The Healthy Young Men’s Cohort Study: Study Design and Methodology

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ABSTRACT

**Background:** No group is at greater risk for acquiring HIV than young men who have sex with men (YMSM), particularly Black/African American (AA) and Hispanic/Latino (L) YMSM living in inner cities, who account for the largest number of new HIV infections each year.\(^1\)\(^-\)\(^3\) While pre-exposure prophylaxis (PrEP), post-exposure prophylaxis (PEP), and treatment as prevention (TasP) hold enormous promise for changing the course of the epidemic, AA/L-YMSM are the least likely population to be receiving primary health care, HIV prevention/care, and are the least likely to be using PrEP and PEP.\(^4\)

**Objective:** The overarching aim of the Healthy Young Men’s (HYM) Cohort Study is to conduct longitudinal research with a cohort of AA/L-YMSM to prevent new HIV infections, reduce transmission, and reduce HIV/AIDS-related disparities by focusing on successful engagement in care. Findings from this research will be used to inform the development of new interventions designed to engage AA/L-YMSM in the HIV prevention and care continua.

**Methods:** Longitudinal research (baseline, follow-up assessments every 6 months for a total of eight waves of data collection) is ongoing with a new cohort of 450 high-risk AA/L-YMSM (400 HIV-, 50 HIV+) in Los Angeles. Participants were recruited using a venue-based and social media sampling design. In addition to self-report surveys, the study protocol includes the collection of urine to assess recent use of illicit drugs and the collection of blood and rectal/throat swabs to test for current STI/HIV infection. An additional sample of blood/plasma (10ml for 4 aliquots and 1 pellet) is also collected and stored in the HYM Cohort Study biorepository for future research. By design, we recruited 400 HIV- participants and 50+ participants. This mixed-methods study design includes collection and triangulated analysis of quantitative, qualitative, and biological measures (i.e., drug use, STI/HIV testing, and adherence to ART among HIV+’s) at baseline and every six months. The HYM Cohort Study will provide a platform from which new and emerging biomedical prevention strategies (e.g., PrEP, rectal microbicides, PEP) and other HIV prevention and care engagement interventions can be
developed and evaluated with AA/L-YMSM.

**Results:** To date, all participants in the HYM Cohort Study have been recruited, and both baseline and 6-month follow-up assessments have been conducted. The retention rate at 12-months is 97%. While the sample included 400 HIV- and 50 HIV+ participants at baseline; nearly 3% of HIV- participants have seroconverted since baseline. We expect to have completed the first three waves of data collection for the entire cohort by the Fall of 2018.

**Conclusions:** The findings from this research will be used to inform the development of new and/or adaptation of existing evidence-based HIV prevention interventions and interventions designed to engage this population in the HIV prevention and care continua.

Children's Hospital Los Angeles' Institutional Review Board (IRB# 14-00279)
INTRODUCTION

The HIV Epidemic and Young Men Who Have Sex With Men: Correlates and Risk

In this third decade of the human immunodeficiency virus (HIV) epidemic, we continue to see 50,000 new infections annually in the United States, with the highest rate of diagnosed HIV infection among adolescents and young adults (approximately 25%). No group is at greater risk for acquiring HIV than young men who have sex with men (YMSM), particularly Black/African American (AA) and Hispanic/Latino (L) YMSM living in inner cities, who account for the largest number of new HIV infections each year. Although African Americans represent only 14% of the US population, they account for 44% of all new HIV cases reported each year. The situation is particularly grave for AA-YMSM, with seroprevalence rates of 19% for ages 15-22 and 26% for ages 23-29. Additionally, while overall rates of HIV infection among Latinos declined from 2005 to 2014, new infections among 13-24 year old L-YMSM increased by 87%. Recent data suggest that YMSM account for 60% of all new infections among all AA-MSM and 45% of new infections among all L-MSM.

AA/L-YMSM in particular have a unique risk profile for tobacco, alcohol and drug use, STIs/HIV, and mental health disorders. Indeed, YMSM are significantly more likely to use tobacco, alcohol, and illicit drugs compared to their heterosexual peers. However, AA/L-YMSM generally report less frequent substance use than Caucasian/White (W) YMSM. For example, evidence suggests that AA-YMSM are less likely to binge drink and use illicit drugs compared to W-YMSM. Moreover, evidence suggests L-YMSM engage in less frequent drug use compared to W individuals. However, our own research found that AA-YMSM who experience violence, discrimination, or harassment are at greater risk for drug use compared to AA-YMSM who do not.

There is also clear evidence that YMSM suffer from more mental health problems than their heterosexual counterparts, including drug use disorders, affective disorders, and suicide ideation. Individuals who experience racial discrimination, homophobia, and gay-related
stigma are at greatest risk for experiencing poor mental health outcomes, including depression and anxiety. These experiences of stigma are also positively associated with high-risk sexual behavior. Emerging adults (those aged 18-25 years) generally engage in a normative process of adult identity integration and reconciliation as they transition into adulthood. However, given that many AA/L-YMSM face stigma from multiple sources and experience instances of racism and homophobia, the process of coming to terms with their gender, sexual, and ethnic/racial identities is even more complex. Also, considering that depressed individuals are less likely to adopt and/or maintain health-promoting behaviors, and anxious individuals are less likely to engage in preventive behaviors, we reason that AA/L-YMSM who are faced with greater challenges and experiences of discrimination/stigma are more vulnerable to mental health problems including depression, anxiety and substance use, thereby increasing their odds of contracting STIs and HIV.

There is a growing literature suggesting that discrimination, racial bias, and stigma in domains such as employment, housing, education, and legal contexts, as well as more routine experiences of being treated with less respect, are perceived as being stressful. These experiences may affect disease risk via mental health pathways and/or through maladaptive behavioral coping mechanisms. This is consistent with our own findings demonstrating that racism, homophobia, internalized homophobia, and stigma are important to understanding risk among AA-YMSM. Millett et al. (2007) suggest that the HIV-related racial disparities that persist among YMSM can be explained by complex and interconnected factors, such as greater prevalence of STIs and unrecognized STI/HIV infection, disparities in access to/use of HIV testing, care and treatment, and social/structural barriers including low income, unemployment, and discrimination.

There are additional developmental and cultural risk factors that have been found to put AA/L-YMSM at increased risk for engaging in behaviors associated with HIV infection. L-YMSM come of age in a culture with a strong emphasis on traditional gender roles, family and having
children.43 Within this context, sociocultural factors such as community connectedness, social support, adherence to cultural values for sex, sexual discomfort (e.g., feeling embarrassed or not being able to speak about sexual matters), and self-efficacy to discuss sexual matters significantly predict sexual risk-taking and illicit drug use.44-46 Our research found differences in religious experiences, internalized and community homophobia, and identification/disclosure of gay identity put L-YMSM at greater risk than W-YMSM.46

**HIV Prevention and the HIV Care Continuum among AA/L-YMSM**

Despite these challenges, today there is greater hope than ever before that we can change the course of the HIV epidemic given a number of biomedical approaches to prevention that leverage the use of anti-retroviral therapy (ART), including pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP). PrEP has enormous promise to limit HIV acquisition, with >90% efficacy among those with high adherence, yet uptake and adherence are extremely low among AA/L-YMSM.47 National data indicate that about 100,000 people are using PrEP, the majority being Caucasian/White and above the age of 30.49 This low uptake points to social and structural determinants, such as poor access to care and financial barriers related to other needs including food and shelter. There is growing evidence demonstrating that YMSM are significantly less likely than adult men who have sex with men to have ever used PrEP. Moreover, AA/L-YMSM are the least likely to have used PrEP.47

Early diagnosis of HIV and timely linkage to and retention in care are vital to survival and quality of life. HIV+ individuals who adhere to ART exhibit slower disease progression, fewer HIV co-morbidities, improved overall health outcomes, and less transmission to partners.50 Unfortunately, there is growing evidence that HIV+ young people are significantly less likely than HIV+ adults to be linked to and retained in care, to initiate ART, and to experience viral suppression.51-53 **Figure 1** reflects the estimated cascade of care in HIV+ youth (ages 13–29 years) in the U.S.52 As reported by Ryscavage et al (2011), AA youth in care were found to have the lowest probability of viral suppression at 6 months and the highest predicted probability of
viral rebound, compared to AA adults, non-AA youth, and non-AA adults. Moreover, foreign-born Latinos may have the poorest HIV-related clinical outcomes.

**INSERT FIGURE 1 ABOUT HERE**

Many of the HIV disparities that currently exist relate to different patterns in HIV testing, linkage to care and engagement/retention in care. Christopoulos and colleagues (2011) concluded that racial disparities in HIV outcomes persist among MSM in large part because of different patterns of engagement in care. Lack of insurance and patient mistrust of health care/providers may also play a key role in this lack of engagement in care. Additionally, Christopoulos et al. argued that limited research has been conducted to better understand barriers to engagement and retention in care among AA/L-MSM in general, and AA/L-YMSM in particular. Moreover, they concluded that there is a dearth of research on culturally relevant strategies designed to engage AA/L-MSM in HIV care, especially AA/L-YMSM.

*The Healthy Young Men’s Cohort Study: Opportunities to Turn the Curve of the HIV Epidemic*

Given these multiple factors and opportunities, the Healthy Young Men’s (HYM) Cohort Study was designed to provide rich data to help further understand and characterize AA/L-YMSM’s engagement in the HIV Continuum of Care and Prevention, including their use of HIV testing services and access to and use of HIV prevention/treatment services. The HYM Cohort Study was designed to inform the development of developmentally appropriate and culturally relevant interventions addressing the many risk factors that serve as barriers to accessing needed HIV prevention and care services.

**Overarching Goal and Specific Aims**

The overarching goal of the HYM Cohort Study is to conduct longitudinal research with a large and diverse cohort of AA/L-YMSM in order to inform the development of developmentally appropriate and culturally relevant interventions that help prevent new HIV infections, reduce
transmission, and reduce HIV/AIDS-related disparities. A specific focus is on successful engagement, linkage, and retention in care. Building on the HIV Continua of Care and Prevention paradigm (i.e., seek, test, treat, and retain in care) and the Syndemic Theory of Risk, this research addresses four overarching research questions: 1) Why do some HIV-negative (HIV-) AA/L-YMSM seroconvert (and not others) and how do we more effectively prevent new infections in this population? 2) How can we more effectively engage AA/L-YMSM in all forms of care, including primary care, HIV testing, HIV prevention, and HIV/AIDS treatment services if HIV+? 3) How can we increase demand/uptake of PrEP and PEP as a prevention strategy in this population? 4) How do we prevent transmission and achieve disease-free survival by achieving viral suppression in this population? The specific aims are as follows:

**Specific Aim 1:** Better understand and operationally define what linkage, engagement and retention to care (both primary health and HIV/AIDS treatment) and adherence mean to HIV- and HIV+ AA/L-YMSM. As well as use this data to inform the development of new assessment tools for future intervention research.

**Specific Aim 2:** Characterize and monitor over time AA/L-YMSM’s: a) use of alcohol and illicit drugs; b) utilization of HIV testing and prevention services; c) incidence of HIV and STIs; d) insurance status and access to health care services, including primary care and HIV/AIDS treatment services; e) engagement in and utilization of health care and HIV/AIDS treatment services; f) retention in HIV/AIDS care and adherence to ART; and g) utilization of biomedical interventions, such as PrEP and PEP. A component of this specific aim will include the procurement of biologic specimens and an annual HIV viral load (VL) test for each member of the cohort. The goal is to be able to query specimens for biologic evidence of adherence, potential markers of increased infectious susceptibility (e.g. HLA typing and whole virus sequencing) and/or variability in disease progression rates.

**Specific Aim 3:** Identify barriers/facilitators of engagement along the HIV Continua of Care and Prevention, including HIV testing and biomedical prevention, care engagement and
retention, and adherence to ART. These data will be used to inform existing interventions, clinical practices, and DEBIs (Diffusion of Effective Behavioral Interventions) to ensure they are developmentally appropriate and culturally relevant for this population. The data will also be used to understand how to increase uptake of new interventions, such as biomedical HIV prevention methods (e.g., PrEP, microbicides), as well as behavioral interventions to support the uptake of these biomedical interventions for HIV- AA/L-YMSM. Other intervention strategies that will be considered include mobile technology, social media, motivational interviewing, and patient navigation to support linkage, engagement, retention, and adherence to ART among HIV+ YMSM.

**Theoretical Model and Conceptual Framework**

**Syndemic Theory:** The Syndemic Theory has increasingly been used to explain MSM and YMSM of colors' involvement in HIV risk-taking behaviors. Syndemic Theory posits that a constellation of health problems, including drug use and alcohol misuse, depression, sexual compulsiveness, and intimate partner violence, accumulate across a lifespan, with each condition potentially amplifying the negative impact of other health problems. For AA/L-YMSM, multiple and overlapping forms of risk – racism, discrimination, and homophobia – correlate with negative health impacts. Our previous research has found that AA/L-YMSM experience the highest rates of risk factors as framed by the Syndemic Theory, including drug use, mental health problems (such as depression) and intimate partner violence. AA-YMSM also experience higher levels of internalized homophobia, which in turn is a strong predictor of sexual risk behaviors. In addition, experiences of racism, homophobia, and violence have been found to be significantly associated with illicit drug use, alcohol misuse, and involvement in HIV sexual risk behaviors. The HYM Cohort Study examines syndemic risk factors as predictors of HIV infection among AA/L-YMSM, as well as engagement in care, including HIV prevention, testing and treatment, and adherence to ART.
Engagement in the HIV Care Continuum: Successful engagement in care, both primary care for HIV-negative (HIV-) and HIV care for HIV-positive (HIV+) individuals is now considered essential to achieving critical outcomes required to ensure disease-free survival and to ultimately end the HIV/AIDS epidemic. Under the Affordable Care Act (ACA), linkage to HIV testing (as well as affordable insurance) may serve as a critical point of care within the healthcare system. For those who test HIV+, early diagnosis and linkage to HIV/AIDS care is essential, and yet it is now very clear that “engagement in care” is a complex construct that is perhaps best represented along a continuum of engagement. Moreover, it is also clear that adherence to ART is more likely to occur if individuals are engaged in their own care. Cheever argues that a “person living with HIV may go through several stages and may also return to earlier stages along this continuum throughout his/her life.”

Mugavero et al. (2013) developed a framework with 7 steps along a continuum of HIV service delivery, ranging from not in care/unaware of HIV status, to diagnosis (aware of HIV status), linkage to care (receiving some medical care but not HIV care; entered HIV care but lost to follow-up; in/out of HIV care or infrequent user), retention in care (fully engaged in HIV care), and adherence to ART with the goal of VL suppression. We believe this framework provides a more nuanced understanding of engagement. In addition, we believe that different types of barriers and facilitators are important determinants of engagement along this continuum. Based on the literature as well as our own research conducted with YMSM, we firmly believe that YMSM of color experience a unique set of challenges to engagement that are developmentally and culturally defined. Figure 2 provides a conceptual framework and analytic plan for our proposed research. We hypothesize that specific demographic and syndemic risk factors/barriers put AA/L-YMSM at significantly greater risk for HIV infection, poor retention in care and poor adherence to ART, and consequently, poor HIV-related clinical outcomes and continued HIV transmission. We also hypothesize that protective/facilitator factors mediate
and/or moderate this risk. The collection of longitudinal data over four years with a large cohort of AA/L-YMSM (e.g., who are both HIV- and HIV+, in and out of care, adherent and not adherent) allows us to examine trajectories along this continuum and identify predictors of who is and is not engaged/retained in care at each step along the continuum, and why.

The purpose of this paper is to describe the HYM Cohort Study protocol – i.e., study design and research methods for this longitudinal study.

METHODS

Consent and Institutional Review Board Approval

This study has been reviewed and approved by Children’s Hospital Los Angeles’ Institutional Review Board (IRB# 14-00279). All participants were identified, screened for eligibility, and if eligible, invited to participate in the study, as further described below. All participants provided written informed consent during a face-to-face consenting visit. A Certificate of Confidentiality was obtained from the National Institute on Drug Abuse and a waiver of parental consent/assent was obtained for participants 16-17 years old.

Study Design

Longitudinal research (baseline and follow-up assessment every 6 months) is in progress with our cohort of 450 AA/L-YMSM in Los Angeles. Participants were recruited using a venue-based and social media sampling design, described below. In addition to self-report surveys, data collection includes: urine collection to assess recent use of illicit drugs; rectal and throat swabs to test for gonorrhea and chlamydia; blood draw for syphilis testing; and the additional collection/storage of additional blood (10ml for 4 aliquots and 1 pellet) and a rectal swab to be stored in the HYM biorepository. This mixed-methods study design includes collection and triangulated analysis of quantitative and biological measures (i.e., drug use, STI/HIV testing, and adherence to ART among HIV+’s) at baseline and every six months for a
total of eight waves of data collection. In addition, qualitative sub-studies are integrated into the study using a modified timeline followback approach; these are conducted outside the regular study visits on an as needed basis. The HYM Cohort Study has been designed to provide a platform from which new and emerging biomedical prevention strategies (e.g., PrEP and PEP) can be developed and evaluated with AA/L-YMSM.

**Study Participants**

YMSM youth were eligible to participate in the cohort if they: 1) were 16 to 24 years old; 2) assigned a male sex at birth; 3) self-identified as gay, bisexual, or uncertain about their sexual orientation; 4) reported a sexual encounter with a male within the previous 12 months; 5) self-identified as Black/African American, Latino, or multiethnic; and 6) lived in Los Angeles or a surrounding county, with no expectation of moving outside this area for at least six months. The recruitment strategy described below resulted in a geographically dispersed cohort recruited from throughout Los Angeles County, as shown in **Figure 3**.

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**Recruitment**

**Identifying Public Venues and Social Media Sites:** Formative research was first conducted to identify public venues frequented by AA/L-YMSM. Staff contacted and met with venue owners/managers (including HIV test sites and clinic directors) of sites identified for recruitment to explain the study and to obtain permission to conduct activities. Facilitated discussions with the study’s community and youth advisory boards (CAB, YAB) identified common social media sites and dating apps that are popular amongst our target population.

**Recruitment in Public Venues:** The recruitment methods in this study matched those used in our previous research with the same target population. Young men were recruited from public venues including bars, coffee houses, parks, and high-traffic street locations where
YMSM spend time or ‘hang out’, social events sponsored by an agency or organization that serves YMSM, and special events such as Gay Pride festivals and Balls.

During sampling events, young men who appeared to meet the study criteria were counted and invited to participate in a screening interview conducted in English or Spanish. One or two researchers counted and identified young men to be screened and tracked individuals to ensure that young men were not approached multiple times. Young men who met the study criteria received a detailed study description, and contact information was obtained from individuals who expressed interest in participating. Follow-up in-person appointments were scheduled within one week of recruitment to complete the informed consent process and to further explain study participation. For each sampling event, the following data were collected: a) number of YMSM observed; b) number of YMSM intercepted; c) age, race, and county of residence of those screened; d) reasons for refusal; e) number of eligible YMSM; and f) number enrolled.

We originally planned to recruit our cohort of AA/L-YMSM using only this recruitment method. However, during our pre-recruitment field observations, the research team noted that few AA/L-YMSM were present at these venues. Discussions with our CAB and YAB indicated the low number of YMSM attending gay-identified venues was a common challenge for outreach, YMSM are simply not attending gay-identified venues as they once did.

**Recruitment Using Social Media:** Given these changes in the community, our team determined that additional recruitment methods were needed to complete recruitment of the cohort within the allotted recruitment time frame. Thus, we partnered with Trialspark, a technology company that supports recruitment for clinical studies/trials using social media sites. The HYM team worked with Trialspark to design social media ads to be placed on sites identified by our YAB including Facebook, Instagram, Grindr and Jack’d. Through our partnership, Trialspark identified and briefly screened 1371 individuals; of these 550 (40%) were identified as eligible. Preliminarily individuals were then independently contacted and re-
screened for enrollment by our research team. Young men were also recruited through participant referrals, as well as referrals from our partner clinical sites. Table 1 below presents the recruitment data for each recruitment method.

Table 1. HYM Cohort Study Recruitment and Eligibility Data

<table>
<thead>
<tr>
<th></th>
<th>Social Media n (%)</th>
<th>Venue/Events n (%)</th>
<th>Participant Referrals n (%)</th>
<th>Clinic n (%)</th>
<th>Total n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approached for screening</td>
<td>1371 (68)</td>
<td>544 (27)</td>
<td>69 (3)</td>
<td>43 (2)</td>
<td>2,027 (100)</td>
</tr>
<tr>
<td>Screened for eligibility</td>
<td>690 (50)</td>
<td>477 (88)</td>
<td>69 (100)</td>
<td>42 (98)</td>
<td>1,278 (63)</td>
</tr>
<tr>
<td>Determined to be eligible for study</td>
<td>550 (40)</td>
<td>206 (38)</td>
<td>64 (9)</td>
<td>31 (72)</td>
<td>851 (42)</td>
</tr>
<tr>
<td>Completed baseline survey</td>
<td>350 (64)</td>
<td>46 (22)</td>
<td>37 (58)</td>
<td>19 (31)</td>
<td>452 (53)</td>
</tr>
</tbody>
</table>

Tracking & Retention

Participants were asked to participate in data collection at baseline and follow-up every six months. We acknowledge the complexities of tracking and retaining a young and highly mobile population such as YMSM. Our past experience taught us that the key to retaining youth in a research study is developing trusting relationships between the study team and the research participants. To that end, we adapted a tracking protocol used in previous studies, which yielded a 94% retention rate across 2½ years and five waves of data collection. An essential piece of this protocol is assigning staff to a specific participant with the goal of maintaining that relationship across the course of the study. Staff turnover is inevitable, and when that occurs we ensure there is contact between the original staff person, the participant, and the newly assigned staff person to ensure continuity in the relationship.

In addition, the protocol also includes gathering tracking and location information including: a) address, b) phone numbers, c) email, d) social media, e) family/friend contact, and f) school/work information. Every six months, this information is reviewed with the participant and updated as needed. Participants are asked to contact their interviewer monthly (e.g., text message, phone call, Snapchat) in return for a $7 monthly incentive (an additional $42 added to
their data collection incentive). These check-ins are an opportunity to determine whether the participant needs any resources (e.g., food bank, physician referrals) and remind them of any upcoming appointments. The HYM team uses this opportunity to catch up on any events in the young men’s lives and enter field notes as needed. We learned that the HYM participants tend to enjoy these check-ins and share photos with their assigned staff person (e.g., prom, weddings) or ask about different services as needed. If the participant fails to make contact after two months, the participant’s assigned interviewer uses tracking and location information and/or criminal justice records to make contact. Between baseline and Wave 2, only 7% had missed one or more check-ins.

**Community & Youth Advisory Boards (CABs & YABs)**

CABs and YABs have played a critical role in our research conducted with YMSM. A HYM CAB and YAB was developed to help to inform all aspects of the study design, implementation, and interpretation of the study findings. CAB members include policy makers, HIV/AIDS service providers and community advocates. The YAB is comprised of members of our target population who were recruited from local clinics serving YMSM. The CAB meets on a bimonthly basis and the YAB meets monthly. Agendas typically include brief study updates, information about new proposals in development and upcoming events, a data presentation on a specific topic or construct, and discussions about how to interpret these data and move them to the next stage. Our CAB assisted in developing community forums, co-authored peer-reviewed manuscripts, assisted in outreach, and co--presented study results with the HYM team. The YAB has reviewed our data collection tools, provided feedback on proposed interventions and assisted in outreach efforts at public venues.

**Measures**

HYM study participants participate in a self-report survey every six-months. The survey is administered by their assigned staff person and questions about more private topics (e.g., substance use, sexual behavior, violence) are self-administered using an online survey to
provide an additional layer of confidentiality and encourage more honest responses.\textsuperscript{66,67} The survey takes approximately 1½ hours to complete; special topics are integrated into individual waves when only a single assessment point of data is needed (e.g., childhood trauma, mindfulness). At baseline, participants completed a “pre-baseline” assessment, a brief (10 minutes) survey completed during the informed consent process and received $10 for the pre-baseline and an additional $55 for completing the baseline assessment. Participants can earn up to $100 at follow-up assessments if they complete each monthly check-in ($55 for the assessment and $42 for the check-ins, rounded up to total $100). A description of the study measures is as follows.

**Demographic Characteristics:** Survey instruments obtain demographic information including age, race/ethnicity, religion residence and residential stability, education/employment, food security/hunger, socioeconomic status, history of foster care and incarceration, and insurance status.

**Alcohol, Tobacco, Marijuana, & Illicit Drug Use:** Scales from the Monitoring the Future study are used to assess lifetime, past 6-month and past 30-day illicit drug and alcohol use.\textsuperscript{68} The drug list includes marijuana, LSD, PCP, mushrooms, cocaine, crack, methamphetamines, ecstasy, stimulants, heroin, fentanyl and prescription drugs used without a physician’s order. We also assessed substance use problems using standardized measures including alcohol and marijuana misuse. Participants are asked the location and circumstances during which they use drugs, particularly around the time when they engage in sexual behaviors. We collect urine samples at baseline and every 6-months to test for metabolites of methamphetamines, cocaine, ecstasy, marijuana, and opiates using the Integrated E-Z Split Key Cup II- 5 Panel (Innovacon Laboratories), which can detect drugs from one to four days after use, except for chronic marijuana use, which can be detected for up to 30 days.\textsuperscript{69,70} Screening for fentanyl is also performed.

**Sexual Risk Behaviors, Partners and HIV Risk, and Protective Behaviors** are
assessed using scales adapted from the EXPLORE study and research we previously conducted with YMSM. Participants are asked about their lifetime and recent sexual experiences (past 1 and 6 months), including insertive/receptive oral sex; insertive/receptive vaginal sex, and insertive/receptive anal sex. Specifically, participants are asked to report the number of times they engaged in each type of sexual activity and the gender of their partners; each of these types of sexual activity for the different partner types (e.g., primary, consistent casual, and casual) they might have had in the past 6 months; and the frequency of condom use by gender of partner and by sexual activity. This measures condomless intercourse.

Participants are asked if they have ever and recently (past 6 months) exchanged sex for money, drugs, food, clothes, etc. **Condom Use Self-Efficacy (CUSES):** The 15-item CUSES measures condom use self-efficacy using 5-point Likert scale. **Condom use intention** is assessed using a 9-item Condom Intention Scale.

**Partner Demographic & HIV Status:** Current partner(s) demographics including race/ethnicity: age, type (primary, casual, hookup; if primary open vs. monogamous); HIV status and HIV concordance/discordance; partner’s use of HIV services and ART adherence if HIV+. **Sexual compulsivity** is also assessed with the 10-item Sexual Compulsivity Scale, which asks respondents to endorse their agreement with statements related to sexually compulsive behavior.

**HIV/STI Testing and Prevention Behaviors:** **HIV Status:** Participants complete HIV testing using 4th generation point-of-care rapid whole blood finger-stick HIV test (Alere, Inc., Waltham, MA), an FDA-approved diagnostic measure of HIV-1 p24 antigen and HIV-1/2 antibodies. This test is performed every six months. We also use scales from our previous study conducted with YMSM to measure self-reported history of HIV/STI testing and HIV-status. **STI Testing:** Participants self-collect rectal and pharyngeal specimens for Neisseria gonorrhea and Chlamydia trachomatis nucleic acid amplification testing at baseline and every six months. Syphilis testing is performed using whole blood collected via venipuncture (or fingerstick) using rapid plasma regain and treponemal antibody testing at
baseline and every six months. Those with positive results meet with the on-site HIV test counselor, then are referred and treated at one of our partner clinical sites.

Depression, Mental health, Spirituality, Well-Being, Health-related Quality of Life, Sensation Seeking, Optimism, Resilience and Mindfulness include the 18-item Brief Symptom Inventory (BSI) is used to assess depression, anxiety and somatization. The PROMIS Depression short scale assessed depressive symptoms during the previous seven days. PROMIS was administered during baseline while BSI was administered at baseline and in all Follow-Up waves. Spirituality was found to be an important aspect of young men’s lives in our prior research; thus we included the Spirituality Scale which taps into self-discovery and eco-awareness, two of the primary components of spirituality.

Psychological Well-Being is assessed using Ryff’s Psychological Well-Being scale, which measures multiple facets of psychological well-being. The scale has high reliability and internal consistency with \( \alpha = .81-.88 \). Health as a value: The 4-item Health as a Value scale measures individuals’ perceived importance of health and wellbeing. Suicidality and self-injurious behavior: history and current risk. Health-related Quality of Life: The 21-item Health Related Quality of Life measure with three subscales that measure current life satisfaction, illness-related anxiety, and illness burden was administered to those who reported currently experiencing one or more chronic health conditions, including those who are HIV positive. The 6-item Sensation Seeking scale assesses participants’ personality traits that may convey a predisposition to sensation seeking. Optimism is measured using the 10-item Life Orientation Test-Revised, and Resilience is measured with the Connor-Davidson Resilience Scale. Mindfulness is measured using the Mindful Attention Awareness Scale, a 15-item scale designed to assess a core characteristic of dispositional mindfulness, namely receptive awareness of and attention to what is taking place in the present.

Emotion Regulation and Coping data are collected annually. The Difficulties in
Emotion Regulation Scale measures participants' ability to be aware of, understand, and accept their emotions, as well their ability to act in desired ways regardless of their emotional state.\textsuperscript{85} We assessed a variety of coping strategies participants may use in response to a specific stressor using the Brief COPE.\textsuperscript{86}

**Childhood Abuse/Trauma, Internalized Homophobia, Partner Violence, Racism, and Discrimination:** Childhood trauma was measured at wave 2 using Bernstein's Childhood Trauma Questionnaire.\textsuperscript{87} Internalized homophobia is assessed using a 4-item measure by Ross and Rosser.\textsuperscript{15} Partner Violence data is collected annually with the Revised Conflict Tactics Scale which measures violence within the context of intimate relationships, and identifies lifetime and past 12 months experiences of physical, sexual and emotional abuse as a victim and perpetrator.\textsuperscript{88} Experiences of Racism and Discrimination are captured using Diaz and Ayala’s 20-item scale which measures lifetime and recent experiences of social discrimination (racism, police brutality, discrimination due to sexual identity).\textsuperscript{35,89} These data are collected every six months.

**Stressful Life Events, Life Chaos** are measured every six months. Stressful Life Events including health-related stress are assessed using a checklist of life events.\textsuperscript{90} The scale provides participants with a list of stressful events and asks them if these events occurred during the previous six months and their level of stressfulness on a scale from 1 to 10. We also measure Life Chaos, a construct found to be associated with poor adherence to ART, using the 6-item Life Chaos scale.\textsuperscript{91}

**Healthcare, Linkage, Engagement & HIV Service Utilization date** are collected every six months. Participants are asked questions about their current health status using modified questions from the Youth Risk Behavior Survey.\textsuperscript{92} These questions ask about the respondent's overall health status, the number of days in the last week they have eaten fruits or vegetables and the number of days in the last week they have exercised. Participants’ access to and use of the healthcare system was measured using both the Addhealth survey.
from the National Longitudinal Study of Adolescent to Adult Health Study and the National
Survey of Children's Health. These measures assess the frequency and type of health
practitioner seen in the past 12 months; insurance status; reasons for use or non-use of
healthcare services in last year; and comfort in speaking with their doctor about sexual health.
Trust/Mistrust of the Healthcare System is measured with the Health Care System Distrust
Scale, a 10- item scale that assesses perceptions of the health care system. Visual
Analogue Scale (VAS) for Medication Adherence asks participants to consider a specific
time period (e.g., last month) and to estimate the percentage of medication doses
taken. VAS has moderate correlations with unannounced pill counts and self-reported
recall and is widely used to assess medication adherence.

Social Support, Connection to Community: Theses data is collected every six
months. The Multidimensional Scale of Perceived Social Support, a 12-item scale, measures
perceived social support from family, friends, and partner(s). Participants’ connection to
community - work, school, spiritual, residential, ethnic - is measured using a 10-item scale
developed by our research team and used in our prior research.

Biological Specimens & Bio-repository: We annually collect and store biological
samples for all 450 participants. Each participant has a 10 mL EDTA anti-coagulated whole
blood sample drawn every 12 months throughout the duration of the study and a rectal swab is
also collected; samples are drawn and banked from the HIV+ participants every 6-months.
Blood specimens are processed to harvest plasma and a cellular pellet. Plasma is then made
into 4 separate aliquots and stored frozen at -80°C. The RBC/Buffy coat pellet is harvested and
stored for future cellular material, and will be made available to investigators for future studies of
patient and/or viral genomes. The maintenance of biological material from this cohort will be
invaluable in the investigation of biological/genetic markers associated with variability observed
in disease progression and in infection rates in individuals with similar high-risk behaviors. The
bio-repository uses a custom requisition form that is completed and delivered with each bio-
specimen. This form includes a unique de-identification number making each participant
anonymous to the laboratory. Trained phlebotomists who are a part of the field research team
draw specimens. All specimens are entered into a secure, password-protected database noting
its position in storage (e.g., rack, box, position) for ease of tracking and retrieval.

**Qualitative Interviews Using Timeline Follow-back (TLFB) Techniques**

TLFB interviews generally use a quantitative approach to capture data related to specific
events and the contexts in which those events occur. We use an adapted, more qualitative
approach for the TLFB interviews to better understand participants’ experiences throughout the
HIV Continua of Care and Prevention. TLFB uses memory aids such as calendars and “anchor
days” to assist respondents in creating a daily diary for specific behaviors. The TLFB technique
is an iterative process with the interviewer and respondent working together to develop a clear
chain of events during the specific time period (e.g., past 6 months). This technique has
acceptable reliability and validity when measuring constructs such as substance use and sexual
behavior. This technique may also be useful to contextualize specific experiences, including 1)
heavy substance use (to understand social cues or other triggers for this use); 2) inconsistent
use of care and/or challenges accessing health services (to address structural barriers to care);
3) HIV testing (to identify why YMSM are not testing as recommended); 4) dropping out of care;
and/or 5) challenges adhering to ART medications and/or achieving viral suppression. These
are areas in which, to our knowledge, this technique has not been used.

Each interview is recorded and structured manuals are developed to guide the interview
and subsequent coding for each session. We have completed data collection for the first TLFB
session which is focused on young men who have seroconverted in the last six months (n=19).
The interview is focused on recalling when they received their positive results, how they coped
with this change in their life, their experiences with care, and their hopes and concerns for the
future.
RESULTS

To date, the HYM Cohort Study sample has been recruited and the baseline and 6-month follow-up assessments have been conducted with all study participants. The retention rate at 12-months is 97%. While the sample included 400 HIV- and 50 HIV+ participants at baseline; nearly 3% of HIV- participants have seroconverted since their baseline assessment. We expect to complete the Wave 3 (12-month) assessment by the Fall of 2018, 18-month assessment will be completed by January 2019, and 24-month assessment will be completed by July 2019.


