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Development and Validation of the Personalized Sexual Health Promotion (SexPro) HIV Risk Prediction Model for Men Who Have Sex with Men in the United States

Hyman Scott¹ • Eric Vittinghoff² · Risha Irvin³ · Albert Liu¹ · LaRon Nelson⁴ · Carlos Del Rio⁵ · Manya Magnus⁶ · Sharon Mannheimer⁷ · Sheldon Fields⁸ · Hong Van Tieu⁹ · Irene Kuo⁶ · Steve Shoptaw¹⁰ · Beatriz Grinsztejn¹¹ · Jorge Sanchez¹² · Steven Wakefield¹³ · Jonathan D. Fuchs¹⁴ · Darrell Wheeler¹⁵ · Kenneth H. Mayer¹⁶ · Beryl A. Koblin⁹ · Susan Buchbinder¹

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Abstract

Accurate HIV risk assessment among men who have sex with men (MSM) is important to help providers assess risk, and target HIV prevention interventions. We sought to develop an evidence-based HIV risk assessment tool for US MSM that is inclusive of Black MSM. Data from four large longitudinal cohorts of MSM were used to develop (EXPLORE), and validate (VAX004, HPTN061, and HVTN505). These data included visits in which participants self-reported HIV risk behavior and underwent HIV testing. We developed a pooled logistic model for incident HIV infection based on self-reported risk behaviors during the 6 months before each study visit. A total of 4069 MSM were used for the development cohort, and 8047 MSM in the three validation cohorts through 2013. The final model includes age ($<35, \ge 35$); Black race and Latino ethnicity; numbers of HIV-negative anal sex partners; number of insertive or receptive anal intercourse episodes; having 1 HIV-negative partner only; self-reported substance use; and bacterial sexually transmitted infection diagnosis. The model showed good discrimination, with C-statistics of 73.1, 71.0, 71.9 in VAX004, HPTN061, and HVTN505 respectively, and acceptable calibration. We developed and validated an HIV risk assessment tool for MSM, which showed good predictive ability, including among the largest cohort of HIV-uninfected Black MSM in the US. This tool is available online (mysexpro.org) and can be used by providers to support targeting of HIV prevention interventions such as pre-exposure prophylaxis for MSM.

Keywords HIV risk assessment · MSM · HIV prevention

Introduction

Men who have sex with men (MSM) are disproportionally impacted by HIV in the United States (US), accounting for two-thirds of new HIV diagnoses in US, while only making up approximately 3% of the US population [1, 2]. There are important racial/ethnic disparities among MSM, with increased HIV prevalence and incidence among Black and Latino MSM despite similar or lower reported HIV risk behavior [3–8]. Highlighting these disparities, the Centers for Disease Control and Prevention (CDC) recently

Hyman Scott hyman.scott@sfdph.org estimated the lifetime risk of HIV infection to be 1 in 6 among MSM overall, but 1 in 2 and 1 in 4 for Black MSM and Latino MSM, respectively [9].

Despite this elevated lifetime HIV risk, self-perceived HIV risk is relatively low among MSM. In a CDC webbased HIV surveillance study, approximately one-third of MSM who had never been tested for HIV reported low perceived HIV risk as the reason for not testing [10]. However, these men often reported high levels of HIV risk behavior: 56% reported more than two male anal sex partners in the past 12 months, and 37% reported condomless anal intercourse. Low perceived HIV risk is even more pronounced among young MSM. In the Young Men's Study, nearly 75% of participants in this study perceived themselves at low lifetime risk for HIV, despite 32% reporting four or more

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partners in the prior 6 months, and 21% having been diagnosed with a recent sexually transmitted infection (STI) [11].

Prior HIV risk assessment tools have been developed for clinicians, without a focus on improving self-assessment of HIV risk among MSM. Menza and colleagues developed an HIV risk assessment tool from a clinical cohort of 1900 MSM who were repeat HIV testers in Seattle, Washington [12]. Based on the answers to four questions about sexual risk behavior, popper or methamphetamine use, and previous STI diagnosis, patients were stratified into one of four categories of HIV seroconversion risk from low (< 5%) to very high (>14%). Another tool, the HIV Incidence Risk Index for MSM (HIRI-MSM), was developed using two longitudinal cohorts of MSM in the US by the CDC, and is intended to support targeting of HIV prevention interventions for MSM [13]. Finally, the San Diego Early Test (SDET) score was developed in a clinical cohort of acute and early HIV infected patients in San Diego [14]. This tool was developed with a focus on MSM who may be at risk for early or acute HIV infection.

These HIV risk tools, primary designed for use by clinicians, have similar ability to identify MSM at risk for HIV using a short behavioral questionnaire. However, they were developed in clinical or longitudinal cohorts of mostly White MSM in the US, and have not been validated in more contemporary cohorts, or cohorts that include large numbers of Black MSM, the group most disproportionally impacted by HIV in the US. A recent study found that these risk tools were poor at predicting HIV seroconversion among a cohort of young Black MSM [15].

Given the limitations of the currently available HIV risk tools, the goal of this project was to develop an evidencebased HIV risk assessment tool for use by providers and individuals at risk, and validate it in a large, contemporary, and diverse cohort of MSM to assess applicability to Black MSM. This Sexual Health Promotion (SexPro) tool could assist providers in appropriately targeting HIV prevention options with their patients, and by MSM to evaluate their HIV risk and support making more informed decisions regarding HIV risk reduction options. Finally, development onto a web-based platform would allow providers and patients to complete the HIV risk assessment on a userfriendly interface in both clinical and non-clinical settings.

Methods

EXPLORE was used to develop the SexPro model, and data from VAX004 was used for initial external validation [16, 17]. Two more recent, large, longitudinal HIV prevention trials—HIV Vaccines Trials Network (HVTN) 505 and HIV Prevention Trials Network (HPTN) 061—were used for additional validation [18–20].

Development Cohort

EXPLORE enrolled 4295 MSM in six US cities from 1999–2001 into a randomized clinical trial comparing an intensive ten-session behavioral intervention to standard risk reduction counseling [16]. Participants were followed every 6 months until study completion in 2003. EXPLORE enrolled HIV-negative men who reported anal intercourse with at least one male partner in the past 12 months, excluding those who had been in mutually monogamous relationships for two or more years with a male partner known to be HIV negative. Because the study did not demonstrate efficacy against HIV acquisition in the behavioral intervention arm, all participants were included in the development of the SexPro model.

Validation Cohorts

Initial external validation of the model was conducted using data from the VAX004, a longitudinal HIV prevention cohort study of MSM in the US. The VAX004 trial enrolled 4643 MSM in 57 sites in the U.S., Canada, and the Netherlands (only participants from US sites were used for this analysis) from 1998-1999 in a randomized placebo-controlled efficacy trial of a recombinant gp120 HIV-1 vaccine [17]. Participants were followed at sixmonth intervals for 36 months and the study was completed in 2002. VAX004 enrolled HIV-negative men who reported anal intercourse with at least one male partner in the past 12 months, and excluded men who had been in mutually monogamous relationships for the previous year or reported injection drug use (IDU) at baseline. This study failed to show efficacy against HIV acquisition in the vaccine arm, so all participants were used in this analysis.

The HIV Prevention Trials Network (HPTN) 061 study was a multi-site cohort study designed to determine the feasibility and acceptability of a multi-component (behavioral and structural) intervention for Black MSM [19, 20]. The study was conducted in six US cities from 2009–2013, and enrolled 1553 Black MSM, including 1164 initially HIV-negative men who were eligible for follow-up for this analysis. Study participants were followed up at 6 months and 1 year.

Finally, HIV Vaccine Trials Network (HVTN) 505 enrolled 2504 MSM and transgender women in 18 US cities from 2009–2013 into a randomized placebocontrolled trial of a DNA/rAd5 vaccine regimen [18]. Participants were followed at 1–3 month intervals for 24 months. The vaccinations were stopped in 2013 by the Data Safety Monitoring Board (DSMB) for lack of efficacy. Accordingly, this analysis used data collected by the time of the DSMB meeting for all placebo and vaccine participants.

Demographics

Participants in all study cohorts were asked to selfreport race and ethnicity at baseline. Participants could report both race and Latino ethnicity in all cohorts except VAX004. Since age categories were available in EXPLORE, exact ages were categorized to \leq 35 or > 35 years for the validation cohorts (VAX004, HPTN 061, and HVTN 505).

HIV Risk Behavior

Self-reported sexual risk behavioral data were collected via audio-computer-assisted self interview (EXPLORE, HPTN 061, and HVTN 505) or structured counselor-administered interview (VAX004), and included sexual behaviors in the past six (EXPLORE, HPTN 061, VAX004) or 3 months (HVTN 505), including receptive and insertive anal intercourse episodes without a condom (ncRAI and ncIAI), as well as receptive anal episodes with a condom (cRAI), all by perceived partner HIV-serostatus. Other self-reported behavioral risk factors collected in all cohorts included use of poppers and methamphetamine, heavy alcohol use (≥ 4 drinks daily, or ≥ 6 drinks on any occasion), and bacterial STIs such as gonorrhea, chlamydia, and syphilis.

Initial Model Development

We developed a pooled logistic model for incident HIV infection at each follow-up EXPLORE visit based on selfreported HIV risk behaviors during the preceding 6 months. Each participant contributed multiple observations, one for each semi-annual visit up until the time of HIV infection or the end of study follow-up. In addition to sexual risk behaviors, we considered included age, race/ethnicity, any use of methamphetamines and/or poppers, heavy alcohol use, and indicators for STIs. To allow for non-linearity, numbers of sexual risk episodes and numbers of sexual partners were modeled allowing different effects above and below counts of 10. Candidate models were compared in terms of the C-statistic, or area under a ROC curve, a measure of discrimination. To help avoid selecting an over-fitted model, the C-statistic was estimated using 10-fold cross-validation. Models with 6-12 different predictors were considered. The selected model had a cross-validated C-statistic near the maximum and satisfactory goodness of fit.

Adaptation of the Prediction Model for Online Self-Assessment

We converted risk predictions based on the final SexPro model to a 1-20 scale, with 20 denoting low HIV infection risk. Positive (or gain) frame messaging has been used extensively to promote health behaviors, so was used in the design of the SexPro score [21, 22]. This was motivated to forestall misinterpretation of small risk probability estimates, and to focus attention instead on changes in the scores resulting from actual or potential changes in risk behavior. Because age and race/ethnicity were important independent risk factors, young men, particularly younger Black and Latino men, were classified as having relatively high HIV risk even if they reported no sexual or drug use risk behaviors. Accordingly, we reset their scores to the highest score of 20 (lowest HIV risk) in the absence of any reported sexual risk behavior. For the same reason, drug use was not allowed to lower the SexPro score below 20 among MSM reporting no sexual risk behaviors. The model has since been implemented on a website (mysexpro.org) to provide access to MSM for self-assessment and to providers to support targeting of HIV prevention interventions.

External Validation

The model coefficients estimated in EXPLORE for the final SexPro model were used to calculate predicted risks for each participant in the validation cohorts. These risks were then used to calculate the C-statistic. To assess calibration, average predicted 6-month risks were compared to observed 6-month HIV infection rates, stratified by categories of the SexPro score. The HIRI-MSM risk tool was evaluated in the three validation cohorts.

Results

In EXPLORE, 22,577 visits and 217 HIV infections during study follow-up were used to develop the SexPro model (Table 1). For external validation, a total of 433 HIV infections were observed over 25,427, 1692, and 10,652 visits from VAX004, HPTN 061, and HVTN 505, respectively (Table 1). Participants under 35 years were the majority in EXPLORE and HVTN 505, but made up approximately half of VAX004 and HPTN 061 cohorts. All participants in HPTN 061 were Black, while the majority of participants in the other cohorts were White. A higher proportion of participants in VAX004 (43.8%) reported having an HIVpositive partner compared with EXPLORE (28.4%), HPTN 061 (14.6%), or HVTN 505 (18.9%).

Table 1	Baseline demographic and HIV risk characteristics of par-	
ticipant	in EXPLORE, VAX004, HPTN 061, and HVTN 505 cohort	
studies		

Variable	EXPLORE N=4069	VAX004 N=4878	HPTN 061 N=973	HVTN 505 N=2196		
	(%)	(%)	(%)	(%)		
Demographics						
Age ≤ 35 years	60.9	48.8	44.8	68.3		
Black	7.4	3.4	100	18.3		
Latino ethnicity	14.8	0.7	7.7	8.5		
Risk behavior and ch	naracteristics					
Any HIV posi- tive anal sex partners*	28.4	43.8	14.6	18.9		
Number of HIV neg	ative anal sex pa	artners ^a				
0	34.6	43.2	31.6	30.9		
1	18.2	16.3	21.0	26.1		
2–5	31.7	29.3	34.0	35.7		
6–9	5.7	4.5	7.3	3.9		
≥10	9.8	6.7	6.2	3.4		
Number of ncRAI ep	pisodes with HI	V positive or	unknown statu	s partners ^a		
0	72.2	79.2	67.6	75.6		
1	9.8	7.2	9.2	9.6		
2–5	11.0	7.8	12.9	10.3		
6–9	2.8	1.6	2.4	1.6		
<u>></u> 10	4.2	4.1	8.0	2.9		
Number of cRAI epi	Number of cRAI episodes with HIV positive or unknown status partners ^a					
0	57.9	55.9	76.4	70.6		
1	9.9	10.2	7.5	10.4		
2–5	18.5	17.6	9.8	13.0		
6–9	5.6	4.6	2.5	3.0		
<u>≥</u> 10	8.2	11.9	3.8	2.9		
Number of ncIAI ep	isodes with HIV	⁷ positive or u	unknown status	partners ^a		
0	63.5	68.1	45.8	66.2		
1	11.4	8.9	14.8	10.5		
2–5	15.2	11.5	18.4	15.5		
6–9	3.8	2.7	5.8	3.2		
≥10	6.2	8.7	15.2	4.6		
Heavy alcohol use ^a	10.2	10.7	40.4	15.2		
Methamphetamine use ^a	12.8	9.1	9.3	5.7		
Popper use ^a	36.7	32.8	10.4	24.7		
STI ^a	6.5	9.7	4.8	4.7		
Outcomes and event	s					
Participant visits (n)	22,577	25,427	1692	10,652		
HIV infections (n)	217	343	25	65		

Heavy alcohol use was defined as ≥ 4 drinks daily, or ≥ 6 drinks on any occasion

STI was defined as gonorrhea, syphilis, or chlamydia diagnosis by self-report

HPTN HIV prevention trials network, *HVTN* HIV vaccine trials network, *ncRAI* receptive anal intercourse without a condom, *cRAI* receptive anal intercourse with a condom, *ncIAI* insertive anal intercourse without a condom

^aSelf-report in the prior 6 months

Final SexPro Model

The final SexPro model includes the following variables: age ($<35, \geq 35$), Black race and Latino ethnicity, the number of ncRAI contacts with HIV-positive partners or unknown status partners (with a leveling of risk after 10 partners), numbers of ncIAI and cRAI episodes with HIV-positive or unknown status partners, as well as numbers of HIV-negative anal sex partners, and having 1 HIV-negative partner only (Table 2). Other HIV risk variables included heavy alcohol use, use of methamphetamine and poppers, and self-report of gonorrhea, syphilis, chlamydia. Coefficient estimates for the final SexPro model variables are listed in Table 2.

The SexPro model showed good discrimination in the EXPLORE internal validation (C-statistic = 79.5). The external validation cohorts showed good discrimination, with C-statistics of 73.1, 71.0, 71.9 in VAX004, HPTN 061, and HVTN 505, respectively. Figure 1 shows the predicted and observed HIV infection risk in the development and validation cohorts, suggesting acceptable calibration in EXPLORE, HPTN 061, and HVTN 505, but under-predicted risk in VAX004. The area under the receiver operator curve (AUC) was greater than 0.70 for both internal and external validation cohorts (Fig. 2). The HIRI-MSM score showed similar discrimination in VAX004, HPTN 061 and HVTN 505, with C-statistics of 74.0, 75.1 and 73.5 respectively.

Table 3 shows sensitivities and specificities of SexPro scores dichotomized at each possible value from 1 to 20, by cohort. Based on these results, a SexPro score cut off of 16 could be used to identify MSM at increased risk for HIV infection, and maximize sensitivity of the score for Black MSM. SexPro scores of 16 or lower had sample sensitivities for HIV acquisition of 81.1%, 64.4%, 100%, and 75.4%, in EXPLORE, VAX004, HPTN 061, and HVTN 505, respectively, with corresponding specificities of 59.6%, 67.4%, 0%, and 51.8%. The sensitivity and specificity of a HIRI-MSM score of \geq 10 was calculated in EXPLORE (sensitivity 86.6%, specificity 35.7%), VAX004 (sensitivity 82.2%, specificity 45.8%), HPTN 061 (sensitivity 86.2%, specificity 43.2%).

Discussion

The SexPro HIV self-assessment risk tool was developed and validated using four longitudinal cohort studies of MSM in the US, including HPTN 061, the largest cohort study of Black MSM. Developed to support accurate HIV risk self-assessment for MSM in clinical and non-clinical settings, SexPro showed good sensitivity in predicting HIV risk similar to the HIRI-MSM, based on a small number **Table 2** Coefficients used in thefinal sexpro multivariate pooledlogistic model

Variable	Coefficient estimate		
Constant	-5.799		
$Age \leq 35$	0.2703		
Black	0.8749		
Latino	0.4284		
Number of ncRAI episodes with HIV positive or unknown status partners			
Per episode, up to 10 episodes	0.2109		
Per episode, after 10 episodes	0.0024		
Number of cRAI episodes with HIV positive or unknown status partners	0.0322		
Number of ncIAI episodes with HIV positive or unknown status partners	0.0053		
Number of HIV negative anal sex partners	0.0985		
1 HIV negative anal sex partner only	-1.0955		
Heavy alcohol use	0.6450		
Methamphetamine use	0.7663		
Popper use	0.1575		
Gonorrhea, syphilis, or chlamydia diagnosis ^a	0.3570		

Heavy alcohol use was defined as ≥ 4 drinks daily, or ≥ 6 drinks on any occasion

The predicted outcome is HIV infection diagnosed at a follow-up visit

ncRAI receptive anal intercourse without a condom, *cRAI* receptive anal intercourse with a condom, *ncIAI* insertive anal intercourse without a condom

^aSelf-report

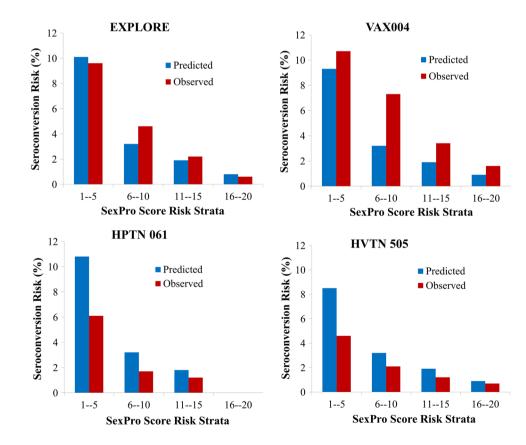


Fig. 1 Predicted and observed HIV infection risk in EXPLORE, VAX004, HIV prevention trials network 061, and HIV vaccine trials network 505 cohort studies. C-statistics for internal validation in the development cohort EXPLORE = 79.5; and external validation cohorts VAX004 = 73.1, HPTN 061 = 71.0, and HVTN 505 = 71.9. The sex pro score risk strata of 16-20 for HPTN 061 is blank because all participants in this cohort had predicted and observed Sex Pro scores of <16

Fig. 2 Area under Receiver Operator Curve (AUC) for Explore, VAX004, HIV Prevention Trials Network 061, and HIV Vaccine Trials Network 505 Cohort Studies. AUC for internal validation in the development cohort EXPLORE = 0.80; and external validation cohorts VAX004 = 0.73, HPTN 061 = 0.71, and HVTN 505 = 0.72

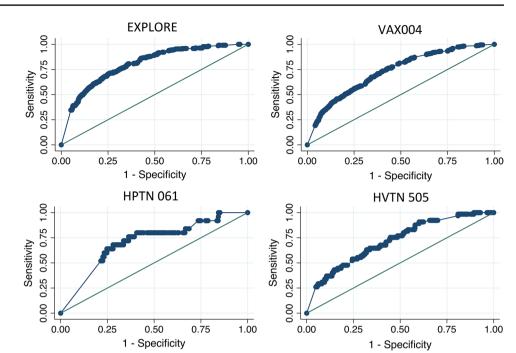


Table 3Sensitivity andSpecificity of SexPro ScoresIn EXPLORE, VAX004, HIVPrevention Trials Network061, and HIV Vaccine TrialsNetwork 505 Cohort Studies

	EXPLORE		VAX004		HPTN 061		HVTN 505	
Score cutoff ^a	Sens.	Spec.	Sens.	Spec.	Sens.	Spec.	Sens.	Spec.
1	34.6	94.9	19.2	95.9	52.0	78.5	26.2	95.1
2	34.6	94.5	20.4	95.5	56.0	77.1	26.2	94.6
3	36.4	94.0	21.3	95.2	60.0	75.3	27.7	94.1
4	39.2	93.5	22.4	94.9	64.0	72.5	29.2	93.6
5	39.2	92.9	23.6	94.5	68.0	69.9	29.2	92.7
6	40.1	92.3	24.2	94.1	72.0	66.1	30.8	91.8
7	41.9	91.6	26.5	93.8	76.0	63.6	30.8	90.9
8	45.6	90.6	28.6	93.1	76.0	60.6	30.8	89.9
9	49.8	89.1	31.5	92.2	80.0	55.9	36.9	88.3
10	52.1	87.6	33.5	91.3	80.0	51.3	36.9	86.6
11	56.2	85.6	35.9	89.9	80.0	46.3	43.1	84.6
12	60.8	82.5	39.9	87.7	80.0	41.0	47.7	80.4
13	63.1	79.6	44.6	84.5	80.0	34.3	53.8	74.9
14	70.0	75.0	49.0	80.6	92.0	22.5	58.5	69.1
15	74.2	69.5	55.1	75.3	92.0	16.1	64.6	61.9
16	81.1	59.6	64.4	67.4	100	0	75.4	51.8
17	92.2	45.9	80.5	51.5	100	0	90.8	38.6
18	96.3	25.7	97.4	19.0	100	0	100	8.8
19	99.1	15.3	100	0	100	0	100	0
20	100	0	100	0	100	0	100	0

The predicted outcome is HIV infection diagnosed at a follow-up visit

HPTN HIV prevention trials network, HVTN HIV vaccine trials network

^aSex Pro scores range from 1–20, with 20 representing the lowest HIV risk

of easily assessed demographic and behavioral variables. SexPro can help MSM get a more accurate assessment of their risk for HIV, and also assist providers in targeting HIV prevention services, in particular PrEP. The SexPro self-assessment tool is available at mysexpro.org.

The SexPro model reflects established understanding of the demographic and behavioral risk factors for HIV acquisition, in particular ncRAI, numbers of partners, heavy alcohol and drug use, and STI, and well as youth and race/ethnicity [23-26]. The substantial inverse weight put by the model on having a single monogamous partner is consistent with CDC clinical practice guidelines against PrEP use by MSM in mutually monogamous relationships with a recently tested HIV-negative man [27]. Similar to other HIV risk prediction scores, substance use was an important predictor of HIV risk in the SexPro model. Methamphetamines were associated with the largest increase in HIV risk, consistent with prior literature [23, 25]. In the model developed by Menza from the clinical cohort in Seattle, Washington, methamphetamine or popper use contributed more than twice as many score points (11 points) as the next highest risk factor, reporting an STI (4 points) [12]. Methamphetamine use is a well described driver of HIV infection among US MSM, although there is regional variability in use [23, 25]. In contrast to the Menza finding, the HIRI-MSM, developed in a cohort in San Diego, did not find non-injection stimulant use (inclusive of methamphetamines) to be an independent risk factor for early HIV infection in their multivariable model [14].

None of the three earlier HIV risk assessment tools for MSM-Menza et al., SDET or HIRI -included race or ethnicity as variables in their scoring algorithms since race and ethnicity were not perceived as modifiable and therefore could not be targeted for risk reduction [12-14]. However, given the important racial/ethnic disparities in HIV risk in the US, often despite similar or lower levels of individual risk behavior, we feel it is important to include these demographic variables in the SexPro risk prediction model [28]. First, a risk score that does not include race and ethnicity will underestimate the HIV risk of Black and Latino MSM, and likely lead to reduced targeting of efficacious HIV prevention options such as PrEP. This was shown by Lancki et al. who found that currently available risk scores have low sensitivity or AUC (HIRI-MSM) among a cohort of young Black MSM with an HIV incidence of 8.5/100 person years [15]. Without accurate risk assessment, these men will be less likely to meet risk criteria for these interventions, exacerbating the already widening HIV disparities [28]. Second, race is a social construct, and the increased risk of HIV infection among Black and Latino MSM is driven by social (i.e., higher HIV prevalence among sexual networks) and structural (i.e., incarceration policies, poverty, etc.) factors disproportionally experienced by these men [29, 30]. So, the social and structural factors that are driving the disparities are potentially "modifiable" at the social or structural level (i.e., incarceration policy changes) and race/ethnicity serves as proxy for these variables [29].

Furthermore, the latest, updated version of the SexPro tool also incorporates U = U, supporting that HIV-positive MSM who are virally-suppressed have negligible risk of transmitting HIV to their sexual partners. Data from several large cohorts covering thousands of condomless anal sex acts among MSM, have not demonstrated any linked HIV transmissions among their HIV-negative partners [31–33]. This message has been supported by many policy, research, and public health organizations including the CDC [34]. While the required data on HIV-positive partner monogamy, treatment, and viral suppression were unfortunately unavailable in the four cohorts used in this report, we have since incorporated the concept of U = U into the SexPro score by adjusting the risk of a virally suppressed HIV-positive partner to the same as a HIV-negative partner. Currently, no other risk tools incorporate the compelling data on the impact of viral suppression of HIV-positive partners on HIV transmission risk.

The SexPro model showed good model fit in all cohorts, but did have a lower specificity at the selected cut off of \leq 16 in HPTN 061 compared with the other cohorts, in part reflecting systematically lower scores for Black MSM. The cut-off of 16 was chosen to emphasize sensitivity, as appropriate for a screening tool used for targeting of HIV prevention interventions [13]. For example, using HIRI-MSM with a recommended score cut-off ≥ 10 had a lower sensitivity in HPTN 061 compared with the other validation cohorts. Our decision to recommend the same cut-off for Black MSM, despite evidence for reduced specificity in this group, was motivated by the disproportionate impact of HIV in this group. SexPro is being used as a screening tool in the clinical trial of injectable cabotegravir as PrEP (HPTN 083) which will provide implementation data in clinical settings [35].

There are important limitations to consider for this study. The initial cohort included MSM from the early combination antiretroviral (cART) era. Since these studies have been completed, there have been advances in HIV treatment recommendations and increases in viral suppression among people living with HIV. However, our prior work demonstrated similar percontact risk for HIV infection among MSM in the pre- and early cART era [26]. The SexPro model was also validated with good model fit in two contemporary longitudinal cohorts of MSM in the US from 2009–2013. Another limitation for the initial development of the SexPro score was the limited racial/ ethnic diversity of the EXPLORE study. The EXPLORE study

sample was only 7% Black and 15% Latino, and VAX004 had even lower proportions of these men. In an effort to ensure applicability to a diverse sample of men, we chose additional validation cohorts with more diverse study participants; it was reassuring that SexPro model fit well in these cohorts. Finally, while the SexPro model requires only a few demographic and sexual risk behavior questions, the calculations are nonetheless complicated, requiring its implementation as a website rather than as a simple checklist with an additive score.

Conclusions

The SexPro tool represents a novel HIV risk self-assessment tool for MSM to assist with targeting HIV prevention strategies. SexPro scores \leq 16 predicted incident HIV infections with good sensitivity and acceptable specificity in large contemporary, diverse cohorts of MSM. This tool can be used by MSM to improve self-assessment of HIV risk, and by providers in targeting and improving uptake of HIV prevention strategies such as PrEP.

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Affiliations

Hyman Scott¹ • Eric Vittinghoff² · Risha Irvin³ · Albert Liu¹ · LaRon Nelson⁴ · Carlos Del Rio⁵ · Manya Magnus⁶ · Sharon Mannheimer⁷ · Sheldon Fields⁸ · Hong Van Tieu⁹ · Irene Kuo⁶ · Steve Shoptaw¹⁰ · Beatriz Grinsztejn¹¹ · Jorge Sanchez¹² · Steven Wakefield¹³ · Jonathan D. Fuchs¹⁴ · Darrell Wheeler¹⁵ · Kenneth H. Mayer¹⁶ · Beryl A. Koblin⁹ · Susan Buchbinder¹

Eric Vittinghoff Eric.Vittinghoff@ucsf.edu

Risha Irvin rirvin1@jhmi.edu

Albert Liu albert.liu@sfdph.org

LaRon Nelson laron.nelson@yale.edu Carlos Del Rio cdelrio@emory.edu

Manya Magnus manyadm@gwu.edu

Sharon Mannheimer sbm20@columbia.edu

Sheldon Fields sheldon.fields@nyit.edu Hong Van Tieu htieu@nybc.org

Irene Kuo ikuo@gwu.edu

Steve Shoptaw sshoptaw@mednet.ucla.edu

Beatriz Grinsztejn gbeatriz@ipec.fiocruz.br

Jorge Sanchez jsanchez@impactaperu.org

Steven Wakefield swakefield@fhcrc.org

Jonathan D. Fuchs jonathan.fuchs@sfdph.org

Darrell Wheeler dwheeler@albany.edu

Kenneth H. Mayer khmayer@gmail.com

Beryl A. Koblin BKoblin@nybc.org

Susan Buchbinder susan.buchbinder@sfdph.org

- ¹ Bridge HIV, San Francisco Department of Public Health, San Francisco, CA, USA
- ² University of California, San Francisco, CA, USA
- ³ Johns Hopkins School of Medicine, Baltimore, MD, USA
- ⁴ Yale School of Nursing, New Haven, CT, USA
- ⁵ Emory University, Atlanta, GA, USA
- ⁶ George Washington University, District of Columbia, Columbia, USA
- ⁷ Columbia University, New York, USA
- ⁸ New York Institute of Technology, Old Westbury, NY, USA
- ⁹ New York Blood Center, New York, USA
- ¹⁰ University of California, Los Angeles, CA, USA
- ¹¹ Instituto de Pesquisa Clinica Evandro Chagas (IPEC), Rio De Janeiro, Brazil
- ¹² Asociacion Civil Impacta Salud y Educacion, Lima, Peru
- ¹³ Fred Hutchinson Cancer Research Center, Seattle, WA, USA
- ¹⁴ Center for Learning Innovation, San Francisco Department of Public Health, San Francisco, CA, USA
- ¹⁵ University at Albany—SUNY, Albany, NY, USA
- ¹⁶ Fenway Health, Boston, MA, USA