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PrEP Chicago: A randomized controlled peer change agent intervention to promote the adoption of pre-exposure prophylaxis for HIV prevention among young Black men who have sex with men

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Abstract

Background/Aims—Advances in biomedical prevention strategies such as Pre-Exposure Prophylaxis (PrEP) represent a new opportunity for reducing HIV incidence among young Black men who have sex with men (MSM), for whom the number of new HIV infections continues to rise. However, studies have documented low rates of PrEP uptake in this community. Research suggests that the peer networks of young Black MSM play important roles in their sexual health decisions. PrEP Chicago is a randomized controlled trial network intervention designed to increase PrEP uptake among young Black MSM living in Chicago. The aims of this study are twofold. Aim 1 is to estimate the effectiveness of a peer change agent intervention for: 1) increasing the number of referrals made to a PrEP information line; 2) increasing the rate of PrEP adoption among non-participant peers; and 3) increasing PrEP knowledge, attitudes and intentions among participants. Aim 2 is to determine the individual and network variables that explain peer change agent effectiveness.

Methods—PrEP Chicago is a social network intervention that utilizes the influence of peer change agents to link young Black MSM in Chicago to PrEP. Young Black MSM participants were recruited using respondent-driven sampling. Once screened for eligibility, participants were

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Trials registration

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Declaration of conflicting interests

The Author(s) declare(s) that there is no conflict of interest.

randomly assigned to either one of two treatment sequences: 1) intervention treatment in Year 1 followed by a minimal contact attention control in Year 2, or 2) the minimal contact attention control in Year 1 followed by treatment in Year 2. The treatment consists of a PrEP/peer change agent training workshop followed by booster calls for 12 months. The attention control consists of a sex diary activity designed to help participants assess sexual risk. Psychosocial, sexual health, and network data are collected from all participants at baseline and at 12- and 24-month follow-ups.

Results—In total, 423 participants aged 18–35 have been enrolled (more than 100% target enrollment) and have completed baseline data collection. A majority of participants in both intervention and control groups reported having heard of PrEP before enrolling in the study, yet also reported having had no current or prior experience taking PrEP. Statistical analyses await completion of Year 1 of the trial in March 2018.

Conclusion—PrEP Chicago addresses a gap in HIV prevention research and intervention design by utilizing the existing social networks among young Black MSM as mechanisms for information diffusion, behavioral influence, social support and empowerment. Therefore, interventions that leverage peer influence processes to facilitate PrEP uptake are promising strategies to improve sexual health engagement and overcome disparities in outcomes among this at-risk population.

Keywords

HIV prevention; pre-exposure prophylaxis; Black men who have sex with men; network intervention; peer change agents; intervention design; social networks

Background

Although estimated incidence of human immunodeficiency virus (HIV) in the United States has stabilized in recent years, some groups remain disproportionately affected, most notably young Black Men who have Sex with Men (MSM) for whom numbers of new infections continue to rise.^{1,2} Biomedical prevention strategies such as Pre-Exposure Prophylaxis (PrEP) represent a new opportunity for reducing HIV incidence among young Black MSM. In controlled settings, PrEP has been shown to be up to 99% effective if taken daily as prescribed,³ and Center for Disease Control and Prevention clinical guidelines were published in 2014. Despite this, studies have documented low rates of PrEP uptake in this community, identifying several implementation issues like low awareness, misperceptions about suitability, and concerns about side effects.^{4–6}

Although individual factors like these are crucial to address, social factors that challenge prevention engagement also need attention. For example, stigma associated with being perceived as HIV positive or sexually promiscuous have been linked to young Black MSMs' reluctance to consider PrEP.⁷ Additionally, as racial and sexual minorities,⁸ young Black MSM must cope with homophobic and racist discrimination in multiple contexts, including clinical spaces, which can complicate their ability to obtain support regarding sexual health decisions.^{9,10}

Social network interventions – i.e., interventions that position members of the target population (i.e., peers) in the roles of *health educators* who disseminate information about

HIV prevention in their networks or *health buddies* who support the engagement of their peers in prevention practices^{11–14} – offer an opportunity to reach larger portions of at-risk populations,^{11,15} while overcoming socially derived barriers like stigma and discrimination through peer leadership and support. Further, network interventions also strengthen community connectedness and resilience^{16,17} and transform social norms,¹⁵ which are critical for sustaining community-level change.^{18,19}

Here, we describe *PrEP Chicago*, an ongoing randomized controlled trial (RCT) intervention developed to leverage the social networks of young Black MSM living in Chicago to facilitate PrEP adoption and to encourage engagement in a community sexual health campaign. This study has two specific aims: (1) to estimate the effectiveness of a peer change agent intervention for a) increasing the number of referrals made to a PrEP information line, b) increasing the rate of PrEP adoption among non-participant peers, and c) increasing PrEP knowledge, attitudes and intentions among participants; and (2) to determine the individual and network factors that explain peer change agent effectiveness. This article describes our study and some baseline data while emphasizing methodological challenges faced thus far.

Methods

Study design

The study uses an RCT design²⁰ where participants randomized to the control group are switched to the intervention after one year (and vice versa). Although similar to a crossover design chosen to increase precision, the motivation and planned analyses here are different. By allowing those initially randomized to the control to switch to the intervention, we double the total number of participants who ultimately receive the intervention, thereby increasing the sample size for Aim 2, and ultimately have the greatest community impact. Finally, continuing to follow those initially assigned to the intervention under the control condition permits us to evaluate the durability of the intervention—a critical factor when determining cost-effectiveness of resource intensive interventions.

Participants are randomized to one of two treatment sequences as shown in Figure 1. Those randomized to the first sequence receive the intervention in year one, followed by an attention control condition in year two. In contrast, participants randomized to the second sequence receive the attention control in year one, followed by the intervention in year two. Participants remain in the study for two years in total, one year under each condition. The Institutional Review Boards of the University of Chicago and the National Opinion Research Center at the University of Chicago provided approval for the study.

Participant recruitment

The study targets young Black MSM living in Chicago. Recruitment of participants occurred between March 2016 and March 2017. Participants were recruited using respondent-driven sampling, a procedure well suited for identifying members of “hard-to-reach” populations like MSM.²¹ A variant of snowball sampling,^{22,23} respondent-driven sampling draws on peer referrals and begins with a set of initial “seeds” that meet study eligibility. Once a seed

is enrolled and completes their baseline data collection, they are instructed to recruit peers (up to 6) into the study. Following enrollment, these new participants are also instructed to recruit peers, and the process continues until the recruitment target is reached. Participants received a \$20 cash incentive for each peer whom they successfully referred into the study.

Seed selection—Selecting seeds is a non-trivial process that can influence which portions of a population are actually sampled.²⁴ Seeds should have large social networks and have ties to a diverse array of people belonging to different subpopulations.^{23,25,26} These same traits – having large networks and ties to different subgroups – are also thought to be important characteristics of effective peer change agents. While popular (or central) network actors have the status and connections needed to influence their peers,^{14,27} those who span the boundaries of unique sub-communities are crucial in getting innovations to spread across regions of the network.^{28,29}

Traditionally, respondent-driven sampling relies on key informants to identify population members who possess these essential traits. Alternatively, we used sociometric methods to identify potential seeds based on their central and/or boundary spanning positions within a previously derived Facebook friendship network³⁰ among the target population. A visual representation of this network is shown in Figure 2.

Specifically, four network metrics were used as measures of social influence, *betweenness centrality*³¹ and *eigenvector centrality*³² as measures of centrality and *key player*³³ and *bridging*³⁴ metrics as measures of boundary spanning. Rosters were created that included the 50 individuals ranked highest for each metric, excluding duplicates. In total, 63 seeds were successfully recruited – 48 from the rosters and 15 through staff referrals – corresponding to about 15% of our recruitment goal (N=420).

Eligibility and randomization—A study information line manned by members of the study team was established to screen interested individuals. Eligibility was based on the following criteria: 1) 18–35 years of age; 2) identifies as a person of color; 3) assigned male sex at birth; 4) has had sex with a man in the past 12 months, and, because the intervention emphasizes social media as a communication tool; 5) has an active Facebook profile. Once deemed eligible, individuals were assigned randomly to one of the two treatment sequences using a random assignment facility built into the screening software and were scheduled for a baseline visit. All participants provided written consent during that visit.

Risks of participation—Study participation poses a few minimal risks to participants. First, any time information is collected about individuals there is potential for loss of confidentiality. For this reason, all data is stored on secure, password-protected servers, to which only key members of the research team have access. Second, participants may feel uncomfortable answering questions, particularly with respect to sexual activity. They may choose to skip questions or withdraw from the study at any time. Third, participants may experience emotional distress about the results of HIV and Syphilis testing. If results are positive, staff will link participants to medical and other forms of assistance. Finally, participants may experience discomfort in initiating conversations with peers about PrEP.

Staff mentors will work with these individuals to overcome those feelings and devise conversational strategies that suit their comfort levels.

Intervention and attention control

Intervention—The intervention is designed to develop a participant’s knowledge about PrEP and their willingness to discuss it with others. The intervention is composed of two parts: 1) a half-day training workshop led by intervention staff conducted among a small group of 6–10 participants; and 2) a series of check-in telephone calls (or “boosters”) between intervention staff and participants. Trained community outreach workers who have experience working with young Black MSM in Chicago administer the intervention.

Training workshop—The intervention workshop adapts the peer educational and mentoring program developed as part of the HIV Prevention Trials Network.^{35,36} The workshop is divided into four modules conducted in a single half-day session. The first two modules focus on knowledge discovery and acquisition. One is an HIV tutorial structured as an interactive *Fact or Myth* activity that provides a context for understanding the implications of PrEP for the Black MSM community. The second module teaches participants about the specifics of PrEP, namely how it works in the body, its clinical development and preventive effectiveness, prescribed intake and adherence instructions, potential side effects, and local accessibility.

The second half of the workshop develops participants’ communication skills in order to increase their effectiveness as peer change agents. In the third module, participants learn to recognize risk factors (e.g., inconsistent condom use, multiple concurrent partners) that make someone a good candidate for PrEP, together with the factors that may impede their willingness to take PrEP (e.g., concerns about side effects, HIV stigma). Through role-playing scenarios, participants rehearse conversational strategies for addressing some of these personal barriers and develop their ability to deliver information effectively. Finally, the last module emphasizes how social media, in particular Facebook, can be used to share information about PrEP with peers. Featured in this demonstration is a public Facebook group, created by project staff as an information resource for study participants and their peers.

Boosters—To maintain contact with participants after the initial session, staff administer a total of eight monthly telephone check-ins (referred to as “boosters”) with each participant, each lasting 10–20 minutes. Each booster has four components: 1) collecting non-identifying information about specific peers with whom the participant wants to speak about PrEP; 2) devising personalized conversational strategies for approaching those peers; 3) troubleshooting communication barriers; and 4) setting personal outreach goals. The same staff mentor conducts all boosters with a given participant.

The attention control—Participants not assigned to the intervention treatment are assigned to a minimal contact attention control condition, in which a placebo activity is conducted to reproduce the nonspecific procedures used to engage with intervention participants without including its specific content.³⁷ The attention control treatment is a risk

assessment workshop anchored around a sexual diary activity. Participants write fictional narratives about what they believe constitute low, medium, and high HIV/STI risk scenarios, after which they are invited to engage in a larger discussion regarding which specific components of their fictional narratives create a risky (or not-so risky) scenario and what they would change in the stories to decrease or increase the risk. Facilitators provide feedback and correct any misconceptions as necessary. There is no subsequent contact between staff and control participants following the workshop.

Data collection

Data collection modalities—Table 1 shows data collected from participants at baseline, 12 and 24 months. A computer-assisted self-administered survey captures information about PrEP knowledge and attitudes, sexual health behaviors, psychographics, and demographics. Blood tests determine the HIV and Syphilis status for each participant. And, digital network data is collected from each participant using Facebook's data download feature. Lists of a participant's Facebook friends, Facebook groups, and timeline posts are retained for analysis. Participants consent to the use of Facebook data prior to the download procedure. A waiver of consent from the institutional review board for third party (non-participant) network members was obtained given the minimal risk to these individuals. Additional data protections to secure third party identities were established.

Outcome measures—Primary outcomes include: 1) the number of individuals successfully referred to a PrEP information line and 2) the number of those individuals who adopt PrEP (adoption is defined as making an initial clinic appointment). As part of a larger effort to connect individuals to PrEP care, the University of Chicago's *Chicago Center for HIV Elimination* established the PrEPline. The PrEPline is a telephone service staffed during regular business hours where callers can speak with a trained social worker who answers questions, assists them in getting linked to care, and follows up with their progress. Call records from the PrEPline are linked to study participants in two ways: 1) callers identify a participant when prompted to indicate from whom they first heard about PrEP, or 2) cross-referencing callers' names against the names of participants' Facebook friends. Although the latter may not reflect direct communication with a participant regarding PrEP, being exposed to their online social interactions may have an effect on one's interest in PrEP.

Secondary outcomes measured among study participants include: 1) PrEP knowledge and attitudes; 2) perceived PrEP barriers; and 3) intended and actual PrEP uptake. In addition to these PrEP-related outcomes, measures of sexual health (e.g., Syphilis diagnoses) and risk and protective behaviors are also obtained. We will evaluate change in these measures over the two-year enrollment period.

Analysis plan

Because of the anticipated carry-over effect among participants initially randomized to the intervention, the main efficacy analysis consists of an intent-to-treat comparison between the intervention and control groups at 12 months. Since study participants are recruited via peer referrals and the intervention involves a social media component, the independence assumption (used to justify a statistical model) or Stable Unit Treatment Value Assumption

(used to justify causal interpretation) are questionable. It is possible that participants recruited as part of the same referral chain will be more likely to have similar outcomes, or that those who are closely tied in a social network may be affected by each other's group assignment. Thus, the primary test of the effect of the intervention will be based on the randomization distribution of the test statistic obtained by randomly permuting group labels. Specifically, we will perform randomization tests comparing the mean number of people referred to the PrEP line and the mean number who adopt PrEP between the intervention and control group. By basing our inference solely on the random assignment of participants to groups, a test of the sharp null hypothesis of no intervention effect will have the correct level even in the presence of dependence among outcomes.³⁸

We will also evaluate intervention effects based on the timing of calls to the PrEP line. If the intervention is effective, we expect the rate of calls to be highest immediately following occurrences of workshops or booster calls. To examine this, we will model the daily rate of PrEP line calls over the study period as a function of time since the last workshop and/or the number of recent booster calls, adjusting for overall time trends (e.g., using penalized splines³⁹) as well as possible confounders such as day of week and other salient events. Remaining time dependence will be accounted for by specifying an appropriate covariance structure (e.g., autoregressive) or using a technique like the moving blocks bootstrap⁴⁰ to estimate the standard errors.

Statistical power for the study was examined under a range of scenarios. Suppose that the intervention increases the mean number of individuals (per participant) referred to the PrEP line over 12 months from 0.13 to 0.44, and that the number of referrals follows a negative binomial distribution with an overdispersion parameter equal to 10. The overdispersion parameter reflects variation in excess of what would be expected under the Poisson distribution, which corresponds to a value of zero; choosing a value of 10 reflects our expectation of considerable variability in performance across participants. This scenario corresponds to an increase in the percentage of participants referring *at least one* peer from 8.0% in the control group to 15.5% in the intervention group, and an increase in the percentage referring *more than three* peers from 0.5% to 3.8%. Under these assumptions, we would have approximately 90% power for testing the null hypothesis of no difference between the groups at the two-sided 0.05 level.⁴¹ Depending on the magnitude of the dependency between participants, the actual power may deviate from this approximation.

Secondary analyses will be based on models of the number of people referred to the PrEP line and the number who adopt PrEP (both per study participant) using an appropriate statistical model (e.g., negative binomial or zero-inflated negative binomial regression).⁴² To evaluate the impact of potential dependency between participants on our inferences, we will use methods for estimating variance from respondent-driven samples (e.g., tree bootstrap)⁴³ and/or incorporate a network autocorrelation model⁴⁴ using participants' Facebook ties to estimate their network proximity. For example, to evaluate the durability of the intervention, we will examine whether the PrEP line referral rate changes during Year 1 and from Year 1 to Year 2 among those initially assigned to the intervention. This analysis will be based on a model of the referral rate as a function of time in order to account for the possibility of a decrease in the referral rate as the effect of the initial training workshop wears off and the

participants exhaust their “easy” referrals (i.e., those closest to them and/or who might be predisposed to consider PrEP).

Finally, we will examine factors associated with a higher rate of referrals and of referrals who adopt PrEP (Aim 2). This analysis will be based on data collected over the first 12 months for the group initially assigned to the intervention, and over the second 12 months for the group initially assigned to control (i.e., following their switch to the intervention). Using an appropriate regression model fit to the pooled dataset that includes an indicator variable distinguishing between the two groups, we will estimate associations between characteristics of the participants and their rate of successful referral. As before, we will accommodate dependence among participants by calculating respondent-driven sampling design-based standard errors. Results from this analysis may help to identify promising peer change agent candidates in future interventions.

Results

Recruitment took place from March 2016 to March 2017. In total, 548 eligible individuals were scheduled for a baseline visit, of which 423 provided consent and completed baseline data collection and the initial intervention (n=209) or control (n=214) treatments. Baseline characteristics of this sample, stratified by group assignment, are shown in Table 2. Participants in both groups are on average 26 years of age. Majorities in both intervention and control groups have a high school diploma or less, identify as gay, are HIV negative, had heard of PrEP before study enrollment, and had never taken PrEP. More intervention participants are employed than not employed, whereas the reverse is true for control participants. Chi-square tests reveal no significant differences between intervention and control participants for these characteristics.

Given that participants entered the study at different times between March 2016 and March 2017, we anticipate that all participants will have completed Year 1 of their enrollment by March 2018. At this time, we will begin to evaluate the intervention’s impact in accordance with Aim 1 and assess facets of participant retention between Year 1 and Year 2.

Discussion

We have described the motivation, design and methods of PrEP Chicago, an innovative social network intervention to increase PrEP uptake among young Black MSM. To our knowledge, PrEP Chicago is one of the first network-based RCTs to focus specifically on PrEP engagement among sexual minorities of color and has several strengths worth discussing.

First, PrEP Chicago takes a culturally-sensitive, community-centered approach. Although there is growing consensus among clinicians and advocates that engagement with biomedical HIV prevention tools like PrEP is critical for reducing new infections, young Black MSM face significant structural and sociocultural barriers to engagement with health services that impede their ability and willingness to adopt PrEP.^{45–47} To fulfill the promise of PrEP for young Black MSM it is critical that interventions address the multidimensional

factors that influence its acceptability in this population and support community-centered approaches to PrEP promotion and care engagement.

To these ends, PrEP Chicago draws on a peer change agent training curriculum that is tailored toward culturally salient issues faced by young Black MSM in Chicago that offer opportunities for engagement. Although community-specific perspectives and modalities of outreach may differ across communities, we believe that PrEP Chicago offers a viable strategy for targeting the specifics of any social context that advance and/or impede PrEP engagement that has potential for replication and adaptation in other communities.

Another strength is the use of informal networks to encourage PrEP engagement. Specifically, PrEP Chicago responds to the mounting evidence that social networks are effective mechanisms for recruiting participants from “hard-to-reach” communities,²³ for identifying candidate peer change agents,^{27,48} for affecting social norms,^{49–51} and for evaluating dynamic change.¹² And, although network mechanisms have been widely studied with respect to HIV prevention more broadly, PrEP Chicago is one of the first studies to leverage network properties and processes with respect to PrEP adoption among sexual minorities of color. In a community where PrEP adoption lags and disenfranchisement from mainstream health services exists, network interventions for young Black MSM offer a cost-effective way to reach larger portions of this at-risk population while also empowering its members to take charge of their sexual health.

Finally, RCTs are the “gold standard” for evaluating clinical interventions and have increasingly been promoted for the evaluation of public health interventions,^{52,53} including network-based ones.⁵⁴ To date, however, few network interventions employ randomized designs. Thus, a third strength of PrEP Chicago is its use of rigorous evaluation methods made possible by participant randomization. Although network interventions pose challenges for evaluation, for example possible “contamination” between treatment and control groups when working in the context of a densely connected population,^{11,55} we acknowledge those issues and respond to them in our analysis plan. Further, if the intended effect of a network intervention is large-scale diffusion of an innovation like PrEP, then such contamination may ultimately be a resource.⁵⁵

Conclusion

We present PrEP Chicago, a peer change agent intervention designed to engage young Black MSM in PrEP care. At the center of this intervention is the premise that the social networks among young Black MSM can be effective mechanisms of information diffusion,^{56,57} behavioral influence,^{14,58,59} social support⁴⁶ and personal and community empowerment⁶⁰ and, therefore, are optimal leverage points for inducing adoption of an HIV prevention technology like PrEP. Given no known socially contextualized intervention models for PrEP engagement among sexual minorities of color and the scant attention paid to how network mechanisms facilitate sustainable change in marginalized at-risk populations, the potential of the PrEP Chicago project remains promising.

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Figure 1.
Study Design.

After Year 1, participants switch conditions; participants initially assigned to the control group switch to the intervention group and vice versa. All measures are assessed at baseline, 12 months (corresponding to the end of Year 1 of a participant's enrollment) and 24-months (corresponding to the end of Year 2) as listed in Table 1. Participants who initially randomize into the intervention group receive the risk assessment training at the 12-month switch over and are no longer boosted by intervention staff. Participants who initially randomize into the attention control receive the PrEP / peer change training at the 12-month switch over and are boosted by intervention staff on a monthly basis as described below. Because of this design, the primary analyses of the effectiveness of the intervention will be comparison between groups of outcomes assessed at the end of Year 1.

Figure 2.

YBMSM Facebook friendship network (N=1,144) generated from downloaded Facebook data among YBMSM who participated in *UConnect*, a longitudinal cohort study of YBMSM in Chicago.

The Facebook friendship network is comprised of UConnect respondents (N=400) and their non-respondent Facebook friends (N=744) that are connected to at least 10% of the respondent nodes. Among these nodes are a total of 51,904 Facebook friendship ties. Influential nodes are colored in red and include network members who score highly on betweenness centrality, eigenvector centrality, Key Player, or Bridging metrics. Influential nodes were identified using algorithms in the influenceR package (<https://cran.r-project.org/web/packages/influenceR/index.html>). The graph visualization was created using the ggnet package in R (<https://briatte.github.io/ggnet/>).

Table 1

Schedule of Variables Collected from Participants in PrEP Chicago Study

Measurement/Collection Method	Baseline visit	12 months	24 months
Survey			
Sociodemographics (i.e., age, education, income, gender identity, sexual orientation)	X	X	X
Personality scales (i.e., innovativeness, leadership, social brokerage)	X	X	X
PrEP knowledge and attitudes (i.e., recommended use, perceptions about efficacy, intentions to adopt, perceived barriers to uptake, PrEP self-efficacy)	X	X	X
Sexual health (i.e., self-reported HIV status, STI history, risk and protective practices)	X	X	X
Blood Lab Tests			
HIV and syphilis	X	X	X
Digital Network Data Download			
Facebook Friends, Groups, Timeline posts	X	X	X

Table 2

Baseline Characteristics Stratified by Year 1 Condition.

Variables	Intervention n (%)^a	Control n (%)	Chi-square p-value
Age, mean (sd)	26.1 (4.2)	25.7 (4.3)	0.28
Education (highest degree earned)			0.17
High school or less	141 (67.5)	165 (77.1)	
Post high school vocational certification	17 (8.1)	11 (5.1)	
Associate's/Bachelor's/Graduate Degree	43 (20.6)	29 (13.6)	
Employment			0.31
Employed	109 (52.2)	92 (43.0)	
Not Employed	81 (38.8)	99 (46.3)	
Disabled	6 (2.9)	7 (3.3)	
Sexual orientation			0.55
Gay	135 (64.6)	123 (57.5)	
Bisexual	46 (22.0)	62 (29.0)	
Straight	5 (2.4)	8 (3.7)	
Other	11 (5.3)	10 (4.7)	
HIV sero-status ^b			0.71
HIV Negative	98 (51.58)	100 (52.48)	
HIV Positive	92 (48.42)	87 (46.52)	
Ever heard of PrEP			0.20
No	50 (23.9)	66 (30.8)	
Yes	156 (74.7)	143 (66.8)	
Experience taking PrEP			0.95
No	180 (86.1)	186 (86.9)	
Yes	20 (9.6)	20 (9.4)	

^aPercentages do not sum to 100% as missing data and refusals to respond are not included.^bHIV status is based on baseline lab results or, where lab results are missing, self-reports collected in the self-administered baseline survey.