality, such as a mobile van, nearby community location, or the study clinical site. Other day appointments were scheduled in cases where women were unable to complete screening and enrollment activities at the time of the initial encounter.

### Community engagement

Study sites used a combination of techniques to develop community partnerships and gain trust within each community. A study-wide community working group (HPTN 064 CWG) with representatives from each study site and local community advisory boards (CABs) were established early in study development. The HPTN 064 CWG and CABs were consulted on a regular basis and provided feedback to the protocol team and study site staff on community engagement plans, community education and recruitment materials, ethnographic assessments, and venue identification procedures.

A study logo and associated branding was developed through a community-based logo contest and selected through collaboration between the study protocol, study sites, and the HPTN 064 CWG. Study staff developed ongoing partnerships with local community organizations and key community gatekeepers (e.g., community advocates, respected neighborhood members). Site staff maintained an active

presence at community events and in day-to-day activities by frequenting community businesses and volunteering at community events.

### Staffing considerations

Study recruiters were predominantly women of color. A minimum of two staff members were required for all recruitment activities to ensure the safety of study staff and to ensure that there was an adequate number of staff to approach and recruit potential participants.

### Retention

Although the focus of this manuscript is study recruitment, it should be noted that a variety of strategies were used to ensure retention of enrolled participants. Retention strategies included: community engagement; interpersonal relationship building (e.g., phone calls and personalized mailings); reduction of external barriers (e.g., study visits outside of traditional business hours, clinical and community visit sites); staff capacity building (e.g., ongoing training); and external tracing (e.g., prison and jail database searches). These strategies are discussed in detail elsewhere.<sup>39</sup>

### Measures and data analysis

Descriptive statistics were obtained using SAS version 9.2 (SAS Inc.). Continuous variables were summarized using medians and interquartile ranges. Categorical variables were tabulated. Screen to enrollment ratio was defined as the number of women screened divided by the number of women enrolled and was generated using site tracking logs and enrollment reports.

For purpose of analysis, study venues categories were grouped into one of seven categories: (1) retail space, (2) outdoor venue (e.g., park, street), (3) social service organization, (4) public housing, (5) special event (e.g., any one-time event such as a community event or concert), (6) other public space (e.g., public transportation, library, church), and (7) space that serves alcohol (e.g., bar, club). These groupings were informed by descriptions of venue categories in available literature and through consultation with team members with expertise in this area (Table 2).<sup>36–38,41</sup>

Exploratory analyses of participant characteristics by venue were conducted using exact logistic regression (SAS version 9.2) in order to assess associations between venue type, participant self-reported eligibility (as described in Table 1), laboratory-confirmed HIV infection (recent and newly diagnosed prevalent), and baseline behaviors associated with increased risk of HIV acquisition (any anal sex in the prior six months (yes/no) and concurrency (sexual partnerships overlapping in time in the prior 6 months)). Both direct concurrency (participant report of nonmonogamous partnerships that overlap in time [yes/no]) and indirect concurrency (participant self-report of being in a sexual partnership where her male partner had one or more additional sexual partners, [yes/no]) were explored. Exploratory analyses modeled venue category as the independent variable and participant characteristics as the dependent variable. Self-reported eligibility criteria modeled included personal characteristics only, partner characteristics only, personal and partner characteristics, specific criteria met (e.g., alcohol misuse [dependence and/or binge]; substance use; history of

TABLE 2. VENUE CATEGORIES

<i>Venue category</i>	<i>Category listed on study enrollment form<sup>a</sup></i>
(1) Retail Space (n = 388)	Restaurant/café <sup>b</sup> (n = 40) Retail (n = 348)
(2) Outdoor location (n = 1,215)	Street <sup>c</sup> (n = 1,108) Park <sup>c</sup> (n = 107)
(3) Social service organization (n = 268)	Social service organization <sup>c</sup> (e.g., WIC) (n = 268)
(4) Public housing <sup>d</sup> (n = 80)	Generated from “other” category, includes participants where a specific public housing complex was listed as the recruitment venue category
(5) Special event <sup>d</sup> (n = 66)	Generated from “other” category, includes participants recruited from a one-time event such as fair
(6) Other public space (n = 65)	Public transport <sup>d</sup> (n = 18) Church <sup>d</sup> (n = 12) Social group <sup>c,e</sup> (n = 5) Library <sup>d</sup> (n = 14) Court <sup>d</sup> (n = 15) Gym <sup>c</sup> (n = 1) Bar <sup>c</sup> (n = 5) Dance club <sup>c</sup> (n = 1) Sex establishment <sup>c</sup> (n = 2) House party <sup>c</sup> (n = 5)
(7) Spaces that serve alcohol (n = 13)	

<sup>a</sup>“Rave or similar event” was included on the study enrollment form; however, no participants were enrolled from this venue type and it is not included in the categories above.

<sup>b</sup>Majority of restaurants/café are fast food restaurants.

<sup>c</sup>Pre-specified enrollment form category.

<sup>d</sup>Developed based on “other” category.

<sup>e</sup>Church group.

STI; exchange of sex for drugs, money, shelter, or other commodities; and incarceration).

Of note, as described in Table 1, all eligibility captured behaviors/characteristics within the prior six months, with the exception of incarceration history, which included at least 24 hours in jail or prison within the prior five years.

**Results**

*Screening*

A total of 8,029 women were screened between May 2009 and August 2010. Screen to enrollment ratios by site ranged from ranged from 2.5 to 6.6, with an average of 3.5 women screened per woman enrolled (Fig. 1). Sixty percent of women screened (n = 4,796) did not meet study eligibility criteria. Reasons for ineligibility are available for 4,342 women (Fig. 2). Reasons for ineligibility are not mutually exclusive; women could screen out of the study for more than one reason. The four most common reasons for ineligibility were: (1) lived outside of the eligible census tract-sampling frame (n = 1591, 37%); (2) no unprotected sex with a man in the prior 6 months (n = 1447, 33%); (3) over 44 years of age (n = 951, 22%); and (4) unprotected sex only reported risk (n = 860, 20%). A total of 3,233 (40%) of women screened were eligible for enrollment. Of those eligible, 1,134 (35%) did not enroll; the majority of these women did not return to the clinical research site for the scheduled enrollment visit (69%).

*Participant characteristics*

A total of 2,099 women were ultimately enrolled (approximately 210 per site). Overall study retention was 92%. Overall, 1 in 300 women in this cohort were identified with newly acquired HIV infection.<sup>17,42</sup> Select baseline charac-

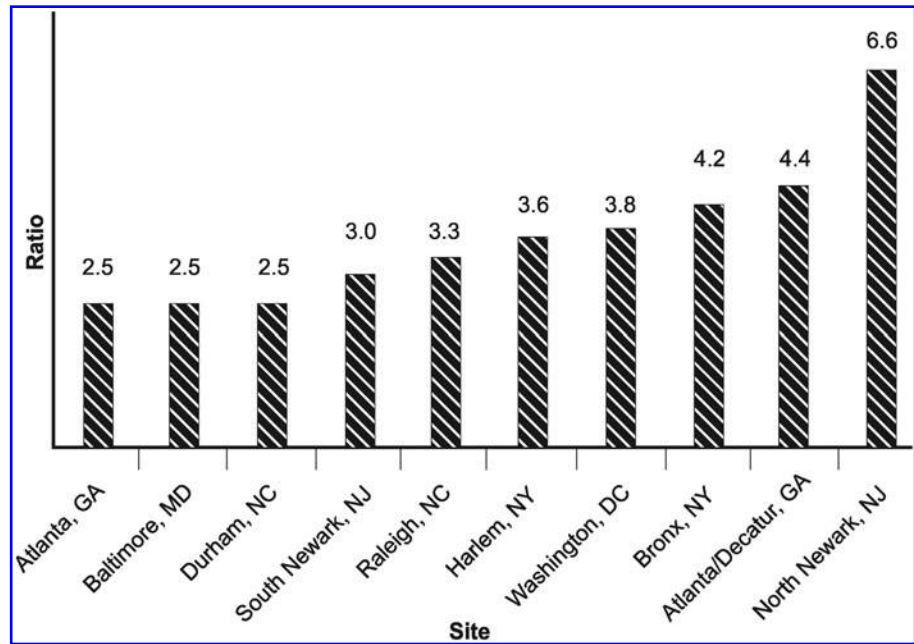
teristics are presented in Table 3. The majority of participants were black (86%). The median age was 29 years. Thirty-seven percent had less than a high school education and 44% percent reported an annual income of \$10,000 or less. Baseline binge drinking and illicit substance use in the last 6 months was high; 62% reported binge drinking and 35% reported illicit substance use (excluding cannabis). Condom use at last sex was low (18%). Thirty-eight percent of women reported anal sex, 37% reported direct concurrency (i.e., non-monogamous partnerships that overlap in time), and 36% reported suspected partner concurrency (i.e., being in a sexual partnership where her male partner had one or more additional sexual partners).

Most participants met both personal and partner eligibility criteria (73%). However, 14% of participants were eligible based on partner characteristics only, and 13% of participants were eligible based on personal characteristics alone (Table 4). Sixty percent of participants met alcohol misuse (dependence and/or binge) criteria, 12% met the substance use criterion, 14% met criteria for self-reported history of STI, 27% met the criterion for sex exchange, and 40% met the incarceration eligibility criterion.

*Participant characteristics by venue*

In the exploratory analyses conducted to determine if participant characteristics were associated with venue category (Table 4), there were no statistically significant relationships between venue type, participant self-reported eligibility, laboratory-confirmed HIV infection (recent and newly diagnosed prevalent), and baseline behaviors associated with higher risk of HIV acquisition (anal sex, participant concurrency, and partner concurrency). Odd ratios, confidence intervals, and associated p-values are not presented.

**FIG. 1** Ratio of Women Screened to Women Enrolled, by Site ( $n = 8029$ ).



*Venue characteristics*

Approximately half of participants were recruited from outdoor venues ( $n = 1,215$ , 58%), followed by commercial spaces ( $n = 388$ , 18%), and social service organizations ( $n = 268$ , 13%) (Table 4). The proportion of women recruited per venue category varied by site (Table 5). For example, 16% of participants were recruited from outdoor venues at the Durham site, whereas approximately 90% of women were recruited from outdoor venues in South Newark, New Jersey and Harlem, New York. The percentage of women recruited from commercial venues ranged from about 1% in South Newark and Bronx, New York to around 43% in Washington, DC, and Raleigh, North Carolina. All participants recruited from special events were located in North Carolina.

**Discussion**

This study demonstrated that it is feasible to engage and recruit women using venue-based sampling based on pre-defined eligibility criteria for location, individual, and partner characteristics associated with high-risk for HIV acquisition. VBS proved a rapid, effective way to recruit a large cohort of predominantly black women from community-based settings, with some sites enrolling over 200 women in less than 3 months. One in 300 women in HPTN 064 acquired HIV, which is substantially higher than estimates of HIV incidence among black women of similar age and comparable to some sub-Saharan African countries.<sup>17</sup>

Fourteen percent of women reported partner risk characteristics only and would not be included in studies targeting personal risk behavior alone. Women at elevated risk of HIV

**FIG. 2** Reasons for Enrollment Ineligibility<sup>1</sup> ( $n = 4342$ ).

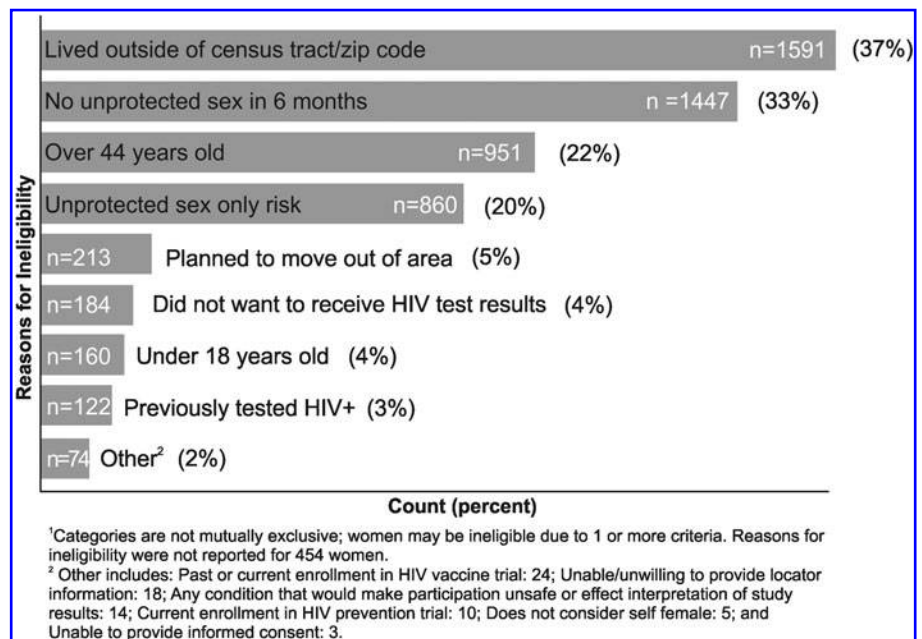


TABLE 3. SELECT PARTICIPANT BASELINE CHARACTERISTICS (IN PREVIOUS SIX MONTHS)

Variable	n=2,099
Median age (interquartile range)	29 (23–38)
Black race	1802 (86%)
Less than high school education	777 (37%)
Condom use at last vaginal sex	376 (18%)
Concurrent sexual partners	
Direct (Self-report of non-monogamous partnerships that overlap in time)	776 (37%)
Indirect (Sexual partner with ≥1 additional sexual partner[s])	763 (36%)
Mental health	
Symptoms indicative of depression <sup>a</sup>	692 (33%)
Symptoms indicative of PTSD <sup>b</sup>	600 (29%)
Abuse history	
Physical, emotional, sexual or feeling unsafe	811 (39%)
Childhood abuse (ever)	934 (44%)
Illicit non-alcohol drug use <sup>c</sup>	726 (35%)
Binge drinking <sup>d</sup>	1300 (62%)
Homeless <sup>e</sup>	182 (9%)
Number of children financially responsible for	
0 or NA	990 (47%)
1	465 (22%)
≥2	644 (31%)
Reported food insecurity	971 (46%)

<sup>a</sup>Symptoms of depression was defined as a score of 7 or greater on a shortened CES-D scale used by DiClemente et al.<sup>57</sup>

<sup>b</sup>Symptoms of post-traumatic stress disorder (PTSD) was defined as a score of 3 or greater on the primary care PTSD screener.<sup>58</sup>

<sup>c</sup>Excludes cannabis.

<sup>d</sup>Defined as four or more drinks at one time (e.g., during the morning, afternoon, or evening).

<sup>e</sup>Baseline housing is not available for 30 participants.

CES-D, Center for Epidemiologic Studies Depression Scale.

acquisition in the United States may not perceive themselves at risk, particularly if this risk is due to male sexual partner or network characteristics.<sup>43</sup> It is likely that these women would not have been identified through recruitment methods, such as flyers, which require women to self-select for screening. Moreover, 38% of women reported anal sex in the prior 6 months at baseline, which is higher than existing cross-sectional estimates among the general population of women in the United States, with 20% reporting anal sex in last 12 months.<sup>44</sup> Anal sex is an HIV risk factor for heterosexual women; however, stigma related to disclosure of anal sex behaviors may be a barrier to recruitment.<sup>45</sup> These results suggest that it may be possible to recruit women who engage in anal sex using VBS, without requiring disclosure of anal sex practices at screening.

Community engagement is a critical element of study implementation, and of recruitment and retention in particular.<sup>46–50</sup> Community partnerships were necessary, not only to identify study communities and venues, but also to establish and maintain the trust of venue owners, management, and potential participants, and also to reduce other structural barriers, such as access to transportation to clinical research sites. It is likely that the substantial ongoing community collaborations, as evidenced by establishment of local community advisory boards and working groups, frequenting of

local businesses, and volunteering at community events, was responsible for rapid recruitment and successful identification of a cohort of women at heightened risk for HIV. Study branding, such as a study-wide logo developed in collaboration with community partners and study t-shirts, facilitated recognition of study staff by community members. Branding has been shown in the past to be an effective way to recruit and retain female study participants.<sup>4,51</sup>

Notably, only 13 women were recruited from a “space that serves alcohol,” but 60% of women met alcohol misuse eligibility criteria. Women may not visit bars and clubs as frequently as some other groups targeted by VBS, such as MSM. Instead, women may be more likely to drink at home or with friends. Off-site alcohol consumption has been associated with higher sexual risk.<sup>52,53</sup> Interestingly, reports of personal risk behaviors provided to satisfy eligibility criteria during recruitment were not always consistent with the risk behaviors reported during the subsequent ACASI interview. Although only 12 percent of women reported non-alcohol substance use in the prior 6 months at screening, 35% of women reported some level of substance use in the prior 6 months at the baseline ACASI, suggesting that substance use was underreported at screening. It is possible that some potential participants may be reluctant to report substance use to recruiters, particularly if recruitment takes place at a locale where revealing substance use could result in the loss of benefits (e.g., social service organizations, public housing).

As described earlier, there are limited data available on the basis for grouping venue categories and the association of venue category to participant attributes. To our knowledge, this is one of the first studies to characterize participant HIV risk characteristics by venue for U.S. women exclusively. For this analysis, study venue categories were created using existing literature to the extent that it applied to a female-only study population but also include unique categories not previously described in the literature. Retail venues, outdoor venues, public spaces, special events, and spaces that serve alcohol have been previously described in VBS literature targeting U.S. adult populations.<sup>36,37</sup> Social service organizations and public housing have not to our knowledge been identified as distinct VBS categories in other HIV cohort or prevention studies enrolling women. These categories were developed using the rationale that each represents a specific venue type and may be frequented by women with different demographics or life circumstances (e.g., social service organizations may represent women who are able to identify and access services).

The proportion of women recruited from each venue category varied across study site, which reflects both the geographic diversity of the sites and of the participant population. VBS allows for the development of a sampling frame based on local ethnography, and as such, this is to be expected. Roughly half of the cohort was recruited from outdoor venues. The success of this approach was in part due to the heavy foot traffic in many of the urban sites and the popularity of parks as “hang-out” areas in warmer months across several sites. Of note, a smaller proportion of women were recruited from outdoor venues in the periurban sites: 16% of women were recruited from outdoor venues in Durham, NC, as compared with 90% in Harlem, NY. Applications of VBS to different settings should consider population density, venue types, weather, and expected foot traffic and tailor strategies and timelines accordingly.



TABLE 4. PARTICIPANT SELF-REPORTED ELIGIBILITY CHARACTERISTICS (N=2,099)

Self-reported characteristics	Venue category							Total Overall (n=2,099)
	Retail space (n=388)	Outdoor venue (n=1215)	Social service organization (n=268)	Public housing (n=80)	Special event (n=66)	Other public space (n=66)	Space that serves alcohol (n=13)	
<b>Personal and partner eligibility criteria met<sup>a</sup></b>								
Personal characteristic only	39 (10%)	175 (14%)	28 (10%)	9 (11%)	9 (14%)	6 (9%)	1 (7%)	267 (13%)
Sexual partner characteristic only	60 (21%)	168 (14%)	33 (12%)	13 (16%)	17 (26%)	11 (17%)	2 (15%)	304 (14%)
Both personal and partner	289 (74%)	872 (72%)	207 (77%)	58 (73%)	40 (61%)	52 (79%)	10 (77%)	1528 (73%)
<b>Behavioral eligibility criteria met<sup>a</sup></b>								
Alcohol misuse (binge and/or dependence)	233 (60%)	726 (60%)	167 (62%)	48 (60%)	26 (39%)	45 (68%)	10 (77%)	1255 (60%)
Non-alcoholic substance use	30 (8%)	183 (15%)	28 (10%)	5 (6%)	5 (8%)	2 (3%)	1 (7%)	254 (12%)
STI	78 (20%)	144 (12%)	37 (14%)	16 (2%)	12 (18%)	14 (21%)	3 (23%)	304 (14%)
Sex exchange	108 (38%)	324 (27%)	84 (31%)	11 (14%)	10 (15%)	22 (33%)	4 (31%)	566 (27%)
Past incarceration	151 (39%)	495 (41%)	120 (45%)	27 (34%)	20 (30%)	29 (44%)	6 (46%)	848 (40%)
<b>Select baseline behaviors<sup>b</sup></b>								
Anal sex	135 (35%)	483 (40%)	111 (41%)	15 (19%)	24 (36%)	25 (38%)	3 (23%)	796 (38%) <sup>d</sup>
Direct concurrency	126 (32%)	449 (37%)	102 (38%)	32 (40%)	28 (42%)	33 (50%)	6 (46%)	776 (37%) <sup>c</sup>
Indirect concurrency	145 (37%)	422 (35%)	99 (37%)	33 (41%)	30 (45%)	28 (42%)	6 (46%)	763 (36%)
<b>HIV infection<sup>c</sup></b>	8 (2%)	25 (2%)	3 (1%)	1 (1%)	1 (2%)	0 (0%)	0 (0%)	38 (2%)

<sup>a</sup>Eligibility as reported on the enrollment study form and follow criteria outlined in Table 1. Categories are not mutually exclusive.

<sup>b</sup>As reported in baseline audio computer-assisted survey instrument (ACASI).

<sup>c</sup>Confirmed by laboratory results.<sup>17,42</sup>

<sup>d</sup>n=2094.

<sup>e</sup>n=2090.

In addition, women were recruited from a number of venues not previously anticipated during the development of study forms (e.g., library, church, public housing). This highlights the need for thorough ethnography prior to initiation of recruitment activities, so as to ensure that the initial sample frame reflects the attributes of the study communities. People and places change over time; the recruitment universe was reviewed on a regular basis by study staff members to determine whether venues should be added or removed

based on site staff experience or additional information obtained from the community. For example, hair and nail salons were initially included in the venue universe but were later removed by the majority of sites due to challenges with participant confidentiality and the low number of women attending the venue during a given recruitment block. In addition, seasonal, temporal, and safety considerations (e.g., gang activity) also influenced hours present at the and monthly venue productivity.

TABLE 5. NUMBER OF ENROLLED PARTICIPANTS BY RECRUITMENT VENUE (BY SITE AND OVERALL) (N=2,099)

Site	Venue category							Total <sup>a</sup>
	Retail space	Outdoor venue	Social service organization	Public housing	Special event	Other public space	Space that serves alcohol	
Bronx, NY	4 (2%)	153 (73%)	28 (13%)	6 (3%)	0 (0%)	19 (9%)	0 (0%)	210
Harlem, NY	11 (5%)	188 (90%)	10 (5%)	0 (0%)	0 (0%)	1 (<1%)	0 (0%)	210
North Newark, NJ	8 (4%)	145 (69%)	56 (27%)	0 (0%)	0 (0%)	0 (0%)	1 (1%)	210
South Newark, NJ	3 (1%)	186 (89%)	21 (10%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	210
Baltimore, MD	41 (20%)	141 (68%)	22 (11%)	0 (0%)	0 (0%)	0 (0%)	4 (2%)	208
Washington, DC	91 (43%)	106 (50%)	13 (6%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	210
Durham, NC	66 (32%)	34 (16%)	9 (4%)	42 (20%)	40 (19%)	18 (9%)	0 (0%)	209
Raleigh, NC	93 (44%)	58 (28%)	2 (1%)	32 (15%)	24 (11%)	1 (<1%)	0 (0%)	210
Atlanta, GA	26 (12%)	90 (43%)	71 (34%)	0 (0%)	0 (0%)	21 (10%)	3 (1%)	211
Atlanta/Decatur, GA	45 (21%)	114 (54%)	36 (17%)	0 (0%)	2 (1%)	9 (4%)	5 (2%)	211
<b>Total</b>	<b>388 (18%)</b>	<b>1,215 (58%)</b>	<b>268 (13%)</b>	<b>80 (4%)</b>	<b>66 (3%)</b>	<b>69 (3%)</b>	<b>13 (&lt;1%)</b>	<b>2,099</b>

<sup>a</sup>Protocol target enrollment for each site was 200 participants and could be exceeded up to 5%.



Exploratory analyses of the associations between venue category and participant characteristics, such as reasons for eligibility, HIV infection, and sexual risk were not statistically significant in exact logistic models. As described, eligible venues were frequented by women living in discrete census tracts. It is possible that the lack of statistical association is reflective of generalized risk among women living in “hot spot” geographic areas with high combined prevalence of HIV and poverty,<sup>54</sup> and as such, sociodemographic characteristics of venue locations, rather than the type of venue may be most critical. However, it is possible that the nonsignificant result is due to small cell sizes and resulting low power. Additional research could further define venue characteristics and help to clarify their association with recruitment of specific populations.

Moving forward, studies using geospatial administrative data sources, such as the U.S. Census, to determine eligibility should be mindful of the timing of collection of these data relative to study activities. Sites initiated ethnographic assessments in 2008, eight years after the collection of the 2000 U.S. Census data. Some sites, such as those in Atlanta, GA, experienced significant gentrification during this time.<sup>55</sup> Early ethnographic assessment in Atlanta revealed that the ranked census tracts generated using 2000 census data did not reflect current socioeconomic characteristics of the tracts, which necessitated the purchase of updated census data for the year 2005 and additional ethnographic assessment, including significant input from community partners. The intricate steps associated with ethnography combined with strong community partnerships can help ensure that the study team is knowledgeable of phenomena such as gentrification or out-migration of communities that would justify the use of updated Census data.

The findings in this manuscript are subject to limitations. Venue-based sampling methods are used to produce estimates for hard-to-reach populations when sampling frames of the individual members of those populations do not exist or are difficult to construct. However, the data in this manuscript are not weighted to account for variations in venue attendance or likelihood of being selected to participate in the survey and do not account for women who do not attend those venues. In addition, the study did not systematically collect data on screening refusals, and as a result, response rates cannot be calculated. Study eligibility criteria were assessed using self-report; socially undesirable behaviors (e.g., drug use) might have been underreported at the time of eligibility determination. Furthermore, partner's risk behaviors may be underreported, since many women may not be aware of their partner's risk. Finally, since high-risk personal or male sex partner behaviors were included as eligibility criteria, the proportions of high-risk behavior are not representative of all women living in these communities. Findings from this study might not be generalizable to other U.S. states or cities.

## Conclusion

In summary, we demonstrated the feasibility and effectiveness of rapid recruitment of a population of women at elevated risk for HIV infection from a range of community-based settings using a venue-based sampling methodology and a combination of geographic, personal, and partner eli-

gibility criteria. Such recruitment approaches require strong community engagement and substantial commitment by study funders and research sites, but are needed to engage women most at risk for targeted HIV prevention research and programs.

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## Disclosure Statement

Sally Hadder, MD has disclosed that she has received consulting fees from Bristol-Myers Squibb, Gilead Science, GlaxoSmithKline/Viiv, and Janssen; and that her spouse has ownership interest in Merck and Becton Dickinson. For all other authors there are no competing financial interests.

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