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Defining Sexual Risk in the Era of Biomedical HIV Prevention: Implications for HIV Research and Practice

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Abstract

Advancing HIV behavioral science and its integration with recent biomedical prevention strategies - Treatment as Prevention (TasP) and pre-exposure prophylaxis (PrEP) - is complicated because traditional definitions of sexual risk (condomless anal sex [CAS] or CAS with a serodiscordant partner) may not suffice given the success of biomedical prevention in the absence of condoms. To better understand how to define and understand risk in the era of biomedical HIV prevention, we assessed correlates of four different definitions of high-risk sexual behavior among a sample of 401 adult HIV-positive MSM (57% African American) residing in the New York City area: 1) a traditional model of risk defined as CAS with an HIV-negative or unknown serostatus partner; 2) a definition that considered participant viral load (VL); 3) a definition that considered partner PrEP use; and 4) a definition that considered participant HIV viral load (VL) and partner PrEP use. Among participants reporting anal sex ($n = 281$) with a man in the past 3 months, 42% were considered high risk under definition 1, 6% under definition 2, 25% under definition 3, and 2% under definition 4. Correlates of risk varied across definitions. For example, while education was the strongest predictor of high-risk sexual behavior in definitions 1 and 2, alcohol use and enacted stigma were the strongest predictors in the model that only accounted for partner PrEP use (definition 3). These findings have implications for whom to reach for intervention efforts, the difficulty in meeting recruitment goals, and the types of interventions that should be used.

Keywords

Men who have sex with men; PrEP; viral load; condomless sex; HIV risk

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Introduction

Over one million people live with HIV in the US, with 38,739 estimated number of new infections in the US and its six dependent areas in 2017 (Centers for Disease Control and Prevention, 2018c). Men who have sex with men (MSM) are disproportionately impacted by HIV in the US, especially young MSM of color (Centers for Disease Control and Prevention, 2018c). HIV diagnosis rates among Black and Hispanic men rose by 87% between 2005 and 2014 (Centers for Disease Control and Prevention, 2018a). The continuing HIV crisis among MSM requires an understanding of current prevention needs of MSM and novel interventions to address HIV transmission risk.

Responding to these urgent prevention needs, biomedical HIV prevention strategies, specifically Treatment as Prevention (TasP) (Cohen et al., 2011) and pre-exposure prophylaxis (PrEP) (Grant et al., 2010; Jiang et al., 2014), have emerged as the primary tools for controlling the HIV epidemic in the US. The US National HIV/AIDS Strategy emphasizes the need for HIV prevention specifically among MSM, and to implement behavioral approaches that “take into account the complex interplay of individual behavior, social structure, and biomedical factors on continuum of care outcomes” (Office of National AIDS Policy, 2014). This, as well as similar recommendations from the National HIV/AIDS Policy and the CDC (Centers for Disease & Prevention, 2011; Marrazzo et al., 2014; Office of National AIDS Policy, 2014), underscores the need for an effective integration of biomedical and behavioral approaches.

Advancing HIV behavioral science and its integration with recent biomedical prevention strategies – specifically TasP and PrEP - is complicated because traditional definitions of sexual risk (condomless anal sex [CAS] or CAS with a serodiscordant partner) may no longer suffice because of the success of biomedical prevention in the absence of condoms. A number of recent studies have identified correlates of high-risk sexual behavior in the era of HIV biomedical prevention. For example, Magidson and colleagues assessed correlates of ‘amplified’ HIV transmission risk among a sample of 749 sexually-active, HIV-positive patients (27% MSM) in Brazil, Thailand, and Zambia enrolled in HPTN 063 (Magidson et al., 2016). Amplified risk was defined as CAS with an HIV-negative or unknown serostatus (collectively referred to throughout as serodiscordant) partner when the participant has a detectable viral load (VL) and/or a sexually transmitted infection (STI). Under one-third (29%) of participants met criteria for amplified risk, which was significantly associated with residing in Brazil and being an MSM. Another study of 2,189 HIV-positive MSM conducted in the United Kingdom (UK) defined risk as CAS with a serodiscordant partner and either not being on ART or HIV VL greater than 50 copies (Daskalopoulou et al., 2017). The results of this study showed that only 4.2% of participants met this definition of high risk, which was significantly associated with younger age, shorter time since diagnosis, reporting financial hardship and harmful alcohol consumption.

These, and other (Mayer, Skeer, O’Cleirigh, Goshe, & Safren, 2014; Wilson et al., 2016), studies have examined correlates of high-risk sex that acknowledge participant VL as an important factor in determining what is considered risky. To better understand how to define HIV risk in the biomedical prevention era and its implications, we assessed correlates of

four definitions of high-risk sexual behavior among a sample of adult HIV-positive MSM residing in the New York City area: 1) a traditional (i.e., pre-dating biomedical prevention options) model of risk defined as CAS with a serodiscordant partner (i.e., either an HIV-negative or unknown serostatus partner); 2) a model that includes participant VL into the definition of risk; 3) a model that includes partner PrEP use into the definition of risk; and 4) a model that takes into consideration both participant VL and partner PrEP use. The results may provide insights into how definitions of sexual risk that incorporate newer biomedical prevention options might impact HIV research and practice.

Methods

Procedures and Participants

Data for this study was taken from the baseline assessment an ongoing randomized controlled trial (RCT) of the Thrive With Me (TWM) intervention that was launched in October 2016. The TWM intervention and study procedures have been fully described elsewhere (author citation). Briefly, TWM is a 5-month mobile-optimized online intervention to improve ART adherence among HIV-positive MSM. A total of 401 HIV-positive MSM residing in the New York City area were enrolled into a two-arm prospective RCT of TWM or a control (weekly email newsletters) condition. Participants were recruited by staff at the Center for HIV Educational Studies and Training (CHEST) in New York City. Recruitment methods included internet-based recruitment efforts, including online venues (websites, email distribution lists, and blogs) and social-medial platforms that cater to MSM and individuals with HIV, as well as field-recruitment strategies such as advertising in clinical settings (author citation). Eligibility criteria included: 1) current male gender; 2) having sex with a man in the past year; 3) HIV-positive serostatus (confirmed by current ART medication prescription when possible); 4) reporting a detectable VL (past year) or potentially suboptimal ART adherence (<90% in the past 30 days using a visual analog scale; Amico et al. (2006)); 5) English proficiency (since the intervention is in English); 6) residing in the New York City metropolitan area (so that men can attend in-person study visits); 7) the ability to send and receive SMS messages; and 8) having internet access over the active (i.e., 5 month) study period.

Once men met study inclusion criteria, they attended the first study visit at CHEST to complete the consent process and a baseline visit procedures. Men completed the baseline CASI survey and were asked to provide a blood sample to assess current VL and a urine sample to detect recent drug use. All assessments were conducted in-person at research offices by trained research personnel and occurred for participants.

Measures

Demographic characteristics—Demographic characteristics included age (in years); how long participants had been living with HIV (in years); race (African American/Black, American Indian/Alaska Native, Asian, Native Hawaiian/Pacific Islander, white, more than one race) and ethnicity (Hispanic identity); highest level of education (high school or less, some college, college degree or more); and employment (full-time, part-time, unemployed, disabled, or retired).

Substance Use—Men completed a urine screen at baseline to assess for the following illicit substances: cocaine, methamphetamines, marijuana, opiates, and amphetamine, using the Integrated E-Z Split Key Cup II-5 panel (Innovacon Laboratories). This test is capable of detecting drugs from one to four days after use, except for chronic marijuana use, which can be detected for up to 30 days (Cone, 1997).

In addition to the urine screen, participants were asked on the baseline CASI survey if they had used any of the following 14 illicit drugs in the past 6-months: marijuana, poppers, pain killers purchased on the street, downers, powder cocaine, crack cocaine, amphetamines, methamphetamines, GHB, ketamine, ecstasy, heroin, speedballs (heroin and cocaine mixed together), and hallucinogens. Two composite drug variables were identified using both the urine screen and self-reported drug use. First, any drug use was defined as either past 6-month self-reported use of any illicit drug excluding marijuana and poppers or a positive urinalysis for cocaine, methamphetamines, opiates, or amphetamines. Second, any stimulant use was defined as either past 6-month self-reported use of powder cocaine, crack cocaine, amphetamine, methamphetamine, or ecstasy or a positive urinalysis for methamphetamines, amphetamines, or cocaine.

The AUDIT (10-item alcohol abuse scale) was used to assess problematic alcohol use (Leonhard, Mulvey, Gastfriend, & Shwartz, 2000; Saunders, Aasland, Babor, de la Fuente, & et al., 1993), with higher scores indicating increased alcohol use disorder symptoms. Alcohol use disorder was defined as a score on the AUDIT 8 or higher.

Psychosocial characteristics—A broad range of mental health factors associated with ART adherence were assessed. Depressive symptoms were measured with the 10-item CES-D scale, a widely used measure of depression in research studies (Radloff, 1992). Participants with a score of 10 or higher (range 0–30) were identified as having elevated levels of depressive symptoms. Perceived stress was measured using the Perceived Stress Scale, which measures how different situations affect feelings and perceived stress (Cohen, Kamarck, & Mermelstein, 1983). Perceived Stress Scale scores were categorized as low (scores 0–13), moderate (scores 14–26), or high (27–40) perceived stress. HIV stigma was assessed using the stigma scale developed by Earnshaw and colleagues (Earnshaw, Smith, Chaudoir, Amico, & Copenhaver, 2013). The scale provides an subscale scores using 5-point Likert-type scales with higher scores indicating greater stigma for internalized HIV stigma, anticipated HIV stigma, and enacted HIV stigma.

Emotional / informational, tangible, affectionate, and positive social interaction support was measured using the Medical Outcomes Study (MOS) Social Support Survey (Sherbourne & Stewart, 1991). One statement (“Someone to love and make you feel wanted.”) from the affectionate support subscale was erroneously excluded and, therefore, this subscale was calculated using the two, instead of three, statements. Items are rated on a 5-point Likert-type scale, with higher scores indicating greater social support, and an average score calculated for each subscale.

Viral Load Measures—Blood draws were taken to assess the effects of the TWM intervention on VL. Blood was drawn by a certified phlebotomist and analyzed by Quest

Diagnostics. For the purpose of the RCT, plasma VL was considered detectable at 20 copies/mL; however, for the purpose of this analysis, we considered unsuppressed VL to be > 200 copies/mL as this is a common cut-off point in clinical trials that examined the impact of viral suppression on HIV transmission (Bavinton et al., 2018). Results of VL testing was provided to participants upon request, as described elsewhere (author citation).

Sexual Partners and Relationships—Each participant's current relationship status was assessed (e.g., "I am legally married", "I am single, and having sex with others") and, if the participant reported being in a relationship, what agreement the participant has with his partner about sex outside the relationship (e.g., "Both of us have sex with others separately", "I have sex with others, but don't know about my partner."). Next, men were asked to report the number of sexual partners they had in the past 3 months, who were male, female, and transgender (male and female separately). For participants' male sex partners, they were asked to report the following: the number of sexual contacts with men; the frequency of anal sex and CAS; CAS acts with HIV-negative, unknown serostatus, and HIV-positive partners; and the number of CAS acts with serodiscordant partners where the partner said he was on PrEP.

Definitions of High-Risk Sexual Encounters

We calculated four separate definitions for a high-risk sexual encounter among the participants who reported having anal sex in the past 3 months (Figure 1). First, we identified HIV-positive men who reported CAS with HIV-negative or unknown serostatus partners among those (n=281) who reported anal sex in the past 3 months (Definition 1). Second, we identified HIV-positive men with an unsuppressed viral load (>200 copies/mL) who had one or more episodes of CAS with HIV-negative or unknown serostatus partners (Definition 2). Third, we identified HIV-positive men who had CAS with HIV-negative or unknown serostatus partners, of which at least one was not using PrEP (Definition 3). Fourth, in the most restrictive definition of risk, we identified virally unsuppressed HIV-positive men who reported CAS with HIV-negative or unknown serostatus partners, of which at least one was not using PrEP (Definition 4). Definitions 2, 3 and 4 were restricted to include only those men reporting CAS in the past 3 months (n=118).

Statistical Analyses

Demographic characteristics, psychosocial characteristics, lifetime and recent drug use, VL measures, and sexual encounters were summarized using descriptive statistics (means and percentages). Differences between those who reported anal sex in the past 3-months and those who reported no anal sex encounters were analyzed using the appropriate test (t-test or chi-square tests).

Generalized Linear Models were run for each of the four definitions of high-risk sexual encounters using the binomial family with log link and robust standard errors to calculate Relative Risk (RR) and the 95% confidence intervals of engaging in high-risk sexual encounters. For each of the models, race was dichotomized into white vs. non-white and education was dichotomized to graduated college vs. some college or less than college. Perceived stress was dichotomized into high or moderate perceived stress vs low perceived

stress. Bivariate models were run for demographic and psychosocial measures. Those variables with $p < 0.1$ were included in the four multivariable models of risk. Statistical analyses were performed using STATA version 14 and statistical significance was set at $p < 0.05$. No adjustments were made for multiple comparisons.

Results

Demographic Characteristics

Baseline demographics for the 401 TWM participants are presented in Table 1. On average, participants were 39 years of age and had been living with HIV for approximately 13 years. More than half of the study participants were persons of color with more than one-quarter being Hispanic. Overall, this sample was educated with more than three-quarters of the men reporting some college or higher, although the largest proportion indicated that they were unemployed (39%) and less than half reported that they were working either full-time (22%) or part-time (22%). Half of the men had reported elevated depressive symptoms based on the CES-D scale (49%) and moderate to high perceived stress was common. At baseline assessment, 21% of men had an unsuppressed VL (> 200 copies / mL).

Baseline Drug Use

Baseline drug use was assessed by self-report (past 6 months) and urinalysis (Table 2). More than half of the men had a positive urinalysis or self-reported any drug use (excluding marijuana and poppers) in the past 6 months and nearly half of the men had stimulant use in the past 6 months (powder cocaine, crack cocaine, amphetamine, methamphetamine, or ecstasy). Marijuana (62%) and poppers (40%) were the two most frequently used drugs in the past 6-months. Marijuana was detected in less than half of the cohort by urinalysis (42%). Less than 15% of the study participants tested positive by urinalysis for methamphetamine (15%), amphetamine (11%), cocaine (13%), and opioids (1%).

Partners & Sexual Encounters

Half of the men reported that they were single and having sex with others while less than 10% reported that they were married, had a civil union or domestic partnership, or had a commitment ceremony. Approximately 20% reported they had a partner or lover, or a boyfriend or girlfriend. Among those who indicated that they were not single (married, civil union, domestic partnership, partner/lover, girlfriend/boyfriend), nearly one-third indicated they were monogamous (29%). Fifty-one participants were single, and not having sex with others (13%).

The majority of participants ($n = 317$; 79%) reported that they had at least one male sex partner, and on average, 8.5 male sex partners in the past 3 months ($sd = 12.3$; range: 1–75). Less than 5% of study participants reported any female sex partners ($n = 18$; 4%), transgender female sex partners ($n = 4$; 1%), or transgender male sex partners ($n = 4$; 1%). Of the 317 participants who reported male sex partners in the past 3 months, 281 (89%) indicated that they had anal sex within the past 3 months. There was no demographic, psychosocial, or behavioral differences between the men who reported anal sex compared to those who did not report anal sex in the past 3 months (Table 1).

Condom Use

Frequency of condom use was evaluated for the 281 participants who reported having anal sex in the past 3 months (Figure 1); 43 participants always used condoms (15%) while 103 participants reported they always had CAS encounters (37%). The majority of participants reported having some sexual encounters where a condom was used *and* other encounters where a condom was not used (i.e., CAS) in the past 3 months (46%). On average, among participants who reported sex with and without condoms, more than half of anal sex encounters in the past 3 months were condomless (58%). A total of 232 participants had at least one CAS encounter with another man in the past 3 months.

HIV status of partners was evaluated among the 232 participants who reported at least one CAS encounter with another man in the past 3 months. More than one-quarter indicated that they had at least CAS encounter with an HIV-negative man ($n = 65$; 28%) and/or a man with unknown serostatus ($n = 74$; 32%) in the past 3 months, while more than half indicated that they had CAS with an HIV-positive man in the past 3 months ($n = 152$; 66%). A total of 1,921 sexual episodes were reported; almost two-thirds (65%; $n=1252$) of CAS episodes were with HIV-positive men, 20% ($n=393$) were with unknown serostatus partners, and 14% ($n=276$) were with HIV-negative partners. On average, study participants who reported at least one CAS encounter had 4.2 CAS encounters with HIV-negative partners ($sd = 6.4$), 5.3 encounters with unknown serostatus partners ($sd = 7.1$), and 8.2 encounters with HIV-positive partners ($sd = 10.6$) in the past 3 months.

Correlates of High-Risk Sex Definitions

We assessed correlates of four definitions of high-risk sex.

Definition 1: CAS with an HIV-negative or unknown serostatus partner (Table 3). Predictors of CAS with serodiscordant partners were evaluated among the 281 participants who had anal sex in the past 3 months; less than half ($n = 118$; 42%) indicated they had CAS with at least one serodiscordant partner. Bivariate predictors of CAS with serodiscordant partners include younger age, living with HIV for fewer years, being white, having a college degree, and depressive symptoms. In a multivariable model with these five predictors, education was the only remaining predictor of CAS with serodiscordant partners.

Definition 2: CAS with an HIV-negative or unknown serostatus partner when VL was unsuppressed (>200 copies / mL) (Table 4). Predictors of CAS with serodiscordant partners when the participants had an unsuppressed VL were evaluated among the 118 participants who had at least one CAS encounter with an HIV-negative or unknown partner. Of these participants, 17 (14%) had an unsuppressed VL, which represented 6% of the total sample (17/281). Bivariate predictors of CAS while having an unsuppressed VL included lower educational attainment, any drug or stimulant use, elevated depressive symptoms, higher internalized and enacted HIV stigma, and lower emotional and affectionate support. In a multivariable model with these predictors, decreased education remained a predictor of CAS while having an unsuppressed VL.

Definition 3: CAS when at least one HIV-negative or unknown serostatus partner was not on PREP (Table 5). We evaluated predictors of having CAS with serodiscordant partners of

which at least one partner in the past 3 months was not taking PREP. Among the 118 men with CAS with serodiscordant partners, 64 men had HIV-negative partners (197 encounters with partner on PrEP; 79 encounters with partner not on PrEP) and 72 men had HIV unknown serostatus partners (116 encounters with partner on PrEP; 277 encounters with partner not on PrEP). Seventy individuals (25% of the 281 men who reported anal sex; 59% of the 118 men who had CAS) had at least one CAS encounter with a serodiscordant partner who was not on PREP, while 48 individuals (41%) had serodiscordant partners who were always on PREP. Possible alcohol use disorder symptoms and lower enacted stigma were bivariate predictors of this definition of risk, which remained significant in multivariable models.

Definition 4: CAS with HIV-negative or unknown serostatus partner when VL was unsuppressed (>200 copies/mL) and at least one partner was not on PrEP (Table 6). We evaluated predictors of having CAS with serodiscordant partners, of whom at least one was not on PrEP, while having an unsuppressed VL. Overall, 17 men with an unsuppressed VL reported at least one CAS episode with a serodiscordant partner. Among those, six men (2% of the 281 men who reported anal sex; 5% of the 118 men who had CAS) had one or more serodiscordant sexual partners who were not taking PrEP and therefore met this definition of risk. Among these six men, a total of 60 CAS episodes in the past 3 months were reported; all six were racial or ethnic minority men, were drug and stimulant users, had elevated depressive symptoms, and had moderate to high perceived stress. Bivariate predictors of this definition of risk include increased internalized stigma as well as decreased emotional, tangible, affection, and social interaction support. Given the small number and homogeneity of the men meeting this definition of risk, multivariable analyses were not possible.

Discussion

Traditional definitions of high-risk sex have become more complicated with the introduction of TasP (Cohen et al., 2011) and PrEP (Grant et al., 2010). While CAS has been used as a primary marker of HIV risk for MSM, studies demonstrate that it no longer serves to identify specific drivers for HIV transmission in the current era of biomedical prevention (Jin et al., 2015; Kelly, 2016; Rodgers et al., in press). However, consensus on best practices for defining amplified transmission risk among HIV-positive samples has not yet been reached. We investigated correlates of four definitions of high-risk sexual behavioral among HIV-positive MSM living in New York City to further understanding and prompt discussion on the topic.

The proportion of this sample of HIV-positive MSM who reported anal sex and were considered high risk varied substantially across definitions, from 42% who were high risk under Definition 1 (CAS with a serodiscordant partners) to 2% under Definition 4 (CAS with an unsuppressed VL and at least one serodiscordant partner not on PrEP). Indeed, despite many men in this sample reporting CAS, 94% would not be considered at amplified risk for transmitting HIV as defined by the U=U (Undetectable=Untransmittable) campaign (Tobin, 2019) because they have a relatively low VL (<200 copies/mL). Prior studies also show variation in the percentage of HIV-positive participants who show amplified HIV transmission risk depending on their definition of risk, ranging from 4.2% of an HIV-

positive MSM sample who reported CAS with serodiscordant male partners while not taking ART or having a VL ≥ 50 (Daskalopoulou et al., 2017) to 69% of an HIV-positive adolescent sample reporting CAS with serodiscordant partners while having a VL ≥ 200 (Wilson et al., 2016). Within-sample variation in the proportion of men meeting different high-risk or amplified risk definitions has also been reported. For example, Mayer and colleagues (Mayer et al., 2014) found that just under half (45%) of HIV-positive MSM in their sample ($n=201$) reported CAS with a serodiscordant partner while having a detectable VL or a sexually transmitted infection (STI); however only 34% of men reported CAS while having a detectable VL and few men (7%) reported CAS while having a detectable VL and an STI. Overall, the results of the current and prior studies show that definitions of HIV risk have a substantial impact on the potential pool of people with HIV that are candidates for intervention.

The four models presented here also reveal that potential intervention targets may be very different depending on how risk is defined. Education was the strongest predictor of the traditional definition of HIV risk (Definition 1) and the definition that also included unsuppressed VL (Definition 2). Conversely, alcohol use and lower enacted stigma emerged as the strongest predictors in the definition that considered only partner PrEP use (Definition 3), while internalized stigma and various forms of social support were associated with the most restrictive definition of high risk (Definition 4). Of note, although only six men met the requirements for Definition 4, all of them were racial and ethnic minorities, and reported illicit drug use, stimulant use, and elevated depressive symptoms. These results are encouraging in that alcohol use, stigma, social support, and drug use are modifiable factors and effective interventions that address the factors have been demonstrated (Kahler et al., 2018; Lyons et al., 2017; Safren et al., 2012). Taken together, these findings serve as a reminder that the ways in which HIV risk is defined has important implications for intervention design. Furthermore, as researchers grapple at this time with how to define HIV risk in the era of biomedical HIV prevention, suggested intervention targets may differ widely across studies until greater consensus on a definition of risk is reached.

There are a number of limitations of the current study. First, and arguably most important, the number of participants meeting criteria in the increasingly stringent definitions of high-risk (especially Definitions 2 and 4) is very small. Although these results serve the primary purpose here of demonstrating how different definitions of risk may impact study findings, studies with larger samples of HIV-positive MSM who meet these stringent definitions of risk are needed to draw firmer conclusions about correlates of risk for intervention purposes. Second, this is a sample of MSM residing in New York City and who are relatively well-educated. Therefore, the results may not be reflective of MSM residing in other areas of the US or among men with lower educational attainment. That said, the sample is predominantly men of color, which does reflect current trends in new HIV infections (Centers for Disease Control and Prevention, 2018b). Third, frequency of anal sex partners, encounters, status of partners, and partner PREP status over the past three-months was assessed with self-report. Although self-report of sexual behavior is most often used to assess sexual risk, errors in self-report are common due to misremembering or social desirability. Future studies may wish to use ecological momentary assessments (Shiffman, Stone, & Hufford, 2008) to possibly reduce these biases in retrospective assessments. Fourth, our sample had a large

population of men who reported having partners who were always on PrEP. This may reflect the broadening availability of PrEP in New York City, or may be the result of reporting error. Future studies are needed to confirm (or not) this finding. Finally, we did not ask participants to report on partner type (primary, casual or exchange partners) or about the sexual positioning (insertive vs receptive) during condomless sex. Future research that incorporates these factors may help further refine definitions of HIV risk.

With these limitations in mind, developing strategies to identify and provide timely intervention to the highest risk MSM will be critical to ending the HIV epidemic in the US. These findings reinforce current intervention practice, as well as suggest a need to re-examine research and community-based approaches. First, since the purpose of this paper was primarily methodological, the selection of predictor variables was not guided by theory. That said, given the potential variability in findings depending on both the definition of risk (assessed here by varying definitions of risk) and the selection of predictor variables (not varied in the current paper), we note that theory would assist in the selection of the latter to assess potential intervention targets. Especially in the context for shifting definitions of risk, developing effective interventions for high-risk MSM in the biomedical era will continue to rely on the use of empirically-supported health behavior theory to understand intervention targets for a small, but high-risk group of MSM. Second, while RCTs are considered the “gold standard” to assess intervention efficacy, they often require large numbers of participants. Reaching a large number of MSM who meet a narrow definition of risk that includes both PrEP and ART will be very challenging for research studies. Adaptive intervention designs provide innovative ways to determine what works with whom (Almirall, Nahum-Shani, Sherwood, & Murphy, 2014), although they still require a relatively large number of participants for hypothesis testing. Third, the narrowing focus on a small group of very high risk MSM may be disincentivized in community service settings since programs are often reimbursed according to the number of persons they reach rather than reaching the most at-risk individuals. Further discussion on how to reach the most at-risk MSM, innovation in research designs to assess effectiveness in smaller samples, and a re-examination of funding priorities for behavioral HIV prevention are warranted to account for these recent developments in HIV biomedical prevention. Greater collaboration and consensus among researchers, funding agencies, and community providers will be needed to more closely align priorities and practices to take full advantage of the opportunities that HIV biomedical options provide.

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Figure 1.
Definitions of High-Risk Sexual Encounters

Table 1.Baseline Characteristics of *Thrive with Me* Study Participants

Demographics	Total (n = 401)	Anal Sex (n = 281)
Age, mean (sd)	39.1 (10.8)	38.5 (10.3)
Years living with HIV, mean (sd)	12.7 (9.1)	12.1 (8.8)
Race, n (%)		
African American or Black	230 (57.4)	160 (56.9)
American Indian / Alaska Native	5 (1.3)	3 (1.1)
Asian	3 (0.7)	1 (0.4)
Native Hawaiian or Pacific Islander	2 (0.5)	2 (0.7)
White	113 (28.2)	84 (29.9)
More than one race	31 (7.7)	22 (7.8)
Not Reported	17 (4.2)	9 (3.2)
Hispanic, n (%)	108 (26.9)	76 (27.1)
Highest Level of Education Completed, n (%)		
High School or Less	97 (24)	57 (20.3)
Some college, Associates Degree, or Technical Degree	167 (42)	126 (44.8)
College, Post Graduate, or Professional Degree	136 (34)	98 (34.9)
Not Reported	1 (0.2)	0 (0)
Employment, n (%)		
Full-Time	87 (22)	67 (23.8)
Part-Time	88 (22)	66 (23.5)
Unemployed	156 (39)	109 (38.8)
Disabled	63 (16)	37 (13.2)
Retired	3 (0.7)	1 (0.4)
Not Reported	4 (1.0)	1 (0.4)
Alcohol Use Disorder Symptoms, n (%)	116 (28.9)	79 (28.1)
Depressive Symptoms, n (%)	194 (48.4)	129 (45.9)
Perceived Stress, n (%)		
Low Perceived Stress	125 (31.2)	88 (31.3)
Moderate Perceived Stress	231 (57.6)	164 (58.4)
High Perceived Stress	45 (11.2)	29 (10.3)
HIV Stigma, mean (sd)		
Internalized Stigma	2.2 (1.1)	2.2 (1.1)
Anticipated Stigma	2.0 (0.9)	2.0 (0.9)
Enacted Stigma	1.5 (0.7)	1.5 (0.7)
Social Support Scale, mean (sd)		

Demographics	Total (n = 401)	Anal Sex (n = 281)
Emotional Support	3.5 (1.2)	3.5 (1.2)
Tangible Support	3.1 (1.4)	3.0 (1.4)
Affectionate Support	3.5 (1.3)	3.5 (1.4)
Social Interaction Support	3.6 (1.3)	3.6 (1.3)
Overall Social Support	3.4 (1.1)	3.4 (1.2)
Viral Load Measures		
Viral Load, n (%)		
Suppressed VL (< 200 copies / mL)	317 (79.1)	222 (79.0)
Unsuppressed VL (≥ 200 copies/mL)	83 (20.7)	58 (20.6)
Not Reported	1 (0.2)	1 (0.4)
Viral Load (Biological) [Categories], n (%)		
< 200 copies/mL	317 (79.1)	222 (79.0)
200 – 999 copies/mL	14 (3.5)	8 (2.8)
1000 – 4999 copies/mL	15 (3.7)	10 (3.5)
5000+ copies/mL	54 (13.5)	40 (14.2)
Not Reported	1 (0.2)	1 (0.4)

Table 2.**Baseline Self-reported Recent Drug Use and Positive Urinalysis Results**

Drug Use Measures	Total (n = 401)	Anal Sex (n = 281)
Marijuana Use, n (%)		
Self-reported Use (Past 6 Months)	250 (62.3)	183 (65.1)
Positive urinalysis	165 (41.9)	116 (41.3)
Methamphetamine Use, n (%)		
Self-reported Use (Past 6 Months)	99 (24.7)	82 (29.2)
Positive urinalysis	58 (14.7)	47 (16.7)
Amphetamine Use, n (%)		
Self-reported Use (Past 6 Months)	16 (4.0)	12 (4.3)
Positive urinalysis	45 (11.4)	39 (13.9)
Cocaine Use, n (%)		
Self-reported Powder Cocaine Use (Past 6 Months)	83 (20.7)	60 (21.4)
Self-reported Crack Cocaine Use (Past 6 Months)	41 (10.2)	26 (9.3)
Positive urinalysis	52 (13.2)	31 (11.0)
Opioid Use, n (%)		
Self-reported Painkillers Use (Past 6 Months)	41 (10.2)	27 (9.6)
Self-reported Heroin Use (Past 6 Months)	6 (1.5)	1 (0.4)
Positive urinalysis	5 (1.3)	4 (1.4)
Other Past 6-Months Drug Use (Self-reported), n (%)		
Poppers	161 (40.1)	131 (46.6)
Downers	8 (2.0)	4 (1.4)
GHB	54 (13.5)	44 (15.7)
Ketamine	14 (3.5)	14 (5.0)
Ecstasy	29 (7.2)	23 (8.2)
SpeedBall	2 (0.5)	1 (0.4)
LSD	8 (2.0)	7 (2.5)
Any Drug Use [*] (Self-Report or Positive Urinalysis), n (%)	221 (55.1)	160 (56.9)
Any Stimulant Use ^{**} (Self-Report or Positive Urinalysis), n (%)	199 (49.6)	147 (52.3)

^{*} 1) Past 6-month self-reported use of pain killers, downers, powder cocaine, crack cocaine, amphetamine, methamphetamine, GHB, ketamine, ecstasy, heroin, speedball, or LSD or 2) Positive urinalysis for methamphetamine, amphetamine, cocaine, or opioids.

^{**} 1) Past 6-month self-reported use of powder cocaine, crack cocaine, amphetamine, methamphetamine, or ecstasy or 2) Positive urinalysis for methamphetamine, amphetamine, cocaine

Table 3.

Definition 1: Predictors of condomless anal sex among those having anal sex with men in past 3 months (n = 281)

Variable	CAS (n = 118)	No CAS (n=163)	Bivariate RR	Multivariable RR
Age, mean (sd)	37.3 (10.2)	39.4 (10.4)	1.0 (1.0, 1.0) [#]	1.0 (1.0, 1.0) [#]
Years living with HIV, mean (sd)	10.4 (7.8)	13.4 (9.2)	1.0 (1.0, 1.0) [*]	1.0 (1.0, 1.0) [#]
White, n (%)	42 (35.6)	42 (25.8)	1.3 (1.0, 1.7) [#]	1.2 (0.9, 1.5)
Hispanic, n (%)	33 (28.0)	43 (26.4)	1.0 (0.8, 1.4)	--
Graduated college or more, n (%)	58 (49.2)	40 (24.5)	1.8 (1.4, 2.4) [*]	1.8 (1.4, 2.4) [*]
Alcohol Use Disorder Symptoms, n (%)	38 (32.2)	41 (25.3)	1.2 (0.9, 1.6)	--
Any Drug Use [^] , n (%)	71 (60.2)	89 (54.6)	1.1 (0.9, 1.5)	--
Stimulant Drug Use [^] , n (%)	66 (55.9)	81 (49.7)	1.2 (0.9, 1.5)	--
Depressive Symptoms, n (%)	64 (55.2)	65 (40.4)	1.4 (1.1, 1.9) [*]	1.2 (0.9, 1.6)
HIV Stigma Scale				
Internalized Stigma	2.3 (1.1)	2.1 (1.1)	1.1 (1.0, 1.2)	--
Anticipated Stigma	2.1 (0.9)	2.0 (0.9)	1.1 (1.0, 1.3)	--
Enacted Stigma	1.6 (0.7)	1.5 (0.7)	1.1 (0.9, 1.3)	--
Moderate / High Perceived Stress	86 (72.9)	107 (65.6)	1.2 (0.9, 1.7)	--
Social Support Subscales				
Emotional	3.4 (1.2)	3.5 (1.2)	1.0 (0.9, 1.1)	--
Tangible	2.9 (1.4)	3.1 (1.4)	0.9 (0.9, 1.0)	--
Affectionate	3.3 (1.3)	3.6 (1.4)	0.9 (0.9, 1.0) [#]	--
Social Interaction	3.5 (1.2)	3.6 (1.3)	1.0 (0.9, 1.0)	--

* p < 0.05

p < 0.10

[^] Self-reported or positive urinalysis

Table 4.

Definition 2: Condomless anal sex with an HIV-Negative or Unknown Serostatus Partner when viral load was unsuppressed (> 200 copies/mL)

Variable	Unsuppressed VL (n = 17)	Suppressed VL (n = 101)	Bivariate RR	Multivariable RR
Age, mean (sd)	34.5 (9.2)	37.7 (10.3)	1.0 (0.9, 1.0)	--
Years living with HIV, mean (sd)	9.2 (6.5)	10.6 (8.0)	1.0 (0.9, 1.0)	--
White, n (%)	3 (17.7)	39 (38.6)	0.4 (0.1, 1.3)	--
Hispanic, n (%)	3 (17.7)	30 (29.7)	0.6 (0.2, 1.8)	--
Graduated college or more, n (%)	5 (29.4)	53 (52.5)	0.4 (0.1, 1.2) [#]	0.4 (0.2, 1.0) [#]
Alcohol Use Symptom Disorder, n (%)	4 (23.5)	34 (33.7)	0.6 (0.2, 1.9)	--
Any Drug Use [^] , n (%)	14 (82.4)	57 (56.4)	3.1 (0.9, 10.2) [#]	2.3 (0.6, 7.9)
Stimulant Drug Use [^] , n (%)	13 (76.5)	53 (52.5)	2.6 (0.9, 7.4) [#]	--
Depressive Symptoms, n (%)	13 (76.5)	51 (51.5)	2.6 (0.9, 7.7) [#]	2.0 (0.8, 5.2)
HIV Stigma Scale				
Internalized Stigma	2.7 (1.1)	2.3 (1.1)	1.3 (1.0, 1.8) [#]	--
Anticipated Stigma	2.3 (0.8)	2.1 (0.9)	1.3 (0.9, 1.9)	--
Enacted Stigma	1.9 (0.8)	1.5 (0.7)	1.5 (1.0, 2.3) [*]	1.2 (0.7, 2.2)
Moderate / High Perceived Stress	17 (100)	69 (68.3)	-- ^a	--
Social Support Subscales				
Emotional	2.8 (1.2)	3.5 (1.2)	0.7 (0.5, 0.9) [*]	0.7 (0.4, 1.3)
Tangible	2.5 (1.4)	3.0 (1.5)	0.8 (0.6, 1.1)	--
Affectionate	2.9 (1.2)	3.4 (1.3)	0.8 (0.6, 1.0) [#]	1.1 (0.7, 1.8)
Social Interaction	3.1 (1.3)	3.5 (1.2)	0.8 (0.6, 1.1)	--

*
p < 0.05

p < 0.10

[^]
Self-report or positive urinalysis

^a
All 17 participants with unsuppressed VL had moderate to high perceived stress.

Table 5.

Definition 3: Predictors of at least one partner not on PREP among those with condomless anal sex with HIV-negative or HIV unknown serostatus partners

Variable	+1 Encounter not on PREP (n = 70)	Encounters always PREP (n = 48)	Bivariate RR	Multivariable RR
Age, mean (sd)	36.9 (10.3)	37.8 (10.0)	1.0 (1.0, 1.0)	--
Years living with HIV, mean (sd)	10.5 (7.8)	10.3 (7.9)	1.0 (1.0, 1.0)	--
White, n (%)	23 (32.9)	19 (39.6)	0.9 (0.6, 1.2)	--
Hispanic, n (%)	21 (30.0)	12 (25.0)	1.1 (0.8, 1.5)	--
College Education or Higher, n (%)	34 (48.6)	24 (50.0)	1.0 (0.7, 1.3)	--
Alcohol Use Symptom Disorder, n (%)	27 (38.6)	11 (22.9)	1.3 (1.0, 1.8) [#]	1.4 (1.1, 1.8) [*]
Any Drug Use [^] , n (%)	42 (60.0)	29 (60.4)	1.0 (0.7, 1.3)	--
Stimulant Drug Use [^] , n (%)	40 (57.1)	26 (54.2)	1.1 (0.8, 1.4)	--
Depressive Symptoms	35 (50.7)	29 (61.7)	0.8 (0.6, 1.1)	--
HIV Stigma Scale				
Internalized Stigma	2.2 (1.0)	2.5 (1.2)	0.9 (0.8, 1.0)	--
Anticipated Stigma	2.0 (0.8)	2.2 (0.9)	0.9 (0.8, 1.1)	--
Enacted Stigma	1.5 (0.7)	1.7 (0.8)	0.8 (0.6, 1.0) [#]	0.8 (0.6, 1.0) [*]
Moderate / High Perceived Stress	49 (70.0)	37 (77.1)	0.9 (0.6, 1.2)	--
Social Support Subscales				
Emotional	3.3 (1.3)	3.5 (1.2)	1.0 (0.8, 1.1)	--
Tangible	2.9 (1.5)	2.9 (1.4)	1.0 (0.9, 1.1)	--
Affectionate	3.3 (1.3)	3.3 (1.2)	1.0 (0.9, 1.1)	--
Social Interaction	3.4 (1.2)	3.5 (1.2)	1.0 (0.9, 1.1)	--

* p < 0.05

p < 0.10

[^] Self-reported or positive urinalysis

Table 6.

Definition 4: Predictors of at least one partner not on PREP among those with CAS with HIV-negative or HIV-unknown partners & having an unsuppressed viral load (≥ 200 copies/mL)

Variable	+1 Encounter not on PREP & detect. VL (n = 6)	Lower Transmission Risk (n = 112)	Bivariate RR
Age, mean (sd)	35.2 (9.9)	37.4 (10.2)	1.0 (0.9, 1.1)
Years living with HIV, mean (sd)	10.3 (8.9)	10.4 (7.8)	1.0 (0.9, 1.1)
White, n (%)	0 (0)	42 (37.5)	--
Hispanic, n (%)	1 (16.7)	32 (28.6)	0.5 (0.1, 4.3)
College Graduate or Higher, n (%)	2 (33.3)	56 (50.0)	0.5 (0.1, 2.7)
Alcohol Use Symptom Disorder, n (%)	3 (50.0)	35 (31.3)	2.1 (0.4, 10.0)
Any Drug Use [^] , n (%)	6 (100.0)	65 (58.0)	--
Stimulant Drug Use [^] , n (%)	6 (100.0)	60 (53.6)	--
Depressive Symptoms	6 (100)	58 (52.7)	--
HIV Stigma Scale			
Internalized Stigma	3.2 (1.4)	2.3 (1.1)	1.9 (1.0, 3.7) [#]
Anticipated Stigma	2.2 (0.7)	2.1 (0.9)	1.2 (0.6, 2.1)
Enacted Stigma	1.8 (1.0)	1.6 (0.7)	1.5 (0.6, 3.7)
Moderate / High Perceived Stress	6 (100)	80 (71.4)	--
Social Support Subscales			
Emotional	2.0 (1.1)	3.5 (1.2)	0.4 (0.2, 0.9) [*]
Tangible	1.4 (0.7)	3.0 (1.4)	0.3 (0.1, 0.8) [*]
Affectionate	2.3 (1.4)	3.4 (1.3)	0.5 (0.3, 1.1) [#]
Social Interaction	2.4 (1.4)	3.5 (1.2)	0.5 (0.3, 1.0) [#]

^{*}
p < 0.05

[#]
p < 0.10

[^]
Self-reported or positive urinalysis