

Global Update on Approaches for Blood Donation by MSM and Current Considerations

Brian Custer, PhD, MPH

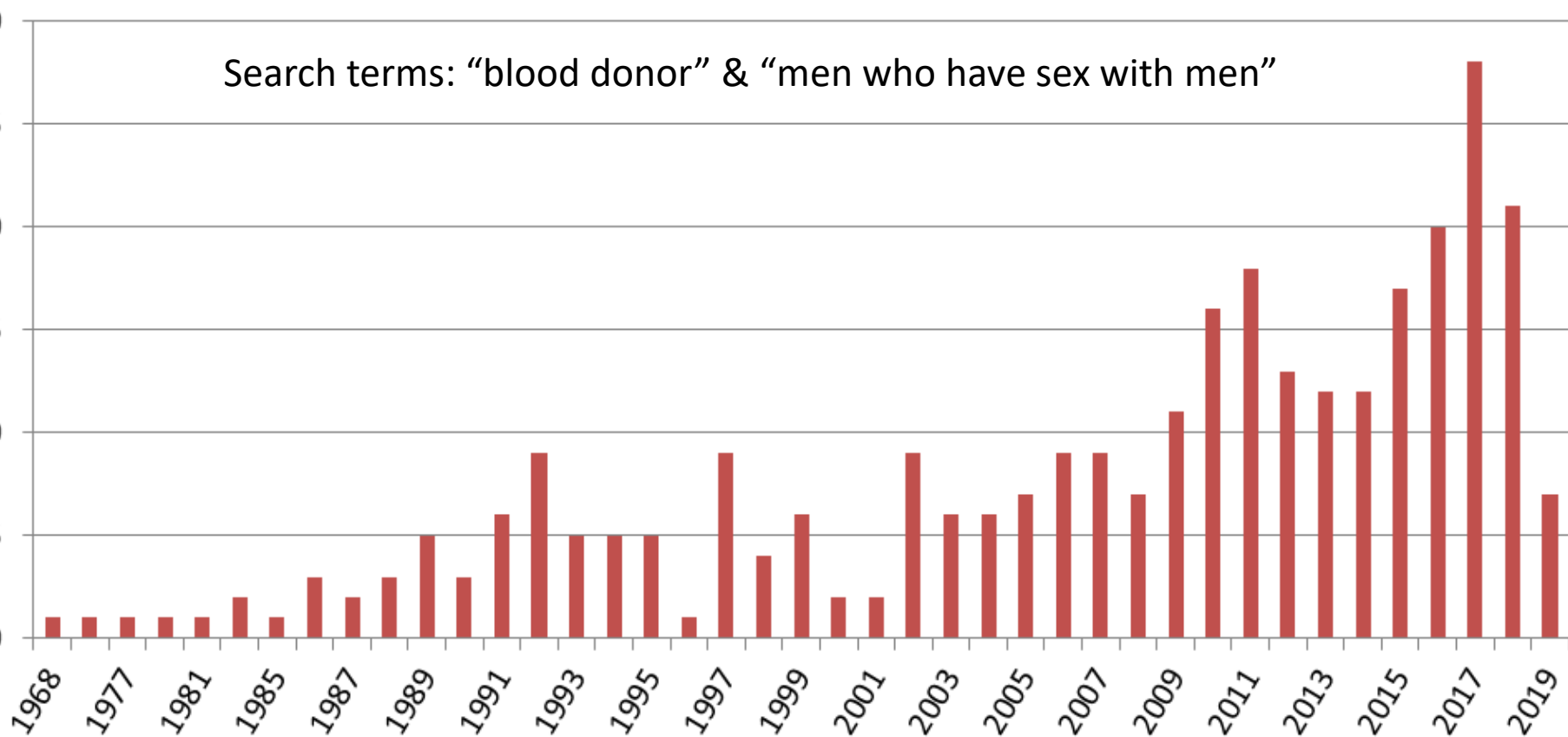
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Krakow, Poland

Outline

1. Conceptual framework
2. Changing approaches to donor deferral
3. Use of shorter deferral periods
4. New initiatives
5. New considerations and concerns

Number of Publications in Pubmed by Year

Search terms: "blood donor" & "men who have sex with men"



International Policies: Policy Divergence

No general consensus

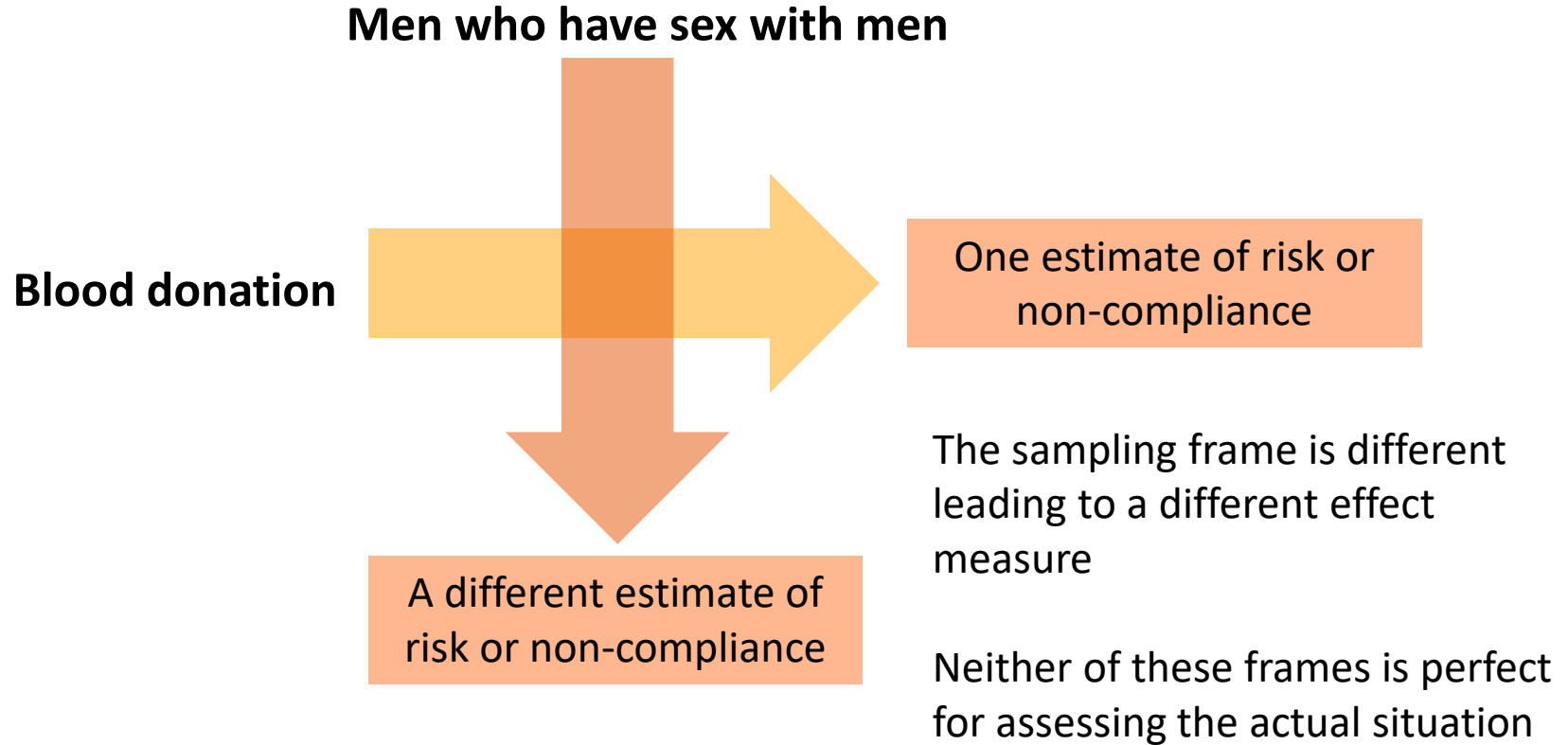
Factors influencing policy include

- Epidemiology of HIV
- Donor screening methods
- Regulatory requirements
- Government decrees
- Risk analysis, modeling
- History of response to threats

Contextual Considerations

- A high level of controversy surrounding what defines evidence- or science-based policy
- Current testing approaches in developed countries do not justify an indefinite deferral
- The primary concern is HIV and other known infections
 - Emerging infections as a primary reason is not justifiable by EID patterns observed in the last 20 years
- Analyses of changes in deferral periods for MSM show that gains to the quantity of blood in the supply are marginal
- Therefore, the issues and implications are more related to equity and broader consequences of negative impact and willingness to donate in all potential donors

Behavioral Intersections



Approaches for Eligibility & Donation

Time-based deferral (indefinite, 5-years, 1-year, 3-4 months)

- Any MSM sex in time period → deferral for given time after last sexual contact

Risk activities based, “gender neutral” policies

- Sexual behaviors considered to be high-risk, regardless of whether partner is same or opposite sex, in a given time frame → deferral for given time after risk factor
- Individual-risk assessment

Alternative criteria + other safety measures

- Plasma quarantine and retest
- Use of pathogen inactivation or donation of plasma for fractionated products only

United Kingdom: Further Reduction in Deferral Period

Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) recommendations accepted in July 2017 (implemented in England, Scotland and Wales, November 2017)

Subject to meeting the other donation rules new deferral period applies to:

- MSM who have had specific sexual activity
- CSW (commercial sex workers)
- Sex partners of groups known to have a high risk of having a sexually transmissible infection (high risk partners)

All are able to donate after three months have passed since the last sexual activity – previously these were all 12-month deferrals

United Kingdom: 3 Month Deferral (ISBT Abstract in Basel)

- UK blood donation surveillance data for 2010-2018 were reviewed and annual prevalence and incidence of HBV and HIV infection were estimated
 - Among new donors, annual HIV prevalence *decreased* significantly by an average of 11.3% each year ($p=0.02$) to 1.49/100,000 donations in 2018
 - No significant trend was observed for prevalent HBV
 - Annual HIV incidence among repeat donors also decreased significantly by an average of 17.3% each year ($p=0.03$) to 0.23/100 000-person years (pyrs) in 2018 (based on 2 seroconverters)
 - Between 2017 and 2018 HBV incidence increased from 0.35/100 000 pyrs to 0.84/100,000/pyrs, but is considered to be due to non-compliance
- FAIR (For the Assessment of Individualised Risk), using the ABO RBDM framework for guidance

Canada

The Canadian federal Minister of Health pledged 3 million dollars in 2016 and additional funding in 2018 to support a broad ranging research program:

- Research to evaluate the impact of alternative risk reduction technologies on donor screening
- Research to evaluate operational feasibility of alternative donor deferral policies and their acceptability by Canadians
- Risk modeling and surveillance to assess the risk associated with alternative donor selection policies
- Research to inform the development of an individual risk assessment donor policy (behaviour based) or to strengthen the existing policy (population based)

Canada: 3 Month Deferral (Announced May 8 and Planned to Implement June 3, 2019)

- Submission to Health Canada to change from a 12-month to 3-month deferral in 2018
 - Change approved earlier this year
- Canadian Blood Services and HemaQuebec will implement policy
- Reduction to 3-month deferral will be implemented along with a question on the donor questionnaire about PEP or PrEP use in the last 4 months, with a 4 month deferral after stopping medication.

Time-Based MSM Deferrals, 2019 - Snapshot

Deferral time	Country		
3 months	England, Scotland, and Wales (late 2017) Canada (June 2019)		
4 months	Denmark (announced by Health Ministry) Netherlands (planning for implementation) France (under consideration)		
12 months	Australia New Zealand USA Brazil	France Finland Switzerland	Sweden Belgium Germany Hungary
Indefinite	Greece		

Modeling of HIV Risk in the Blood Supply

Changing the deferral for men who have sex with men – an improved model to estimate HIV risk

Katy Davison – UK, Yves Grégoire, Marc Germaine – Canada, Brian Custer – USA, Sheila O'Brien – Canada, Whitney Steele – USA, Josianne Pillonel – France, Clive Seed – Australia

Supported by ISBT TTID WP and Canada MSM Research Grant

- Used to model the impact of a 12-month deferral and also used to model the 3-month deferral in Canada

Brazil – Research on alternative approaches to direct questioning

Brazil Supreme Court

At this time the court is considering a ruling that would compel all blood collectors in the country to change predonation interview criteria, including not allowing blood centers to ask blood donors whether their sexual partners are the same or opposite sex, or inquiring about other aspects of the donor's sexual partners.

Brazil

Can alternative approaches to eligibility assessment without specifically asking about sexual orientation or the sex of your sex partners be identified?

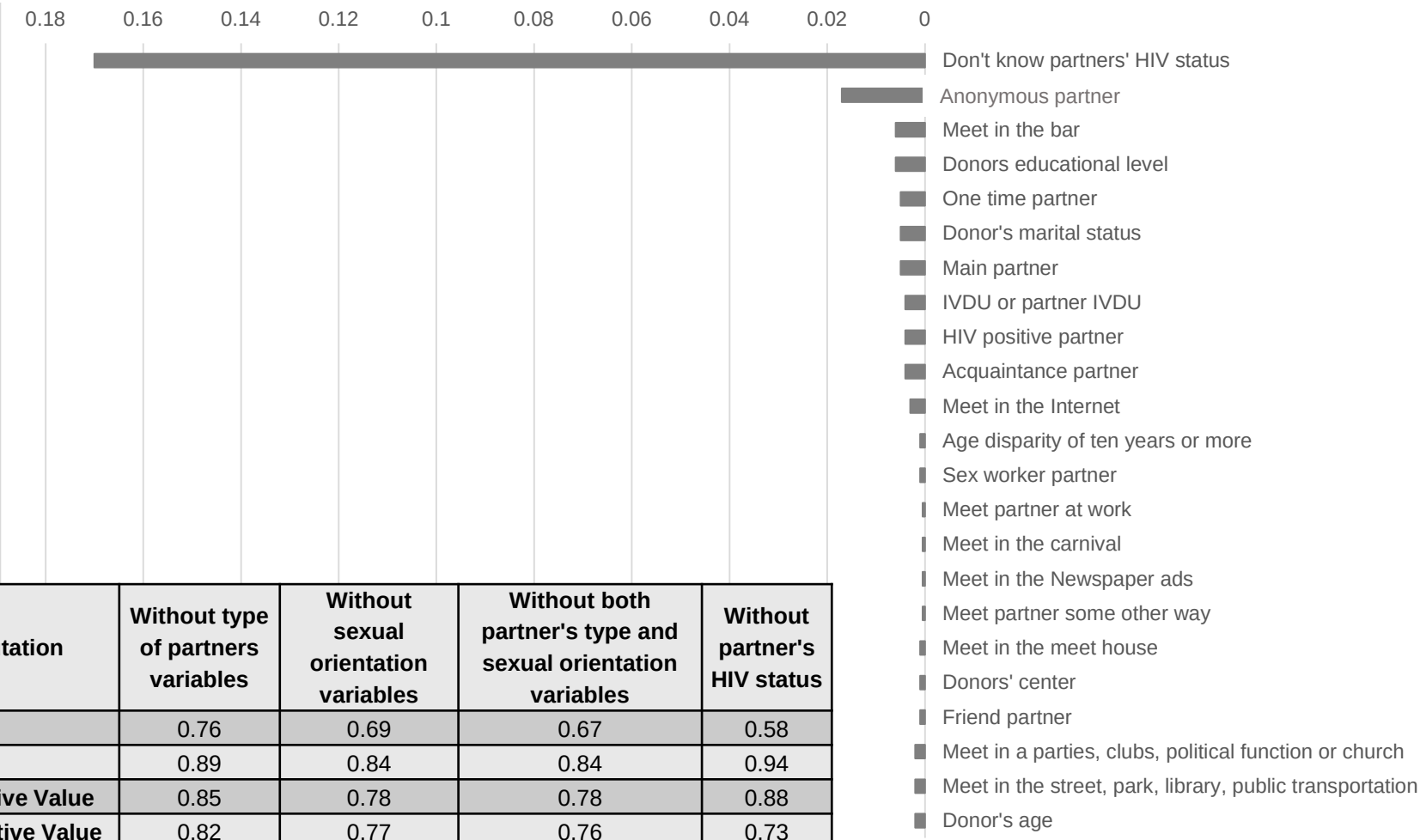
Used two analytical approaches:

1. Latent class analysis
2. Decision tree learning (a type of machine learning approach)

To assess if questions other than sexual orientation or gender of your sex partners can be used to differentiate between HIV-positive and HIV-negative donors

Decision Tree Analysis

Variable importance values



Measures/Permutation	Without type of partners variables	Without sexual orientation variables	Without both partner's type and sexual orientation variables	Without partner's HIV status
Sensitivity	0.76	0.69	0.67	0.58
Specificity	0.89	0.84	0.84	0.94
Positive Predictive Value	0.85	0.78	0.78	0.88
Negative Predictive Value	0.82	0.77	0.76	0.73

Quarantined apheresis plasma donation by MSM with deferral rules identical to those applied to all other blood donors

- Plasma quarantine program: quarantine until a new donation and repeat testing at least 2 months later, thus enabling the detection of HIV window period donation
 - MSM allowed to donate under the same conditions than other donors, i.e. no more than one sexual partner over the last for 4 months.
- Unique opportunity to safely assess HIV epidemiology among MSM blood donors subjected to the same deferral rules than other donors.

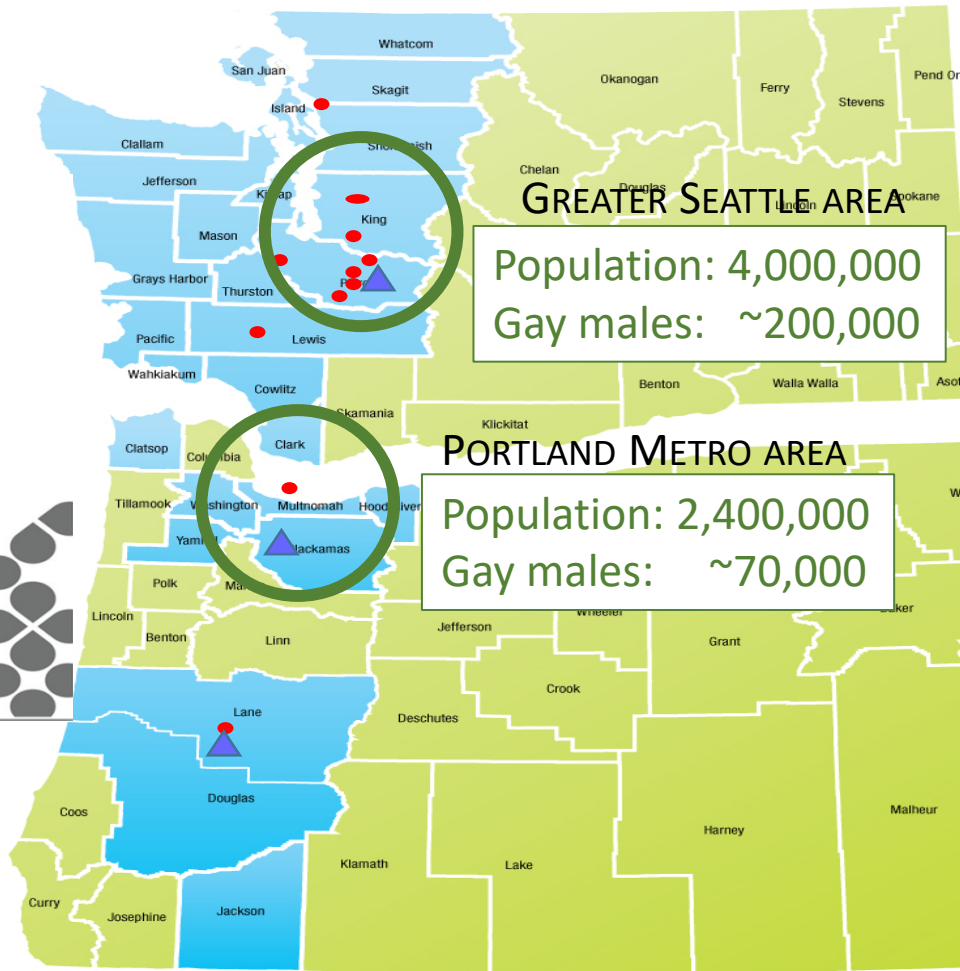
Quarantined apheresis plasma donation by MSM with deferral rules identical to those applied to all other blood donors

Preliminary assessment:

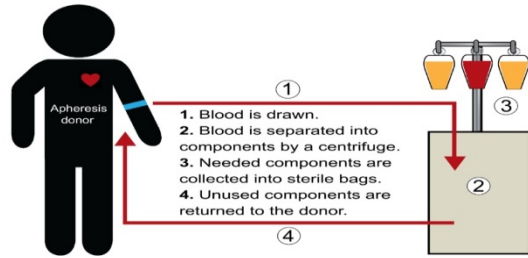
- Low donor accrual
 - Potential contributing factors:
 - insufficient knowledge by putative candidates
 - limited access to apheresis donation (fixed sites only)
 - low attractiveness of this type of blood donation, especially for new donors
- High deferral rate
 - limited access to apheresis donation (fixed sites only)
 - higher deferral frequency for sexual risk factors among MSM blood donor
- (Moderately) low return rate
- In donors having undergone apheresis plasma donation:
 - Increased frequency of syphilis seropositivity
 - No discernable differences regarding HIV, HCV and HBV
 - No new infectious markers in returning donors
- **Too early to draw any firm conclusions**

Expanding the Rolls *Making Blood Donation by MSM a Reality*

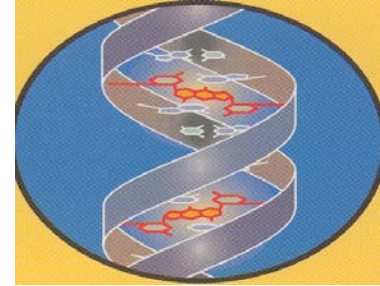
James P. AuBuchon, MD, FCAP, FRCP(Edin)
President & CEO
Bloodworks Northwest



BloodWorks Northwest Variance Request



Negative test results



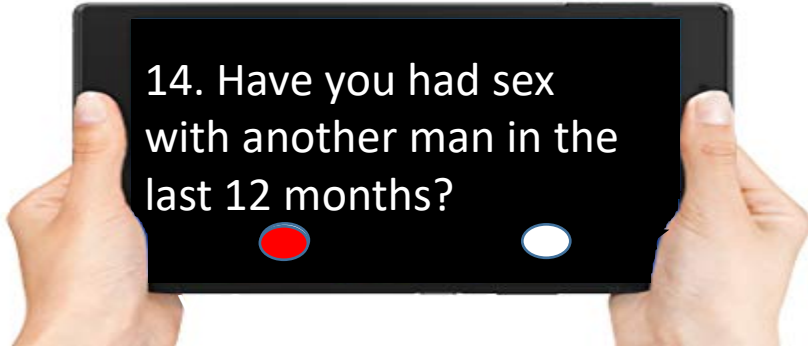
Accept as apheresis platelet donor:

- **MSM regardless of sexual activity**
- **Woman with MSM contact in last 12 months**

Conversion to Intercept platelets

Applying new technology to offer new possibilities

Process Control: Recognizing the Situation



WITH VARIANCE:

Apheresis platelet collection
ONLY.
Requirement for **conversion**
to Intercept platelet unit
before release.

Automatic deferral overridden →
“Attributes” automatically applied to donation

Where is this headed?

Companion approach: Malaria travel-deferred donors for PRT platelets

Partnerships with LGBTQ+ community for recruitment

- Current: Research product donation
- Future: Platelet donation

Preparation of hospitals for PRT platelets

- Increased recipient safety
- Simplest approach to bacteriologic safety improvement

Diversity engagement with key customers

Safety engagement with recipient groups

Internal preparations

- SOP development
- BECS programming and validation
- Training
- Interim: Capture of expressed interest

It's all about:

- Diversity
- Equity
- (Improved) safety
- Donor recruitment

Non-compliance: Data from Canada

- Anonymous online surveys of male whole blood donors to assess compliance before and after implementation of shorter deferral periods:

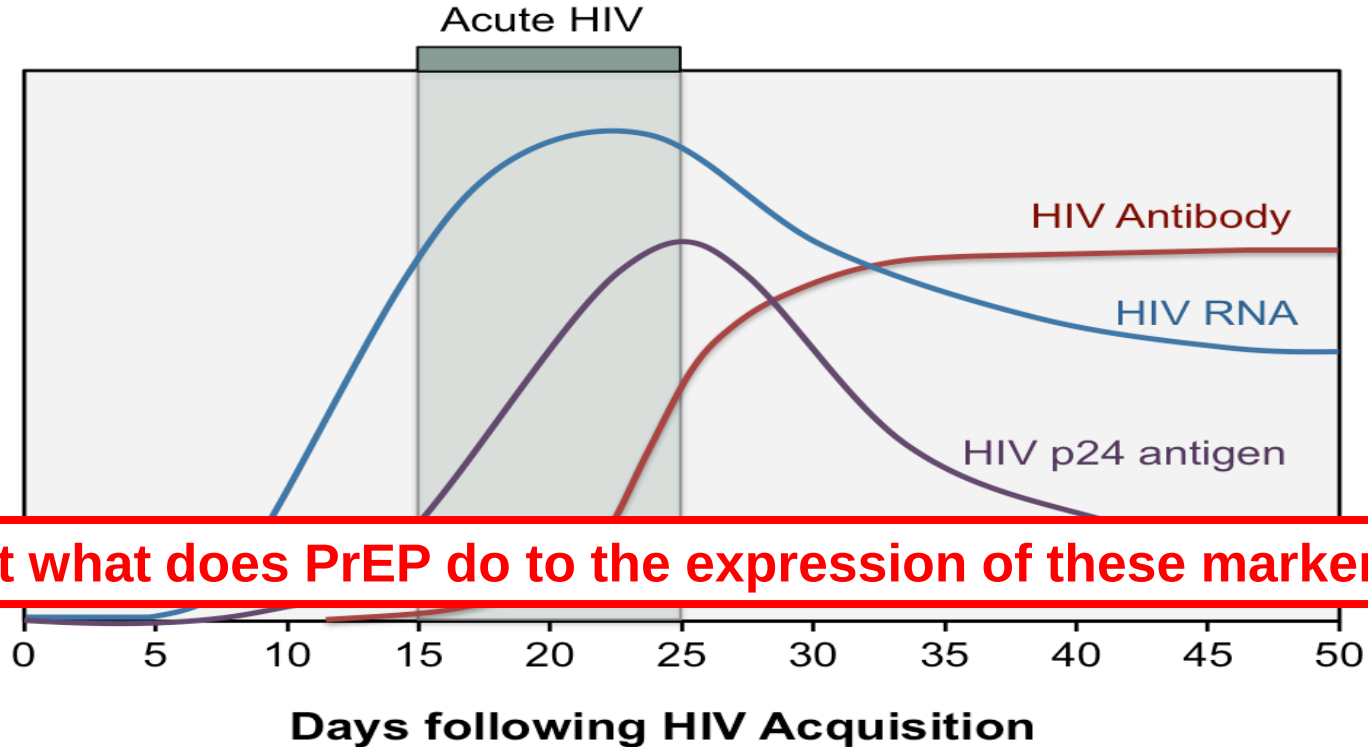
Survey 1: October 2012 to March 2013 pre-implementation of 5-yr deferral

Survey 2: October 2014 to March 2015 post implementation of 5-yr

Survey 3: October 2017 to March 2018 post implementation of 1-yr

Deferral length (period)	Survey size (response rate)	Percent non-compliance with deferral	P-value	Percent non-compliance with sex in the 1-year before donation	P-value
Indefinite (1985 – 2013)	9,669 (49.7%)	0.67	0.04	0.21	>0.05
5-Year (2013 – 2017)	6,881 (36.3%)	0.44		0.19	
12-Month (2017 – current)	6,772 (36.3%)	-	-	0.26	

Laboratory Markers with Acute HIV



But what does PrEP do to the expression of these markers?

Pharmaceutical Success in HIV Control and Prevention May Not Directly Translate to Blood Safety

Conflicting messages between public health and blood safety

- Undetectable equals untransmittable: U = U
- Volume of plasma in a component will be directly related to infectious risk
- Size of inoculum and intravenous route

Gosbell et al. Vox Sang. 2019 May 20. doi: 10.1111/vox.12790.

Actual donor motivation and behavior need to be evaluated

- Short on data

Approaches to Assessing PrEP Use

Compliance Revisited

- Rates of non-compliance have been shown to vary widely in different countries
- Donors' willingness to respond honestly to a health history question about PrEP is going to vary
 - It is likely to vary in proportion to the HIV infection rate in the donor population of each country
- Research to test donations for PrEP will be conducted to inform or monitor, but is not a long term viable strategy for most settings

CDC National HIV Behavior Surveillance (NHBS)

MSM, IDU, and HET survey cycles

NHBS-MSM conducted 6 times (2003-2005, 2008, 2011, 2013, 2015, 2017)

NHBS-MSM Methods – Venue-Based, Time-Space Sampling

1. Formative research to learn the venues, times, and methods to recruit MSM

Venues include bars, dance clubs, parks, cafes, street locations, and social organizations (i.e. gay sport leagues, community centers, etc.).

2. Monthly sampling frames of eligible venues and day-time periods that met attendance, logistical, and safety criteria

3. Recruitment of participants in accordance with randomly generated venue calendars

22 locations in recent NHBS-MSM survey – Each survey has core content (demographics, sexual behaviors, HIV/STD testing, drug/alcohol use) plus additional questions may be added by local study teams.

CDC NHBS Project Locations – Blood donation questions



In 2017, seven sites added a short set of questions – analysis underway at this time

- Geographic assessment of non-compliance with 1-year deferral policy and PrEP use
- Initial Results:

21 out of 483 (4.2%, 95%CI 2.6 – 6.3%) of the respondents at four sites (circled in purple) reported donating in 2016 or 2017 and PrEP use proximate to the time of donation

US Transfusion Transmissible Infections Monitoring System (TTIMS) – ongoing projects:

- Donor and donation database to monitor TTID prevalence and incidence in >60% of the US blood supply
- Risk factor monitoring comparing persons with infections to controls without infection
- Various laboratory studies of genotypes/drug resistance, viral load and recency testing of HIV
- **Protocol to assess whether donors who test HIV-positive are taking ARVs at the time of donation**
- **Protocol to assess if a subset of the first-time donor population is taking PrEP at the time donation**

Summary

Blood donation policy for MSM is evolving rapidly in several countries:

- Shorter time-limited deferrals
- Operational experiences in the UK, Canada, and other countries will be informative
- Compliance is important and so far changes to shorter deferral lengths have been associated with improved compliance (where it has been measured)
- Special programs to allow MSM to donate specific components
- Yet the story is becoming increasingly complex with local epidemiological and public health considerations even more relevant

Acknowledgements

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Thank you

bcuster@vitalant.org