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Perceived Versus Calculated HIV Risk: Implications for Pre-exposure Prophylaxis Uptake in a Randomized Trial of Men Who Have Sex With Men

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Background: Inaccurate HIV risk perception by men who have sex with men is a barrier to HIV prevention. Providing information about objective HIV risk could improve pre-exposure prophylaxis (PrEP) uptake.

Methods: PrEP Accessibility Research & Evaluation 2 (PrE-PARE2) was a randomized controlled trial of men who have sex with men to determine whether an objective risk score affects future PrEP uptake. Participants completed a baseline survey to assess demographics, risk behaviors, and HIV self-perceived risk (SPR). The survey generated a calculated HIV risk (CalcR) score, estimating HIV risk based on reported condomless anal intercourse and sexually transmitted infections, and was provided to individuals in the intervention arm. Participants were contacted 8 weeks later to determine whether they initiated PrEP.

Results: Of 171 participants (median age 32 years; 37% Hispanic or non-Hispanic Black; median 5 sexual partners in the past 6 months), 81% had heard of PrEP, and 57% believed they were good PrEP candidates. SPR had poor agreement with CalcR (kappa = 0.176) with 38% underestimating their HIV risk. At week 8, only 14 of 135 participants had initiated PrEP with no difference between arms (CalcR 11%, control 10%, P > 0.99). The most common reason for not starting PrEP was low HIV risk perception. There was a relative decrease in SPR over time (P = 0.06) but no difference between arms (P = 0.29).

Conclusion: Providing an objective HIV risk score alone did not increase PrEP uptake. HIV testing performed at testing sites may be a crucial time to correct misperceptions about risk and initiate sameday PrEP, given enthusiasm for PrEP on the testing day to facilitate greater uptake.

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Key Words: pre-exposure prophylaxis, HIV risk perception, men who have sex with men

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INTRODUCTION

Three decades after the onset of the AIDS epidemic, men who have sex with men (MSM) continue to bear a disproportionate burden of HIV, accounting for 67% of incident infections in the United States. The development and licensure of oral pre-exposure prophylaxis (PrEP) with tenofovir disoproxil fumarate and emtricitabine (TDF/FTC) has raised hope in changing this trajectory. Promising trials over the past several years suggest that taking PrEP substantially reduces the risk of HIV infection in high-risk populations including MSM. Oral TDF/FTC has been available through some demonstration projects and is currently covered by most public and private insurance providers, but may require financial assistance through the drug manufacturer or other patient assistance programs.

Despite high efficacy and insurance coverage, PrEP has not been evenly implemented in high-risk communities, which may result in a blunted population level impact.^{9,10} In our previous study, Pre-Exposure Prophylaxis Accessibility Research and Evaluation (PrEPARE), we examined barriers to adopting this mode of HIV prevention among MSM.¹¹ Most subjects were concerned about long-term side effects, daily pill-taking or cost, of which cost/insurance coverage continues to be a significant barrier to PrEP uptake and continuation.¹² However, an additional 35% did not want to take PrEP because they did not perceive themselves to be at high risk of HIV infection. In contrast to their self-perceived risk (SPR), over half of these responders reported unprotected receptive anal sex exposure in the previous 12 months and 7% reported having at least 25 different sex partners. These findings highlight the strong disconnect between an individual's perceived risk of infection and their actual risk that would be estimated by behavioral and demographic risk factors.

Risk perception is an individual's subjective appraisal of the likelihood of an undesirable outcome. Within the context of HIV, it is the perception of the risk of acquiring HIV and the seriousness afforded to seroconversion. It is

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inherently difficult to study because it encompasses both conscious and unconscious thought processes. What confounds the situation further is that medical professionals themselves cannot reach a consensus on what degree of unsafe behavior should define low-, moderate-, and high-risk populations. ^{13,14} Data have shown that low SPR may contribute to increased incidence of HIV in marginalized populations and that there is a great divide between perception and behavior. ^{15–19} Reconciling perceived risk, real-life behaviors, and validated risk indices is essential to effectively implement preventive measures such as PrEP. ^{20–23}

Throughout the course of biomedicine, this reconciliation has often been achieved through the development of objective risk calculators. Incidence of cardiovascular disease and osteoporosis, for example, has been drastically reduced through the use of Framingham and DXA scores, respectively. 24–26 The provision and use of an HIV risk score is hoped to yield similar effects. In 2014, the Center for Disease Control and Prevention (CDC) published the HIV Incidence Risk Index for MSM (HIRI-MSM), the only nationally established HIV risk calculator for MSM. 22,27 In this trial, we use this risk tool and a newly developed HIV risk tool, based on specific HIV transmission events among MSM.

In this study, we investigated whether informing highrisk MSM in San Diego County of their calculated HIV risk would affect their uptake of PrEP and alter their perceived risk. We hypothesized that although MSM would underestimate their risk of HIV acquisition, informing them of their calculated risk would create durable alterations in risk perception and would increase PrEP uptake.

METHODS

Study Procedures

From April 2014 to June 2016, participants were recruited from 3 San Diego HIV testing sites. All participants tested negative by a rapid HIV antibody testing, followed by HIV nucleic acid amplification testing. Inclusion criteria were verified verbally by an independent interviewer who enrolled the subject and included: HIV-negative by rapid test, MSM older than 18 years, and at least 1 act of condomless anal intercourse with an HIV-positive partner or partner of unknown status in the past 6 months. Exclusion criteria included current active usage of PrEP, inability to provide written consent, lack of significant risk of acquiring HIV, and/or signs or symptoms suggestive of acute HIV infection.

Eligible subjects were randomized 1:1 by a computer program to the intervention or control arm. All subjects were given an iPad survey that assessed demographics, SPR, and risk behavior questions and generated an objective risk score. The iPad survey contained 32 questions in total with 3 main components: 3 questions assessing their level of SPR, 13 demographic questions, and 16 questions assessing risk behaviors used to calculate 2 different objective risk scores, the HIRI-MSM and the calculated HIV risk (CalcR) scores, described in the following text in more detail. The survey was only offered in English, and all participants referred for the study were proficient in English.

After completing the survey, participants in the intervention arm were provided their CalcR score result compared with the average risk of HIV seroconversion in MSM, which was then further categorized as low, moderate, high, or very high risk, with a short explanation of each category. These results were given to the intervention arm both on the iPad and verbally by the interviewer. Both groups received standard risk reduction counseling along with a brief description of PrEP and how to access it on their own if desired, but no prescriptions or study drug were provided.

Participants were contacted by phone 8 weeks after the enrollment/survey date (week 0) to determine whether they initiated PrEP or not (defined as having taken a single dose or more of PrEP in the 8-week period) and to reassess their HIV risk. They were also asked to complete an online survey (week 12) with questions about SPR and recent risk behaviors to calculate a second CalcR score.

The study plan and subsequent changes were approved by the University of California San Diego Human Research Protections Program Institutional Review Board. The first 76 subjects were mailed a \$5 gift card after completing the follow-up phone call and online survey. To increase enrollment, the subsequent 95 subjects were given a \$5 gift card after enrollment and a second \$5 gift card on study completion.

HIV Risk Measures Objective

HIRI-MSM

As described above, the HIRI-MSM was developed through statistical analysis of behavioral and HIV testing data from 2 large prospective studies including 6654 MSM participants. ²² The HIRI-MSM uses the following 7 questions to generate an HIV risk score: age, number of MSM partners, number of HIV-positive partners, instances of unprotected receptive anal intercourse, instances of unprotected insertive anal intercourse, use of amphetamines, and use of poppers over the past 6 months. ²² Scores range from 0 to 47; scores of 10 or higher confer substantial HIV risk and should prompt providers to discuss HIV prevention strategies including PrEP. ²⁷

CalcR Score

The CalcR Score was developed as an alternative tool to evaluate HIV risk based on patient-specific HIV transmission events. The score is generated from a mathematical equation that focuses on sexual transmission methods and biological factors that may increase HIV acquisition: condomless receptive and insertive anal intercourse acts and sexually transmitted infections (STIs) including gonorrhea, chlamydia, syphilis, and herpes. It previously included shared needle events via injection drug use (IDU) but was removed because of extremely few self-reported IDU events in this study and a previous study using the CalcR Score. It incorporates event frequencies over the past month and established event probabilities of HIV transmission because of condomless anal intercourse acts²⁹ or STI occurrence. ³⁰ As

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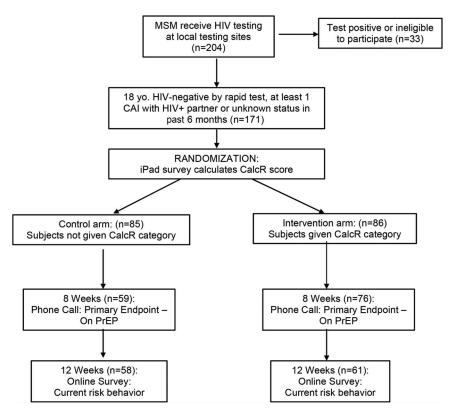


FIGURE 1. Participant study flow. CAI, condomless anal intercourse.

sex frequency is a potential driver of HIV and STI risk among MSM, estimates of sex frequency combined with estimates of HIV risk per sexual act may be useful to model risk by sexual behaviors.³¹ In addition, the short time frame used reduces recall bias that may occur in highly sexually active cohorts. 32,33 The calculated risk score is extrapolated to the percent likelihood of HIV seroconversion in 1 year if their sexual activities persisted at the same rate and is categorized into low (<0.12%), moderate (0.12%-0.59%), high (0.6%-5.9%), and very high (>5.9%) risk groups. Classification is based on the average percent likelihood of HIV seroconversion among MSM in the United States.³⁴ Further details on the CalcR score are available in Supplementary Materials. The CalcR score has not been validated in prospective clinical studies primarily because of the specific data collected, which include condomless anal sex act frequency per partner over a short period of time. Traditional sexual risk surveys among MSM elicit information regarding sexual behaviors including number of sex partners over long recall periods (eg, 3 or 6 months), despite the known effect of number of sex acts (or possible HIV exposures) on HIV acquisition risk.³⁵

Subjective

SPR Score

The SPR score is based on 3 questions about self-perceived HIV risk adopted from a validated HIV SPR survey²¹ using Likert scales: (1) How likely is it that you will become HIV-positive in the next year? (0 = extremely unlikely; 1 = very unlikely; 2 = somewhat likely; 3 = very likely; or 4 = extremely likely); (2) How likely is it that you

will become HIV-positive in your lifetime? (0 = extremely unlikely; 1 = very unlikely; 2 = somewhat likely; 3 = very likely; or 4 = extremely likely); and (3) My gut feeling is that I will NOT get infected with HIV (0 = strongly disagree; 1 = disagree; 2 = somewhat disagree; 4 = agree; or 5 = strongly agree). The SPR score was calculated as the sum of 3 questions and ranged from 0 to 13 and was divided into 4 risk categories: low (0-3), moderate (4-6), high (7-9), and very high (10-13). The SPR score was obtained at weeks 0 and 12.

Self-perceived Likelihood of HIV Acquisition (LHA Score)

The LHA score is the percent likelihood from 0% to 100% that participants believed they would become HIV-infected in the next year. At weeks 0 and 12, it was obtained through a survey, and at week 8, it was reported to the study coordinator by phone.

Statistical Analysis

Baseline characteristics were summarized and compared between study arms using the Wilcoxon rank-sum test for continuous variables and the Fisher exact test for categorical variables. Cross-tabulation was used to compare SPR versus CalcR and HIRI-MSM risk categories. Cohen's kappa coefficient was calculated to assess the agreement between the subjective and objective risk measures. Self-perceived underestimation of HIV risk was defined if SPR score category was below the CalcR risk category.

The primary outcome was the initiation of PrEP at week 8. The Fisher exact test was used to compare the proportions between the study arms. Secondary outcomes included the

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TABLE 1. Demographics and Baseline Risk Behaviors

	Control n = 85, N (%)	Intervention n = 86, N (%)	Total n = 171, N (%)
Age*	36 (27–44)	30 (24–40)	32 (25–42)
Race			
White	51 (60%)	51 (59%)	102 (60%)
Black	7 (8%)	6 (7%)	13 (8%)
Other	27 (32%)	29 (34%)	56 (33%)
Ethnicity			
Latino	20 (26%)	26 (31%)	46 (29%)
Education†			
Some college or higher	81 (95%)	76 (88%)	157 (92%)
Monthly income			
<\$3000	39 (48%)	50 (63%)	89 (55%)
Insurance			
Public	12 (14%)	13 (15%)	25 (15%)
Private	53 (62%)	53 (62%)	106 (62%)
None	15 (18%)	13 (15%)	28 (16%)
No. of partners past 6 months*	5 (3–10)	5 (3–10)	5 (3–10)
Substance use	23 (27%)	29 (34%)	52 (30%)
Methamphetamine use	4 (5%)	4 (5%)	8 (5%)
Popper use	10 (12%)	14 (16%)	24 (14%)
PrEP awareness	71 (84%)	68 (79%)	139 (81%)
Previous PrEP use	3 (4%)	4 (5%)	9 (5%)
Perceived PrEP candidacy	47 (55%)	50 (58%)	97 (57%)
SPR score*	3 (2–5)	4 (3–5)	3 (2–5)
SPR HIV transmission score*	14 (4–32)	16 (10–28)	15 (6–29)
CalcR score*	0.23 (0-0.42)	0.26 (0.1– 0.51)	0.26 (0.1–0.44)
HIRI-MSM*	18 (11–23)	18 (14–22)	18 (13–22)

P values < 0.05.

proportion of those considering PrEP and change in objective and subjective risk measures. The Wilcoxon signed-rank test was used to assess the overall change, and the Wilcoxon ranksum test was used to compare the change between study arms. A P value of <0.05 was considered statistically significant. No adjustments were made for multiple comparisons. Statistical analyses were performed in R (http://cran.r-project.org), version 3.3.3.

RESULTS

Participant Flow and Baseline Characteristics

A total of 204 MSM were approached for the study if they expressed interest in the study and potentially met study criteria based on information they provided to HIV testing counselors during testing. Thirty-three of these individuals were ineligible to participate because of lack of sufficient risk (ie, did not have any condomless anal sex with a HIV-positive or unknown status partner) or already on PrEP. One hundred seventy-one individuals were enrolled and randomized to control or intervention arms. Retention was 79% (n = 135) for the primary endpoint at week 8 and 67% (n = 119) at week 12 (Fig. 1). Of 171 participants enrolled, the median age was 32 years [interquartile range (IQR) 25-42], 29% identified as Latino, 60% as White, and 8% as Black. Ninety-two percent had some college education or more, 55% earned less than \$3000 per month, and 16% were uninsured. The median number of sexual partners in the past 6 months was 5 (IQR 3-10). Thirty percent of participants reported drug use in the past 6 months with 5% using methamphetamines and 14% using amyl nitrates (ie, poppers). Although only n = 7 (4%) had used PrEP before, 81% had heard of PrEP and 57% believed they would be a good candidate to take PrEP. Objective and subjective measures of risk were balanced between arms. Further details are shown in Table 1.

Comparison of Subjective and Objective HIV Risk

Based on the SPR score, n = 90 (53%) considered themselves low risk, n = 65 (38%) moderate risk, and n = 16(9%) high or very high risk. The median CalcR score was 0.26% (IQR 0.1%-0.44%) with n = 60 (35%) categorized as low risk, n = 79 (46%) as moderate risk, and n = 32 (19%) as high or very high risk. Thus, n = 65 (38%) underestimated their HIV risk, n = 83 (49%) had concordant predictions, and n = 23 (13%) overestimated their risk (kappa = 0.176) (Table 2). The 32 MSM in the CalcR high-risk category were particularly poor at estimating their risk with over 90% underestimating their risk. Using the HIRI-MSM score, the mean HIRI-MSM score was 18 (SD 8) with n = 24 (14%) categorized as low risk and n = 147 (86%) as high risk. When comparing SPR score with HIRI-MSM, n = 75 (44%) underestimated their risk, n = 87 (51%) had concordant predictions, and only n = 9 (5%) overestimated their risk (kappa = 0.053) (Table 3).

Comparison of Objective HIV Risk Scores

Table 4 shows the comparison between the CalcR risk and HIRI-MSM risk. Only 8 of the 111 individuals in the moderate or high CalcR risk group were classified as low risk by the HIRI-MSM. However, nearly three-quarters (44/60) of the individuals considered low risk by CalcR were classified as high risk by HIRI-MSM, resulting in overall moderate concordance (kappa = 0.226) (Table 4).

PrEP Uptake

At week 8, n = 135 participants were reached for follow-up, notably n = 76 (88%) in the intervention arm and n = 59 (69%) in the control arm (P = 0.003). Attrition rate for the primary endpoint was 21%, with these participants unreachable by phone despite repeated call attempts. Of the 135 who reached for follow-up, only n = 14 (10%) started PrEP including n = 8/76 (11%) who received their risk score and n = 6/59 (10%) who did not. Nearly 70% (n = 93)

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^{*}Median (IQR).

[†]P values < 0.05 except for education.

TABLE 2. Objective Compared With Subjective HIV Risk (CalcR Versus SPR)

	CalcR			
	Low	Moderate	High/Very High	Total
SPR				
Low	42 (25%)	36 (21%)	12 (7%)	90
Moderate	10 (6%)	38 (22%)	17 (10%)	65
High/very high	8 (5%)	5 (3%)	3 (2%)	16
Total	60	79	32	171

Forty-nine percent concordant (bold); 38% underestimated risk (italics); and 14% overestimated risk (bold italics) (kappa = 0.176).

believed about starting PrEP with n = 54 (71%) in the intervention and n = 39 (66%) in the control. There were no differences by arm in either PrEP uptake or consideration. We did find that higher risk participants by CalcR were more likely to be on PrEP at follow-up compared with those with lower risk, regardless of risk score receipt (15% in high and moderate risk groups versus 2% in the low-risk group (P =0.042). Of the 121 participants who did not start PrEP, the most common reasons were low SPR (36%) and concerns about side effects (19%) with no difference by arm. Of note, n = 18 (15%) reported waiting to get into a study or see a provider to get PrEP. We included these participants as having reached the primary endpoint and observed a slight separation in PrEP uptake in the intervention and control groups but still did not observe a statistically significant difference (28% versus 19%, P = 0.31). A complete summary of participants' reasons for not going on PrEP is shown in Table 5.

Change in Subjective HIV Risk

SPR was compared at baseline and week 12. There was a trend toward decreased SPR overall (median = 0, IQR: -2 to 1, P = 0.06) but no difference between study arms (P = 0.29). The LHA score was compared at baseline, week 8, and week 12. Overall, there was a significant decrease in LHA score from baseline to week 8 (median = -3.6%, IQR: -15% to 5.5%, P = 0.006) but no difference by study arm (P = 0.604). From baseline to week 12, there was a trend toward decreased LHA overall (median = -1.8%, IQR: -11.5% to 5%, P = 0.06) but no difference by study arm (P = 0.39).

TABLE 3. Objective Compared With Subjective HIV Risk (HIRI-MSM Score Versus SPR)

	HIRI-MSM		
	Low	High	Total
SPR			
Low	15 (9%)	75 (44%)	90
>Low	9 (5%)	72 (42%)	81
Total	25	146	171

Fifty-one percent concordant (bold); 44% underestimated risk (italics); and 5% overestimated risk (bold italics) (kappa = 0.053).

There was no change in perceived PrEP candidacy between baseline and week 12 (57% versus 58%, P > 0.99).

DISCUSSION

Despite enrolling a high-risk population of MSM who often underestimated their risk for HIV acquisition, providing an objective HIV risk score to individuals did not increase their likelihood of starting or even considering PrEP. Our study suggests that by itself, a risk score elucidating actual HIV risk may not be enough to increase PrEP uptake. However, individuals who received their HIV risk score were more likely to follow-up, which may indicate some acknowledgment of true risk and interest in PrEP. An assessment of HIV risk may be a starting point for further discussion around prevention methods.

MSM who test at dedicated HIV-testing sites may be acceptable to discussion and even initiation of PrEP. Although there are individuals who regularly test and who may be part of the "worried well," 65% of our study population was found to be at substantial objective risk of HIV acquisition based on CalcR score and 85% with the HIRI-MSM score at baseline. The reason for this discrepancy between CalcR and HIRI-MSM risk scores is likely due to a higher dependency of objective HIV risk related to condomless sex acts during a discrete period of time in CalcR compared with a composite of behavioral factors in HIRI-MSM over a longer time course. This difference could be interpreted as CalcR missing individuals with certain highrisk behaviors (eg, methamphetamines). Alternatively, CalcR scores may be more accurate because it recognizes that non-IDU does not in itself confer HIV risk—it is the associated sexual acts that are pertinent. In addition, the shorter time period used in CalcR score decreases the potential for recall bias. Of the 14 individuals who initiated PrEP, it is worth noting that 93% of these PrEP users had moderate (n = 9) or high (n = 4) objective HIV risk. This finding not only indicates that PrEP was appropriately used by those at substantial risk of HIV in our study but also suggests that the CalcR risk score may be a useful tool to predict which individuals will start PrEP. To determine whether patientspecific HIV transmission events can accurately predict HIV acquisition, further validation of CalcR is needed against an HIV acquisition data set with event-level data for STIs and the number of sex acts that preceded HIV incident cases.

TABLE 4. Comparison of Objective HIV Risk (CalcR Versus HIRI-MSM)

	HIRI-MSM		
	Low	High	Total
CalcR			
Low	16 (9%)	44 (26%)	60
Moderate/high	8 (5%)	103 (60%)	111
Total	24	147	171

Sixty-nine percent concordant (bold); 26% high-risk HIRI-MSM/low-risk CalcR (italics); and 5% high-risk CalcR/low-risk HIRI/MSM (bold italics) (kappa = 0.226).

TABLE 5. Reported Reasons for Not Going on PrEP

Reason	Control (n = 53)	CalcR (n = 68)	Total (n = 121)
Did not think they were at risk	18 (34%)	25 (37%)	43 (36%)
Side effects/toxicity	12 (23%)	11 (16%)	23 (19%)
Waiting to get into the study or see a doctor to get it	5 (9%)	13 (19%)	18 (15%)
No insurance or physician	6 (11%)	7 (10%)	13 (11%)
Too expensive	6 (11%)	3 (4%)	9 (7%)
Wanted more data/info	2 (4%)	3 (4%)	5 (4%)
Stigma	1 (2%)	1 (2%)	2 (2%)
No free study available	0	1 (2%)	1 (1%)
HIV+ by nucleic acid test	1 (2%)	0	1 (1%)
Other	2 (4%)	4 (6%)	6 (5%)

In addition, despite no statistically significant change in self-perceived HIV risk throughout the study, there was a trend toward lower SPR at follow-up. Studies have found that perceived elevated risk is a common reason for HIV testing that underscores the importance of discussing and offering PrEP around HIV testing. After receiving risk reduction counseling, individuals may also believe they can make behavioral changes to gain better control over their HIV risk. Thus, affording individuals time and space to consider PrEP and other HIV prevention strategies could ultimately dissuade them from starting PrEP.

As in previous studies, many individuals underestimated their risk of HIV acquisition compared with actual risk.^{38–40} Low perceived HIV risk has been shown to be related to erroneous beliefs about HIV transmission and epidemiology.41,42 Thus, PrEP screening in MSM should include education about behaviors that increase HIV acquisition risk. Beyond HIV knowledge, HIV risk perception in MSM is likely influenced by nonepidemiologic factors including relationship type, partner trust, and perceived threat of HIV infection, 43 which objective risk scores do not take into account. As a result, there may be instances when objective risk is overestimated and subjective risk is more accurate. Further research is needed to understand the constructs that shape HIV risk perception, which may lead to better alignment of subjective and objective HIV risk and more appropriate HIV prevention interventions for MSM.

The study had several limitations. Most significantly, the study was underpowered because of initial slow study uptake and attrition at week 8. In addition, follow-up at 8 weeks may not have been sufficient time to reach the primary endpoint. As a result, it is difficult to draw final conclusions about PrEP uptake and consideration. Data capture was different at all 3 time points because of study constraints with the use of an iPad survey at the study site at baseline, verbal report through phone call to the study coordinator at week 8, and an online survey to be completed at the participant's choosing at week 12. Similar to HIRI-MSM, our intervention also does not adjust for viral load of partnership and therefore can overestimate actual risk for individuals who have partners with suppressed viral loads. Assessing viral status of HIV-infected partners is difficult, as

it relies on accurate knowledge of partners' HIV status, ART use, and adherence. Providing ranges of risk probability with and without partner viral suppression could be a strategy to improve the validity of CalcR scores. Finally, as previously discussed, the CalcR score and categories have not yet been validated in prospective studies of HIV incidence because of data element incompatibility with traditional sexual behavior questions.

In this cohort of at-risk MSM, providing an objective HIV risk score alone did not increase future PrEP uptake or change self-perceived HIV risk despite most recognizing PrEP candidacy. Discordance between perceived and actual risk may be a barrier to effective PrEP implementation, and efforts to develop population-specific HIV risk tools that combine an assessment of both local epidemiological and behavioral risk. Nevertheless, because HIV risk perception may be slightly higher around HIV testing, HIV testing may be a crucial time to help correct misperceptions about HIV risk and acquisition and initiate same-day PrEP to facilitate greater uptake.

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