BLOOD DONATION IN THE ERA OF BIOMEDICAL HIV PREVENTION AND GENDER-NEUTRAL DONOR SCREENING

by

Robert Higgins
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Supervisory Committee

Dr. Nathan Lachowsky, Supervisor
School of Public Health and Social Policy

Dr. Kiffer Card, Co-Supervisor
School of Public Health and Social Policy

Abstract

Objective.

Canada's implementation of gender-neutral sexual behaviour screening allows sexually active men who have sex with men to donate blood for the first time. Public health campaigns promoting effectiveness of pre-exposure prophylaxis (PrEP) and undetectable = untransmittable (U=U) for HIV prevention heavily target sexual and gender minorities. Donor deferral policies remain in place for both methods. This thesis explores the tension between the effectiveness of these HIV prevention methods and donor policies considering them indicators of HIV risk.

Methods.

I wrote an algorithm approximating donor eligibility producing two analytic samples; one including PrEP use, one including HIV-negative men using U=U. I then estimate the proportion of donors who would be deferred for each prevention method. Chapter Two uses logistic regression to investigate PrEP use as a motivator for blood donation. Chapter Three describes HIV risk and protective factors for HIV and compares these observations to population health estimates of HIV incidence risk.

Results.

The algorithm identified *n = 2,301* potential donors when PrEP users were included. Of these *n = 85 (3.7%)* would have been deferred for PrEP use. When repeated with HIV-negative donors using U=U, *n= 2,354* donors were identified and *n = 53 (2.3%)* would have been deferred. PrEP use was not associated with willingness to donate. Estimates of HIV acquisition risk observed in the U=U analytic sample showed high risk of HIV acquisition. Contradictorily, a high number of combination HIV prevention strategies were also observed in the sample.

Conclusion.

It is likely donors are deferred solely for their choice of HIV prevention method. Having made a past donation was the best predictor of willingness to donate blood. Observed combination HIV prevention strategies employed by the U=U analytic sample did not support high public health estimates of HIV acquisition risk. Future research should explore PrEP adherence in samples of donors deferred for PrEP use and adjusting estimates of HIV acquisition risk to consider PrEP and U=U in risk estimates.

Table of Contents

List of terms

AIC – Akaike Information Criteria

ART – Anti-retroviral therapy

CAS – Condomless anal sex

CBRC – Community-Based Research Centre

CBS – Canadian Blood Services

DBS – Dried blood spot

GBMSM – Gay, bi and other men who have sex with men

HIV – Human immunodeficiency virus

MSM – Men who have sex with men

PEP – Post-exposure prophylaxis

PLWHIV – People living with HIV

PrEP – Pre-exposure prophylaxis

SGM – Sexual and gender minorities

TasP – Treatment as prevention

U=U – Undetectable equals untransmitable

Preface

This is an original intellectual work by Robert G. Higgins. The two studies discussed in this thesis were approved by the University of Victoria's Research Ethics Board (UVIC HREB: BC17-487).

Chapters Two and Three are planned submissions to the journal *Vox Sanguinis* and follow those publication guidelines. As such, you may find some repetition of concepts or ideas as you read through. Chapter Two will be submitted as an original manuscript and Chapter Three will be submitted as a short report. Data for these studies come from the Sex Now Survey 2019. Sex Now is a community-based and participatory research project run with the Community-Based Research Centre in Vancouver B.C., and the Community-based Health Equity Research group at the University of Victoria. Data collection was funded in part from Canadian Blood Services MSM Research Grant program, which is in turn funded by the federal government (Health Canada) and the provincial and territorial ministries of health. The views herein do not necessarily reflect the views of Canadian Blood Services or the federal, provincial, or territorial governments of Canada.

The Sex Now Study was originally conceptualized and designed by members of the queer community. The first academic partnership and subsequent national recruitment cycle was designed by Dr. Nathan Lachowsky who advised on research direction, reviewed and edited protocols, and supported project implementation. Data collection and recruitment were led by Robert Higgins, supported by community organizations and volunteer community researchers. Dr. Dana Devine reviewed and edited drafts, advised on research direction and blood donation

policy development. Dr. Kiffer Card gave advice on analyses, reviewed and edited drafts. Robert Higgins planned and conducted analyses, interpreted results and led manuscript development.

Acknowledgments

This thesis was only possible because of the years of dedicated activism and community organizing by queer people across Canada. I acknowledge with gratitude the work of Drs. Richard Marchand and Terry Trussler who founded the Community-Based Research Centre and the Sex Now Survey in Vancouver British-Columbia, Canada in 1999. Your vision made this work possible. I am also humbled by the work of the many great community organizers who hosted me in cities and towns across Canada, and with whom I had the privilege of working alongside during data collection. Finally, I'd like to thank my dedicated and endlessly patient supervisory committee Drs. Nathan Lachowsky, Dana Devine and Kiffer Card. I will be forever grateful for your guidance, patience and support on this long and difficult journey.

1.0 Chapter One: Introduction

1.1 Policy Background: A very brief overview

Many gay, bisexual and other men who have sex with men (GBMSM) asserted that Canada's previous three-month blood donation deferral policy for 'men who have sex with men' (MSM) is unnecessarily discriminatory and stigmatizing (1). Canadian Blood Services is regulated by Health Canada and has made efforts over the years to reduce the deferral period from a lifetime ban down to a policy of three months since last 'same sex' contact. The ban and subsequent time and gender-based deferrals originate from reforms made in response to a nationwide public health disaster in the late 1970s and 1980s. Canada's national blood supply – then managed by the Canadian Red Cross – was contaminated by two infectious agents; HIV and hepatitis C. A Royal Commission of Inquiry into the incident led by Justice Horace Krever found the Red Cross negligent in their management and made recommendations to prevent such an incident from occurring in the future (2). The Commission found that the Canadian Red Cross failed to deploy pathogen inactivation technology available at the time, did not appropriately screen donations, and collected donations from American prison populations. The Commission recommended – amongst a host of other regulatory and structural changes – that blood donations not be collected from populations at elevated risk of contracting HIV and hepatitis C, including gay men. Since the initial lifetime deferral was implemented, policy makers have reduced the deferral time to five years, then 12-months, then three months. The policy assumed a man is cisgender and delineates transgender people's sex by whether they have undergone lower genital gender affirming surgery at least 3 months prior to donation (rather than by gender identity). A 2019 study into the health of LGBTQIA2 Canadians by the House of Commons Standing

Committee on Health recommended the Government shift away from the time-based MSM deferral policy to one that is 'gender neutral' – meaning not specific to 'men' or other genders (3). The then three-month policy resulted in negative outcomes for sexual and gender minority (SGM) community members (who experience discrimination), blood operators (who face community and political backlash), and blood product recipients (who are reliant on a safe and sufficient blood supply). Health Canada approved Canadian Blood Services and Héma-Québec's applications to shift to individual risk-based assessment of all donors – regardless of sex or sexual orientation – on April 4, 2022 and September 6, 2022 respectively (4,5). The two organizations no longer screen donors based on their partner's gender, instead asking about a donor's recent and new sexual partner(s) in the past 3 months and specifically about anal sex with these partners (6,7). Many newly eligible donors are likely to be deferred for the use of biomedical HIV prevention strategies such as the use of Pre-exposure prophylaxis (PrEP) and treatment as prevention (TasP). PrEP and TasP are discussed in detail in sections 1.3 and 1.4.

This work will build on the work of other scholars who utilize queer theory and post structuralism as a framework to critique public health constructs of queer health and HIV (8). Queer theory shifts focus away from "normal" and reduces inequities associated with difference or otherness that arise from the dominant social order (9). Post structuralism describes a group of theories that is concerned with language and meaning, and who is in control of that meaning (10). Blood system operators around the world are slowly moving away from screening based on gender towards systems that instead screen more specifically for sexual behaviour risk factors for HIV; Spain and Italy are common examples(11). The landscape of deferral policies for MSM is discussed in more detail in the following section.

1.2 Risk and time-based deferrals for Canadian MSM

A 2008 risk analysis by Leiss, Tyshenko and Krewski investigated alternatives to the then lifetime deferral for men who had sex with another man even once since 1977 using risk management principles considering Canadian legal constructs concerning discrimination (12). They briefly considered the inclusion of MSM but ultimately decided not to pursue the direction due to higher incidence of HIV in the MSM population. Potential differences in risk within MSM communities were never investigated and the authors focused solely on evaluating risk associated with shortening the deferral period based on abstinence since last same sex contact. This approach has framed the research and policy agenda for blood operators in Canada until recently. Leiss et al ultimately recommended a five-year abstinence policy for MSM, which was adopted in 2013. Following this change Canadian blood operators showed minimal change in risk and continued to propose reductions in deferral length further reducing the waiting period in 2016 to 12 months and three months in 2019 (1,13,14). In spring 2021, the Board of Canadian Blood Services announced that they would submit a proposal to Health Canada to include some sexually active MSM in blood donation following the 2021 change to do so in the United Kingdom (15). Previously, some work has been done investigating potential alternatives used in jurisdictions such as Spain, Italy and Israel, but these models were deemed incompatible with the Canadian blood donation system by the authors (11). Although a shift to gender neutral screening was surely welcome news to activists, the current system defers donors with EITHER a new or more than one sexual partner in the last three months AND if anal sex occurred with any of those partners; it also defers all potential donors who have used HIV PrEP in the past four months and who have had sex with an HIV-positive partner regardless of that partner's HIV viral suppression status in the past year (6,7,16). While this gender-neutral policy is certainly more inclusive, researchers and policy makers should consider that these criteria continue to disproportionately

impact sexual and gender minority communities by deferring a significant portion of those who are most likely to choose these biomedical HIV prevention strategies. Also of note, is that Leiss et al published their risk assessment 10 years before both Canada's first publicly-funded general population PrEP program (2016) and the results of the landmark Partner II study which showed those with undetectable viral loads do not transmit HIV to their same sex partners (17). Further research is necessary to modernize Canada's research agenda with regards to HIV risk in blood donation from HIV-negative people who use PrEP or HIV-negative people whose partners are living with HIV and maintain undetectable viral loads.

1.3 HIV Pre-exposure prophylaxis and blood donor screening

Canadian blood operators currently defer donors taking PrEP for three months following the last dose despite estimates that PrEP is ~99% effective at preventing HIV acquisition when taken as prescribed (18). The deferral is due to concerns regarding capacity of current testing technologies – including gold standard pooled nucleic acid testing (NAT) – to clearly identify breakthrough cases of HIV infection (19,20). Seed et al write that PrEP creates the possibility that an acutely HIV-infected individual may fail to seroconvert or may serorevert resulting in a reactive NAT but negative serology. Such grey zone results are problematic for interpretation and the authors ultimately recommend that PrEP use continue to be grounds for exclusion in blood donation. The authors acknowledge that PrEP is highly effective, but take issue with the fact that it is only 99% effective and not 100% effective. Their concern is well illustrated by Zucker et al. who describe a case in which a client with multiple partners and inconsistent condom-use initiated PrEP around the time of HIV exposure. In this case a nucleic acid test (NAT) and OraQuick® Rapid HIV-1/2 Antibody test were negative and non-reactive on day-0, the rapid test

was again non-reactive on the day of PrEP initiation. On day-35 the NAT was repeated, and HIV was detected, the rapid test also screened reactive. On day-53 the rapid test was reactive, and HIV-1/2 supplemental test by Geennius was HIV-1 indeterminate, an HIV-1 RNA quantitative polymerase chain reaction (PCR) test did not detect HIV-1, and an HIV-1 DNA/RNA qualitative PCR detected HIV-1, an HIV-1 NAT did not detect the target. This type of case is uncommon, and it is unclear if this client would be eligible for donation at any point in this timeline. This case nonetheless underscores the need for research examining the intersection of biomedical HIV prevention and blood donation.

Several studies note that adherence is key to PrEP's efficacy (21–23). Given how effective PrEP is for adherent clients, it is important in the context of blood donation to understand factors that contribute to PrEP use non-adherence and if it is possible to reliably measure self-reported adherence using a single question. An international study investigating factors associated with PrEP use found that taking other steps to protect oneself from HIV and sexually transmitted infection diagnosis or treatment was associated with PrEP use. This suggests PrEP users may be a lower risk group than some have suggested for HIV. A systematic review found that common factors associated with non-adherence were stigma, low risk perception, low decision-making power, unacceptable dosing regimen, side effects and logistics of daily life (24). Finally, due to the importance of adherence to the effectiveness of PrEP (and therefore HIV prevention) finding cost-effective and accurate measures of adherence has been the focus of several studies. These studies compare various non-biological measures of adherence with drug concentration levels observed in biological samples and provide some insight as to what might be adaptable for blood donor screening. In Brazil, researchers investigated this using a cross-sectional study that assessed three indirect measures of adherence, one of which was self-reported adherence, and

compared these measures with observed tenofovir-diphosphate (TFV-DP) concentrations in dried blood spot samples (DBS) (25). They concluded that high indirect adherence measures were predictive of protective drug levels and that self-reporting can be used to predict PrEP adherence in a public health context in Brazil for gay and bisexual MSM and transgender women. The Australian study PRELUDE compared both clinician-facilitated and online self-reporting of adherence in GBMSM with protective drug concentration blood levels and found that 99% of their sample had protective drug levels consistent with >4 pills per week (26). The authors concluded that physician-facilitated self-reported adherence was concordant with protective drug levels. However, online reporting did show some decline in perfect adherence. Another study investigated self-reported adherence of female sex workers in Benin in West Africa, and this study suggested that adherence was over reported in that population (27). In Canada, Clinique L'Actuel in Montréal investigated PrEP adherence in their PrEP cohort which was predominantly MSM and although they did not investigate concordance of self-reported and biological measures of adherence, they did observe strong adherence and also noted a decrease in sexual risk taking in more than half the cohort which contradicts the theory of risk compensation which posits that PrEP users may engage in riskier sexual acts as a result of perceived increase in protection (28). Together these studies show that indirect measures of adherence can predict protective levels of drug concentration, but that there is variability in accuracy by location, method and population. Blood donor screening questionnaires in Canada warrant dedicated investigation to determine sensitivity and specificity as an indirect measure of adherence.

More research is needed to understand what proportion of GBMSM who indicate interest in blood donation are PrEP users, and what is the level of concordance of self-reported adherence and protective levels of drug concentration. Although evaluating self-reported PrEP adherence

against an objective measure is beyond the scope of this thesis, the estimates resulting from this project could be grounds for future research to do so.

1.4 Treatment as prevention (TasP) for HIV-negative donors

Currently, anyone who has had sex with an HIV-positive person in the last 12-months is not eligible to donate blood. Since the discovery of treatment as prevention (TasP) there has been increasing evidence that people living with HIV do not transmit HIV if their viral load can be sufficiently reduced (29–31). The PARTNER and PARTNER2 studies were landmark studies that explored this by following heterosexual and same-sex couples, respectively, who were in serodifferent relationships where condomless intercourse was reported (17,32). PARTNER2 followed men who reported condomless anal sex (CAS) with their same sex partner. The objective was to estimate incident HIV infections at the within-couple level through phylogenetic analysis of any transmissions that occurred. Although 15 infections did occur over the eligible partner years of follow-up, zero were phylogenetically linked and therefore could not be attributed to the virally suppressed HIV-positive partner in the couple. The authors of the final report stated that their findings were supportive of the HIV prevention campaign U=U or 'undetectable equals untransmittable' – a community empowerment campaign that communicates those with supressed viral loads cannot pass HIV to their partners (33).

Viral suppression is achieved through consistent adherence to antiretroviral therapy (ART) and is generally defined as having a viral load of less than 200 viral copies per millilitre of blood (34,35). This and other biomedical advancements have raised questions about what it means to be at elevated risk for HIV. Traditionally, researchers investigating HIV transmission in GBMSM populations used a simple definition of any condomless anal sex (CAS) having been reported as

sufficient to define an individual as being at high risk. Horvath et al challenge this and estimate that the number of GBMSM who are at high risk for HIV would be much smaller if biomedical prevention methods were considered in public health's conceptualization of risk (36). They examined four definitions; 1) a traditional model defined as CAS with an HIV-negative or unknown serostatus partner; 2) a definition that considered viral suppression; 3) a definition that considered partner PrEP use; and 4) a definition that considered participant HIV viral load and partner PrEP use. The authors found that only six percent of their participants were considered high risk under the definition that considered viral suppression compared with 46% under the traditional definition. This has implications for blood operators as such a definition could significantly increase the number of GBMSM donors who are eligible for blood donation, thus contributing to sufficient supply. These findings are discussed in context of our results in Chapter Three.

Although viral suppression can be achieved through antiretroviral therapy for HIV (ART), it is not always achieved despite generally high adherence and viral suppression for those who start treatment in Canada (37). If TasP were to indicate eligibility for HIV-negative people with HIV-positive partners in the future, it would be important that people living with HIV (PLWHIV) are aware of their viral suppression status and can accurately recall their adherence to medication given the role ART plays in viral suppression.

Multiple studies have investigated how these dynamics manifest at the within-relationship level. Levine et al found that higher discrepancies between electronically monitored adherence (the objective measure of adherence in their study) and self-reported adherence were associated with lower cognitive functioning and an externalized locus of control – a concept in psychology that describes a belief that external rather than internal factors dictate one's personal

circumstances (38). Conroy et al conducted a longitudinal study of male couples in which at least one partner was living with HIV to understand better viral load beliefs within the partnership over time. They found that the odds of having an accurate viral load belief about their partner decreased over time (OR=0.83), and that within-couple dyadic adjustment (a measure of acclimation to life in a partnership) (OR=0.66) and feelings of commitment (OR=0.82) were negatively associated with accurate viral load beliefs (39). In this sample primary partners were frequently inaccurate with a tendency to overestimate that their partner was virally suppressed. Most importantly for blood donation, when a partner was inaccurate, the majority – roughly 80% at baseline – assumed their partner was virally suppressed when they were not. A brief report of another study published in 2020 by Stephenson et al came to a similar conclusion and found relatively high levels of inaccuracy in reporting of viral suppression with only 72.5% of HIV-positive men accurately reporting their viral suppression status (40). In this study the demographics of those whose self-reported viral load was inaccurate were compared, and the authors found no statistically significant differences based on demographics. Only those who also had biomarkers for syphilis were more likely to inaccurately report their viral load. The authors were clear that they did not feel that this misreporting was intentional and point out that although viral load testing is recommended every three to four months that does not always happen. They also found that 48% of their sample reported less than 100% adherence to medication. Mustanski et al. build on the idea that inaccuracy of reporting may be due to infrequency of viral load testing (41). They compared self-reports of viral suppression to both medical records and biomarkers and found a higher concordance between self-reports and medical records from last doctor's visit (80%) and lower concordance between self-reporting and study lab results (73%).

It is important to note that all of these studies were conducted in the United States of America with the exception of the PARTNER studies which were conducted in Europe. Although there are differences between the Canadian provinces in how they deliver HIV care (and medications), they are all alike in that the Canada Health Act guarantees access to medically necessary services (42). This has ramifications for Canadians in serodifferent partnerships and it is entirely possible that increased physician access and no-cost-to-patient laboratory testing mean that Canadians are better able to accurately self-report viral suppression than those without these advantages. Certain Canadian provinces also make HIV medication more accessible. In British Columbia, for example, all PLWHIV are given the option of having free HIV medication by participating the BC Centre For Excellence's HIV research program – authors affiliated with the BC Centre For Excellence illustrate the importance of low-barrier access to treatment and testing (43,44). It is also important to understand how many HIV-negative men in Canada are interested in donating blood and report having serodifferent relationships. If this population makes up a significant proportion of GBMSM who are willing to donate, that should be considered in the research dedicated to viral suppression status self-reporting.

1.5 Study scope and theoretical underpinnings

This study stems from years of community activism on behalf of GBMSM and others in queer communities who have long advocated for modernization of Canadian blood donation deferral policies. Community members demand that policy makers design deferrals that better align with their lived experiences and understandings of HIV risk and science (45–47). As Canadian blood operators look to international examples and begin to include more sexually active MSM in whole blood donation, an opportunity is presented to further explore the impact

of biomedical HIV prevention strategies that are increasingly popular supplements or alternatives to condoms in our communities. Doing so will not only benefit GBMSM communities, but those in the entire population who use these HIV prevention strategies, and further destigmatize two very efficacious HIV prevention strategies.

The purpose of this study was to estimate the number of GBMSM donors who were interested in donating blood (who would otherwise be eligible) but would ultimately be deferred due to their use of a biomedical HIV prevention strategy. Descriptive statistics and estimates of likeliness to donate identify opportunities for future research that may ultimately expand eligibility to those who use PrEP and U=U (or TasP) to prevent HIV. This research was interdisciplinary in that it draws on both public health and HIV medicine's constructions of transmission and acquisition risk and utilized a constructivist epistemology to attempt to reconcile any differences. Positivist quantitative methodologies were used to produce population estimates of otherwise eligible GBMSM donors who use biomedical HIV prevention strategies.

At this time, no estimates exist regarding the number of GBMSM donors who would be deferred for PrEP or having had an HIV-positive virally suppressed partner. Blood operators could benefit through improving the specificity of their screening questions and increasing donor recruitment. GBMSM communities will benefit through increased inclusion and a reduction in stigma. As a society, we should not ask GBMSM to decide between using efficacious measures to prevent HIV acquisition and blood donation.

1.5.1 Research objectives

The objectives of this research are to; a) better understand the number of GBMSM donors who will continue to be deferred under a gender-neutral policy for reasons related to biomedical

HIV prevention use (either PrEP or TasP), b) Assess the impact of PrEP use on donation intention, and in the TasP sample, c) describe HIV risk and protective factors, and compare these observations to population health estimates of HIV risk – thus allowing us to explore whether or not these estimates 'reasonably' describe HIV acquisition risk using recent literature. Together these objectives will inform Canada's larger research agenda regarding the intersection of biomedical HIV prevention and blood donation.

1.6 Methodological design

This thesis is based on a secondary analysis of cross-sectional community health survey data of GBMSM. Descriptive statistics and logistic regressions were used to quantitatively explore the impact of biomedical HIV prevention on willingness to donate blood and to estimate how many GBMSM will be affected by deferral policies that target those using PrEP and TasP.

1.6.1 Data Source

The Sex Now Survey is a community-based periodic cross-sectional survey run by the Community-Based Research Centre in Vancouver, British Columbia. The Community-based Health Equity Research group at the University of Victoria in Victoria, British Columbia is the study's primary academic affiliation. The University of Victoria serves as the board of record and granted ethics approval for the study (BC17-487.) It has been conducted both in-person and online and is Canada's largest and longest running survey of GBMSM. Participants provided informed consent by providing a pseudonym or initialing an informed consent document if participating in person, and by confirming informed consent using an online form if participating online. In 2019 the online portion of the self-complete survey (full access to questionnaire available here) recruited over 7,000 participants who were asked questions about their sexual behaviour, sexual health (including questions regarding HIV prevention strategies), and views on

blood donation. Participants had to be 15 years old to participate and 18 years old to be given questions concerning sexual assault. They had to identify as a man (cis or trans) or Two-Spirit, live in Canada, and have had sex with a man in the last five years. Participants could complete the study only once in a given year. Participants could complete the study in English or French. Participants were recruited online over social and sexual networking sites and online promotion through a national network of grass-roots organizations that serve queer men. A $10.00 incentive was provided to participants in person, and online participants were entered into a draw for an Air Canada Travel Voucher.

Participants also underwent a HIV risk assessment by responding to the HIV Incidence Risk Index for men who have sex with men (HIRI-MSM) (4). Participants were then given a score according to their responses and told that HIRI-MSM score of ≥10 indicated high risk for HIV infection in line with national clinical guidelines (48).

Participants were also asked if they felt that Canada's current three-month blood donor deferral policy for men who have sex with men was fair and then asked to rank a selection of potential alternative donor deferral policies. They were also asked if they would donate blood if they were eligible to do so today.

1.6.2 Statistical analyses

Both chapters Two and Three will address my first objective and estimate the number of otherwise eligible donors in our study sample deferred solely for biomedical HIV prevention. My second objective is to assess the impact of PrEP use on donation intention. The Sex Now Survey asks participants about their PrEP use and their intention to donate blood. We selected participants who would likely be eligible blood donors – if not for their use of PrEP or TasP – by replicating the Canadian Blood Services Donor Questionnaire deferrals using study data to the

extent possible (48). The survey did not ask questions about recent travel, general health or medications – the algorithm therefore likely overestimates eligibility. We explore the effect of PrEP use on 'willingness to donate' using multiple logistic regression. We use parameter coefficients to produce odds ratios quantifying the effect PrEP use has on donor willingness. We hypothesize PrEP users believe themselves better candidates for blood donation as some literature investigating PrEP adherence has shown that those who engage in other HIV prevention tactics are likely to also be PrEP adherent (49). Such donors may see themselves as being lower risk given their combination prevention strategies and view themselves as ideal donors. This could inform research exploring the expansion of eligibility to PrEP users. In Canada the HIRI-MSM is often used to assess PrEP eligibility and is a proxy measure of sexual risk for HIV acquisition (50). Having recently heard the three-month donor deferral policy discussed in the media, any trans experience, African, Caribbean and Black (ACB) ethnicity, age, agreement or disagreement with the three-month deferral and having made a past donation will be explored as covariates, and confounders. The donor deferral policy was contentious and political at the time of data collection. Having heard the policy discussed in the media may impact pre-existing attitudes towards blood donation. Due to limited a priori knowledge these parameters will be tested interchangeably as covariates and confounders during final model selection. Model parameters were determined using automatic backward-stepwise regression which tested all possible combinations of variables allowing for up to two interaction terms (51,52). Limitations of automatic selection processes are well documented, further rationale for this model is provided in Chapter Two. PrEP was protected during programming as a variable of interest and could not be removed automatically under any circumstance. Further justification of this approach is given in Chapter Two. We evaluated the final model using McFadden's pseudo-

R squared test to determine the model's predictive power and calculated the area under the receiver-operator curve to assess the model's capacity to discriminate between willing donors and those unwilling (53,54).

My third objective is to describe HIV risk and protective factors and compare these observations to population health estimates of HIV incidence risk – thus allowing us to explore whether or not these estimates 'reasonably' describe HIV acquisition risk using recent literature. Descriptive statistics will count participants who report sex with a person whose viral load is undetectable. Sex Now asks participants to indicate what kind of sexual partners they've had using a select-all-that-apply question. We describe the study sample in terms of demographic characteristics, HIRI-MSM scores, a modified HIRI-MSM score controlling for one HIV-positive undetectable partner, history of sexually transmitted infections associated with increased risk of HIV-acquisition, and HIV prevention strategies used. Chapter Three describes the modified HIRI-MSM score and rationale further. These descriptive results are compared with both an individual assessment of risk (HIRI-MSM) and a population health level estimate of residual risk to the blood supply – a risk management concept describing risk that remains after precautions are implemented. I will discuss these findings in terms of current HIV prevention science to assess if the HIRI-MSM and residual risk estimate 'reasonably' describe HIV risk for the sample. This may identify opportunities for future research into public health level estimates that would consider viral suppression, and potentially other protective factors, during donor screening.

2.0 Chapter Two: Pre-exposure prophylaxis for HIV and blood donor intention

2.1 Introduction

Canada's evolving whole blood donation policies for gay, bi and other men who have sex with men (GBMSM) are historically controversial. Canadian Blood Services (CBS) and Héma-Québec have been the subject of legal action, boycotts, and protests in response to what many viewed as deferral policies based on sexual orientation (11,45,46). The Parliament of Canada's Standing Committee on Health conducted a study and recommended a change to a gender-neutral deferral policy – the gender of one's sexual partner should not be used in determining 'risk' to the blood supply (3). CBS in partnership with Héma-Québec began exploring alternatives and implemented a policy like the United Kingdom, which screens out donors based on specific higher risk sexual activities rather than gender. Health Canada approved Canadian Blood Services and Héma-Québec's applications to shift to individual risk-based assessment of all donors – regardless of sex or sexual orientation – on April 4, 2022 and September 6, 2022 respectively (4,5). Under this policy, blood operators ask potential donors if they've had new or multiple sex partners in the last three months, if so whether they've had anal sex with any of these partners; if the answer to the anal sex question is yes, they will be deferred from donation (48). Canada's new approach advances social inclusivity and expands the donor pool to include sexual and gender minorities who were previously deferred. Despite this advancement, disparities persist.

Anal sex remains a screening criterion as the epidemiology of HIV has shown sexual transmission is more likely to occur during anal sex than vaginal or oral sex (55–59). Further,

those who participate in anal sex with new or multiple partners are deferred regardless of any measures they take to protect themselves and partners. Indeed, some will be deferred *because* of the measures they take to protect themselves. If researchers and blood operators do not investigate alternatives to these 'adjacent' deferral policies for men with same sex partners, systems are then inclusive in name but not design and practice.

Deferrals for use of pre-exposure prophylaxis (PrEP) for HIV prevention will likely increase as the number of men with same sex partners who seek to donate blood increases. PrEP is an increasingly popular pharmaceutical approach for HIV prevention and remains grounds for deferral from blood donation in Canada (6,48). PrEP has been shown to be highly effective with the United States Centre for Disease Control estimating up to 99% effectiveness at preventing HIV infection when taken as prescribed (18,22,60–62). Although effective, PrEP can interfere with HIV testing and yield grey zone results for acutely infected individuals in the rare case of a breakthrough infection (19,63,64). PrEP awareness and uptake by sexual and gender minority men is increasing across Canada and some research indicates publicly-funded access impacts the decision to start PrEP (65–68). Many provinces fund public programs subsidizing the cost of PrEP for those at higher risk of acquiring HIV and some provinces, such as British Columbia and Alberta, publicly fund the entire cost of the medication for those clinically eligible (69,70). In 2018, the Sex Now Survey – Canada's largest survey of GBMSM – found that 92% of participants would donate blood if they were eligible to do so (unpublished data). As the landscape of pharmaceutical prevention of HIV continues to evolve, national blood operators must consider how HIV prevention strategies intersect with donor criteria and donor populations. We sought to understand what proportion of GBMSM who were screened-in to donation would be deferred for PrEP use, and if PrEP use might be associated with increased odds of willingness

to become a blood donor – perhaps due to self-perceived decreased risk of HIV acquisition due to protection conferred by PrEP use, or some similar latent factor not measured.

2.2 Methods and Materials

2.2.1 Questionnaire and data

The Sex Now Survey is a periodic cross-sectional biobehavioural study of cis and trans gay, bi and other men who have sex with men, inclusive of Indigenous Two-Spirit men. It is a community-based participatory research project organized in partnership by the University of Victoria's Community-based Health Equity Research group and the Community-Based Research Centre (CBRC) in Vancouver British Columbia, Canada. Community partner organizations across the country collaborate to promote the study and recruit participants. The survey is conducted both in-person and online. The University of Victoria serves as the board of record and granted ethics approval for the study (BC17-487.) To be eligible participants had to identify as a man or trans-masculine and have had sex with another man in the past five-years. Participants gave informed consent and were made aware of research objectives, potential risk and benefits using an informed consent page before the online survey. In 2019, the recruiting partners were based in British Columbia, Alberta, Manitoba, Ontario, Québec and Nova Scotia (complete list in Appendix 1) and recruited through online advertising and direct email campaigns to their membership and client lists. Canada-wide paid advertisements with sociosexual networking websites and apps for sexual minority men also support participant recruitment. This cycle included questions investigating blood donation sentiment and intentions among sexual and gender minority Canadians.

Blood donation questions were optional. We developed a complete case cohort for analysis from those who opted to respond to those questions and gave any answer to the

question, “If I were allowed to, I would donate blood in the future.” *Table 1* gives the survey questions and response options. Except for age, all responses were dichotomized into binary outcomes for analysis.

Table 1. Sex Now 2019 Survey Questions

Survey question	Response options
“Have you ever used PrEP?”	● “Yes! I’m taking PrEP now.” ● “No” ● “Yes, but I stopped.”
“If I were allowed to, I would donate blood in the future.”	● “Strongly disagree.” ● “Disagree.” ● “Agree.” ● “Strongly agree.”
“How would you rate your CURRENT risk for getting HIV?”	● “Low.” ● “High.” ● “I think I already have HIV.” ● “Don’t know.”
“How old are you? (In years)”	*Participants selected an age from a drop-down menu.*
“Do you have trans experience? (i.e. your gender is different than the sex you were assigned at birth.)”	● “Yes” ● “No” ● “I prefer not to answer.”
“Have you ever donated blood at any point in your life?”	● “Yes, in the past year.” ● “Yes, but longer than a year ago.”

	• "No, never." • "I don't remember."
"The current 3-month deferral policy for MSM is JUSTIFIED."	• "Strongly disagree." • "Disagree." • "Agree." • "Strongly agree."
"The current 3-month deferral policy for MSM is DISCRIMINATORY."	• "Strongly disagree." • "Disagree." • "Agree." • "Strongly agree."

During community consultation Black stakeholders and academic partners highlighted issues of systemic racism within Canada's blood donation systems and highlighted ways in which Black sexual and gender minority Canadians are disincentivized to donate. Dr. OmiSoore Dryden argued in an opinion piece published to their website that, "As a practice, narratives of blood have been used to detail the terms and conditions of community and national belonging. With the language of purity informing national identity, citizenship, and the ideal body politic. Nation-based blood narratives (blood protection, blood quantum, one-drop and miscegenation) play a constitutive role in legalizing norms of behaviour; these norms, which attempt to govern and regulate both the private and public social spheres, serve to construct and implement racial hierarchies. Blood safety is thus used to facilitate the nationalist boundaries formed through the imagination of a political community. These historical and contemporary blood beliefs and practices depend upon a manufactured physical legibility of identity and surveillance to ensure

that othered bodies – those considered impure, “bad,” foreign, and dangerous (gay and black/African) – remain readily identifiable.” ("Blood Out of Bounds",71). To investigate if this could be observed in our sample we derived an ethnicity variable based on self-reported ethnic identity. Participants who indicated African, Caribbean or Black ethnicities regardless of additional ethnicities were considered ‘ACB’ and anyone who did not was considered ‘not-ACB.’ Ethnicity options in the questionnaire were informed by the Statistics Canada ethnicity options and community consultation(72). At the time of data collection Canadian blood operators deferred any man who had sex (anal or oral) with another man in the past three months. Gender was determined by surgical status for trans people. The deferral for PrEP use existed before the implementation of gender-neutral screening and remains today.

2.2.2 Sample and cohort selection

An online convenience sample of *n=14,364* was recruited and *n=6,723* responded to questions concerning blood donation representing *46.80%* of the total sample. We used the Canadian Blood Services donor screening questionnaire to approximate an analytic sample that would likely be eligible to donate blood, if not for their use of PrEP, resulting in a final complete case sample of *n=2,301*. Our approximation likely overestimates eligibility for blood donation. First, Sex Now and the CBS donor questionnaires do not ask comparable questions related to overall general health and the Sex Now questionnaire did not ask any questions related to medications not related to sexual health or any questions related to travel history. Further, temporal windows for questions did not always align between the questionnaires. If the recall-period used in the Sex Now Survey fit within the recall-period of the donor questionnaire it was kept as exclusion criteria for the analysis cohort. For example, the Sex Now questionnaire asks participants about recreational substance use in the last six months, Canadian Blood Services

uses a recall-period of 12-months. A participant who used cocaine in the last six-months falls within a 12-month window – this donor would be deferred by Canadian Blood Services and so meets our exclusion criteria using the six-month recall period. Therefore, our exclusion criteria were almost exclusively based on Canadian Blood Services' 'additional questions' exclusion criteria. A full description of the algorithm used to approximate the donor screening questionnaire is included in Appendix 2 along with corresponding donor screening questions using the online version accessed December 2022 (5).

2.2.3 Statistical analysis and model building

Analyses were performed using R Studio with necessary packages (73–81), the program can be found in Appendix 3 . Frequency distributions, percentages, means and standard deviations were used to describe sample characteristics. Differences between those who indicated willingness to become a blood donor and those who did not were tested using Pearson's χ^2 test for categorical variables (82).

We used logistic regression to estimate if PrEP users were more or less likely to indicate willingness to donate blood than non-PrEP user (83,84). We investigate how various independent variables may impact the probability that a participant would be willing to donate blood, to what extent PrEP may impact that decision, and what other factors may contribute to, or confound, that probability. In general terms this can be expressed as:

$$P\left(\widehat{Y_i}\right) = \frac{e^{\beta_0+\beta_1X_1+\beta_2X_2\ldots\beta_iX_i}}{1+e^{\beta_0+\beta_1X_1+\beta_2X_2\ldots\beta_iX_i}} \qquad (1)$$

Where $P\left(\widehat{Y_i}\right)$ is the probability of a particular outcome, X represents an independent variable and β represents a given independent variable's beta-coefficient, or weight indicating how much of an influence variable (*i)* contributed compared with the others.

Variables were selected for exploration based on community consultation and the literature review. Little is known about specific motivators for blood donation among sexual and gender minorities due to long-standing exclusion from donation. The model building strategy – backward-stepwise elimination – was similarly selected given limited understanding of the relationship between HIV prevention tools and sexual and gender minorities attitudes towards becoming blood donors. The complete case cohort was partitioned into training and validation datasets with replacement to preserve sample characteristics in both datasets. Backward-stepwise elimination begins by including all independent variables of interest in the initial model, they are then removed one at a time until only statistically significant independent variables remain(85). We used the automated *stepAIC()* function in the MASS package to remove least significant variables and compare models using Akaike information criteria (AIC). The model with the lowest AIC was selected as the final model. Variables were tested in all possible combinations for interaction terms allowing up to two interaction terms. *StepAIC()* allows the analyst to specify the number of interaction terms that will be allowed in final model and tests combinations of terms from the full model to accomplish this. Because PrEP-use is our primary predictor of interest, we protected the PrEP variable from automatic elimination during programming, keeping it forced into the model. Stepwise elimination has been criticized by some as being overly vulnerable to mathematical chance in sample populations. In situations such as ours, however, stepwise elimination – when combined with community experience – can help refine research questions, support hypothesis building and point inquiry in new directions (85,86).

We used beta-coefficients to calculate odds ratios for effect interpretation. We used McFadden's pseudo-R squared test to evaluate predictive power of the model and the area under

the receiver operator curve (ROC-AUC) to evaluate the model's ability to accurately discriminate between willing blood donors and those not willing to donate (54).

2.3 Results

2.3.1 Sample and cohort description

Of the initial *n=14,364 (100.00%)* Sex Now Survey participants *n=7,406 (51.56%)* opted-in to answering the additional questions related to blood donation and *n=6,723 (46.80%)* provided a response to the prompt, "If I were allowed to, I would donate blood in the future." After applying the eligible donor screening algorithm and removing incomplete cases, the final analysis cohort was *n=2,270* or *15.80%* of total participants, *30.65%* of participants who consented to the additional blood donation questions, and *33.76%* of participants who gave any answer regarding future blood donation intentions. The final analytic sample represents participants who have expressed interest in blood donation and deferral policies. This has likely introduced some bias and divergence from the whole of the participant sample – participants not interested in blood donation are not represented in the analyses. However, this may bias the analytic sample towards a 'true' donor population – people not interested in blood donation and blood donation issues may be less likely to donate blood. Table 2 shows how deferral policies (other than PrEP use) were applied by the exclusion algorithm across participants. Participants were allowed to receive multiple flags for exclusion – the table does not show individuals deferred rather the proportion of deferral flags by policy reason.

Table 2. *Participant exclusion flags by screening criteria*

Deferral Reason	Deferral flags n (%)
Diagnosed with HIV[a]	n = 485 (9.81)

Either giving or receiving money or drugs in exchange for sex	n = 418 (8.46)
Gender-neutral sexual behaviour criteria (partner count[b] and anal intercourse)	n = 3,233 (65.42)
Recent positive HCV[c] test result	n = 7 (0.14)
Lifetime injection drug use	n = 159 (3.22)
HIV-positive sexual partner	n = 640 (12.95)
Total	*n = 4,942 (100.00)*

Footnotes:

[a] *Human immunodeficiency virus*

[b] *Includes new and multiple partners see appendix 2 for complete algorithm*

[c] *Hepatitis C virus*

Had the PrEP deferral policy been used as an exclusion criterion an additional 85 participants would have been excluded and an additional 1,040 flags applied highlighting the strong overlap in non-discriminant screening criteria – many deferred for other reasons would also have been deferred for PrEP. Of the PrEP users in the final analytic sample, *n=74 (87.05%)* were willing donors and *n=11 (12.94%)* were not. Of the non-PrEP users, *n=1,942 (88.85%)* were willing donors and *n=243 (11.14%)* were not *($\chi^2 = 0.27$, $p = 0.60$)*. Participant age ranged from 17 (the

minimum age required for blood donation in Canada) to 78. Participants skewed younger with a median age of 32 and a mean of 35.64 with a standard deviation of 12.97 years. *Table 3*gives cohort characteristics of those who would donate if eligible compared with those who would not.

Table 3.

Sex Now 2019 analytic sample characteristics and intentions to donate.

	Would donate if eligible *n (%)*	Would not donate *n (%)*	X^2 *test p-value*
Agreement with 3-month deferral for men with same sex partners			*p < 0.005*
Agree	344 (15.15)	94 (4.14)	
Disagree	1,672 (73.65)	160 (7.04)	
Having donated in the past			*p < 0.005*
Have never donated	1,142 (50.30)	202 (8.89)	
Have donated	874 (38.50)	52 (2.29)	
Ethnicity			*p = 0.233*
ACB [a]	43 (1.89)	9 (0.39)	
Not ACB	1,973 (86.91)	245 (10.79)	
Gender identity			*p = 0.161*
Cis	1,759 (77.48)	230 (10.13)	

Trans	257 (11.32)	24 (1.05)	
Self-perceived risk of HIV[b] acquisition			*p = 0.131*
High	44 (1.93)	10 (0.44)	
Low	1,972 (86.87)	244 (10.74)	

NB: Results are based on final analytic sample after donor screening.

Footnotes:

[a] *African, Caribbean or Black ethnicity*

[b] *Human immunodeficiency virus*

2.3.2 Model building and evaluation

The initial model included all variables of interest derived from the survey questions in *Table 1* above. PrEP use, ACB ethnicity, trans experience, having donated blood in the past, and self-perceived higher or lower HIV-risk were dichotomous and age remained continuous. The final model included PrEP use, opinion on the three-month deferral policy for men who have sex with men, age, and whether a participant had donated in the past. No statistically significant interaction terms were identified. Self-perceived HIV risk, ACB ethnicity and trans experience where not found to significantly improve the performance of the model and were removed during backward-stepwise selection. PrEP use also did not significantly impact the fit of the final model. Recall that because PrEP use was the primary variable of interest in our hypothesis it was protected from automatic removal during programming – it was forced into the final model for exploration. *Table 4* below gives the regression coefficients, odds ratios, 95% confidence intervals and p-values for the final model.

Table 4.

Logistic regression results for predicting likelihood of willingness to donate blood among sexual minority men in Sex Now 2019

Characteristic	Coefficient Value	Odd Ratio	95% Confidence Interval	*p-value*
PrEP [a] Use	-0.26	0.77	0.38 – 1.74	*0.5*
Opposition to the deferral	1.01	2.77	1.95 – 3.91	*<0.001*
Age	-0.02	0.98	0.97 – 0.99	*<0.05*
Made a past donation	1.34	3.83	2.58 – 5.81	*<0.001*

Footnote:

[a] *Pre-exposure prophylaxis*

From the above we can see that there is no evidence to support that PrEP use can be used to predict whether someone may or may not be willing to donate blood. The 95% confidence interval for the PrEP odds ratio crosses 1 indicating that, while the estimated odds ratio is 0.77, the true value may fall on either side of 1 which gives no clear effect direction. Further, a p-value = 0.5 is not sufficient to reject the null hypothesis that PrEP use has no effect on the intention to donate blood. We do not have evidence to support our hypothesis that PrEP users are more likely to be willing blood donors due to a self-perceived lower risk of HIV acquisition. The most likely individuals to be willing blood donors were those who had donated in the past. They were almost 4 times more likely to be willing to donate blood than participants with no history of donation with an odds ratio of 3.83 and a 95% confidence interval of 2.58 – 5.81.

The purpose of this model was to explore correlations in the sample data. Although subject to omitted variable bias we were able to test these correlations. Despite this not being intended to be an explanatory model, we did evaluate predictive power in two ways; 1) using McFadden's pseudo-R^2; and 2) by calculating the area under the receiver-operator curve (AUC). While both these techniques examine predictive power, McFadden's pseudo-R^2 estimates the proportion of variance explained by the variables in the final model and AUC evaluates the model's ability to discriminate between outcomes using the variables in the model. The pseudo-R^2 was 0.08 indicating approximately 8% of the variance is explained by this model. The AUC was calculated to be 0.70. This statistic falls between 0.5 -1.0 with 0.5 indicating no ability to discriminate between outcomes and 1.0 indicating perfect discrimination. Although the model did not fit the data well, it did show what is generally considered an acceptable ability to discriminate between outcomes.

2.4 Discussion

2.4.1 Key finding and policy implications

Our study identified characteristics associated with increased willingness to donate blood among sexually-active sexual and gender minority men – a new donor population in Canada. However, we did not find any evidence to suggest that HIV PrEP use was one of those characteristics. Those opposed to the three-month deferral policy and those who had made a past donation were more likely to be willing to donate if eligible. Younger participants were more likely than older participants to be willing donors. Of all characteristics tested, a past donation was the greatest predictor of willingness to donate. This aligns with research that shows repeat donors are slightly more likely than first time donors to donate blood (87). Blood operators should consider this when planning targeted donor recruitment campaigns. But perhaps most

importantly, those opposed to the former three-month deferral policy could be up to nearly three times more likely to donate than someone who was not opposed *(OR = 2.77, 95% CI = 1.01 – 3.91, $p < 0.001$)*. This indicates an opportunity for Canadian blood operators to recruit new donors from a population that is more likely to donate again after donating once. We found characteristics Canadian blood operators should consider when promoting blood donation. It is estimated that only 3 per cent of Canadians will donate blood (88). Population health trends – particularly those concerning Canada's aging population – strongly suggest that the pool of blood donors will shrink in the future, while the need for blood products will certainly grow (88).

The current PrEP deferral criteria for PrEP use results in deferral of potential donors who would otherwise qualify for donation. In our sample,3.74% (n= 85) donors would have been excluded from our approximated donor population. Future research should consider that PrEP is highly effective with adherence (21–23). If PrEP use is the only reason a donor is deferred, we must ask if the use of an HIV-preventative medicine that itself augments HIV acquisition is indeed a risk to the blood supply. This could be investigated using donors who are deferred for PrEP use as the only reason for deferral. Any research that investigates PrEP-use in the context of blood donation must consider the important role adherence plays in preventing HIV-acquisition. Questionnaires and clinic interviews cannot determine if there is sufficient drug concentration in the blood – or that there has been protective levels since last testing negative for HIV. Instead, researchers should explore optimal recall periods to determine if adherence can be assessed with confidence in a clinical setting using existing screening methods. Researchers interested in adherence measures have compared various non-objective self-reported measures of adherence with drug concentration levels observed in blood samples providing some insight into what might be adaptable for blood donor screening. In Brazil, researchers conducted a cross-sectional study that

assessed three indirect measures of adherence, one of which was self-reported adherence, and compared these measures with observed tenofovir-diphosphate (TFV-DP) concentrations in dried blood spot samples (DBS) (25). They concluded that high indirect adherence measures were predictive of protective drug levels and that self-reporting can be used to predict PrEP adherence in a public health context in Brazil for gay and bisexual MSM and transgender women. The Australian study PRELUDE compared both clinician-facilitated and online self-reporting of adherence in GBMSM with protective drug concentration blood levels and found that 99% of their sample had protective drug levels consistent with >4 pills per week (26). The authors concluded that physician-facilitated self-reported adherence was concordant with protective drug levels. However, online reporting did show some decline in perfect adherence. Another study investigated self-reported adherence of female sex workers in Benin in West Africa, and this study suggested that adherence was over reported in that population (27). In Canada, Clinique L'Actuel in Montréal investigated PrEP adherence in their PrEP cohort which was predominantly MSM and although they did not investigate concordance of self-reported and biological measures of adherence, they did observe strong adherence and also noted a decrease in sexual risk taking in more than half the cohort – contradicting risk compensation theory which posits that PrEP users may engage in riskier sexual acts as a result of perceived increase in protection (28). Together these studies show that indirect measures of adherence can predict protective levels of drug concentration, but that there is variability in accuracy by location, method and population. Blood donor screening questionnaires in Canada warrant dedicated investigation to determine sensitivity and specificity as an indirect measure of adherence.

We did not observe any significant effects related to race or having had trans experience. However, Black participants and those with any trans experience were not well represented in

our analytic sample. Past research has shown that Black people are underrepresented as donors (some qualitative research points to mistrust in health systems and past experience with healthcare inequity to explain this) despite there being need for donors of African ancestry (89–92). Future research should dedicate focus to Black communities to better understand attitudes, motivators and barriers to donation for Black people and further elucidate the role race might play in donor recruitment. With the rise of social justice in public consciousness it will become increasingly important for blood operators' messaging to resonate with historically oppressed minority groups and consider what role the blood system as institutions may have played in that oppression. Research that specifically engages these groups will give blood operators the opportunity to address and heal past harms communicating knowledgeably, sensitively, and directly to a new generation of potential donors. Doing so may give blood operators renewed opportunity for establishing blood donation as a social responsibility.

2.4.2 Strengths and limitations

The Sex Now Survey is Canada's largest survey of sexual and gender minority men. While the sample may not be truly random, Dr. Salway and colleagues have shown that large nonprobability venue-based samples of sexual and gender minorities tend to demonstrate similar effect size and direction of associations when compared with each other (93). Community consultation regarding design and implementation of the study meant increased reach and awareness of research objectives and participation. This consultation was also important for variable selection in logistic regression modelling. Online access increased accessibility and participation opportunities for sexual and gender minority men who do not live near major urban centres where a majority of queer research takes place. At the time of data collection, most of our sample was not allowed to donate blood; indeed, the majority would still be deferred today. We

gained insight into blood donation sentiment within a group not well represented in blood operators' clinic data. The final model's ROC-AUC showed acceptable discernment between those who were willing to donate blood and those who were not. The model also demonstrated strong effect size and statistical significance for repeat donors. Additional variables should be considered in future work attempting to identify traits that might predict willing donors in populations not currently represented in databases blood operators rely on for their research.

While the Sex Now Survey historically oversamples people of colour and gender minorities, these populations were not well represented in the final analysis cohort. Dr. Dryden's work explores how systemic racism has discouraged Black Canadians from engaging with Canada's blood donation systems and medical racism in Canada (94–96). Blood donation questions were optional in the online questionnaire, a history of systemic racism in blood donation may have impacted participation in these optional questions. Given the low representation of Black and gender minority people in the analysis cohort, the generalizability of our results beyond cis-gender white people may be limited – additionally participation would only have been available to those with either a smartphone or laptop and an internet connection, those targeted by online ads, or those subscribed to a partner agency's e-mail distribution lists. Further, the Sex Now Survey is primarily a HIV-surveillance study and the data available for exploring phenomena related to blood donation was limited, primarily with regards to characteristics that might motivate blood donation. Finally, the donation deferral policy for men who had sex with men was highly politicized and deemed by many in the community to be offensive and unnecessarily discriminatory and homophobic. Our model showed that those who believed the policy was discriminatory were significantly more likely to be willing blood donors. The causal pathway of that finding is unclear – did feelings about the policy drive willingness to

donate or did a desire to be included in blood donation drive dissatisfaction with the policy? Survey takers at community events and online may be more prosocial than others – research on prosociality shows people prefer to help 'in-group' members, and that prosocial behaviour and emotions are involved with the decision to donate blood (97,98). Prosiciality is a concept in psychology that describes our willingness to help others. Related, the 'good-subject' effect explains participants may respond to studies in a way they believe confirms researchers' hypotheses depending on their attitudes towards an experiment and other individual differences (99). This speaks to the need to conduct further research with recently eligible donors. If community activism and politicization of donor deferral policies for MSM have impacted our findings in a significant way, future research may find different results than we have here.

2.5 Conclusion

PrEP use does not predict willingness to donate. Our model showed the strongest predictors were age, opinion on deferral policy, and having made a donation in the past. The model was not well fit and had low predictive power, but acceptable discrimination between those who were willing to become donors if eligible and those who were not. Future research should repeat similar studies with sexual and gender minority Canadians now that they are no longer deferred based on the gender of their sexual partners. A key finding was that having made a donation in the past was the strongest predictor of willingness to donate. Blood operators should continue to investigate deferral policies that disproportionately impact sexual and gender minority men – such as the deferral for PrEP use and the deferral for having a partner who is HIV-positive (regardless of viral load) – and sincerely invest in reconciliation with these communities. There remains a significant opportunity to engage and recruit sexual and gender minority men for blood donation. With an increasing sense of social justice in Canada, minority

population reconciliation and recruitment strategies will become increasingly important if voluntary donation is to remain relevant in the minds of donors.

3.0 Chapter Three: 'Undetectable = Untransmittable' and blood donation – A short report

3.1 Introduction

Canadian Blood Services and Héma-Québec have shifted to gender neutral screening criteria for allogenic blood doors – putting an end to the deferral policy for men who have sex with men; deferrals continue for having a sexual partner who lives with HIV (4,5). Canada's shift to gender neutral screening criteria will likely mean an increase of sexual and gender minority donors (SGM) who choose biomedical HIV prevention methods. There have been significant advancements in antiretroviral-based HIV prevention. Undetectable equals untransmissible (U=U) and Treatment as Prevention (TasP) convey that a person living with HIV, who has an undetectable, i.e., suppressed, viral load cannot pass the virus sexually to their partner. U=U is a community-based social marketing campaign that empowers those living with HIV(33,100). U=U as a social marketing campaign has educated HIV positive and negative men about protection conferred by viral suppression (101,102). Many who are otherwise eligible may be deferred and feel this policy is discriminatory and stigmatizing. TasP was coined by the BC Centre for Excellence in HIV/AIDS and positions HIV testing and treatment as a secondary prevention intervention(103,104). This policy may be seen to be serophobic (discrimination against those with a different HIV-serostatus) (105,106). Blood operators risk continued alienation of donors and may be unable to achieve meaningful reconciliation with queer communities. Historic gendered deferral policies and ongoing policies that defer for biomedical HIV prevention strategies, such as U=U, disproportionately impact sexual and gender minority donors – specifically those whose communities experience a higher burden of HIV.

Donors with risk factors for transmissible infections are deferred to reduce the risk of window period infections (time between infection and detection) (107). Viral suppression due to

highly active anti-retroviral treatment (HAART) effectively reduces the chance of acquiring infection for HIV-negative sexual partners to zero (108). At the time of writing there was no literature available that considers residual risk of HIV transmission from donors whose partners are HIV "undetectable". We used descriptive statistics to examine a sample of gay, bi and other men who have sex with men (GBMSM) whose partners were undetectable. We describe demographics, prevalence of sexually transmitted infections associated with HIV acquisition, and use of HIV prevention strategies to identify opportunities for further inquiry on more inclusive blood donor screening.

3.2 Methods

The 2019 Sex Now Survey collected an online convenience sample of cis and trans men who had sex with another man Participants responded to a questionnaire regarding their sex lives, community connection, mental health and substance use as well as optional blood donation questions. Sex Now is a community based-participatory research program operated by Community-Based Research Centre in Vancouver, British Columbia in partnership with the Community-based Health Equity Research Lab at the University of Victoria. The University of Victoria serves as the board of record and granted ethics approval for the study (BC17-487.) Participants were eligible if they self-identified as Two-Spirit, a cis or trans man, or transmasculine and had sex with another man in the past five-years, lived in Canada, and could complete the survey in French or English. Participants gave informed consent and were made of research objectives, potential risk and benefits through an informed consent page online – to proceed to the online survey they acknowledge risks, benefits and research objectives and confirmed consent. As incentive, participants could optionally provide contact information to be

entered into a draw for a $500.00 flight voucher. Contact information and study information are housed separately and it is not possible to link the two datasets.

The analytic sample was restricted to self-reported HIV-negative participants who were 17 years of age or older (the minimum age to be eligible to donate blood) and had a sex partner who was living with an undetectable HIV viral load. Precise definitions of 'undetectable' vary. Generally, a viral load < 200 copies / mL is considered virally supressed i.e., undetectable (35,100,104). Only participants who responded to the optional blood donation questions were included and we replicated the CBS donor selection criteria to the extent possible. The Sex Now Survey doesn't ask questions related to general health and travel – our approximation algorithm focuses on sexual behaviour and substance use. Look-back periods for Sex Now questions and donor screening questions did not always align, if the survey's look-back window fell within the donor questionnaire's look-back window it was kept as exclusion criteria in the algorithm. See Appendix 2 for complete algorithm.

Analyses describe the analytic sample's; 1) demographics, 2) prevalence of STIs associated with increased risk of HIV acquisition, and 3) prevalence of HIV prevention strategies participants employed in the past six months. The HIV Incidence Risk Index for men who have sex with men (HIRI-MSM) and a modified HIRI-MSM score were used to assess HIV risk (109). See Appendix 4 for complete list of HIRI-MSM items. A HIRI-MSM score of 10 or higher is considered high risk for HIV acquisition. We calculated modified HIRI-MSM scores by subtracting the points the scale grants for having had one HIV-positive sex partner; this modification helps to correct some overestimation of risk in the HIRI-MSM because a partner with an undetectable viral load cannot pass HIV. We also estimate period prevalence of self-reported syphilis, gonorrhea, and chlamydia diagnosis within the year prior to survey; these

infections are associated with increased susceptibility to HIV acquisition when present in the rectum (110). All analyses were conducted using R and R Studio.

3.3 Results

The final analytic sample included 53 men. 36 participants were in a relationship with another man, 15 were single, and a small number were in polyamorous relationships. Participants were predominantly white and well distributed across age categories. Table 1 summarizes sample demographics. Age categories align with HIRI-MSM age categories (109).

Table 1

Demographic characteristics of Sex Now 2019 participants with HIV undetectable partners

	N
Gender Identity	
Man (cisgender)	53
Transgender	≤ 4
Ethnicity	
Black	≤ 4
Caribbean	≤ 4
Indigenous	≤ 4
Latin American	≤ 4
Southeast Asian	≤ 4

white	40
Other	0
Relationship status	
Single	15
Partnered	36
Polyamorous	≤ 4
Age Category	
< 18	≤ 4
18-28	10
29-40	17
41-48	7
49+	18

Past-year prevalence of STIs associated with increased risk of HIV infection were low. There were no observed cases of syphilis. The Public Health Agency of Canada reported that the rate of infectious syphilis for men in Canada was 35.5 cases per 100,000 people in 2019 and estimates that 38% of infectious syphilis cases reported were attributable to MSM – while syphilis cases may be on the rise in Canada, given this rate it was unlikely we'd observe a case in a sample of 53 people (111). The prevalence of gonorrhea and chlamydia were the same at 7.5% with a 95% confidence interval of 0.4% –14.7%. Participants were also asked if they had been diagnosed specifically with a rectal STI in the past six months, longer than six months ago or never. In the past six month 7.5% had a diagnosis of a rectal STI and 11.3% had received a rectal

STI diagnosis but longer than six months ago for a total of 18.9% with a 95% confidence interval of 11.8% – 25.9%.

Both the HIRI-MSM modified scores and unmodified scores are provided in Table 2 and were on average over 10 across all age groups except for the modified scores of participants 41 and older; a score of 10 indicates elevated risk for HIV acquisition.

Table 2

HIRI-MSM and Modified HIRI Minimum, Maximum, Median and Mean Scores

	Age Group					
		< 18	***18-28***	***29-40***	***41-48***	***49+***
HIRI	Min/Max	14 /14	8 / 35	8 / 29	2 / 23	4 / 23
	Median	14.0	25.0	16.5	10.0	13.5
	Mean	14.0	23.5	16.9	12.1	12.8
		(NA)				
Modified	Min/Max	10 / 10	4 / 31	4 / 25	0 / 19	0 / 19
HIRI [1]	Median	10.0	21.0	12.5	6.0	9.5
	Mean (std)	10	19.5	12.9	8.1	8.8
		(NA)	(7.2)	(6.9)	(7.5)	(6.2)

NOTE:
[1]Modified HIRI scores give 0 points for 1 HIV positive-partner and 4 points for more than one,, unmodified HIRI scores give 4 points for 1 HIV-positive partner and 8 points for more than one.

Participants employed multiple HIV prevention methods each – 53 participants selected a total of 120 prevention methods from seven options in the past six months. The most common were monogamy, being the insertive partner during anal sex, and practicing U = U. Figure 1 gives the frequency proportion of prevention methods utilized.

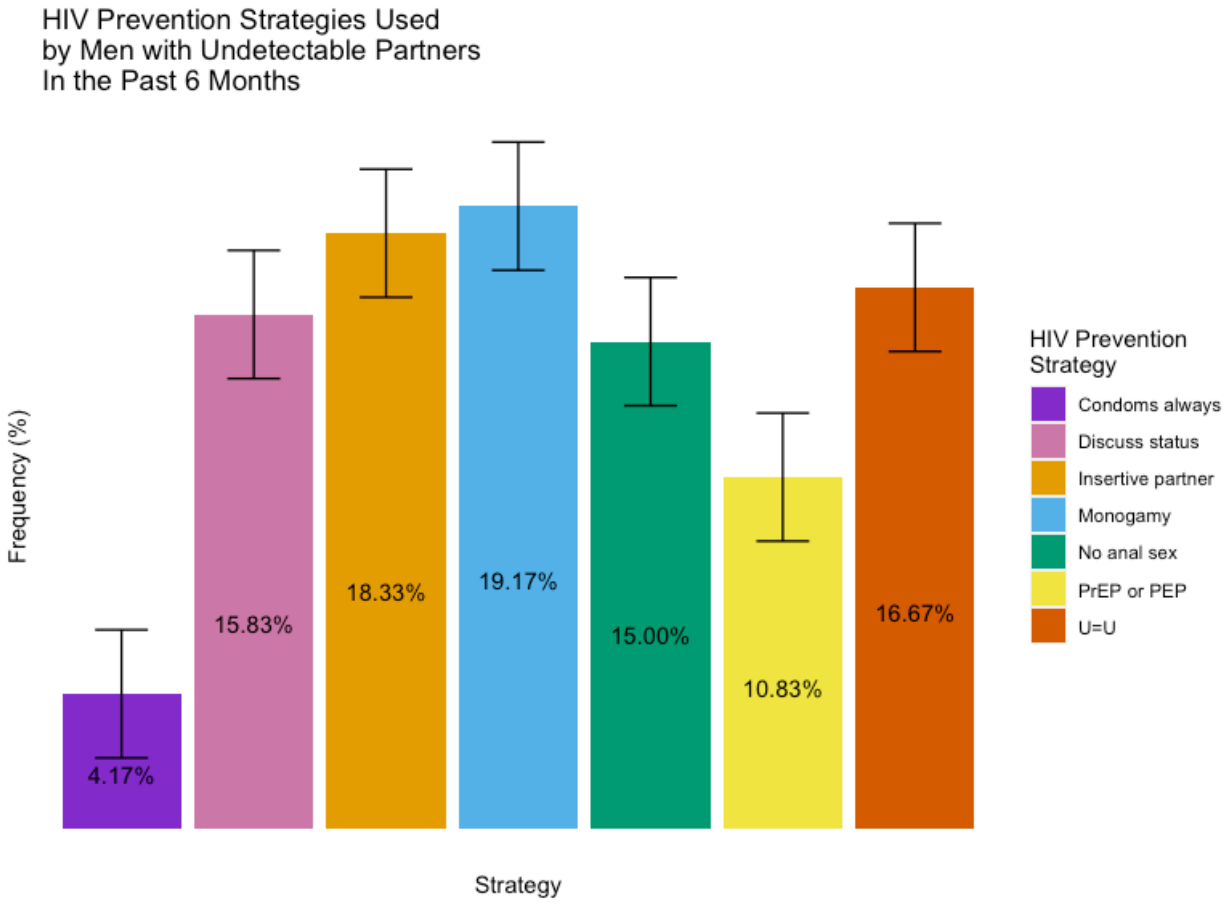

Fig. 1

3.4 Discussion

The high number of HIV prevention strategies participants employed in addition to their partners' undetectability stands in stark relief to average HIRI-MSM scores over 10. Recall this is true even after having Canadian Blood Services sexual behaviour and lifestyle screening applied. These prevention strategies would confer additional protection beyond their partner's HIV undetectability. We also observed a limited prevalence of STIs associated with increased risk of HIV acquisition in our sample. However, a larger sample would need to be observed over a longer period to understand what impact this might have on shaping residual risk estimates. To

understand how blood-operators estimate residual-risk to the blood supply – which is attributable to those with virally supressed HIV-positive partners – we attempted to gather literature on the subject but found none as of this writing. There are significant knowledge gaps to address before reconsidering the deferral policy for having an HIV-positive sexual partner.

Canada recommends HIRI-MSM for HIV risk acquisition evaluation in clinical settings for individual risk assessment (112). A donor in the 18-28 age group whose sexual partner has an undetectable HIV viral load would already be deemed high risk with a score of 12, as viral load is not considered. If no other risk factors were present our modified score would place them below the 'high-risk' threshold with a score of 8. Before any policy consideration is undertaken researchers will need tools to accurately assess 'risk' in the biomedical prevention era. Blood operators are less interested in individual risk and instead estimate 'residual risk' – remaining risk to the blood supply after donor screening and donation testing estimated at a population level(14). O'Brien et.al. estimated residual risk in Canada as being equal to HIV window period risk, plus HIV prevalence, multiplied by the sum of testing error and assay sensitivity; no data input definition considered donor HIV prevention of any kind – an individual level factor. In 2019 Horvath et. al. quantitatively compared three different definitions of 'risk' against the traditional construct defined as condomless anal sex (CAS) with an HIV-negative or unknown serostatus partner (36). The authors explored definitions of risk that considered viral load and found that despite many of their participants reporting CAS, 94% would not be considered at amplified risk for transmitting HIV using the U=U criteria concerning viral load (< 200 copies/mL). Residual risk estimates that consider HIV prevention during donor screening could improve specificity and provide insight into policy change that could both increase inclusion and result in donor clinics needing to refuse fewer donors.

Blood donor screening tools would need validation to ensure a potential donor can accurately assess their partner's HIV viral load status. Some research in the United States has shown that awareness of one's own viral load or partner's viral load can vary over time (40). Similar research needs to be conducted in Canada. There are significant differences in health care systems in Canada and the United States that could impact these findings – namely cost to the client and health insurance coverage (113,114).

Our analysis demonstrated that GBMSM with an HIV-undetectable sexual partner engaged in multiple HIV prevention methods in the last six months. A significant limitation of these descriptive analyses is the small sample size. The generalizability of an online convenience sample of 53 people is questionable. Further, our donor approximation only captured questions related to 'lifestyle' from the Canadian Blood Services Donor Questionnaire. Sex Now 2019 doesn't capture information about general health and medication or travel – we likely overestimate eligibility.

Many HIV risk estimates such as HIRI-MSM don't consider biomedical prevention use in their estimation but do consider physical prevention methods like condoms. Our analysis uncovers more questions than answers and identifies many opportunities for further inquiry.

3.5 Conclusion

Canadian blood operators' gender-neutral deferral policy opens the door to more sexual and gender minorities, which means the system will likely see an increase in deferrals related to biomedical HIV prevention more common in these communities. Even after screening through donor-approximation, GBMSM with undetectable partners were still considered high risk for HIV acquisition. This stands at odds with current understanding of TasP and U=U and the high number of additional HIV prevention methods participants engaged in. We identified several

opportunities for further inquiry and made observations suggesting blood operators' policies concerning biomedical HIV prevention produce overestimation of residual risk.

4.0 Chapter 4: Conclusions

4.1 Summary of findings

This thesis project set out to answer; Does the use of HIV PrEP impact willingness to donate blood? Do public health constructs of HIV 'risk' from SGM men with 'undetectable' partners reasonably estimate risk when their partners' supressed viral load is accounted for? And to what extent are potential blood donors who meet sexual behaviour and lifestyle criteria differed for biomedical HIV prevention use? To answer these questions I selected two analytic samples using an algorithm that approximated donor eligibility among online participants of the 2019 Sex Now Survey. Each analytic sample was selected for their use of a biomedical HIV prevention strategy. The first sample kept PrEP users who were otherwise eligible for blood donation; and the second sample kept participants who reported having an undetectable HIV-positive partner i.e., they use TasP and U=U as one of their HIV prevention strategies. Chapter Two explored PrEP use in the first sample as a motivator for blood donation and estimated the proportion of otherwise-eligible donors who would be deferred for their use of PrEP. Chapter Three described risk and protective factors observed in the sample and compared these to individual and population estimates of their risk for acquiring HIV.

PrEP users willing to donate if eligible outnumbered those who not willing, *n = 74 (87.05%)* compared to *n = 11 (12.94%),* We did not find evidence that PrEP use impacted willingness to donate *(OR = 0.77, 95% CI* = 0.38 – 1.74, *p = 0.5.)* However, that PrEP users were screened into the analytic sample at all gives weight to the argument that deferring donors for PrEP use; a) costs the blood supply donors and that, b) there are PrEP users that would likely not be screened out for any other reason. Questions remain regarding screening for PrEP users in donation clinics – particularly considering the important role adherence to medication plays in

the protection PrEP provides. Opposition to the three-month deferral policy *(OR = 2.77, 95% CI = 1.95 – 3.91, p <0.001),* age *(OR = 0.98, CI = 0.97 – 0.99, p < 0.05)* and having made a past donation *(OR = 3.83, 95% CI = 2.58 – 5.81, p < 0.001)* were the significant parameters in the final model with having made a past donation being the strongest predictor of willingness to donate blood if eligible in the future. These findings provide evidence that retention of MSM donors is likely if they can be engaged for a first donation. Blood operators should consider reconciliation strategies and communication strategies specifically tailored to SGM communities. The history of activism and experiences of oppression the deferral policy for men who had same sex contact and gender diverse people were discussed in earlier chapters. Reconciliation efforts may build trust between blood operators and SGM communities and improve donor recruitment and retention. Together these findings provide direction for future investigations into further expansion of Canada's donor pool and the exploration PrEP, and the protection conferred by PrEP, may or may not play when donors consider blood donation.

For potential donors whose partners were HIV undetectable we observed a variety of protective factors beyond TasP including PrEP use, condom use, not engaging in anal sex and monogamy. Despite this, even our modified HIRI-MSM score (which controlled for sex with the one known undetectable partner we were able to discern using study data) classified participant age groups under 41 years old as 'high-risk.' The unmodified HIRI-MSM score classified, on average, all participants as 'high-risk.' Mean and median scores were above 10 for participants under 41 using the modified HIRI-MSM score and above 10 for all ages using the un-modified HIRI-MSM scores. In terms of 'real world risk' this seems incongruous with protection conferred by the combination HIV prevention strategies we observed. The parameters Canadian Blood Services used in their estimation of residual risk did not consider HIV prevention

strategies (14). These findings align with those of other researchers that assert current models of HIV risk estimation are overestimating risk by not considering biomedical HIV prevention in their models (36,60,108,115–117). There is no consensus on the best way to do so, and proposing such a model is recommended future work.

4.2 Knowledge mobilization

Research products will be shared back with the Community-Based Research Centre (CBRC) to support knowledge mobilization to SGM communities. Chapters Two and Three will be submitted to academic journals for publication. The target journal is Vox Sanguinis – the official journal of the International Society of Transfusion Medicine.

These findings will set the stage for future research that could expand blood donor eligibility to those who use biomedical interventions for HIV prevention and further reduce stigma experienced by these men. Given the support SGM communities have shown for the Sex Now study nationally, returning results to these communities will make tangible the impact their support has had on our knowledge.

4.3 Strengths and limitations

4.3.1 Strengths

The Sex Now Survey samples a large number of SGM masculine identified people providing data that are not readily available in other Canadian datasets. The online sample used for the analyses presented here is not bound by the geographical confines of venue-based sampling some research shows this improves geographical diversity for hard to reach samples (118,119). The large sample size was particularly important given the small number of biomedical HIV-prevention users who were screened-in to the study cohorts using the donor approximation algorithm. The algorithm itself was a strength as it allowed us to create analytic

samples that more closely resemble an eligible donor population. With little a priori knowledge, community engagement with the Sex Now Survey was particularly important for informing direction of inquiry and variable selection. Similarly, automatic backward-stepwise variable selection – while not without vulnerabilities – allowed us to identify significant variables for further study in a subject area with little literature available. In Chapter Three the modified HIRI-MSM allowed us to evaluate this popular clinical tool's estimate of individual risk accounting for one undetectable partner. By bringing a critical lens and methods of risk estimation from different sectors we were able to identify opportunities to improve these estimates in future research.

4.3.2 Limitations

Only those with internet access who would be targeted by online recruitment advertisements for the study, and those with closer relationships to the Community-Based Research Centre or one of their partner organizations' would have increased likelihood of being aware of the study via social media. As such, the sample is not truly random and results from these analyses may not be generalizable to the entire Canadian GBMSM population despite the large sample size and geographical reach. However, a systemic review of characteristics of studies that had nonprobability community-oriented venue sampling methods found strong agreement between associations compared across studies of this population with different recruitment strategies (51); Salway et al found the more than 50% of the studies examined for nine variables found effects in the same direction. They also found that these studies tended to oversample those with a higher income, more sexual partners, higher substance use rates, higher suicidal ideation and past-year sexually transmitted infection diagnoses – they underrepresented married and partnered sexual minority people. These factors should be kept in mind when

interpreting results – samples with bias towards higher substance use, higher partner counts and higher past year sexually transmitted infections will bias findings towards higher risk estimates.

Our algorithm for likely donor approximation did not perfectly recreate the Canadian Blood Services Donor Questionnaire. The Sex Now survey did not ask questions regarding, travel, general overall health, or current medications outside those used for HIV prevention or STI treatment. It is likely our analytic samples in Chapters Two and Three overestimate participant eligibility for blood donation. In Chapter Two, the chosen variable selection strategy – automatic backward-stepwise regression – has the benefit of identifying significant variables in a landscape where there is little a priori knowledge. Yet, many argue it is vulnerable to coincidence and can exclude variables that narrowly lie outside a given threshold and, conversely, select 'noise' variables the appear mathematically relevant but may not be in reality (84,85). The goal of this work was not to develop an explanatory model, rather to identify associations in the data. The associations found here should be used for hypothesis forming and a beginning point for more rigorous investigations of motivations for MSM blood donors who may or may not also be PrEP users. In Chapter Three conclusions are drawn from a small sample that is predominantly white and cis-gender, Canada is far more diverse.

4.4 Future directions

4.4.1 Recommendations for future research

We found evidence in our sample indicating GBMSM donors are deferred solely for their use of biomedical HIV-prevention. The true impact of these deferrals cannot be inferred from this study and to understand truly the cost of these deferrals to Canada's blood supply more accurate estimates should be produced using data from Canada's blood operators i.e., Canadian Blood Services and Héma-Québec. Ongoing community engagement with sexual and gender

minority communities will be valuable. A major policy goal of the shift to a gender-neutral deferral model was to be more inclusive and lessen unnecessary discrimination. Continued research, community engagement and transparent sharing of results can support the goal of greater inclusivity.

Population health research into the intersection of PrEP use and donor deferral eligibility should investigate the prevalence of PrEP use among those who would donate blood if eligible – expanding beyond sexual and gender minority communities into the general donor population. Given PrEP effectiveness is highly reliant on adherence, more research is needed into indirect measures of adherence, and ideal recall periods when asking about medication adherence. A significant barrier to any policy change regarding the PrEP deferral will be testing technology and 'grey zone' results. 'Break through' cases – incidence of HIV when PrEP is used – are rare in Canada and have not been observed within the context of perfect treatment adherence. Nonetheless, they do occur and how that may impact residual risk to the blood supply should be quantified.

Treatment as prevention presents a different challenge in that HIV prevention is reliant on potential donors' partners, not the donor themselves. Canadian researchers have not published studies investigating accuracy of viral suppression self-reporting and communication between partners. This work would need to precede any estimates of residual risk were regulators to consider including those with undetectable partners. Additionally, the exact definition of what it means to be 'undetectable' ranges in Canada from ≤ 50 copies/mL to ≤ 200 copies/mL. A consensus definition should be defined and adopted by future research.

4.4.2 Implications

When used properly biomedical HIV strategies reduce risk of HIV acquisition to very near zero. Despite many studies asserting risk estimates where biomedical HIV prevention strategies are ignored overestimate risk, there is no consensus on a best practice (116,117,120). With post pandemic blood supply levels reaching dangerously low levels it is important blood operators turn as few people away from donation centres as safely possible (121–124). Health Canada and Canadian blood operators' primary objective is to maintain a safe and sufficient blood supply, their methods of residual risk estimates are necessarily conservative. In 2022 Caffrey et. al. published a model estimating residual risk if the deferral for 'men who have sex with men' were removed using available public health data and the previously validated model discussed in Chapter Three (125). The model predicts the removal of the three-month deferral would result in similar residual risk to if it had not been removed and concluded that, "As a range of HIV risk questions are already asked, extra behavioural risk questions may not be necessary, although they may add extra security." *p 203* Our results provide evidence that there are likely donors who use biomedical HIV prevention methods for whom this same logic holds true.

4.5 Conclusion

While we did not find evidence that PrEP impacts a potential donor's willingness to donate blood, we did find evidence in both the literature and our results that support further research into risk constructs that account for biomedical HIV prevention in the context of blood donation. We saw that a small percentage of donors are deferred for both PrEP and TasP but would otherwise be eligible according to HIV risk screening questions. Deferrals for biomedical HIV prevention in the blood system do not align with public health organizations' promotion

about the individual protection they confer. There are real challenges to lifting these donor deferrals, and a lack of knowledge that needs to be addressed before policy change can be considered.

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Appendix 1. Sex Now Survey Community Partners

Organization Name	Location	Region Served
Advance - Avancer	Canada	Canada
AIDS Committee of Toronto	Toronto, Ontario	Toronto, Ontario
AIDS Coalition of Nova Scotia	Halifax, Nova Scotia	Nova Scotia
Community-Based Research Centre	Vancouver, Canada	Canada
Centre for Sexuality	Calgary, Alberta	Southern Alberta
Edmonton Men's Health Collective	Edmonton, Alberta	Edmonton, Alberta
Gay Men's Sexual Health Alliance	Toronto, Ontario	Ontario
Health Initiative for Men	Vancouver, British Columbia	Coastal British Columbia
Max Ottawa	Ottawa, Ontario	National Capital Region
Men's Health Initiative	Kelowna, British Columbia	Interior British Columbia
Ontario HIV Trial Network	Toronto, Ontario	Ontario
Our Own Health Centre	Winnipeg, Manitoba	Winnipeg, Manitoba
Rézo-Santé	Montréal, Québec	Montréal, Québec
Sunshine House	Winnipeg, Manitoba	Winnipeg, Manitoba

Appendix 2. Eligible Donor Algorithm Criteria

Survey Question	Exclusion Criteria	CBS Donor Questionnaire Item
How many sex partners have you had in the PAST 6 MONTHS, and Of those, how many were in the PAST 3 MONTHS? In the PAST 6 MONTHS, what kinds of sex have you had? When did you last have a new sex partner?	• IF number of partners in last 3 months < 2 AND; • IF last new sex partner ≤ "1-3 months" AND; • IF kind of sex in last 6 months = any anal sex THEN EXCLUDE. OR • IF number of partners in last 3 months > 1 THEN EXCLUDE.	Have you had any new or multiple sex partners in the last three months? If yes have you had anal sex with any of them?
In the PAST 6 MONTHS, what kind of partners have you had?	• A partner who gave me money, goods or services for sex. • A partner I gave money or goods for sex.	• In the last 12 months have you taken money or drugs for sex? • In the last 12 months have you had sex with a sex trade worker or anyone else who has taken money or drugs for sex?
When were you last tested for hepatitis C? **AND** What was the result of your last hepatitis C test?	In the last 6 months (Derived from 1-3 months and 4-6 months.) **AND** positive, I had hepatitis C.	In the last 6 months have you had hepatitis?
What was the result of your last HIV test?	Positive, I had HIV.	Have you ever had a positive test for the HIV/AIDS virus?
Have you ever been diagnosed with HIV?	Yes, I am living with HIV.	Have you ever had a positive test for the HIV/AIDS virus?
In the PAST 6 MONTHS, what kind of men have you had anal sex with?	An HIV+ undetectable partner.	In the last 12 months have you had sex with anyone who has HIV/AIDS or has tested

		positive for HIV/AIDS virus?
In the PAST 6 MONTHS, what kind of men have you had anal sex with?	A man whose HIV status was different than mine.	In the last 12 months have you had sex with anyone who has HIV/AIDS or has tested positive for HIV/AIDS virus?
Have you ever injected any drugs?	• Yes, in the last 6 months. • Yes, longer than 6 months ago.	Have you ever taken illegal drugs with a needle even one time?
Check any that you've used EVER in the last 6 MONTHS	• Yes, cocaine, in the last 6 months.	Have you used cocaine in the last 12 months? (Removed October 16, 2022.)
In the PAST 6 MONTHS, what kind of partners have you had?	• A partner who gave me money, goods or services for sex. • A partner I gave money or goods for sex.	• In the last 12 months have you taken money or drugs for sex? • In the last 12 months have you had sex with a sex trade worker or anyone else who has taken money or drugs for sex?
When were you last tested for hepatitis C? **AND** What was the result of your last hepatitis C test?	In the last 6 months (Derived from 1-3 months and 4-6 months.) **AND** positive, I had hepatitis C.	In the last 6 months have you had hepatitis?
What was the result of your last HIV test?	Positive, I had HIV.	Have you ever had a positive test for the HIV/AIDS virus?
Have you ever been diagnosed with HIV?	Yes, I am living with HIV.	Have you ever had a positive test for the HIV/AIDS virus?
In the PAST 6 MONTHS, what kind of men have you had anal sex with?	An HIV+ undetectable partner.	In the last 12 months have you had sex with anyone who has HIV/AIDS or has tested positive for HIV/AIDS virus?

In the PAST 6 MONTHS, what kind of men have you had anal sex with?	A man whose HIV status was different than mine.	In the last 12 months have you had sex with anyone who has HIV/AIDS or has tested positive for HIV/AIDS virus?
Have you ever injected any drugs?	• Yes, in the last 6 months. • Yes, longer than 6 months ago.	Have you ever taken illegal drugs with a needle even one time?

Appendix 3. R Program for Regression Analysis

```
#Read in data and load necessary packages
library(tidyverse)
#sn_19 <- read_csv([server path])
sn_19 <- read_csv(
  "/Volumes/Sex Now/2019/Finalized Data/2021-12-10_SexNow2019DataClean_noDBS.csv")
#Build working data frame with study variables
w_df <- as_tibble(sn_19)
sco1 <- tibble(blood_cohort = w_df$p13_69_blood_skip,
               will_donate = w_df$p14_72_blood_donation_would_donate,
               prep = w_df$p34_128_PrEP_used_ever,
               hiv_risk = w_df$p34_126_HIV_risk_getting,
               age = w_df$p2_12_eligible_age,
               eth_afcn = w_df$p3_19_ethnicity_african,
               eth_arab = w_df$p3_19_ethnicity_arab,
               eth_asn = w_df$p3_19_ethnicity_asian,
               eth_blk = w_df$p3_19_ethnicity_black,
               eth_crbn = w_df$p3_19_ethnicity_caribbean,
               eth_euro = w_df$p3_19_ethnicity_european_NIQ,
               eth_indig = w_df$p3_19_ethnicity_indigenous,
               eth_ltn = w_df$p3_19_ethnicity_latin_american,
               eth_oth = w_df$p3_19_ethnicity_other,
               eth_sasn = w_df$p3_19_ethnicity_south_asian,
               eth_seasn = w_df$p3_19_ethnicity_south_east_asian,
               eth_yt = w_df$p3_19_ethnicity_white,
               trans = w_df$p7_41_trans,
               past_donate = w_df$p14_70_blood_donation_ever, #small thing but there's a typo here, consider changing to
past_donate instead
               pro_dfrl = w_df$p14_72_blood_donation_justified,
               opp_dfrl = w_df$p14_72_blood_donation_discriminatory,
               num_sex_partnrs_6mo = w_df$p9_51_sex_partner_num_P6M,
```

```
            num_sex_partnrs_3mo = w_df$p9_52_sex_partner_num_P3M,
            anal_topc = w_df$p9_54_sex_behaviour_anal_insertive_condom_P6M,
            anal_topnc = w_df$p9_54_sex_behaviour_anal_insertive_no_condom_P6M,
            anal_btmc = w_df$p9_54_sex_behaviour_anal_receptive_condom_P6M,
            anal_btmnc = w_df$p9_54_sex_behaviour_anal_receptive_no_condom_P6M,
            last_prtnr = w_df$p9_57_last_new_partner,
            sw = w_df$p9_56_sex_partners_received_money_P6M,
            swc = w_df$p9_56_sex_partners_gave_money_P6M,
            hcv_lt = w_df$p27_107_HCV_last_test_date,
            hcv_rslt = w_df$p27_108_HCV_last_test_result,
            hiv_rslt = w_df$p31_115_HIV_last_test_result,
            hiv_sts = w_df$p31_116_HIV_diagnosis_ever,
            prtnr_diff_sts = w_df$p47_201_male_sex_partner_different_status,
            prtnr_un = w_df$p47_201_male_sex_partner_undectable,
            idu = w_df$p39_153_injection,
            cocaine = w_df$p40_155_substance_cocaine)
#Run exclusion criteria and apply 'eligible donor' approximation algorithm, steps below:
#Remove rows with missing or ineligible future donor data
sco2 <- filter(sco1, will_donate %in% c("Disagree", "Strongly Agree", "Agree",
                                        "Strongly Disagree"))
#Filter HIV +ive
sco3 <- filter(sco2, prep != "8888: Diagnosed with HIV")


#Sex trade flag
sco3$strade <- "0"
sco3$strade[sco3$sw == "No"] <- "0"
sco3$strade[sco3$swc == "No" ] <- "0"
sco3$strade[sco3$sw == "Yes"] <- "1"
sco3$strade[sco3$swc == "Yes"] <- "1"
sco3$strade[sco3$sw == "9999: Missing"] <- "9999"
```

```
sco3$strade[sco3$swc == "9999: Missing" ] <- "9999"


table(sco3$sw, sco3$swc, useNA="always")
table(sco3$strade, useNA="always")



#Create numeric partner and recency counts
table(sco3$num_sex_partnrs_3mo, useNA = 'ifany') #SA: to confirm how many missing there should be beforehand
sco3$num_sex_partnrs_3mo <- recode(sco3$num_sex_partnrs_3mo, "8888: In a monogamous relationship"
                                   = "1") %>%
  as.numeric()
sco3$num_sex_partnrs_6mo <- recode(sco3$num_sex_partnrs_6mo, "8888: In a monogamous relationship"
                                   = "1") %>%
  as.numeric()

table(sco3$last_prtnr, useNA = 'ifany')
sco3$last_prtnr <- recode(sco3$last_prtnr, "1 -3 months ago" = "3",
                          "8888: In a monogamous relationship" = "3.5", "2-4 weeks ago" = "1",
                          "4-6 months ago" = "6", "7-12 months ago" = "12",
                          "Longer than a year ago" = "13", "I have never had sex" = "13.5",
                          "This week" = "0", "9999: Missing" = "9999") %>%
  as.numeric()

#Anal sex flag - 6mo

sco3$any_anal <- "0"
sco3$any_anal[sco3$anal_topc == "No" & sco3$anal_topnc == "No" & sco3$anal_btmc == "No"
              & sco3$anal_btmnc== "No"] <- "0"
sco3$any_anal[sco3$anal_topc == "Yes" | sco3$anal_topnc == "Yes" | sco3$anal_btmc == "Yes"
              | sco3$anal_btmnc == "Yes"] <- "1"
sco3$any_anal[sco3$anal_btmc == "9999: Missing" & sco3$anal_btmnc == "9999: Missing" &
```

```
        sco3$anal_topc == "9999: Missing" & sco3$anal_topnc == "9999: Missing"] <- "9999"

#CBS sex behaviour flag

sco3$cbs_sxflg <- "0"
sco3$cbs_sxflg[sco3$num_sex_partnrs_3mo < 2 & sco3$last_prtnr <= 3 & sco3$any_anal == "1"] <- "1"
sco3$cbs_sxflg[sco3$num_sex_partnrs_3mo > 1 & sco3$any_anal != "9999"] <- "1"
sco3$cbs_sxflg[sco3$any_anal == "9999"] <- "9999" #SA: don't think you need the 9999 considering how the variable is being used and people missing for all 3 variables to create cbs_sxflg aren't included
#HCV recodes and flag

sco3$hcv_lt <- recode(sco3$hcv_lt, "4-6 months ago" = "6", "7-12 months ago" = "12",
                      "7777: Prefer not to answer" = "7777", "9999: Missing" = "9999",
                      "I dont know" = "6.5", "I have never tested for Hep C" = "7.5",
                      "In the past 3 months" = "3", "Longer than a year ago" = "13",
                      "Other (please specify)" = "9999") %>%
  as.numeric()

table(sco3$hcv_lt, useNA = 'ifany')
table(sco3$hcv_lt, sco3$hcv_rslt, useNA = 'ifany')
sco3$hcv_flg <- "0"
sco3$hcv_flg[sco3$hcv_lt <= 6 & sco3$hcv_rslt == "Positive (I had Hepatitis C)"] <- "1"
sco3$hcv_flg[sco3$hcv_lt >= 7777] <- "9999"
sco3$hcv_flg[sco3$hcv_rslt == "9999: Missing"] <- "9999" #SA: don't think you need this line considering how the variable is used
table(sco3$hcv_flg, useNA = 'ifany')

#IDU flag

sco3$idu_flag <- "0"
sco3$idu_flag[sco3$idu == "No, never"] <- "0"
```

```
sco3$idu_flag[sco3$idu != "No, never"] <- "1"
#idu <= 6 mo data problem, "Yes" not being picked up by logic,
#"!= never" fix catches them according to table count below but should bring up with data team
sco3$idu_flag[sco3$idu == "9999: Missing"] <- "9999"
table(sco3$idu) #from the table there's a non-breaking space (\xa0) in one of the categories, it's a weird thing that pops up every
now and again,
#looks like a regular space in excel but it's actually a special character.
table(sco3$idu_flag)

#HIV+ve partner flag
sco3$phiv_flag <- "0"
sco3$phiv_flag[sco3$prtnr_diff_sts == "Yes" &
        sco3$hiv_sts == "No (I have never been diagnosed with HIV)"] <- "1"
sco3$phiv_flag[sco3$prtnr_un == "Yes"] <- "1"
sco3$phiv_flag[sco3$prtnr_diff_sts == "9999: Missing"] <- "9999"
sco3$phiv_flag[sco3$hiv_sts == "9999: Missing" |
        sco3$hiv_sts == "7777: Prefer not to answer"] <- "9999"
sco3$phiv_flag[sco3$prtnr_un == "9999: Missing"] <- "9999"

table(sco3$phiv_flag)
table(sco3$hiv_sts, sco3$prtnr_diff_sts, useNA = 'always')
table(sco3$prtnr_diff_sts, sco3$prtnr_un, useNA = 'always')
with(sco3, xtabs(~prtnr_diff_sts+prtnr_un+hiv_sts, addNA = TRUE, drop.unused.levels = FALSE))

####Script 3####
#Filter out flags and run final variable transformations to finalize analysis cohort and data
#Check for any remaining PLHIV
table(sco3$hiv_sts)
table(sco3$hiv_rslt)
sco3 <- filter(sco3, hiv_rslt != "Positive (I had HIV)")
table(sco3$hiv_rslt)
```

```
table(sco3$hiv_sts)

#SA -check

table(sco3$hiv_sts, sco3$hiv_rslt, useNA = 'ifany')


#Filter on flags

#Sex trade, CBS sex behaviour, HCV, IDU, HIV+ve partner


sco4 <- filter(sco3, strade != "1",
               cbs_sxflg != "1",
               hcv_flg != "1",
               idu_flag != "1",
               phiv_flag != "1") %>%
  as_tibble()


#Dichotomize donor intention

table(sco4$will_donate, useNA = 'ifany')

sco4$d_willdnr <- 0

sco4$d_willdnr[sco4$will_donate == "Strongly Disagree"] <- 0

sco4$d_willdnr[sco4$will_donate == "Disagree"] <- 0

sco4$d_willdnr[sco4$will_donate == "Agree"] <- 1

sco4$d_willdnr[sco4$will_donate == "Strongly Agree"] <- 1

table(sco4$d_willdnr)


#Dichotomize PrEP

table(sco4$prep)

sco4$d_prep <- 0

sco4$d_prep[sco4$prep == "No"] <- 0

sco4$d_prep[sco4$prep == "Yes, but I stopped. Why?"] <- 0

sco4$d_prep[sco4$prep == "Yes, Im taking PrEP now!"] <- 1

sco4$d_prep[sco4$prep == "7777: Prefer not to answer"] <- 7777

sco4$d_prep[sco4$prep == "9999: Missing"] <- 9999
```

```
table(sco4$d_prep)

#Derive ACB
table(sco4$eth_blk, useNA = 'ifany')
table(sco4$eth_afcn, useNA = 'ifany')
table(sco4$eth_crbn, useNA = 'ifany')

sco4$acb <- 0
sco4$acb[sco4$eth_blk == "Yes"] <- 1
sco4$acb[sco4$eth_afcn == "Yes"] <- 1
sco4$acb[sco4$eth_crbn == "Yes"] <- 1
sco4$acb[sco4$eth_blk == "7777: Prefer not to answer"] <- 7777
sco4$acb[sco4$eth_afcn == "7777: Prefer not to answer"] <- 7777
sco4$acb[sco4$eth_crbn == "7777: Prefer not to answer"] <- 7777
table(sco4$acb)

##(6) Create numeric versions of:
#Current HIV Risk
#Age
#Past donation
#Trans experience
#Agree/Disagree with deferral

c_hivrisk <- class(sco4$hiv_risk)
c_age <- class(sco4$age)
c_past <- class(sco4$past_donate)
c_trans <- class(sco4$trans)
c_prodefer <- class(sco4$pro_dfrl)
c_antidefer <- class(sco4$opp_dfrl)

#Current HIV Risk
```

```
sco4$hiv_risk_num <- 0

sco4$hiv_risk_num[sco4$hiv_risk == "High"] <- 0

sco4$hiv_risk_num[sco4$hiv_risk == "Low"] <- 1

sco4$hiv_risk_num[sco4$hiv_risk == "I think I already have HIV"] <- 0

sco4$hiv_risk_num[sco4$hiv_risk == "Dont know"] <- 8888

sco4$hiv_risk_num[sco4$hiv_risk == "9999: Missing"] <- 9999


#Past donation

sco4$past_donate_num <- 0

sco4$past_donate_num[sco4$past_donate == "No, never"] <- 0

sco4$past_donate_num[sco4$past_donate == "Yes, in the past year"] <- 1

sco4$past_donate_num[sco4$past_donate == "Yes, but longer than a year ago"] <- 1

sco4$past_donate_num[sco4$past_donate == "I dont remember"] <- 8888

sco4$past_donate_num[sco4$past_donate == "9999: Missing"] <- 9999


#trans experience

sco4$trans_num <- 0

sco4$trans_num[sco4$trans == "No"] <- 0

sco4$trans_num[sco4$trans == "Yes"] <- 1

sco4$trans_num[sco4$trans == "7777: Prefer not to answer"] <- 7777


#agreement with deferral

sco4$pro_dfrl_num <- 0

sco4$pro_dfrl_num[sco4$pro_dfrl == "Agree"] <- 0

sco4$pro_dfrl_num[sco4$pro_dfrl == "Strongly Agree"] <- 0

sco4$pro_dfrl_num[sco4$pro_dfrl == "Disagree"] <- 1

sco4$pro_dfrl_num[sco4$pro_dfrl == "Strongly Disagree"] <- 1

sco4$pro_dfrl_num[sco4$pro_dfrl == "9999: Missing"] <- 9999


#select final cohort variables

cc_cohort_vars <-tibble(prep = sco4$d_prep,
```

```
                dfrl_opin = sco4$pro_dfrl_num,
                age = sco4$age,
                past_donate = sco4$past_donate_num,
                acb = sco4$acb,
                trans = sco4$trans_num,
                hiv_risk = sco4$hiv_risk_num,
                donor = sco4$d_willdnr)

#Final complete case cohort
cc_cohort <- filter(cc_cohort_vars, cc_cohort_vars$prep == 0 | cc_cohort_vars$prep == 1,
                cc_cohort_vars$dfrl_opin != 9999,
                cc_cohort_vars$past_donate == 1 | cc_cohort_vars$past_donate == 0,
                cc_cohort_vars$acb != 7777,
                cc_cohort_vars$trans != 7777,
                cc_cohort_vars$hiv_risk == 0 | cc_cohort_vars$hiv_risk == 1,
                cc_cohort_vars$age >= 17)

####Script 4####
library(car)

#set categorical vars to factors
cc_cohort$prep <- factor(cc_cohort$prep)
cc_cohort$dfrl_opin <- factor(cc_cohort$dfrl_opin)
cc_cohort$past_donate <- factor(cc_cohort$past_donate)
cc_cohort$acb <- factor(cc_cohort$acb)
cc_cohort$trans <- factor(cc_cohort$trans)
cc_cohort$hiv_risk <- factor(cc_cohort$hiv_risk)
cc_cohort$donor <- factor(cc_cohort$donor)

###################### BEGIN REGRESSION ANALYSIS ############################
#############################################################################
```

```
#Load packages
library(MASS)
library(gtsummary)
library(survey)
library(DescTools)
library(ROCR)
library(caTools)
library(caret)

#create training and test datasets, this data partition keeps characteristics of og data
trainindex <- createDataPartition(cc_cohort$donor, p=0.7,
                                  list = FALSE,
                                  times = 1)
train <- cc_cohort[trainindex,]
test <- cc_cohort[-trainindex,]



#Full model

mod1 <- glm(donor ~ . ,
            family = binomial(logit),
            data = train)

#Backward step-wise selection

#Specifying 'prep' in the lower model ensures it will be included in the final model for evaluation
step1 <- stepAIC(mod1, scope = list(lower=~prep^2, upper=~.^2),
                 direction = "backward", trace = FALSE)

#View final model with an ANOVA table for removed variables
```

```
step1$anova

#Program final model with results from 'step1'
final <- glm(donor ~ prep + dfrl_opin + age + past_donate, family = binomial(logit),
             data = train)
sig.vrs.only <- glm(donor ~ dfrl_opin + age + past_donate, family = binomial(logit),
                    data = train)

summary(final)
tbl_regression(final, exponentiate = TRUE)

#Find McFadden's pseudo r^2

PseudoR2(final, which = "McFadden")

#Wald Chi-Squared Test for coefficient significance

regTermTest(final, "prep") # p=0.91
regTermTest(final, "dfrl_opin") # p < 0.005
regTermTest(final, "age") # p < 0.005
regTermTest(final, "past_donate") # p < 0.005

#AUROC-ROC
#Compute AUC
prob <- predict(final, newdata = test, type = "response")
pred <- ROCR::prediction(prob, test$donor)
perf <- ROCR::performance(pred, measure = "tpr", x.measuure = "fpr")
plot(perf)
auc <- ROCR::performance(pred, measure = "auc")
auc <- auc@y.values[[1]]
auc # auc = 0.7
```

Appendix 4. HIV Incidence Risk Index for Men Who have Sex with Men

HIRI-MSM Risk Index		
1. How old are you today?	≤ 18 years	Score 0
(yrs)	18 – 28 years	Score 8
	29 – 40 years	Score 5
	41 – 48 years	Score 2
	≥ 49 years	Score 0
2. How many men have you	> 10 male partners	Score 7
had sex with in the last 6	6 – 10 male partners	Score 4
months?	0 – 5 male partners	Score 0
3. In the last 6 months, how	1 or more times	Score 10
many times did you have anal	0 times	Score 0
sex (you were the bottom)		
with a man?		
4. How many of your male	> 1 positive partners	Score 8
sex partners were HIV	1 positive partner	Score 4
positive?	< 1 positive partner	Score 0
5. In the last 6 months how	5 or more times	Score 6
many times did you have	0 times	Score 0
insertive anal sex (you were		
the top) with a man who was		
HIV positive?		

6. In the last 6 months, have you used methamphetamines such as crystal or speed?	Yes No	Score 5 Score 0
7. In the last 6 months have you used poppers (amyl nitrate)?	Yes No	Score 3 Score 0

Notes:

* To identify sexually active MSM in practice we recommend that clinicians ask all men the standard question, “In the past (time) have you had sex? (If yes) with men women or both?”

** If score 10 or higher, recommend evaluating for PrEP or other HIV intensive prevention services; If score 9 or lower, recommend indicated standard HIV prevention services.