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## Background

Most Western countries (temporarily) exclude men who have sex with men (MSM) from blood donation. The ethical and scientific justification of donor deferral of MSM is heavily debated, especially after the introduction of highly-sensitive nucleotide amplification testing for HIV, hepatitis B virus (HBV) and hepatitis C virus (HCV).

## Objective

- To investigate the suitability of MSM to donate blood by comparing the antibody reactivity to ten sexually transmitted and/or blood born infections ('infection pressure') in MSM versus the general male donor population.

## Methods

### Study setting:

- Period: January – August 2016
- 583 MSM from the Amsterdam Cohort Studies
- 583 age-matched repeat male donors from Amsterdam

### Classification for MSM:

- Low (lr) versus medium to high (hr) sexual risk behavior (self-reported)
  - Low risk = no anal sex, a monogamous relationship, or consistent condom use with casual partners in the past year
- Eligible versus non-eligible (permanent deferral criteria for Dutch donors)

### Antibody testing:

- Class A infections: HIV, HBV (anti-Hbcore), HCV, human T-cell lymphotropic virus (HTLV), syphilis
- Class B infections: cytomegalovirus (CMV), herpes simplex virus 1/2 (HSV), human herpes virus 8 (HHV-8), hepatitis E virus (HEV) and Parvovirus B19

**Infection pressure:** number of class B infections + 2 \* number of class A infections, based on antibody reactivity

**Recent infection:** seroconversion within the previous year (retrospective testing)

## Results

### MSM group categorization

- Eligible lr-MSM: n=197
- Non-eligible lr-MSM: n=48
- Eligible hr-MSM: n=183
- Non-eligible hr-MSM: n=92

### Infection pressure

Median 3 (IQR 2-4) infections in both eligible lr-MSM and eligible hr-MSM (see table 1), significantly higher than in donors (median 2; IQR 1-2;  $p < 0.001$ ).

In all MSM groups the seroprevalence of CMV, HSV, HHV-8 was higher than in donors ( $p < 0.001$  for each).

### Low-risk MSM, eligible for donation

- No antibodies to HIV, HCV, HTLV or syphilis
- Antibodies to HBV (n=15; 8%); 1 (1%) chronic HBV infection (HBsAg positive)
- No recently acquired Class A infections

### Medium to high-risk MSM, eligible for donation

- Antibodies to syphilis (n=5; 3%) and HBV (n=17; 9%); 1 (1%) chronic HBV infection (HBsAg positive)
- 2 recent syphilis infections and 2 recent HBV infections

### MSM non-eligible for donation

- Lr-MSM: infection pressure 4 (IQR 3-5); no antibodies to HIV and HTLV; antibodies to HBV in 6 (13%), HCV in 1 (1%) and syphilis in 23 (48%) MSM. No recently acquired Class A infections.
- Hr-MSM: infection pressure 4 (IQR 4-6); no antibodies to HIV; antibodies to HTLV in 1 (1%), HBV in 26 (28%), HCV in 2 (2%) and syphilis in 23 (48%) MSM. One (1%) recent HBV infection, 6 (7%) recent syphilis infections.

### Willingness to donate blood

73% of MSM had a moderate or high intention to donate blood once MSM deferral policies would be lifted, determined using a seven point Likert scale. Intention to donate did not differ significantly between the four MSM groups.

**Table 1. Age, infection pressure and antibody reactivity in donors and eligible MSM.**

	Repeat male blood donors (n = 583)		MSM 'eligible' for donation				
	median	IQR	Low risk (n = 197)	IQR	Medium to high risk (n = 183)	IQR	
<b>Age</b>	42	[34 - 48]	42	[36 - 47]	40	[34 - 49]	
<b>Infection pressure</b>	2	[1 - 2]	3	[2 - 4] *	3	[2 - 4] *	
	N	%	N	%	N	%	
<b>Antibody-reactivity</b>							
Class A	HIV	0	0%	0	0%	0	0%
	HBV <sup>a</sup>	6	1%	15	8% *	17	9% *
	HCV	0	0%	0	0%	0	0%
	HTLV	0	0%	0	0%	0	0%
	Syphilis	0	0%	0	0%	5	3% *
Class B	HEV	116	20%	29	15%	23	13% *
	CMV	220	38%	134	68% *	140	77% *
	HSV	267	46%	160	81% *	154	84% *
	Parvo B19	432	74%	145	74%	142	78%
	HHV-8	30	5%	77	39% *	86	47% *
<b>Recent infections</b>							
Class A	HIV	0	0%	0	0%	0	0%
	HBV	0	0%	0	0%	2	1%
	HCV	0	0%	0	0%	0	0%
	HTLV	0	0%	0	0%	0	0%
	Syphilis	0	0%	0	0%	2	1%

\* P-value  $< 0.05$  compared to repeat male blood donors, obtained from the unpaired t-test, Mann-Whitney U test or Chi-square test as appropriate; <sup>a</sup>anti-Hbcore positive.

## Conclusions

- MSM with medium to high sexual risk behavior are not suitable for blood donation. Hr-MSM have a higher HBV and syphilis prevalence compared to male donors, and the diagnosis of recently acquired Class A infections among hr-MSM implies an increased risk of window-period donations and hence a potential threat to blood safety.
- MSM with low sexual risk behavior may be suitable for blood donation. Lr-MSM have a higher HBV prevalence compared to male donors, but the absence of recently acquired Class A infections suggests that lr-MSM will be correctly deferred by routine donor screening and pose no additional threat to blood safety. The significance with regards to blood safety of the higher seroprevalence of human herpes viruses in lr-MSM (and hr-MSM) compared to donors remains unclear.