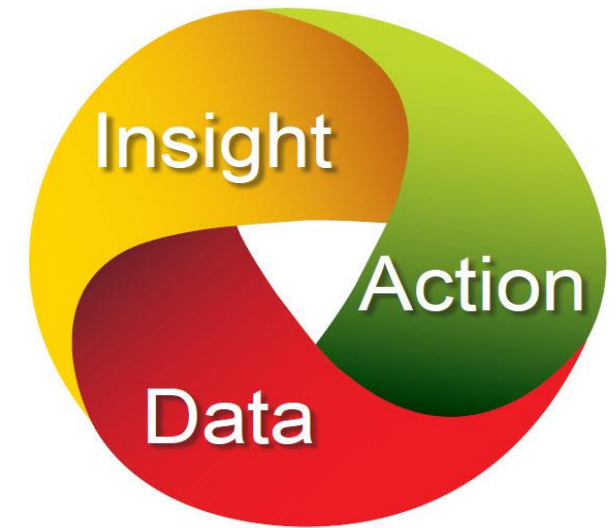


Evolving criteria for sexual risk behaviours at Canadian Blood Services

**IPFA/PEI International Workshop on Surveillance
and Screening of Blood-borne Pathogens
Sept 21, 2022**

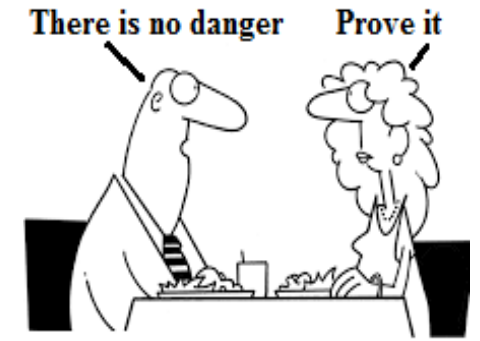


Mindy Goldman, Medical Director, Donation Policy & Studies
Sheila O'Brien, Associate Director, Epidemiology & Surveillance

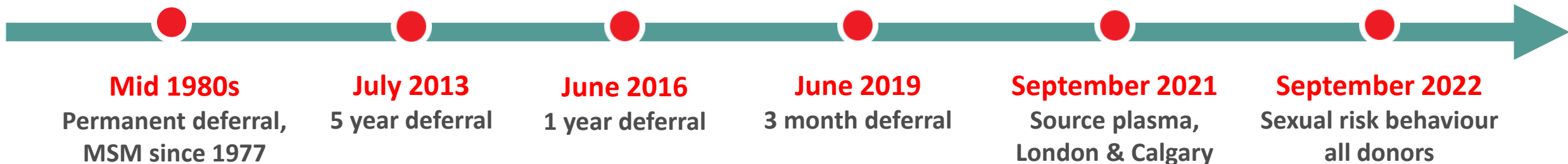
Conflict of Interest

- I have no relevant conflict of interest to declare

How do changes in criteria happen in Canada?

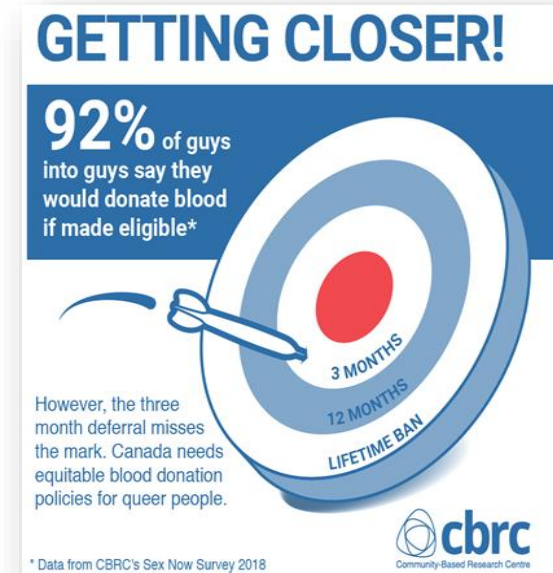


- Blood is regulated by Health Canada as a biologic
- Changes might affect the safety of the blood supply or quality of components must be submitted to Health Canada for approval before implementation
- Research program supported by the federal government has assisted in generating necessary data for more recent changes



Why change to a sexual risk behaviour approach?

- Shortening the time-based deferral period has maintained safety but sexually active gay, bisexual and other men who have sex with men (gbMSM) are still deferred
- We are committed to increasing diversity and inclusiveness in our donor base, while maintaining safety and adequacy
- Research studies and stakeholder feedback demonstrate that asking male donors about sex with other males is perceived as discriminatory and stigmatizing
- Gender neutral criteria, where all donors are asked the same sexual risk questions would allow trans donors (donors whose current gender identity differs from their sex at birth) to self-identify in their affirmed gender



Why change to a sexual risk behaviour approach?

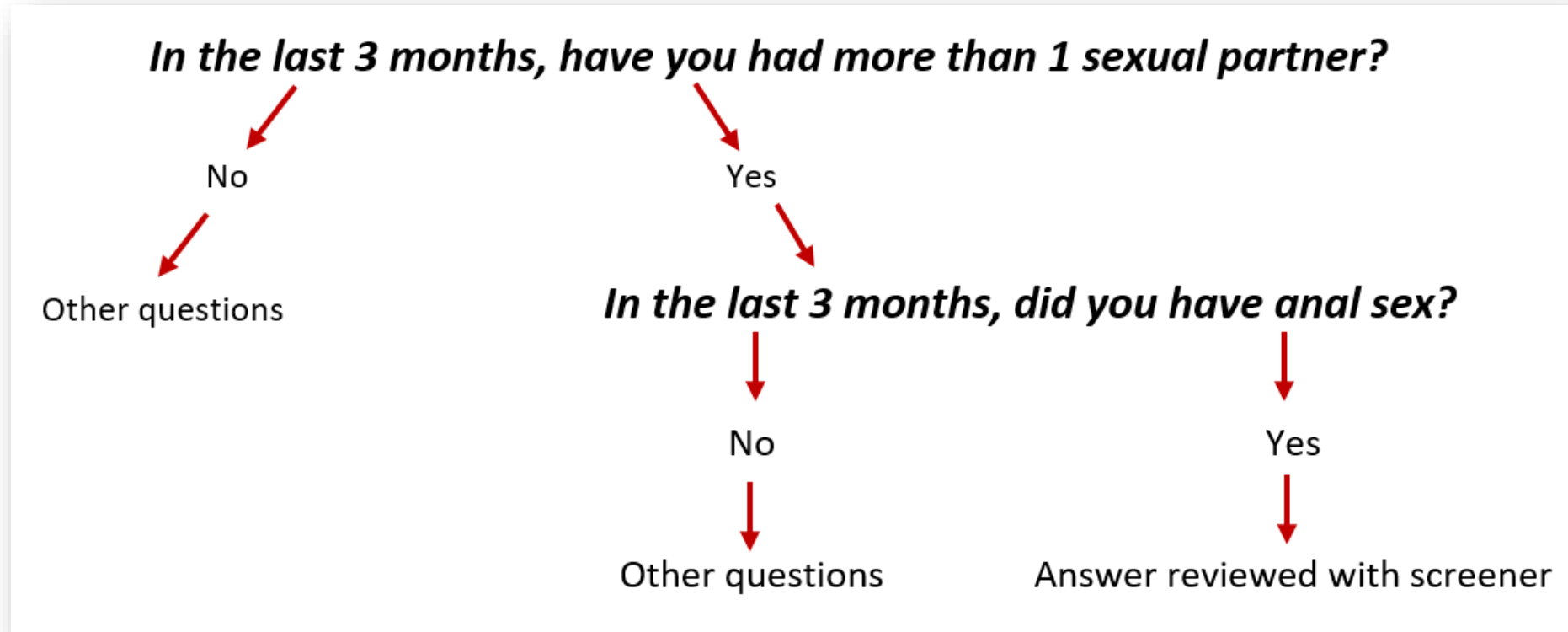
- Criteria should allow gbMSM who are in a stable relationship to donate, while deferring those with recent, high risk sexual behaviours
- Risk in the last 3 months is the most relevant, since we are concerned about new (incident) infections, that may occur during the window period
- Older (prevalent) infections acquired more than 3 months ago would be detected by testing
- Risk is related to risk of exposure by activity (such as oral sex, vaginal sex, anal sex) and number of sexual partners
- Sex with another man would not be used as a surrogate for high risk sexual activity

Questions and Criteria, all donors



- If the donor has had anal sex with a new partner, they will be deferred for 3 months from the date of last anal sex or from the date of their donation attempt if they are unsure of the date

Questions and Criteria, all donors



- If the donor has had more than one sexual partner, and anal sex with at least 1 partner, they will be deferred for 3 months from date of last anal sex or the date of their donation attempt if they are unsure of the date

How do we assess safety of changes?

- Safety is assessed by:
 - **Surveillance** of known and emerging pathogens
 - **Assessment of compliance** in our donors
 - **Modeling of risk increment** for proposed change
- Additionally, for this shift to sexual risk behaviour deferral:
 - Review of epidemiologic studies of HIV transmission/sexual behaviours
 - Cohort study of HIV transmission in gbMSM population (Engage)
 - Assessment of **impact on adequacy of supply**

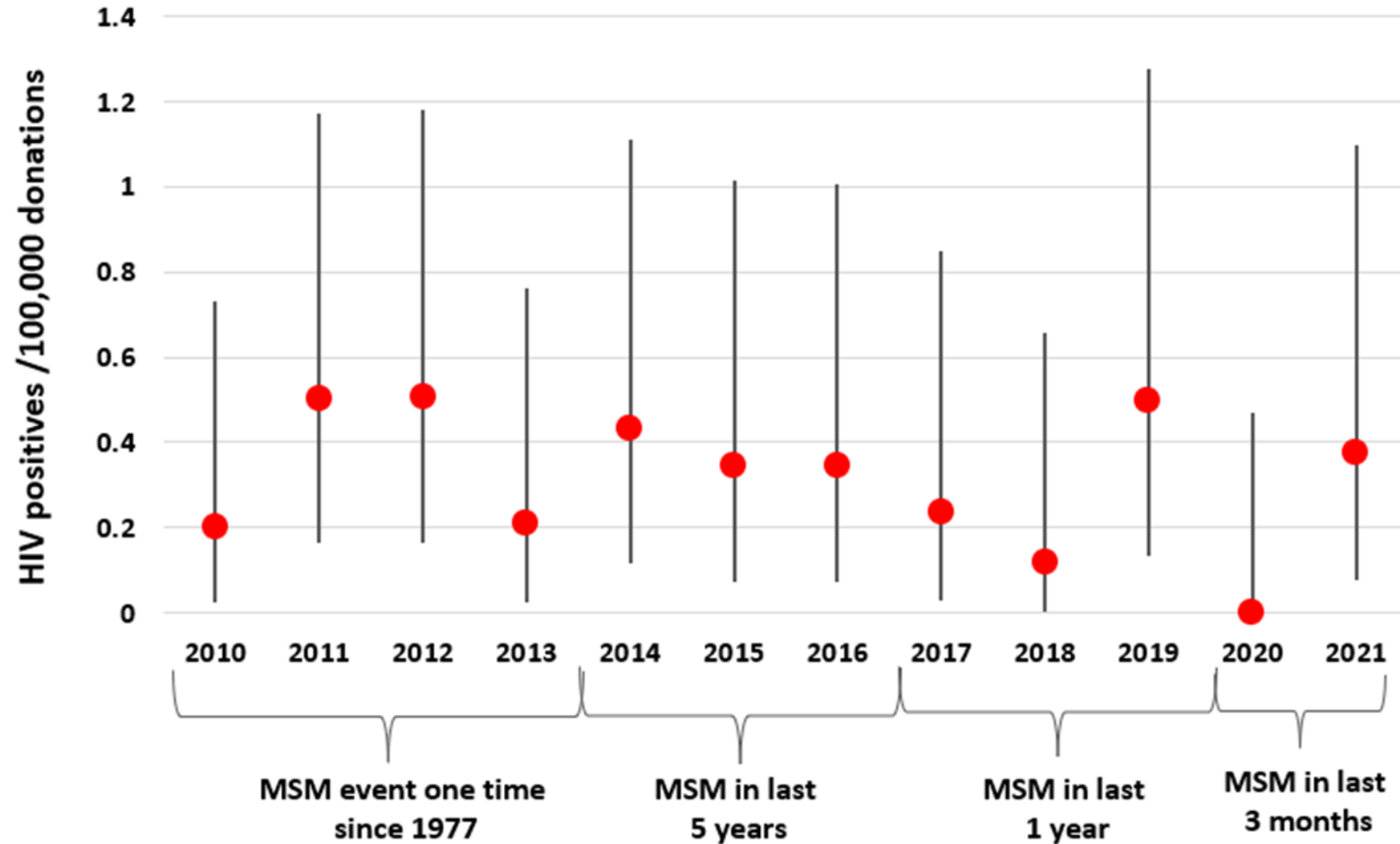


Surveillance

- Monitor infectious disease marker rates over time
- Calculate residual risk using window period and rates in donors: risk of HIV infection by a transfusion = 1 in 12.9 million
- Interviews with TD positive donors
- Lookback and traceback
- Surveillance of emerging threats and their modes of transmission



Surveillance report, HIV rates over time



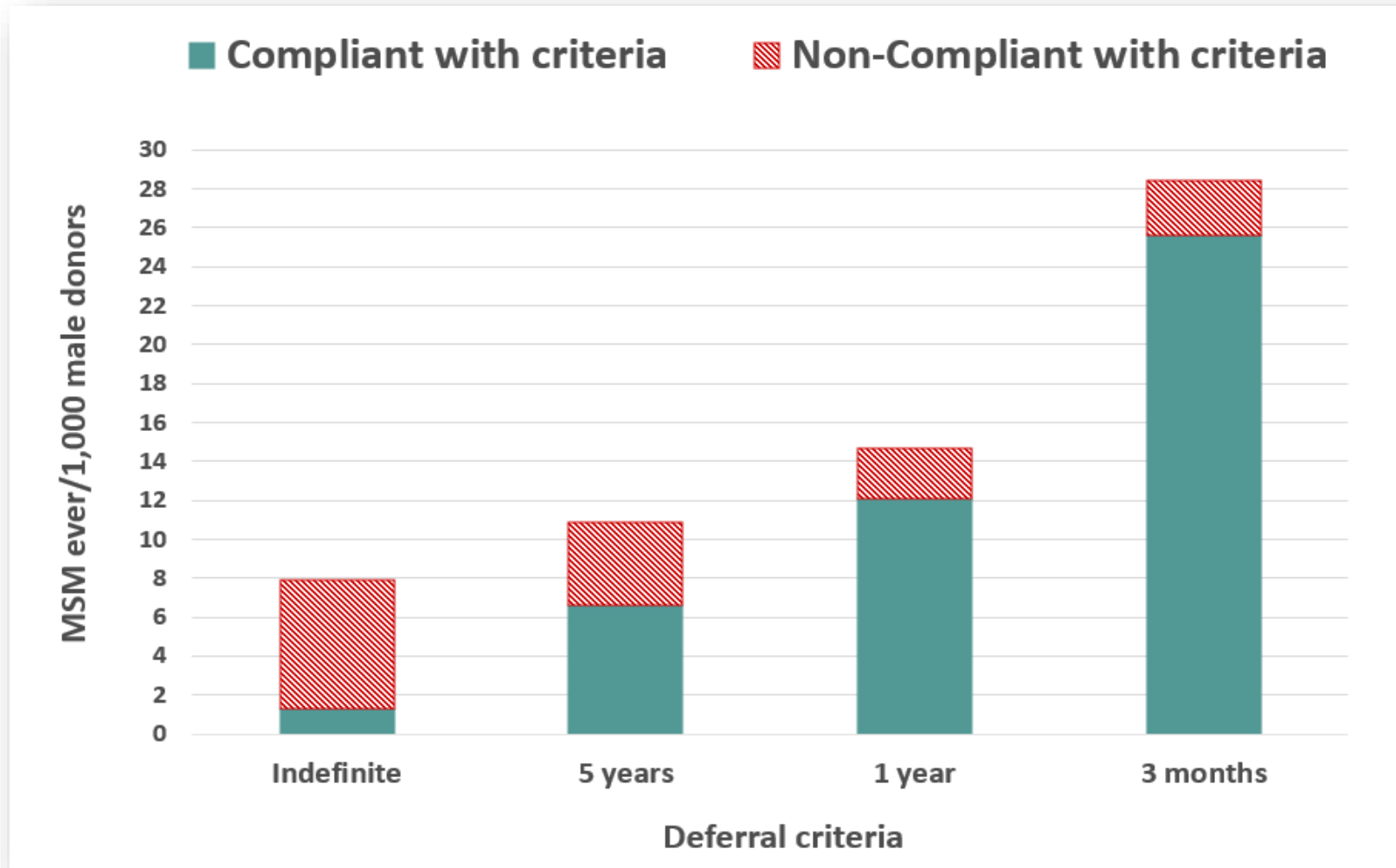
Compliance studies



Are donors answering the questions truthfully?

- Anonymous donor surveys of approximately 20,000 male donors who recently successfully donated before and after every change in sexual behaviour criteria
- compare answers on survey and actual donor questionnaire
- Answers to question about PrEP/PEP use and other risk questions

MSM in donors: frequency/1,000 male donors, and compliance with criteria in place at time of study



Modeling studies

If current 3 month deferral for MSM was removed, but all other standard risk questions remained, what would be the additional increased risk of HIV per transfusion?

- Use of Canadian surveillance and compliance data in model developed by ISBT modeling group
- Standard risk questions include deferral for injection drug use, sex with an HIV positive partner, positive test for HIV, paying or accepting drugs or money for sex, PrEP/PEP use
- This is the worst case scenario, then add in expected impact of proposed new criteria

Parameters

Estimated HIV incidence and HIV rates

HIV test sensitivity	1 per 500,000 tests				
HIV error rate	1 per 100,000 tests				
HIV window period	6.1 days ($\pm$ 0.87 days)				
New donor incidence adjustment	1.65 ($\pm$ 1.0334)				
Average inter-donation interval in repeat donors	113.8 days (0.31 year)				
Parameter input values (PHAC)	Current scenario	Baseline scenario	90% deferred scenario	95% deferred scenario	99% deferred scenario
N non-gbMSM seroconverters (CBS incident cases)	0.5 (all scenarios)				
N prevalent cases in regular donors	1.5 (all scenarios)				
N additional gbMSM expected to donate per year	-	13,122 (all scenarios)			
N additional HIV-positive gbMSM donations per year	-	95	9.5	4.7	0.95
N gbMSM HIV incident (new) donations per year	-	26.7	2.7	1.3	0.27

Estimated HIV risk and CI, with 0, 90, 95, or 99% of HIV positive gbMSM donors deferred by standard risk questions

	HIV Residual Risk	95 % CI
Current	1 per 25.9 million	1 per 4.8 - 129,988 million
Base scenario (0% deferred)	1 per 0.46 million	1 per 0.3 - 0.7 million
90% deferred scenario	1 per 4.0 million	1 per 1.9 - 13.2 million
95% deferred scenario	1 per 7.3 million	1 per 3.0 - 7,774 million
99% deferred scenario	1 per 20.6 million	1 per 5.3 - 66,079 million

Risk Model - Conclusions

- If we assume risk reduction in gbMSM with our standard risk questions will be similar to non-gbMSM, removal of the time deferral would have a minimal risk increment
- The residual risk increment would be below 1 in 5 million donations for fresh components
- The additional criteria would provide additional risk reduction
- Additional risk reduction would occur for pathogen reduced components, such as source plasma

Sexual transmission risk, epidemiologic studies

ESTIMATES OF THE PER-SEX-ACT AND PER-INJECTION RISK OF HIV TRANSMISSION

Route of transmission	Transmission probability
Receptive anal intercourse	0.5% to 3.38 %
Insertive anal intercourse	0.06% to 0.16%
Receptive vaginal intercourse	0.08% to 0.19%
Insertive vaginal intercourse	0.05% to 0.1%
Oral intercourse	low but non-zero
Sharing contaminated needle and syringe	0.67-0.84

Engage Study

Followed over 2,000 gbMSM in Vancouver, Toronto, and Montreal



Risk factors for recent HIV infections (last 6 months)

Behaviour	Standard current criteria (not including MSM deferral)	New proposed criteria
> 1 HIV positive partner	✓	
Condomless anal sex with HIV positive partner	✓	
Injection drug use (IVDU)	✓	
Syphilis diagnosis	✓	
MSM risk index score > 21	±*	✓
No exclusive sex partner	no	✓
> 1 anal sex partner	no	✓
Methamphetamine (crystal) use using sex	no	no

* Many would be on pre-exposure prophylaxis therapy (PrEP)

Respondents reporting one risk had a higher probability of reporting others

- There were 19 cases of HIV per 4,438 person-years of observation
- Approximately 75% would have been deferred with “standard” current risk criteria (not including MSM in the last 3 months)
- This percentage may be higher since the Engage study did not ask participants all standard risk questions
- New criteria would defer donors with multiple sexual partners, or having anal sex with more than 1 partner, identified as risk factors for recent HIV infection
- **Standard plus new criteria would defer all 19 participants with recent infections**

Possible impact on adequacy of supply

How many currently eligible donors may be deferred with various possible criteria changes?

- 2 large on collection site surveys, over 30,000 donors each

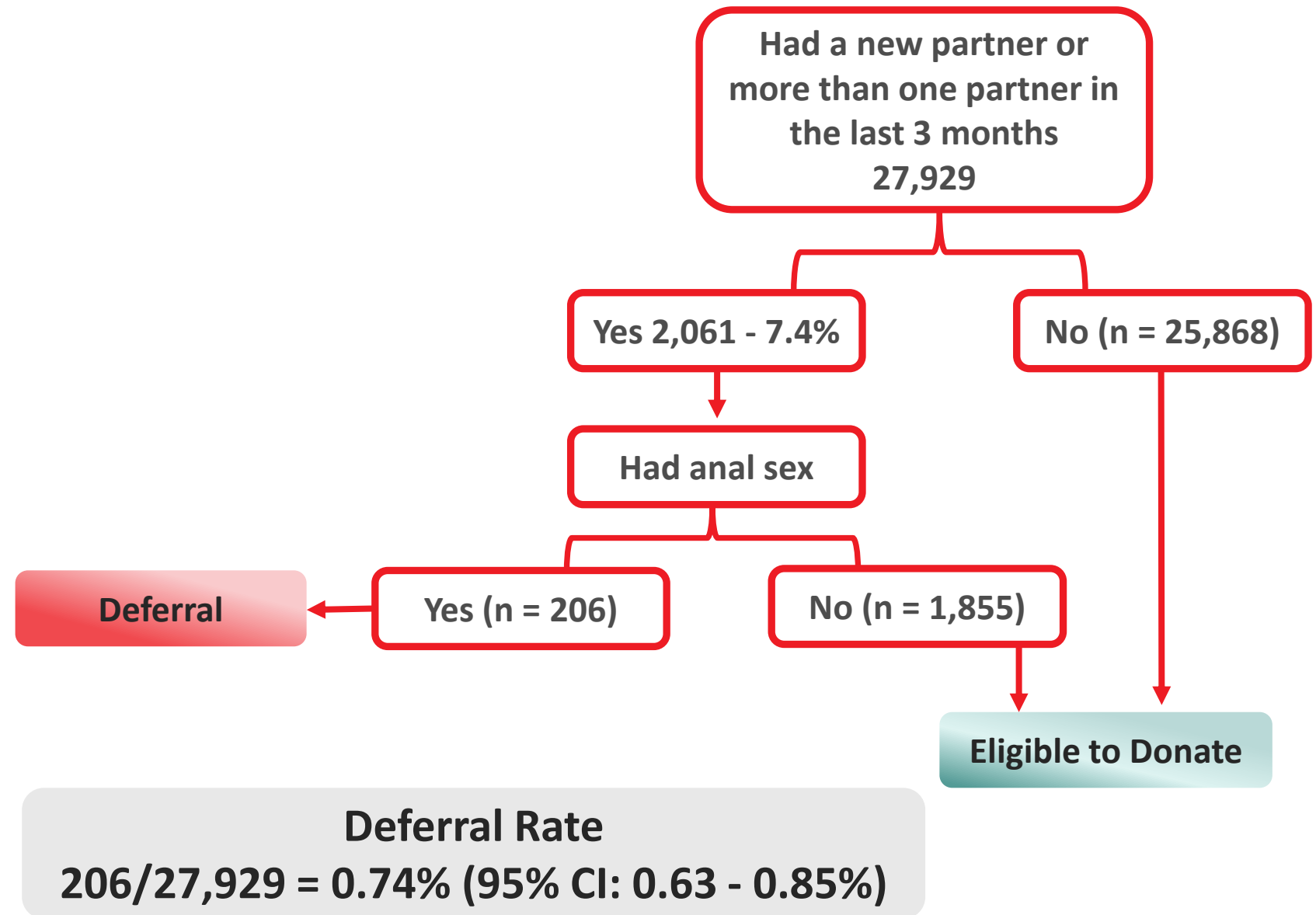
Would you be comfortable answering a question about this behaviour?

Have you engaged in this behaviour in the last 3 months?

- Some donors provided consent for follow-up in depth interviews
- Allowed us to assess feasibility of UK approach



Flow diagram of
percentage deferred
using **For the
Assessment of
Individualised Risk
(FAIR)** screening
questions



Post-implementation Monitoring

- Monitor infectious disease marker rates, with focus on HIV
- Interview and identify risk factors in HIV positive donors
- Conduct an anonymous donor survey to assess compliance
- Monitor emerging pathogens, international developments and data
- Test for the presence of antiviral agents (PrEP/PEP) in a subset of samples
- Further characterize the molecular epidemiology of NAT positive HIV samples, and recency of antibody positive HIV infections

Surveillance Reports:

<https://professionaleducation.blood.ca/en/transfusion/publications/surveillance-report>



HIV incidence and compliance studies:

- HIV incidence and compliance with deferral criteria over three progressively shorter time deferrals for men who have sex with men in Canada. Caffrey N, Transfusion 2022;62:125
- Evaluation of PrEP/PEP deferral policy among blood donors. Saeed S, Transfusion 2021;61:1684

Modeling studies:

- HIV residual risk in Canada for apheresis source plasma donation without deferral for MSM. Aube E, Vox Sang 2022;117:201
- Removing the men having sex with men blood donation deferral: informing risk models using Canadian public health surveillance data. Caffrey N, in press Transfusion Clinique et Biologique

Impact on adequacy of supply:

- Donor screening question alternatives to men who have sex with men time deferral: potential impact on donor deferral and discomfort. O'Brien SF, Transfusion 2021;61:94
- Behaviour based screening questions and potential donation loss using the “for the assessment of individualized risk” screening criteria: a Canadian perspective. Caffrey N, Transfusion Medicine, epubed June, 2022