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ORIGINAL RESEARCH

TRANSFUSION

HIV incidence and related risks among gay, bisexual, and other men who have sex with men in Montreal, Toronto, and Vancouver: Informing blood donor selection criteria in Canada

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Abstract

Background: An individualized behavior-based selection approach has potential to allow for a more equitable blood donor eligibility process. We collected biological and behavioral data from urban gay, bisexual, and other men who have sex with men (GBM) to inform the use of this approach in Canada.

Study design and methods: Engage is a closed prospective cohort of sexually active GBM, aged 16+ years, recruited via respondent-driven-sampling (RDS) in Montreal, Toronto, and Vancouver, Canada. Participants completed a questionnaire on behaviors (past 6 months) and tested for HIV and sexually transmitted and blood-borne infections at each visit. Rate ratios for HIV infection and predictive values for blood donation eligibility criteria were estimated by RDS-adjusted Poisson regression.

Results: Data on 2008 (study visits 2017-02 to 2021-08) HIV-negative participants were used. The HIV incidence rate for the three cities was 0.4|100 person-years [95%CI:0.3, 0.6]. HIV seroconversion was associated with age <30 years: adjusted rate ratio (aRR) 9.1 [95%CI:3.2, 26.2], 6–10 and >10

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anal sex partners versus 1–6 aRR: 5.3 [2.1,13.5] and 8.4 [3.4, 20.9], and use of crystal methamphetamine during sex: 4.2 [1.5, 11.6]. Applying the combined selection criteria: drug injection, ≥2 anal sex partners, and a new anal sex partner, detected all participants who seroconverted (100% sensitivity, 100% negative predictive value), and would defer 63% of study participants from donating.

Conclusion: Using three screening questions regarding drug injection and sexual behaviors in the past 6 months would correctly identify potential GBM donors at high risk of having recently contracted HIV. Doing so would reduce the proportion of deferred sexually active GBM by one-third.

KEYWORDS

behavior-based screening, blood donation, blood donation policy, blood donor deferral, men who have sex with men, residual HIV risk, risk of transfusion-related infection, selection criteria, sexual behavior

1 | INTRODUCTION

In the context of blood or plasma donation, the residual risk for HIV acquisition represents the chance of a donation from a viraemic donor being undetected when using available screening assays.[1,2] In 2020, the estimated residual risk of acquiring HIV through a blood transfusion in Canada was 1 in 12.9 million donations.[3] In most countries, gay, bisexual, and other men who have sex with men (GBM) are either permanently or temporarily deferred from donating blood.[4] Canadian blood operators reduced this deferral period to 3 months in 2019.[5,6]

However, shorter time-based deferral periods still exclude most sexually active GBM from donating blood. Blood donation policy must balance the need to protect blood recipients with the goal of avoiding "inequitable risk tolerance" (i.e., donation deferral of an entire population when one would not defer an individual from another group with the same objective level of risk).[7] Therefore, individualized behavior-based approaches, recently introduced in countries like the United Kingdom (UK), Italy, and the Netherlands,[8–10] advocate for a shift to selecting donors based on individualized levels of risk for HIV acquisition, using more targeted and specific information on sexual and other relevant behaviors.

Important developments in biomedical HIV prevention have taken place in recent years, including the widespread use of antiretroviral therapy for all individuals living with HIV and the use of antiretroviral medication as Pre-Exposure Prophylaxis (PrEP).[11] Updated context-specific Canadian biological and behavioral data are required to inform the implementation of an individualized behavior-based approach and to guide the selection of targeted screening questions. We conducted an analysis of HIV-negative participants in a biobehavioral cohort study of GBM in three Canadian cities to examine: (1) current HIV risk-related behaviors and estimates of recent HIV seroconversion; (2) factors associated with recent HIV seroconversion; (3) performance and predictive power of potential donor screening questions; and (4) participants' comfort with potential donor screening questions.

2 | MATERIALS AND METHODS

2.1 | Study recruitment and follow-up

Recruitment for the Engage Study was initiated in February 2017. Individuals eligible for participation were French or English-speaking, cis- or transgender men 16+ years old, who reported sex with at least one man in the 6 months prior to study visit, and who resided in Vancouver, Toronto, or Montreal. Participants were recruited using respondent-driven sampling (RDS), a common chain referral method for sampling hard-to-reach populations like GBM.[12,13] After initial recruitment, participants were invited to return for subsequent visits at 6- (in Vancouver) or 6–12 month (in Montreal and Toronto) intervals. The present analysis considers the baseline visit and all visits up until and including August 2021.

2.2 | Measures

At each visit, participants completed a questionnaire using computer-assisted self-interviewing and underwent screening for sexually transmitted and blood-borne

infections (STBBI). Based on expert knowledge and a literature review, the variables for the present analysis were selected and grouped into the following categories: (1) sociodemographic, (2) sexual partners, (3) methods of finding sexual partners, (4) substance use (including during sex), and (5) STBBIs (Table 4). Details on how these variables were defined and operationalized are provided in Data S1. Factors corresponding to risk assessment criteria considered by blood operators in France, the United Kingdom (UK), and the United States (US) were also examined.[8,14,15] In addition, participants were asked to report on their level of comfort with ten potential blood donation screening questions inspired by the UK blood donation working group FAIR (For the Assessment of Individualized Risk).[8] *Chlamydia trachomatis* and *Neisseria gonorrhoeae* infections were detected using culture or nucleic acid amplification testing (NAAT) of urine, pharyngeal and rectal specimens. Syphilis was detected using an anti-treponemal antibody test, a rapid plasma reagin (RPR) test and, if needed, a complementary treponemal-specific test. HIV infection was ascertained through fourth-generation HIV testing (detection of HIV antibodies and p24 antigen), and a confirmation test (Western blot analysis or Bio-Rad Geenius™HIV 1/2 confirmatory assay). In Montreal, all participants were tested regardless of self-reported HIV status. In Vancouver and Toronto, participants who were known to be HIV-positive were offered the option of either confirming their diagnosis with a point-of-care or laboratory HIV test, or by requesting confirmation from their primary care physician. New HIV diagnoses were also measured through data linkages with the BC HIV Drug Treatment Program for all participants in Vancouver.

This analysis considered recent HIV seroconversions that occurred retrospectively (up until 18 months before baseline) and prospectively from baseline (until dataset closure in August 2021). All seroconversions were biologically ascertained. The 18-month retrospective period is a compromise recognizing that shorter periods would result in fewer events while longer periods would introduce greater uncertainty regarding the time of infection.[16] For retrospective seroconversions, the time of infection was estimated using the following questions: *When were you last tested for HIV? When were you first tested HIV-positive? Before your first positive HIV test, when was the last time you tested negative for HIV?*

2.3 | Statistical analysis

All analyses were adjusted using RDS-II weights in order to minimize selection bias due to RDS recruitment.[12,17] RDS-II weights are inversely proportional to the participants' network size so that data for individuals with large social networks who were more likely to be recruited were weighted less (Data S2). For all pooled analyses, RDS-II weights were normalized by city, recognizing three distinct networks. Covariate imbalance between participants who had at least one follow-up visit and participants who were lost-to-follow-up (LTFU) was assessed using standardized mean difference (SMD) (Data S3).

Time contribution was measured using follow-up time with an origin set at 18 months before baseline for all participants. The risk set consisted of all participants that were HIV-negative 18 months before baseline. Censored participants contributed time up to their last visit. HIV incidence rates were calculated by dividing the number of seroconversions weighted with RDS-II weights by the total time contribution.

Adjusted rate ratios (aRR) of recent HIV seroconversions were estimated for selected risk factors by Poisson regression. All Poisson models were weighted with RDS-II weights, used an offset for the time of exposure, and included city and age as covariates. A final Poisson model with multiple risk factors was built using bi-directional elimination taking into account study goals, model fit, and multicollinearity for variable selection.[18]

Point estimates of sensitivity, specificity, positive predictive values (PPV), and negative predictive values (NPV) of various criteria for detecting HIV seroconversions were derived from contingency tables, reconstructed after fitting Poisson models. Values of risk factors and selection criteria were taken at baseline, and at the visit immediately preceding the occurrence of HIV infection, for retrospective and prospective seroconversions, respectively. The criteria examined were selected from the list of factors explored for association with HIV seroconversion, also considering whether the criterion is proposed by blood operators elsewhere and the practicality of asking the corresponding question to potential blood donors.

Adjusted odds ratios (aOR) of feeling (very) uncomfortable with being asked potential screening questions for blood donation were estimated for selected variables using marginal (GEE) models. All GEE models were weighted with RDS-II weights and included city and age as covariates. The correlation between answers to the ten potential screening questions for each participant was accounted for with an exchangeable correlation structure.

2.4 | Ethical approval

The Engage Study was approved by the research ethics boards of each principal investigators' respective institutions.

TABLE 1 RDS-adjusted proportions of sociodemographic characteristics for HIV-negative participants, by city, at baseline ($n = 2008$)

	Montreal ($n = 968$)		Toronto ($n = 417$)		Vancouver ($n = 623$)	
	RDS%	95% CI	RDS%	95% CI	RDS%	95% CI
Age (years)						
29 or less	41.2	[36.1;46.4]	57.6	[48.1;66.8]	54.1	[46.7;61.4]
30 to 45	37.7	[31.6;44.1]	30.8	[23.9;38.4]	30.9	[24.6;37.8]
46 or more	21.1	[16.4;26.5]	11.5	[5.3;20.6]	14.9	[10.3;20.5]
Gender identity						
Cis man	88.0	[82.6;92.3]	90.1	[82.7;95.2]	95.3	[91.3;97.9]
Trans man	1.9	[0.7;3.9]	1.3	[0.3;3.5]	0.9	[0.1;3.3]
Other gender[a]	10.1	[6.2;15.2]	8.5	[3.5;16.3]	3.9	[1.7;7.3]
Ethnocultural group						
French or English Canadian	52.3	[46.1;58.5]	30.6	[22.6;39.4]	39.5	[32.4;46.9]
European	15.4	[11.6;19.8]	27.0	[19.3;35.8]	14.9	[11.0;19.5]
South or East Asian	6.5	[4.0;9.8]	15.3	[10.2;21.4]	24.5	[18.3;31.5]
Arab or North African	6.0	[3.1;10.1]	0.8	[0.1;2.7]	0.5	[0.1;1.8]
Latin American	10.9	[7.6;14.9]	9.4	[5.4;14.6]	13.5	[8.1;20.5]
East or West African or Caribbean	2.9	[1.5;4.9]	7.5	[3.0;14.6]	0.7	[0.2;2.1]
Indigenous	1.3	[0.2;4.1]	2.8	[0.1;2.8]	1.7	[0.5;3.8]
Other	4.8	[2.9;7.4]	6.7	[3.7;11.0]	4.7	[2.2;8.5]
Education level						
High school degree or less	24.2	[19.1;29.8]	17.2	[9.9;26.6]	14.4	[9.5;20.4]
More than high school degree	75.8	[70.0;81.4]	82.8	[73.5;90.0]	85.6	[79.6;90.0]
Annual income (CAD)						
29K or less	66.5	[61.2;71.5]	59.7	[50.6;68.3]	55.5	[48.2;62.7]
30K to 59K	25.2	[20.8;30.0]	27.6	[19.6;36.8]	29.3	[22.6;36.8]
60K or more	8.3	[6.0;11.1]	12.7	[8.6;17.7]	15.2	[11.5;19.5]
Sexual orientation						
Gay	75.0	[69.4;80.1]	71.8	[62.7;79.9]	81.9	[75.1;87.6]
Bisexual	13.3	[9.6;17.8]	11.3	[5.7;19.4]	11.4	[6.4;18.1]
Queer	4.9	[3.2;7.1]	10.9	[7.2;15.6]	4.5	[2.5;7.2]
Immigration						
Born in Canada	62.8	[57.0;68.4]	55.0	[46.2;63.6]	55.7	[47.6;63.6]
Immigrated to Canada in the past 2 years	14.7	[10.4;19.9]	16.5	[10.8;23.6]	18.0	[12.5;24.7]
Marital status						
Single	82.0	[77.6;85.8]	78.8	[72.0;84.7]	82.3	[76.0;87.6]
Married or common law partner	18.0	[14.2;22.4]	21.2	[15.2;28.1]	17.7	[12.1;24.4]

[a]Includes participants identifying as genderqueer, non-binary, or two-spirit.

3 | RESULTS

A total of 2449 participants were recruited across the three cities at baseline. Participants included in analyses were those determined to be HIV-negative at or within 18 months preceding baseline ($n = 2008$). Their sociodemographic characteristics and selected HIV risk behaviors are presented in Tables 1 and 2 (Data S2 presents crude proportions).

3.1 | Incidence rates of recent HIV seroconversions

A total of 31 recent HIV seroconversions (16 in Montreal, 9 in Toronto, and 6 in Vancouver) were observed for a total time contribution of 7373 person-years (Table 3). For the 13 seroconversions that occurred during the 18 months prior to baseline, the mean time of infection was 7.4 months and ranged from 2 to 15 months before baseline. RDS-adjusted

TABLE 2 RDS-adjusted proportions of HIV risk behaviors among HIV-negative participants, by city, at baseline ($n = 2008$)

	Montreal ($n = 968$)		Toronto ($n = 417$)		Vancouver ($n = 623$)	
	RDS%	95% CI	RDS%	95% CI	RDS%	95% CI
Sex partners (past 6 months)						
Number of sex partners						
5 or less	62.1	[56.3;67.7]	63.1	[55.0;70.8]	57.6	[50.3;64.7]
6 to 10	22.5	[17.7;27.8]	19.9	[13.9;27.0]	23.7	[17.9;30.3]
11 or more	15.5	[12.4;18.9]	17.0	[12.3;22.5]	18.7	[13.5;24.8]
Number of anal sex partners						
5 or less	79.9	[75.3;84.0]	77.5	[70.9;83.2]	76.4	[69.8;82.2]
6 to 10	12.6	[9.1;16.7]	12.3	[7.9;17.8]	14.6	[9.9;20.4]
11 or more	7.5	[5.4;10.1]	10.3	[6.6;14.9]	9.0	[6.1;12.5]
Number of anal sex partners (alternate categories)						
0	15.2	[10.4;21.1]	10.5	[5.7;17.1]	10.1	[6.2;15.1]
1	28.2	[23.1;33.8]	30.9	[22.1;40.7]	25.8	[18.6;34.0]
2 or more	56.5	[50.5;62.4]	58.6	[49.1;67.7]	64.1	[55.9;71.8]
One or more HIV+ sex partners	15.5	[11.2;20.6]	13.1	[9.0;18.1]	12.3	[8.9;16.3]
Sexual behavior (past 6 months)						
Condomless anal sex at least once	58.3	[52.0;64.4]	58.2	[48.4;67.5]	66.6	[59.3;73.3]
High HIV risk sexual act[a]	19.6	[15.0; 24.8]	16.4	[11.8; 21.9]	23.2	[16.8; 30.5]
Substance use (past 6 months)						
Chemsex[b]	19.3	[15.3;23.9]	16.4	[11.8;21.8]	21.8	[17.0;27.2]
Injection drug use (IDU)	3.7	[2.1;5.9]	3.1	[0.5;9.4]	1.1	[0.3;2.7]
HIRI-MSM score[c]						
11 to 20	33.5	[28.1;39.3]	28.6	[21.9;36.1]	39.8	[32.1;47.8]
21 or more	20.6	[16.7;24.9]	20.3	[14.9;26.5]	23.0	[17.1;29.7]
STBBI detected at baseline						
C. trachomatis infection	2.6	[1.4;4.3]	2.4	[0.8;5.1]	4.9	[2.8.8]
N. gonorrhoeae infection	4.6	[2.7;7.2]	3.6	[1.5;7.0]	2.6	[1.2;4.8]
Recent/current syphilis infection[d]	0.7	[0.2;1.7]	0.1	[0.0;2.2]	3.2	[0.3;11.9]
PrEP use or HIV testing (past 6 months)						
No PrEP use	92.6	[90.0; 94.7]	89.0	[84.3;92.8]	83.9	[79.2;88.0]
Not tested for HIV	50.1	[44.1;56.1]	49.7	[40.2;59.2]	45.4	[37.7;53.2]

[a]Condomless anal sex while not on PrEP with a partner of unknown HIV status or of HIV+ status having a detectable or unknown viral load, at the last sexual relation with any of the last five sexual partners in the past 6 months.
[b]Crystal methamphetamine, GHB (gammahydroxybutyrate), ecstasy/MDMA (3,4-methylenedioxy-methamphetamine), or ketamine consumption in the 2 h before or during sex with at least one of the last five partners participants reported having sex with in the past 6 months.
[c]Possible score values ranged from 0–45, with participants scoring 0–10 points defined as having "low risk," those scoring 11–20 points as "moderate risk" and those scoring 21 or more points as "high risk" for HIV seroconversion in the next 6 months. Refer to Data S1 for a detailed definition.
[d]Reactive anti-treponemal antibody test and rapid plasma reagin titer of 1/16+at baseline.

TABLE 3 RDS adjusted incidence rates of recent HIV seroconversions in Montreal, Toronto, and Vancouver

	Montreal ($n = 968$)	Toronto ($n = 417$)	Vancouver ($n = 623$)	Pooled ($n = 2008$)
HIV seroconversions	16	9	6	31
RDS adjusted HIV seroconversions	16.6	7.6	5.2	29.4
Total person-years	3973	1349	2051	7373
RDS adjusted rate [95% CI]	0.4 [0.2; 0.7]	0.6 [0.2; 1.2]	0.3 [0.1; 0.5]	0.4 [0.3; 0.6]

TABLE 4 RDS-adjusted rate ratios (aRR) of recent HIV seroconversions ($n = 31$) for selected factors[a] among HIV-negative participants, controlling for age and city ($n = 2008$)

	HIV seroconversions	aRR	95% CI
Models with a single risk factor			
Sociodemographics			
Age <30 years old	22	9.5	[3.3;26.9]
French or English Canadian ethnocultural group	14	0.5	[0.2;1.1]
Born outside of Canada	11	1.5	[0.7;3.1]
Immigrated to Canada in the past two years[b]	1	—	—
High school degree or less	6	1.0	[0.4;2.7]
Annual income <30 K	17	0.7	[0.3;1.4]
Financial strain (current)[a]	—	1.7	[0.9;3.2]
Gay (vs. queer or other sexual orientation)	28	1.2	[0.5;2.9]
Sex partners (past 6 months)			
No main sex partner	25	3.2	[1.2;8.3]
Non monogamous relationship[b]	31	—	—
New anal sex partner	13	1.0	[0.5;2.0]
One or more HIV+ sex partners	19	3.9	[1.8;8.3]
Number of sex partners			
• 6 to 10 (vs. 5 or less)	9	4.4	[1.7;11.4]
• 11 or more (vs. 5 or less)	19	7.4	[3.0;18.2]
Number of anal sex partners			
• 6 to 10 (vs. 5 or less)	10	5.4	[2.2;13.4]
• 11 or more (vs. 5 or less)	15	10.5	[4.5;24.6]
Two or more anal sex partners[b]	30	–	–
Methods of finding sexual partners (past 6 months)			
Attendance of a bath house or sex club	17	2.5	[1.2;5.3]
Attendance of a group sex event	15	3.4	[1.6;7.3]
Attendance of a barebacking party	10	9.2	[3.9;21.8]
Attendance of a party n' play event	10	6.3	[2.1;19.3]
Accepting money or drugs for sex	9	3.7	[1.4;10.0]
Use of the internet to connect with other men (at least once a day)	18	6.8	[2.9;15.7]
Substance use (past 6 months)			
Crystal methamphetamine during sex[c]	11	8.0	[3.1;20.8]
Gamma hydroxybutyrate during sex[c]	8	4.1	[1.5;11.1]
Alkyl nitrites during sex[c]	17	3.8	[1.8;8.1]
Chemsex[d]	13	4.0	[1.7;9.1]
Injection drug use (IDU)	5	9.8	[2.9;33.0]
Problematic alcohol use[b]	2	—	—
Problematic use of any drug (other than alcohol or tobacco)	5	1.7	[0.5;6.0]
STBBI detected (at any visit)			
C. trachomatis infection	5	5.9	[2.2;15.6]
N. gonorrhoeae infection	7	8.0	[3.4;19.0]

TABLE 4 (Continued)

	HIV seroconversions	aRR	95% CI
Recent or current syphilis infection[b,e]	3	—	—
HIRI MSM score			
• 11 to 20 (vs. 10 or less)	5	2.7	[0.8;9.1]
• 21 or more (vs. 10 or less)	24	8.4	[2.7;26.6]
Model with multiple risk factors			
Age <30 years old	22	9.1	[3.2;26.2]
Number of anal sex partners (past 6 months)			
• 6 to 10 (vs. 5 or less)	10	5.3	[2.1;13.5]
• 11 or more (vs. 5 or less)	15	8.4	[3.4;20.9]
Use of crystal methamphetamine during sex[c]	11	4.2	[1.5;11.6]

[a]The concept of "cases observed for a given level of a variable" does not apply for a continuous variable.
[b]Too few HIV cases were observed in at least one of the levels of the variable for reliable estimation.
[c]Consumption in the 2 h before or during sex with at least one of the last five partners participants reported having sex with in the past 6 months.
[d]Crystal methamphetamine, GHB (gammahydroxybutyrate), ecstasy/MDMA (3,4-methylenedioxy-methamphetamine), or ketamine consumption in the 2 h before or during sex with at least one of the last five partners participants reported having sex with in the past 6 months.
[e]Reactive anti-treponemal antibody test and rapid plasma reagin titer of 1/16+at baseline visit or new/reinfection at prospective visits.

HIV incidence rates, expressed in cases per 100 person-years, were 0.4 [95% CI 0.2;0.7] in Montreal, 0.6 [0.2;1.2] in Toronto and 0.3 [0.1;0.5] in Vancouver. No statistically significant difference was detected between cities ($p = 0.65$); the pooled incidence rate for the three cities was 0.4 [0.3;0.6].

3.2 | Risk factors for recent HIV seroconversions

Table 4 shows aRR of recent HIV seroconversions, controlling for age and city. Many sexual relationships and partnering factors (sex with partners living with HIV, attending a barebacking event, frequent use of the internet to connect with other men, etc.), substance use factors (crystal methamphetamine use during sex, drug injection), and detection of an STBBI at the study visit, were associated with recent seroconversions. Table 4 also provides point estimates and 95%CI for aRR obtained by fitting a weighted Poisson model with multiple explanatory variables in addition to city and age. Age <30 years: 9.1 [3.2;26.2], 6–10 anal sex partners: 5.3 [2.1;13.5], more than 10 anal sex partners: 8.4 [3.4;20.9], and use of crystal methamphetamine during sex: 4.2 [1.5;11.6] were significantly associated with recent HIV seroconversion.

3.3 | Performance of potential selection criteria

Table 5 presents the sensitivities, specificities, and predictive values of various selection criteria and selected combinations thereof, relative to recent HIV seroconversion. The NPV of each selection criterion is the probability that a donor's blood is not infected with HIV, given that the donor does not meet that respective criterion. The NPV should be as close as possible to 100% to optimize blood safety. The first row of Table 5 with no criterion corresponds to the scenario where all donors are accepted. In this scenario, sensitivity and specificity are 0% and 100%, respectively. Applying no selection criteria, the NPV is 99.6%. The single criterion with the highest NPV (99.9%) was having two or more anal sex partners. The criterion "injection drug use" (IDU) is included in all composite scenarios as it is currently applied by all blood operators. The inclusion of this criterion does not change the NPV or the deferral rate of participants observed with any single criterion greatly, since IDU is reported by a minority of participants. When using the composite criterion IDU or "two or more anal sex partners," sensitivity and NPV reach 88.7% and 99.9%, respectively. Then, adding the criterion "chemsex" does not lead to a higher NPV (even when chemsex is restricted to crystal methamphetamine use). However, adding the criterion "new anal sex partner" to the composite criterion IDU or "two or more anal sex partners" results in a sensitivity of 100%, and an NPV of 100%. Indeed, adding the "new anal sex partner" criterion captures the only case that was not already included using the "two or more anal sex partners" criterion, however, by doing so the deferral rate jumps from 51% to 63%. The adapted FAIR combination of selection criteria produces similar values but requires more questions. Gonococcal and syphilis infections are included in both FDA and FAIR selection criteria combinations, but each of these criteria exhibits low sensitivity.

TABLE 5 Predictive values of an HIV seroconversion based on various potential selection criteria for blood donation among HIV-negative participants ($n = 2008$): Sensitivity (Sens), specificity (Spec), negative predictive value (NPV), positive predictive value (PPV), and estimated proportion of those deferred.

Selection criterion	Sens (%)	Spec (%)	NPV (%)	PPV (%)	Deferred(%)
None	0	100	99.6	NA	0
Single criterion (past 6 months)					
Two or more anal sex partners	88.8	50.9	99.9	0.7	49.3
Three or more anal sex partners	73.6	65.6	99.8	0.8	34.6
Six or more anal sex partners	64.0	82.5	99.8	1.4	17.7
One or more HIV+ sex partners	35.0	86.3	99.7	1.0	13.8
New anal sex partner	57.2	48.4	99.6	0.5	51.6
Chemsex[a]	26.6	92.5	99.7	1.5	7.6
Received money or drugs for sex	17.1	96.2	99.6	1.8	3.8
Given or received money or drugs for sex	19.2	94.9	99.7	1.5	5.2
Injection drug use (IDU)	9.9	97.7	99.6	1.8	2.2
Use of crystal methamphetamine during sex	18.4	96.7	99.6	2.3	3.4
Recent/current syphilis infection[b] (detected at visit)	11.1	99.1	99.6	4.6	1.0
Syphilis infection (self-reported)	7.0	97.8	99.6	1.3	2.2
N. gonorrhoeae infection (detected at visit)	23.7	96.9	99.7	3.0	3.2
N. gonorrhoeae infection (self-reported)	3.5	93.8	99.6	0.2	6.2
Composite criteria (past 6 months)					
IDU OR one/more HIV+ sex partners	34.8	84.5	99.7	0.9	15.6
IDU OR one/more HIV+ sex partners OR Recent/current syphilis infection[b]	40.7	83.7	99.7	1.0	16.4
IDU OR one/more HIV+ sex partners OR recent/current syphilis[b] OR six/more anal sex partners	70.7	72.7	99.8	1.0	27.5
IDU OR two/more anal sex partners	88.7	49.3	99.9	0.7	50.8
IDU OR two/more anal sex partners OR chemsex[a]	88.6	44.9	99.9	0.7	55.2
IDU OR two/more anal sex partners OR new anal sex partner	100.0	37.6	100.0	0.5	62.6
IDU OR new anal sex partner OR (two/more sex partners AND anal sex with at least one of them)	100.0	30.7	100.0	0.6	69.4
Adapted FDA combination[c]	36.7	75.0	99.7	0.6	25.0
HIRI-MSM[d] score 11 or more	88.1	47.2	99.9	0.7	53.0
Adapted FAIR combination[e]	100.0	35.2	100.0	0.6	65.1

Note: Partner or transactional sex (given or received) or diagnosis/treatment of syphilis or of gonococcal infection. The FDA combination also contains the following criteria which are not included in the Engage questionnaire: sex with someone who had multiple partners, who exchanged sex for money or who injected drugs and blood exposure related variables: acupuncture, tattoo, body piercing, and needle injury.

[a]Crystal methamphetamine, GHB (gamma hydroxybutyrate), ecstasy/MDMA (3,4-methylenedioxy-methamphetamine), or ketamine in the 2 h before or during sex with at least one of the last five partners participants reported having sex with in the past 6 months.

[b]Reactive anti-treponemal antibody test and rapid plasma reagin titer of 1/16+ at baseline visit or new/reinfection at prospective visits.

[c]Non-prescription injection drug use or sex with an HIV-positive.

[d]Index based on age, non-prescription injection drug use, condomless anal sex, number of sex partners, sex with HIV-positive partners and crystal methamphetamine use.

[e]Non-prescription injection drug use or chemsex or syphilis diagnosis or gonococcal infection diagnosis or new anal sex partner or more than one anal sex partner. The PrEP use criterion was removed here to allow comparisons with other composite criteria listed in the table.

3.4 | Comfort with potential screening questions

Table 6 presents proportions of HIV-negative GBM who felt "uncomfortable" or "very uncomfortable" with being asked potential blood donation screening questions. For any of the 10 questions proposed, the city-level proportion of GBM who were "uncomfortable" or "very uncomfortable" varied from 11% to 21% (question on the use of PrEP) to 31%–36% (question on the number of anal sex

TABLE 6 RDS-adjusted proportions of HIV-negative GBM who felt uncomfortable or very uncomfortable with being asked potential questions as part of a blood donation screening questionnaire ($n = 1320$)

	Montreal		Toronto		Vancouver	
	RDS%	95% CI	RDS%	95% CI	RDS%	95% CI
Recent sexually transmitted infection (STI)	22.0	[17.3;27.3]	19.8	[12.3;29.0]	25.5	[14.9;38.5]
Use of HIV pre-exposure prophylaxis medication (PrEP)	18.7	[13.6;24.6]	11.4	[5.3;20.4]	20.7	[10.3;34.5]
Use of HIV post-exposure prophylaxis medication (PEP)	19.1	[13.8;25.2]	13.3	[7.3;21.5]	22.2	[11.9;35.5]
Having HIV-positive male sex partners	25.1	[20.6;30.0]	28.6	[19.3;39.4]	32.1	[21.4;44.2]
Consumption of any illegal drugs	25.6	[20.3;31.4]	23.9	[16.1;33.1]	25.9	[15.9;37.9]
Anal sex without condoms	29.3	[24.1;34.9]	26.7	[18.6;36.1]	34.4	[23.8;46.2]
The viral load of HIV-positive male sex partners	28.0	[22.9;33.5]	40.5	[29.9;51.8]	35.0	[24.4;46.6]
Number of new sex partners	28.1	[21.9;34.9]	25.8	[16.7;36.7]	32.1	[21.9;43.6]
Number of sex partners	27.3	[21.5;33.6]	30.4	[20.9;41.2]	36.2	[25.7;47.7]
Number of anal sex partners	32.5	[26.8;38.5]	30.5	[20.9;41.4]	36.1	[25.6;47.6]

TABLE 7 RDS-adjusted odds ratios (aOR) of feeling (very) uncomfortable with being asked various potential questions as part of a blood donation screening questionnaire, among HIV-negative participants, controlling for age and city ($n = 1320$).

	aOR	95% CI
Age 30 years old or older	1.4	[1.2;1.7]
High school degree or less	0.7	[0.6;0.9]
Annual income <30 K	1.1	[0.9;1.3]
Immigrated to Canada in the past 2 years	1.1	[0.8;1.4]
French or English Canadian ethnocultural group	0.9	[0.7;1.0]
Number of anal sex partners (past 6 months)		
2 to 5 (vs. 1 or less)	1.2	[1.0;1.4]
6 or more (vs. 1 or less)	1.8	[1.5;2.2]
Chemsex (past 6 months)	1.1	[0.9;1.3]
HIRI-MSM score		
11 to 20 (vs. 10 or less)	0.7	[0.6;0.8]
21 or more (vs. 10 or less)	1.8	[1.5;2.3]

partners). Table 7 presents the aOR of feeling "uncomfortable" or "very uncomfortable" versus comfortable. Three variables, age ≥ 30 years, having more than one anal sex partner, and a HIRI-MSM score ≥21, were significantly associated with discomfort. Among those who expressed being uncomfortable with the question on anal sex partners, only 6%–11% indicated that they would be unwilling to donate blood if they were asked questions about topics such as number of sexual partners, illegal substance use or any of the previous set of 10 questions, including anal sex partners.

4 | DISCUSSION

In this study of sexually active Canadian GBM, we estimated HIV incidence, evaluated related sociodemographic and behavioral characteristics as potential selection criteria for blood donation, and reported on the acceptability of potential blood donor screening questions.

Recent developments in biomedical HIV prevention have modified the risk of contracting HIV through a sexual act. At baseline, 16%–23% (three-city range) of Engage participants reported condomless anal sex while not on PrEP, with a partner of unknown HIV status or with a partner living with HIV with an unknown or detectable viral load. This was based on reported sexual behaviors with any of their five most recent sexual partners in the past 6 months. Therefore, the majority of GBM is not participating in sexual acts that put them at risk for acquiring HIV. Between 2015 and 2019, the total annual reported new HIV diagnoses among GBM decreased by 23.3% in Canada (not including Quebec)[19,20] and by 16.6% in Quebec.[21] Within a cross-sectional biobehavioral study among Montreal GBM, the estimated HIV incidence obtained from applying a detuned antibody assay algorithm was 1.28 per 100 person-years (95% CI:0.7; 2.4) in 2005.[22] In Vancouver, the 2012–2015 HIV incidence rate resulting from observational study follow-up and data linkage was 1.25 per 100 person-years (95% CI: 0.7;2.1).[23] As reported here among Engage

participants for the period 2017–2021, the RDS-adjusted recent HIV incidence rate was 0.4 per 100 person-years [0.2;0.7] in Montreal, and 0.3 [0.1;0.5] in Vancouver. In addition, among Engage participants with confirmed HIV infection at baseline, only 0.2–3.3% were unaware of their infection.[24] The residual risk for HIV acquisition associated with blood donations from the GBM population is likely decreasing.

Donors' psychosocial experiences were not explored in the present work despite being STBBI determinants,[25–27] considering their low practicality as screening questions. Multiple, often co-occurring, and well-established HIV risk factors, such as methods of finding sexual partners, HIV-positive sex partners, IDU, and chemsex were all identified as risk factors. Ultimately, three factors were retained in the multivariable analysis: age <30 years, number of anal sex partners, and use of crystal methamphetamine during sex. Beyond the number of sexual partners, use of crystal methamphetamine may reflect links with members of core groups having riskier sexual behavior profiles[27–30] as well as risk for mucosal damage due to repeated and prolonged sex.[31–35]

The objective of the blood donor eligibility process is to use a minimum number of screening questions to optimize the chances of deferring donors recently infected with HIV while retaining donors who are not. We derived the predictive values of a variety of potential selection criteria. The three following criteria: "injection drug use," "two or more anal sex partners in the past 6 months," and "a new anal sex partner in the past 6 months" appear to constitute the best combination based on performance criteria (highest sensitivity and NPV). This combination uses fewer criteria than other blood operators and focuses on the number of sexual partners, as per the current policy in France, where GBM are allowed to donate if they have not had more than one sexual partner in the past 4 months (and are otherwise eligible).[14] This combination constitutes a deferral rate of 63%. However, this rate is likely overestimated since within Engage, participants' behaviors are reported for the past 6 months, whereas blood donor deferral would be based on behaviors reported in the past 3 months before a blood donation. PrEP, which is highly effective in preventing HIV transmission, may also affect the detection of early HIV infection through suppression of viral load and delayed seroconversion,[36–38] therefore, a PrEP use selection criterion is considered advisable.[38] Adding the "PrEP use" criterion to the criteria combination we identified would result in a 3% increase in the deferral rate (66%), based on mean PrEP use between 2017 and 2021. This is a small increase, but as PrEP use increases among Canadian GBM (in 2020–2021, PrEP use among HIV-negative Engage participants ranged from 17.9%–36.2% between cities), over time the PrEP use selection criterion may ultimately exclude more GBM.

The specific and sensitive nature of some screening questions may affect compliance[39] or deter potential donors. Of the selection criteria that performed best, the question regarding number of anal sex partners resulted in the highest levels of discomfort among Engage participants across cities, with 31%–36% reporting that it made them (very) uncomfortable. However, among these, only 6%–11% would be deterred from donating if they were asked about subjects pertaining to sexual behavior including number of anal sex partners. Among a general donor population study in the United Kingdom, 21% of participants reported being "somewhat or completely uncomfortable" with the question "Have you had anal sex with anyone in the past 6 months?"" and 3% reported that this question would stop them from donating.[8] In Canada, 17.2% of general population donors reported being uncomfortable if asked about "having had anal sex with anyone," and 1.6% said they would not donate if asked about anal sex.[40,41] However, discomfort for any new or repeat donors can be mitigated.[42,43]

4.1 | Strengths and limitations

Despite adjustment using RDS-II weights,[12,17] some GBM could still be under-or overrepresented. Since recruitment was limited to the three largest cities in Canada, results may not be generalizable to GBM living outside large urban areas. However, the HIV epidemics in each province are highly concentrated among GBM living in these cities.[21,44,45] The proportion of participants that were LTFU after baseline, having no follow-up visits, was 16%, 29% and 22% in Montreal, Toronto and Vancouver, respectively. Covariate imbalance between LTFU and non-LTFU participants was small (SMD values between 0.1 and 0.31[46]) and limited to the following HIV predictors: chemsex, sex with HIV-positive partners, age under 30 years and IDU (Data S3). As such, it is unlikely that LTFU affected NPV estimates.

Blood operators are concerned by HIV infections acquired in the 3 months preceding a blood donation, whereas Engage provides information on participants' behaviors in the 6 months preceding study visits. Due to missed visits, three participants were diagnosed with HIV more than 1 year after their last study visit. Behaviors reported then were assumed to reflect behaviors at the time of infection.

Pooling estimates across cities improved the stability of the results, allowing for the exploration of many potential predictors of HIV infection and blood donor selection criteria. Considering both retrospective and prospective

seroconversions (culminating in a 5-year observation period) increased the number of events that were analyzed and improved the precision of the estimates. The timeframe of retrospective seroconversions was limited to 18 months so that covariates at baseline could reflect the behavior of participants at the time of infection. A sensitivity analysis based on these 18 prospective seroconversions alone yielded very similar estimates for the incidence rate and rate ratios which were all well within the range of the CIs obtained using all 31 recent seroconversion events. While the observation of 31 events prevented complex modeling, valid inference was nonetheless possible. The normal approximation to the Poisson distribution is considered fairly good when 10 events or more are expected.[18] The number of predictors included in the regression models was limited to 3–4, maintaining a reasonable 8–10 events per predictor.[47] Because of the low HIV incidence, NPV scores started at 99.6% and although NPV scores could be estimated for different deferral policies, too few seroconversions were observed to conclude any statistically significant differences between scores.

5 | CONCLUSION

An individualized behavior-based approach to blood donor eligibility for sexually active GBM may increase the donor pool by allowing more GBM who are at low HIV risk to donate. Furthermore, a move towards such an approach would make the blood donation process more ethical and inclusive, as many GBM perceive that they experience population-based discrimination from blood operators. It would also permit a greater number of willing GBM to donate, allowing them to gain pride and satisfaction from doing so.[48] Engage has generated new data on the HIV epidemic among Canadian GBM and relevant risk forecasting to help guide Canadian blood donor policies. These results may be useful in other countries with similar HIV epidemics and blood donor policies. Irrespective of other blood donation screening questions, a question on drug injection and two concerning sexual behavior (in the past 6 months) would correctly identify GBM donors at risk of having recently contracted HIV and would reduce the proportion of sexually active GBM deferred by one-third. Despite this reduction in deferral rate, a number of GBM at low risk of HIV will still be excluded. However, these criteria provide blood operators with evidence-based options to advance more equitable blood donor eligibility processes while the reality of HIV continues to evolve, for example: the level of HIV incidence, the efficacy of recent HIV seroconversion detection, and the effectiveness of PrEP.

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CONFLICT OF INTEREST

The authors declare that they have no competing interests.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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