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Three limited interaction approaches to understanding the epidemiology of HIV among YMSM in the US

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Abstract

Background Using a theoretically-grounded approach to the epidemiological study of HIV incidence among a national, diverse sample of sexual and gender minority (SGM) men (age 17 -29 years), as well as examining HIV incidence through an innovative geospatial lens, is of considerable public health significance. Our overarching objectives are to assemble a U.S.-based national cohort of diverse SGM men: (1) to estimate HIV incidence in SGM men followed every 6 months for up to 24 months, (2) to assess the association of individual and geospatial factors associated with HIV incidence and (3) to determine the relative efficiency and acceptability of three different, discrete study enrollment approaches (including completion of remote HIV testing). The purpose of this manuscript is to describe the study protocol.

Methods The cohort is composed of English- and/or Spanish-speaking SGM men at risk for HIV, age 17–29 years and living in the United States and its territories. We used multiple methods to recruit our sample including social networking apps like GrindrTM. If a participant was eligible for the study, they completed an address intake form so an HIV test could be mailed to their home or chosen address. We assembled three cohorts using different enrollment approaches. Cohort 1 used Zoom video calls with study staff observing participants use of OraQuick test with oral swabs at the baseline visit. Cohort 2 used No Zoom and OraSure oral fluid tests that participants mailed to an external lab. Cohort 3 used No Zoom/self-administration of OraQuick tests and participants uploading test results to an online portal (REDCap).

Discussion This study will provide important data on multilevel determinants of HIV incidence among SGM men at the national level, allowing us to examine important differences by local jurisdiction, region and state and to better understand the impact of individual, social and geospatial factors on HIV incidence to help inform future prevention strategies.

Keywords Geospatial epidemiology, Sexual and gender minorities, HIV testing

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Introduction

There is a critical need to better understand the epidemiology of HIV seroconversion in the U.S., particularly among high-risk demographic groups, to strengthen HIV prevention efforts. Overall, domestic U.S. HIV transmission rates have declined modestly over the last decade; however, progress has been uneven, and rates have risen among certain subgroups, particularly gay, bisexual and other sexual and gender minority (SGM) men, key populations essential to End the HIV Epidemic (EHE) initiatives [1]. While SGM men, as a key vulnerable population, are 2% of the U.S. population, they represent > 50% of persons living with HIV and account for nearly 70% of new HIV infections annually [2]. The Centers for Disease Control and Prevention (CDC) estimates this will result in ~ 1 in 6 MSM being HIV-diagnosed in their lifetime [2].

In today's post-COVID world, digital technology is a steady factor in the on and off-line lives of a multi-cultural group of SGM men and provides a unique opportunity to conduct an epidemiology investigation, including focusing on geospatial factors. Among SGM men, risk for HIV seroconversion is *not* evenly distributed. Racial/ethnic minority SGM men have the highest rates of new HIV infections, [3] albeit less research has been conducted using national samples and little attention has been paid to geospatial factors. Using a theoretically grounded approach to the epidemiological study of HIV incidence among a national, diverse sample of young SGM men (age 17 -29 years), as well as examining HIV incidence through an innovative geospatial lens, is of considerable public health significance [4]. This epidemiologic data is also sorely needed to inform, hone, and optimize intervention efforts, such as those that use digital technologies that aim to curb the epidemic among this high-risk demographic group of young men. This presents an opportunity to use innovative electronic methods for recruiting and retaining a large, diverse national cohort of high-risk young SGM men to better understand antecedents of HIV risk and seroconversion.

National cohorts are also critical to monitoring epidemic trends and how major events (e.g., epidemics, policy changes, and new biomedical interventions) impact HIV and other health conditions [5]. Sustained national cohorts focused on sexual and gender minorities are needed to monitor epidemic trends unique to these health disparate populations and to assess whether and how national health policies and HIV prevention efforts impact HIV seroconversion in the U.S.

HIV cohorts are either facility based [6] or exclusively digital in implementation [7, 8]. Exclusively digital cohorts have historically used two of the three strategies described in our approach. To date, this is the only digital cohort of SGM men which uses Zoom video calls to verify the identity of participants and allows the research team to have relatively limited and remote interaction with participants. Importantly, participants in this cohort show us the results of their OraQuick test during these Zoom calls and can receive support, education and linkage to care information if they test positive. This model of testing may have important clinical implications for care in rural or remote areas without readily available HIV testing and PrEP services.

Objectives

The overarching objectives of this research are to assemble a U.S.-based, national cohort of diverse SGM men: (1) to estimate HIV incidence in SGM men followed every 6 months for up to 24 months, (2) to assess the association of individual and geospatial factors associated with HIV incidence and (3) to determine the relative efficiency and acceptability of three different, discrete study enrollment approaches (including completion of remote HIV testing).

Methods

Overview

Addressing the End the HIV Epidemic initiatives, this study uses dating apps in use by SGM men and online advertising to recruit and retain a diverse national sample of high-risk young SGM men of any birth sex who have sex with other men (defined per enrollment criteria as "someone with a penis"), 17–29 years of age, to better understand HIV incidence within the context of a theoretically-grounded social ecological framework.

Conceptual framework

A social ecological model (SEM) guides this study (Fig. 1) [9]. There is an increasing recognition of the importance of complex structural (e.g. geospatial and public policy) drivers of seroconversion and transmission of HIV [10, 11]. These drivers [11–13] do not directly cause the seroconversion or onward transmission of HIV; rather, they mediate lower order risks such as those at the individual or network levels. The social ecological model contextualizes individuals' behaviors using dimensions including individual (e.g., race/ethnicity, HIV knowledge, motivation, self-efficacy, substance & alcohol use), interpersonal/network (social networks, social support), geospatial (e.g. neighborhood, community), and public policy constructs to provide a framework for describing the interactions between these levels [14]. The SEM is composed of five layers of risk for HIV infection: individual, network, community, and public policy levels, and stage of the HIV epidemic. We operationalized this model for this study and focus on individual, network,

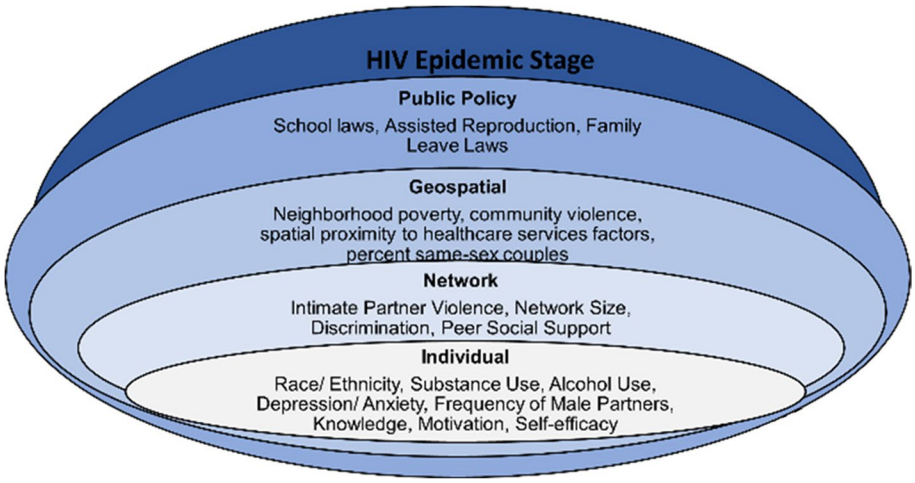

Fig. 1 A social ecologial model for the digital study of young SGM men

geospatial, and public policy factors recognizing that inequitable social and structural contexts influence individual's sexual practices and access to HIV prevention services [13, 15].

Recruitment

Our recruitment strategies are built on prior experiences [16, 17] and strategies successful in other studies [18–22]. Strategies include web-based advertising methods such as Instagram and Twitter and top LGBTQ Dating Apps (Grindr, Growlr, Scruff, Jack'd, and Adam4Adam). Given disparities in HIV by race, ethnicity, and geographic location, we ensured diversity by providing recruitment materials in English and Spanish, using diverse images, and implementing geotargeted advertising to southern United States and EHE priority areas. To track and collect data on different recruitment strategies, a unique link source ending was added to the REDCap Screening URL. The link source is auto populated into the Screening Survey and is not visible to the participant.

Power considerations and sample size calculation

Using the 3,000 young SGM men assigned to each of 3 testing and enrollment napproaches, we will examine individual, network, and geographic correlates of HIV seroconversion throughout the entire study period (i.e., ~ 2050 person years). We estimate 59 incident cases in this group (i.e., 2.9 per 100 person-years, with 20% attrition) will occur during the course of the study. Using Cox proportional hazard models to examine the association between these variables and seroconversion, the minimum detectable effect size (at 0.80 power) is a hazard ratio of 2.08, ample statistical power to assess individual, network, geospatial, and public policy factors correlates of HIV risk and health seeking behaviors (e.g. PrEP uptake and adherence).

Study population

The cohort is composed of English- or Spanish-speaking SGM men at risk for HIV, age 17 -29 years and living in the United States and its territories. Age 17 years is the lower age limit as that is the youngest someone can use HIV OraQuick home tests without parental consent per the FDA. Inclusion criteria include: identify your gender as male, trans male, or non-binary of any birth sex; understand and read English and/or Spanish; live within U.S. and its territories; self-report anal sex with someone who has a penis in the past 12 months; and be HIV-negative, status unknown, or diagnosed HIV-positive in the past 12 months (defined as self-reporting receiving a first HIV positive test result in the past 12 months). Our eligibility criteria are intended to ensure enrollment of young SGM men most at risk for HIV seroconversion as evidenced by recent sexual behavior.

Inclusion of participants who report PrEP use

Despite its efficacy, PrEP uptake among SGM men (for whom it is indicated) has been modest at best [23] with vast disparities in PrEP use across racial/ethnic minorities, [24, 25] age, [25, 26] and geographic groups. In addition, for SGM men, self-reported PrEP adherence is significantly overestimated by self-report versus biological markers such as tenofovir levels [27]. As a result (e.g., evidence of modest uptake in the proposed study population and data suggesting that inconsistent dosing may limit protective benefits), we will allow enrollment of young SGM men who report use of PrEP at baseline.

Procedures

Study eligibility screening will be conducted using REDCap using automated calculations. Screening in REDCap is self-administered using the public URL, but screening can also be interviewer-administered by study staff on the phone while logged in administratively in REDCap. If a participant is eligible for the study, they then complete an address intake form so an HIV test can be mailed to their home or chosen address. At baseline, in Cohort 1, eligible participants schedule a Zoom video visit to verify identity and complete a consent form with study staff. Participants then completed the baseline survey remotely and study staff observed participants' use of oral swabs and confirmed the results of the OraQuick tests. In the other cohorts, eligibility verification, consent and the baseline survey are conducted remotely and the OraSure (Cohort 2) and OraQuick (Cohort 3) test kits are sent to participants to be completed independently. In Cohort 2, OraSure test kits are mailed to an external lab for processing. In Cohort 3, participants are asked to upload OraQuick test results to a secure online portal (RedCap). Follow-up survey assessments and HIV tests are then collected from all cohort participants every 6 months for up to 24 months. At their follow-up visits, all surveys are completed through an online link to the assessment instrument. Regarding HIV tests, at follow-up visits, Cohorts 1 & 3 use self-administered OraQuick tests with participants uploading their test results to the online portal. Cohort 2 continues to mail their OraSure test kits to an external lab. Participants who seroconvert or acquire HIV at any point during follow-up will be referred to care in their local community. Study staff members are available via telephone to support cohort participants with access to the survey or with assistance with home-based HIV testing.

Remote digital studies are increasingly challenged by fraudulent entries by scammers, bots and duplicate entries [28]. We have built on best practices described by other investigators [29–31] and our own experiences to develop a comprehensive method to mitigate the risk of duplicate or fraudulent enrollments. These efforts include two parts of verification procedures. Staff members first review three variables from screening data (name, phone number, and email address), and mark the records duplicated if any of these data in two records are duplicated. Staff members then review another four variables (age, gender identity, prior HIV test, and prior HIV test result) and flag the screeners if they provide distinctly different responses between two records. Research coordinator verifies their eligibility and legitimatcy in the visits to prevent fraud. The procedures run three times a week, and staff members do not reach out to the new participants until the procedures are completed.

To promote study retention, emails and SMS text messages are sent to the participants for reminders about upcoming and closing study assessments. The window for participants' follow-up assessments begins 30 days (or 4 weeks) prior to the target follow-up date and ends 30 days after. The acceptable window for follow-up assessment begins 6 weeks before the target date and ends 6 weeks after. The target follow-up dates are calculated in 6 month increments from the baseline visit date. SMS text messages are sent to the participant's device once the ideal window opens. If a participant is unresponsive to five SMS text messages, an email will be sent to their provided email address. If a participant is unresponsive to five SMS text messages and one email, their follow-up window will be closed, and contact will be reattempted once their next window opens.

Survey measures

Core measures are repeated at each time point (sexual partnerships, mental health, PrEP use, etc.), while others are asked either only at baseline (e.g., static variables such as date of birth, country of origin, and race/ ethnicity). Survey measures include, but are not limited to, the following: individual-level measures include self-reported data on demographics, including the zip code of residence, age, race, ethnicity, education, income, employment status, health insurance, housing, housing mobility, food insecurity, and history of detention or incarceration; sexual health history and access or uptake of HIV services (including postexposure prophylaxis and PrEP); substance use; depression and anxiety symptoms, HIV knowledge, and interpersonal violence.

HIV seropositivity is measured with either OraQuick (rapid point-of-care test) or OraSure (lab based, oral fluid) testing at each visit, following the procedures outlined below.

Cohort 1: Zoom video calls with study staff observing use of OraQuick tests at baseline

Participants in this cohort have a remote video visit via secure Zoom with the study coordinators. Study coordinators consent study participants, deploy the study survey which is completed during the Zoom visit and observe the participant using the OraQuick HIV home test. Participants in this cohort are contacted prior to the target date to validate current address. At follow-up timepoints, participants complete a survey and use an OraQuick test and upload their test results via REDCap. Participants complete follow-up visits independently unless they request a Zoom visit with a study coordinator.

Cohort 2: Self-administration of OraSure tests and analysis at laboratory

Participants in this cohort complete several forms via REDCap. First, study staff confirm the participants' identity and address by reviewing the information entered into REDCap. Participants are required to upload a photo of their identification card with their date of birth. After study staff verify the participant's identity and date of birth, the consent form is emailed to the participant to review and sign. Once the consent form is completed, participants complete the study survey. Participants receive an OraSure Oral Fluid Collection Device (OraSure Technologies) test via FedEx and a pre-paid return shipping package for return of the sample to the lab for processing. Participants provide a sample of oral fluid using the OraSure test and mail it to the Alameada County Public Health Department laboratory, which processes tests received and communicates results to our study team. HIV testing from the oral specimen is done via enzyme immune assay, with positive results being confirmed via western blot. Test performance is estimated to have a sensitivity of 99.6% and specificity of 99.9% [32]. Notification of nonreactive HIV test results are automatically emailed to the participant. Staff members contact participants with a reactive result to provide post-test counseling and localized referrals for confirmatory testing and care. Staff members contact participants with an indeterminate result or rejected specimen to discuss the collection of another specimen or other testing options.

Cohort 3: No Zoom/self-administration of OraQuick Tests and uploading test results to an online portal (REDCap)

Procedures in this cohort are identical to Cohort 2 other than the type of HIV home test that is used. Participants in this cohort receive an OraQuick HIV self-test, which they complete independently. After completing the OraQuick test, participants are asked to upload a photo of their test to REDCap. If a participant uploads a reactive test, study staff call participants to provide post-test counseling and localized referrals to confirmatory testing.

Study retention

The use of detailed tracking and retention procedures increases the likelihood that attrition will be random and not systematic. We use tracking and retention procedures proven effective in prior studies. Participants can update email addresses, phone numbers, and physical mailing addresses at any point to ensure contact information is as up to date as possible. Contact information can be updated by contacting study staff through email, phone or text. Assessment reminders are sent to participants through telephone, email, or text once assessment windows open and periodically during the assessment window if the assessment has not been completed. Aligned with our goals of a welcoming and supporting research environment and scientific rigor, participants who have previously withdrawn and request to re-enter the study will be screened and reassessed for eligibility and, if the timeline allows, administratively considered for re-enrollment.

Analytic plan

We will first characterize the sample of all young SGM men at baseline, including which electronic method they were recruited from. We will also compute descriptive statistics for the study variables including HIV risk behavior, geographic regions, and neighborhood-level characteristics based on participants' mailing addresses (e.g. means, standard deviations, ranges) [33–42]. Then we will examine how individual-level (e.g., race/ ethnicity, substance use, [43, 44] alcohol use, [45, 4647 frequency of male partners, [48]) influence HIV incidence and related outcomes (e.g. HIV risk behavior and PrEP uptake), followed by test statistics for multicollinearity and temporal autocorrelation, such as variance inflation factor and Durbin-Watson test. The primary observational longitudinal analysis will assess the association between incidence of HIV and all individual, network, and geographic variables. These associations will be estimated using a Cox proportional hazard model, which allows for examining both time-varying and time-invariant exposure variables.

In addition, we will identify "hot spots (i.e., clusters)" of HIV-related outcomes via point pattern analyses using the mailing address of participants. We will run Global and Local Moran's I statistics to determine special patterns of HIV. Following these analyses, we will compute spatial and spatiotemporal scan statistics, which allow us to control for demographic and other potential cofounding variables in the cluster detection [49]. In case of detected "hot spots" of HIV-related outcome, the clusters will be examined in relation with the neighborhood characteristics to identify geospatial contributors. After there analyses, we will analyze our geospatial variables and apply standard and multilevel regression methods, recognizing that potential for spatial autocorrelation in regression residuals that can bias effect estimates and standard errors [33–35, 37]. Spatial autocorrelation will be tested using Global Moran's *I* statistics; if detected, we will implement spatial regression models [33–35, 37]. As appropriate, we will implement standard spatial econometric regression models (e.g. spatial error model and spatial lag model) as well as geographically weighted spatial regression

models which can address non-stationary relationships among geospatial variables and spatial autocorrelation. [50] In longitudinal analyses, separate models will be run for each neighborhood characteristic to examine their unique contribution on the HIV-related outcomes (e.g., incidence, PrEP use and adherence) and to guard against multicollinearity between the features of the neighborhood environment being examined [36]. The regression modeling strategy will include bivariate models followed by multivariable models.

Analyses will also explore efficiency (number of individuals enrolled/eligible, and enrollment and retention rates) across each of the three cohorts. We hypothesize that the first cohort will have the highest eligible/enrolled and retention rates, given the interface and facilitation with staff. Statistical analyses of attrition will include survival analyses to investigate rates of loss to follow-up overall and among demographic and geographic subgroups [51]. Risk ratios will be used to examine individual (eg, demographics and HIV risk behaviors), interpersonal (eg, social factors) and geospatial predictors of loss to follow-up.

HIV incidence rates will be estimated as the number of observed HIV seroconversions divided by the number of person-years accumulated; rate ratios and 95% CIs will be estimated using Poisson regression models. Trends by 6-month time intervals will be monitored. HIV incidence rates measured in the entire cohort at 12- and 24-months will be estimated. In all trend analyses, a continuous variable for time in the Poisson regression model will test the null hypothesis that there is no difference (ie, no trend) in HIV incidence by 6- or 12-month interval of time since study entry. Assuming a sufficient number of events, a competing risks approach [52] will be used to account for the mortality. We will also visualize the Kaplan–Meier estimates of HIV cumulative incidence with a time-to-event approach that defines the time of origin as study entry and uses log-rank tests for differences, as well as Cox proportional hazards models to estimate hazard ratios and 95% CIs (standard for the competing risk of death) [53]. Analyses will be conducted overall and by subgroups such as racial and ethnic minority groups and geographic areas.

Incorporating both cohort survey measures and geospatial data, individual, interpersonal, and geospatial risk factors will be included in the Poisson regression models. To account for the nonindependence of observations within geographic areas, generalized estimating equations with a robust estimation of variances will be used to estimate the association of individual, interpersonal, and structural risk factors with HIV incidence [54].

Ethical considerations

Columbia University Institutional Review Board (Protocol #AAAU2559) reviewed and approved this study and served as the institutional review board of record for all partner institutions in this multisite study. Participants are asked to provide e-consent in the English or Spanish language in web-based format prior to initiating research activities. Upon the completion of the study procedures at each time point, participants receive an e-gift card of $45 at baseline, $55 at 6-months, $65 at 12-months, $75 at 18-months and $85 at 24-months. Identifiers were collected from participants for the purposes of shipping specimen collection kits; however, only deidentified data are available for analysis.

Results

Cohort 1 enrollment began on 11/03/2022. Cohort 2 enrollment began on 10/02/2023. Cohort 3 enrollment began on 04/22/2024. As of September 1, 2024, a total of 34956 people were screened for participation. Of those screened, 45.4% ($n=15872$) were considered eligible.19% ($n=2988$) of the preliminarily eligible participants screened consented to participate in the study and completed the consent form. 94% ($n=2803$) of those who consented completed the baseline survey. 86% ($n=2403$) completed the consent, survey and HIV testing activities and are considered fully enrolled into the study. Recruitment is ongoing and will continue until we enroll at least 1,000 participants into each cohort.

Figure 2 displays the continuum from screening to enrollment with arrows displaying the percentage remaining from the prior step in the continuum. The most significant drop in the continuum occurred at between eligible participants and those who consented to enrolling. Table 1 displays the characteristics of individuals ultimately enrolled in the study as of September 2024.

Discussion

Anticipated findings

This study will provide important data on multilevel determinants of HIV risk among SGM men at the national level, allowing us to contrast by region and state to better understand the impact of individual and geospatial factors on HIV prevention and the overall epidemic. The study design builds upon successfully used protocols to recruit SGM that our study team has utilized in the past and aims to address gaps in exclusively digital or exclusively facility-based methods, particularly as this gap relates to differences in study population and HIV vulnerabilities. This protocol innovatively examines

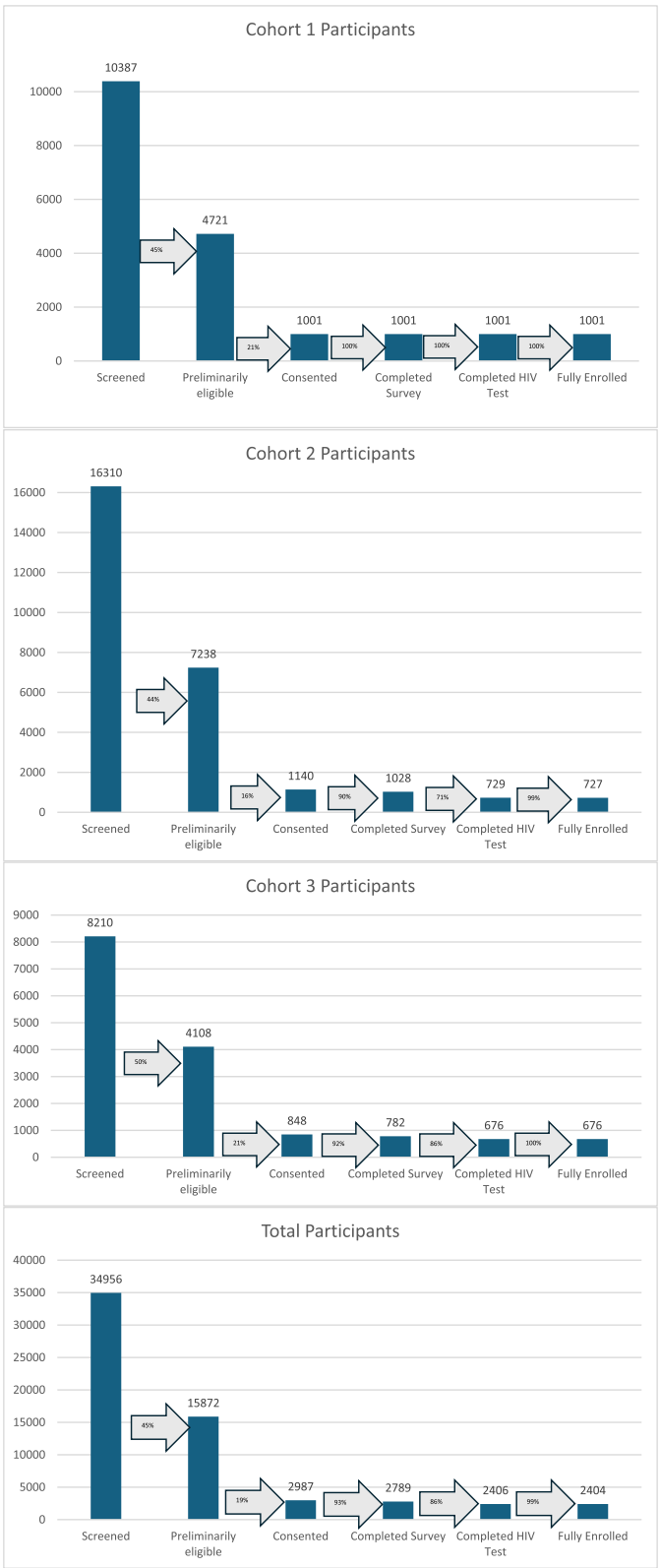

Fig. 2 Enrollment continuum in the nationwide cohort of sexual and gender minority men

Table 1 Characteristics of individuals enrolled into a U.S. national HIV incidence study

Characteristic	Cohort 1 (*N* = 1001), *n* (%)	Cohort 2 (*N* = 726), *n* (%)	Cohort 3 (*N* = 676), *n* (%)
Age group (y)			
17–24	428 (42.8%)	269 (37.1%)	301 (44.5%)
25–29	573 (57.3%)	457 (62.9%)	375 (55.5%)
Race and ethnic identity			
Hispanic Black	34 (3.4%)	8 (1.1%)	8 (1.2%)
Hispanic White	120 (12.0%)	70 (9.6%)	72 (10.7%)
Hispanic and more than 1 or another race	25 (2.5%)	67 (9.2%)	103 (15.2%)
Non-Hispanic Black	136 (13.6%)	92 (12.7%)	87(12.9%)
Non-Hispanic White	397 (39.7%)	300 (41.3%)	282 (41.7%)
Non-Hispanic and more than 1 or another race	40 (4%)	91 (12.5%)	44 (6.5%)
Hispanic and unknown race	138(13.8%)	21 (2.9%)	10 (1.5%)
Non-Hispanic and unknown race	15 (1.5%)	8 (1.1%)	5 (0.7%)
Unknown ethnicity	96 (9.5%)	61 (8.4%)	27 (4.0%)
US census region			
Midwest	177 (17.7%)	164 (22.6%)	136 (20.1%)
Northeast	245 (24.5%)	128 (17.6%)	141 (20.9%)
Puerto Rico	6 (0.6%)	5 (0.7%)	1 (0.1%)
South	308 (30.8%)	249 (34.3%)	259 (38.3%)
West	257 (25.7%)	180 (24.8%)	139 (20.6%)
Recruitment source			
Adam4Adam	35 (3.5%)	12 (1.7%)	27 (4.0%)
Grindr	341 (34.1%)	502 (69.1%)	482 (71.3%)
Jack'd	47 (4.7%)	117 (16.1%)	0 (0%)
Scruff	63 (6.3%)	0 (0%)	63 (9.2%)
Facebook	60 (6%)	0 (0%)	2 (0.3%)
Sniffies	72 (7.2%)	15 (2.1%)	82 (12.1%)
Other	385 (38.5%)	80 (11.0%)	20 (3.0%)

three different approaches to enrollment and participant engagement to inform future digital cohort methodology.

With the 3-cohort design described above, we are also uniquely positioned to explore scientific questions comparing these different approaches to outcomes in HIV case finding, retention in longitudinal research and incidence, among other possibilities. Further, introducing these additional two cohorts will allow us to compare the cost, efficiency and return rate of tests and retention rates between three different remote enrollment approaches: 1) Zoom calls with study staff observing use of the OraQuick tests, 2) self-administration of OraSure tests which are mailed to a lab for processing and 3) self-administration of OraQuick tests and uploading test results to an online portal (REDCap).

Limitations

This study has several important limitations. First, there is selection bias since nearly all of the study participants were recruited through social media and dating apps targeting SGM men. Second, sexual health behavior data and PrEP usage data is self-reported. Finally, the study sample is not adequately powered to detect significance in sub-groups.

Conclusions

Study findings will have critical implications for the design of future cohorts, given the disparities underlying the HIV epidemic. Our understanding of HIV incidence and risk for HIV among SGM men will be augmented by the inclusion of geospatial data, which allows us to examine larger social and structural factors that affect the health and well-being of SGM men and can serve as modifiable factors and intervention targets beyond the individual level.

Abbreviations

HIV Human immunodeficiency virus
YMSM Young men who have sex with men

U.S.	United States
SGM	Sexual and gender minority
EHE	End the HIV Epidemic
CDC	The Centers for Disease Control and Prevention
COVID	Coronavirus disease
PrEP	Pre-exposure prophylaxis
SEM	Social ecological model
LGBTQ	Lesbian, gay, bisexual, transgender, and queer

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Authors' contributions
RS, DTD, LMK, and RG contributed to the design of all aspects of the study. RS, DTD, LMK, MA, ORW, PRV and RG contributed to the proposed study design. PFJ designed the proposed data analysis. FX analyzed the current data. RS drafted the manuscript. All authors have read and approved the final manuscript.

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Data availability
Deidentified individual data and a data dictionary will be made available upon reasonable request after the approval of a proposal and signing of a data use agreement. Further details and forms can be obtained by emailing RS, RG and DD.

Declarations

Ethics approval and consent to participate
Columbia University Institutional Review Board (Protocol #AAAU2559) reviewed and approved this study and served as the institutional review board of record for all partner institutions in this multisite study. Participants are asked to provide e-consent in the English or Spanish language in web-based format prior to initiating research activities. Upon the completion of the study procedures at each time point, participants receive an e-gift card of $45 at baseline, $55 at 6-months, $65 at 12-months, $75 at 18-months and $85 at 24-months. Identifiers were collected from participants for the purposes of shipping specimen collection kits; however, only deidentified data are available for analysis.

Consent for publication
Not applicable.

Competing interests
The authors declare no competing interests.

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