

MEN HAVING SEX WITH MEN (MSM) AND BLOOD DONATION

An accelerating rate of change around the globe

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OBJECTIVES

- The ‘ancient history’ of MSM deferrals
- The impact of more liberal criteria on blood safety
- More recent initiatives:
 - Quarantine plasma programs (France, Israel)
 - The Brazilian ‘experiment’
- Coming to you soon:
 - The UK initiative
 - The Netherlands approach
 - Quarantine plasma program in Canada
- Final considerations



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WHERE WE'RE COMING FROM...

- Until fairly recently : Most countries applied a **lifetime deferral** for MSM;
- **AIDS** epidemic: **MSM at high risk**;
- The deferral of MSM from blood donation greatly reduced the risk of transmission by transfusion;
- Introduction of screening tests (**serology, NAT**);
- **'Window period' donations** became the only remaining risk;
- Why not apply a **'temporary' deferral**, i.e. allow MSM to donate after a minimum period of abstinence from sex with other men?

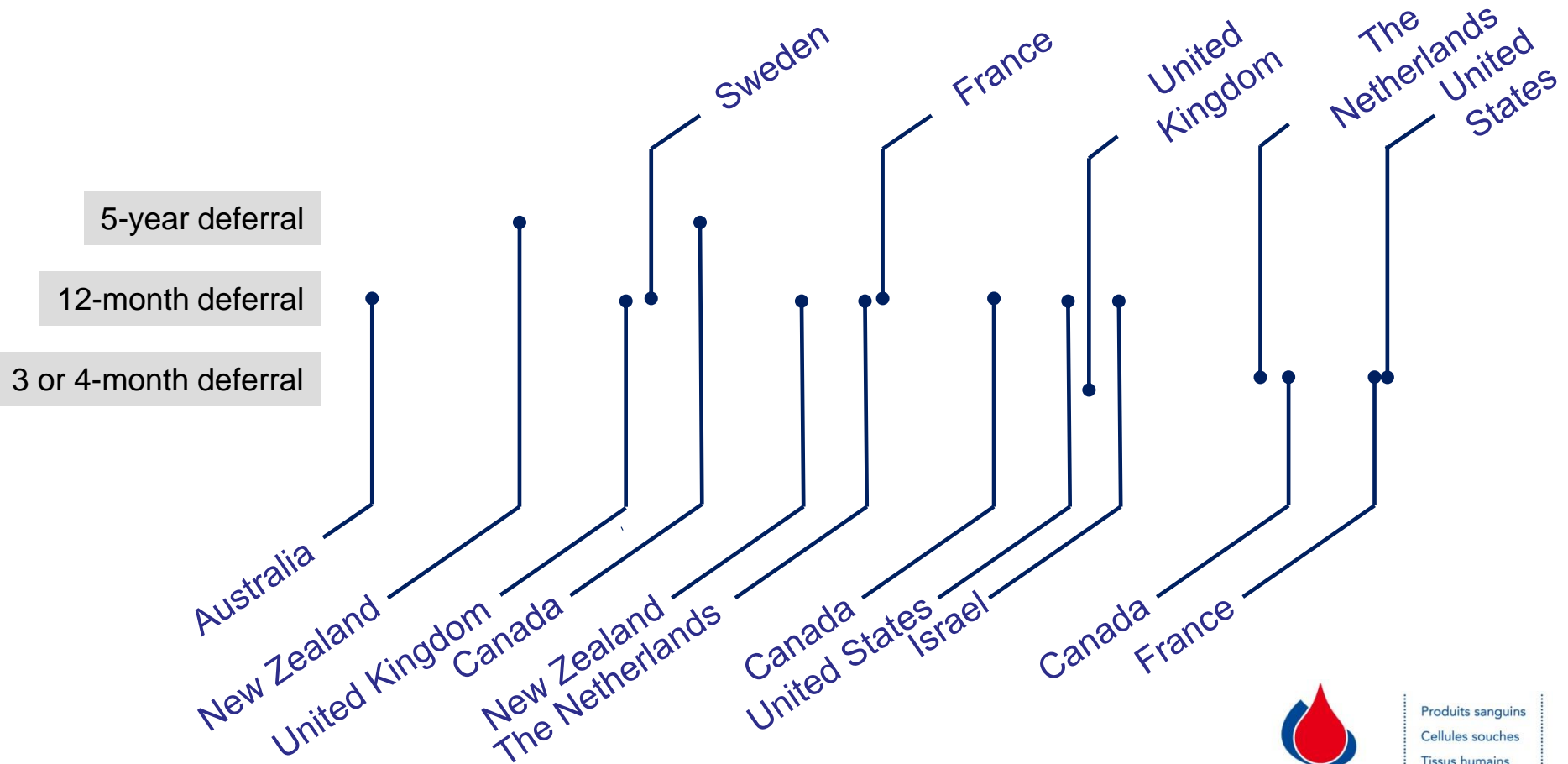


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THE EVOLUTION OF 'TIME-BASED' DEFERRALS FOR MSM

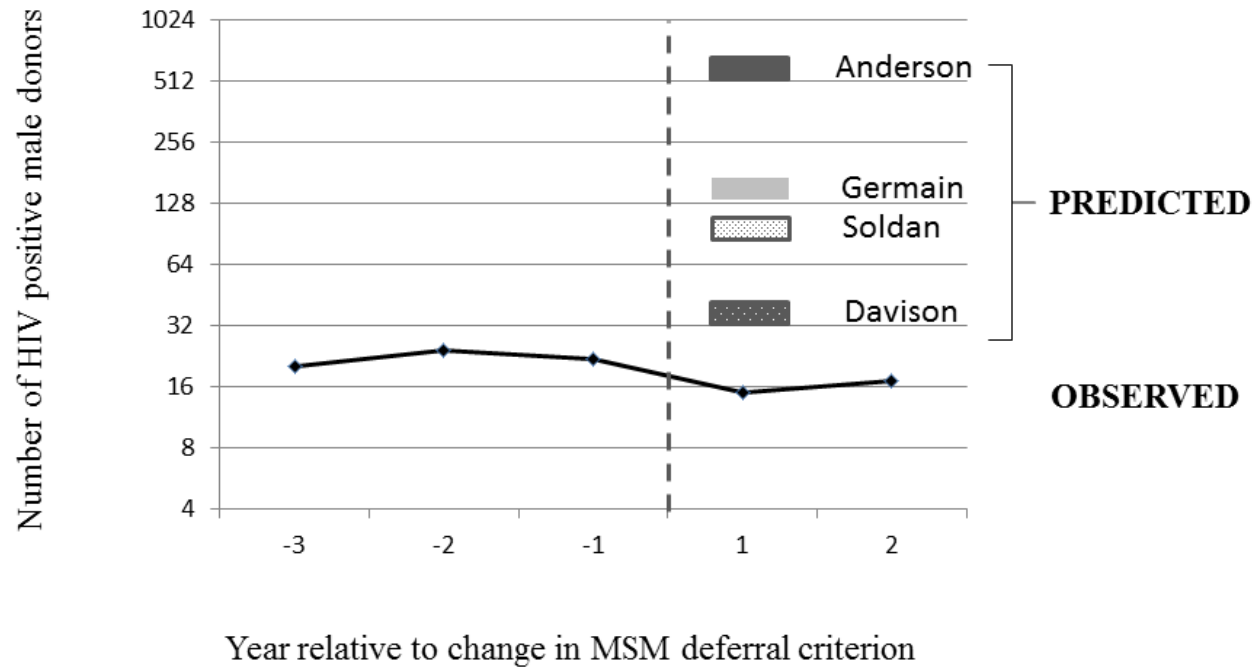
2001 2012 2013 2014 2015 2016 2017 2018 2019 2020 2021



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THE IMPACT OF GOING FROM A PERMANENT TO A TEMPORARY DEFERRAL FOR MSM

Observed and predicted number of HIV-positive male donors before and after the implementation of a temporary MSM deferral (United Kingdom, Australia, and Canada).



Germain M. The risk of allowing blood donation from men having sex with men after a temporary deferral: predictions versus reality. *Transfusion*. 2016;56(6 Pt 2):1603-7

THE IMPACT OF GOING FROM A PERMANENT TO A TEMPORARY DEFERRAL FOR MSM

Steele WR, Dodd RY, Notari EP et al. Transfusion-Transmissible Infections Monitoring System (TTIMS) HIV, HCV, and HBV incidence and residual risk in US blood donors before and after implementation of the 12-month deferral policy for men who have sex with men. *Transfusion* 2021;61:839-850

TABLE 6 Repeat incident, estimated first-time and weighted all donor incidence rate per 100 000 person-years with 95% confidence intervals and per donation residual risk of HIV, HCV, and HBV

Donor type	Data type	Pre-MSM	Post1-MSM	Post2-MSM
HIV				
Repeat donors	Repeat incident cases	27	24	18
	Incidence rate ^a (95% CI)	2.19 (1.45-3.19)	1.88 (1.21-2.80)	1.57 (0.93-2.49)
	Residual risk ^b per donation	1:1831502	1:2133505	1:2554770
First-time donors	Incidence rate ^c (95% CI)	8.54 (5.66-12.44)	7.33 (4.72-10.92)	6.12 (3.63-9.71)
	Residual risk ^b per donation	1:469565	1:546993	1:654998
All donors, weighted	Incidence rate ^d (95% CI)	4.09 (2.70-5.95)	3.54 (2.28-5.28)	2.96 (1.75-4.70)
	Residual risk ^e per donation	1:1151127	1:1337943	1:1606972



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THE IMPACT ON NON-COMPLIANCE

O'Brien SF et al. Compliance with time-based deferrals for men who have sex with men. *Transfusion* . 2019;59:916-920.

TABLE 1. Percentage of male donors and projected number of male donors with MSM history during progressively shorter MSM deferral periods

Last had sex with another man	Before implementation (N = 9,669)			After implementation of 5-year deferral (N = 6,881)			After implementation of 1-year deferral (N = 6,772)		
	Male donors (%)	95% CI	Male donors (N projected)	Male donors (%)	95% CI	Male donors (N projected)	Male donors (%)	95% CI	Male donors (N projected)
In past 6 months	0.10	0.05–0.19	203	0.13	0.06–0.25	263	0.12	0.05–0.24	250
In past year, not in past 6 months	0.11	0.05–0.19	222	0.06	0.02–0.15	131	0.14	0.06–0.26	283
In past 5 years, not in past year	0.16	0.09–0.27	335	0.24	0.14–0.40	500	0.32	0.19–0.48	666
Since 1977, not in past 5 years	0.29	0.19–0.42	604	0.49	0.34–0.69	1,024	0.67	0.49–0.90	1,405
Before 1977	0.13	0.07–0.23	275	0.17	0.09–0.30	360	0.22	0.13–0.37	458

0.66%

0.46%

0.26%

Non-compliance to current deferral criterion



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WHAT ABOUT COUNTRIES WITH NO TIME-BASED DEFERRALS FOR MSM?

🔴 Italy

- No MSM deferral since ministerial decree in 2001
- 4 months or permanent deferral for higher risk sexual behaviours, regardless of same or opposite sex partner

🔴 Spain

- No MSM deferral
- 12-month deferral for more than 1 partner or occasional partner

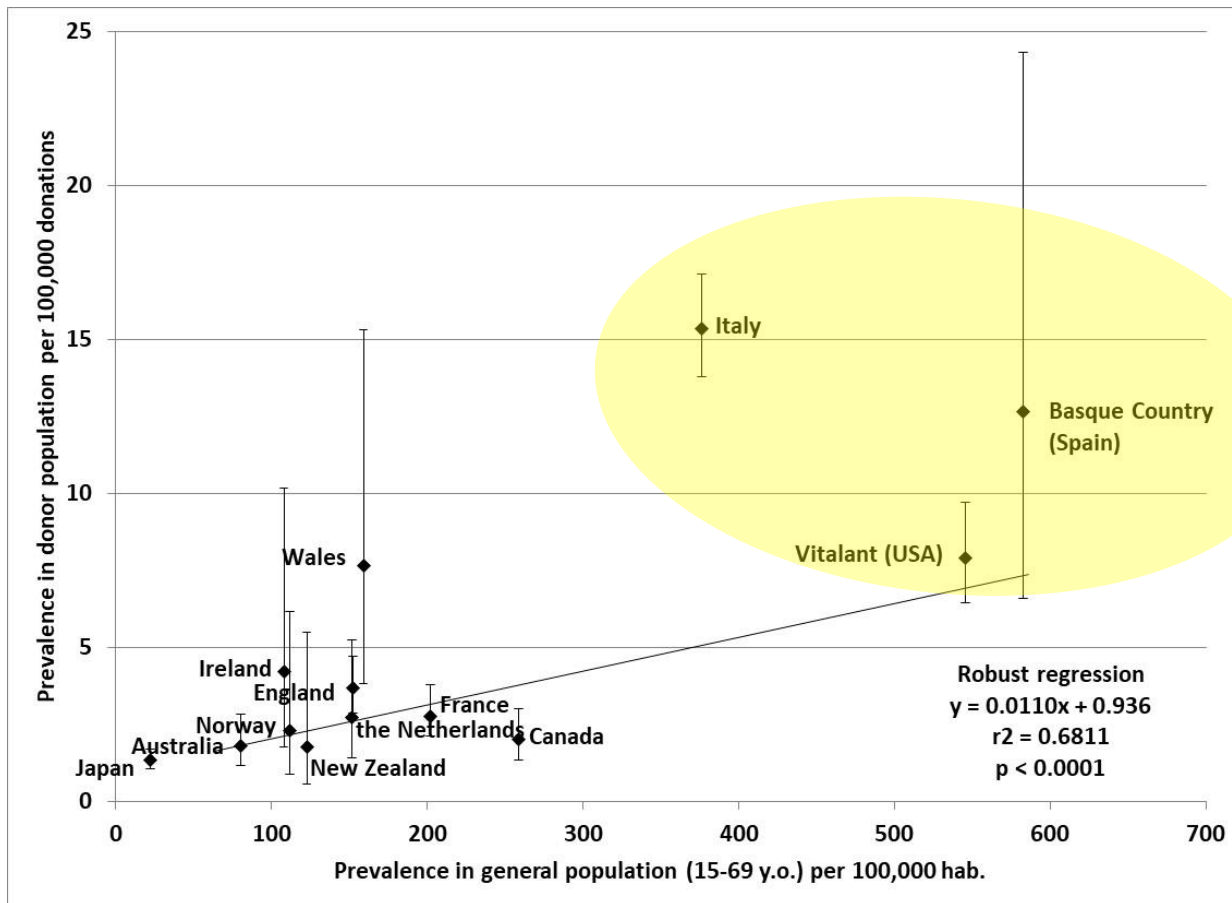


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WHAT ABOUT COUNTRIES WITH NO TIME-BASED DEFERRALS FOR MSM?

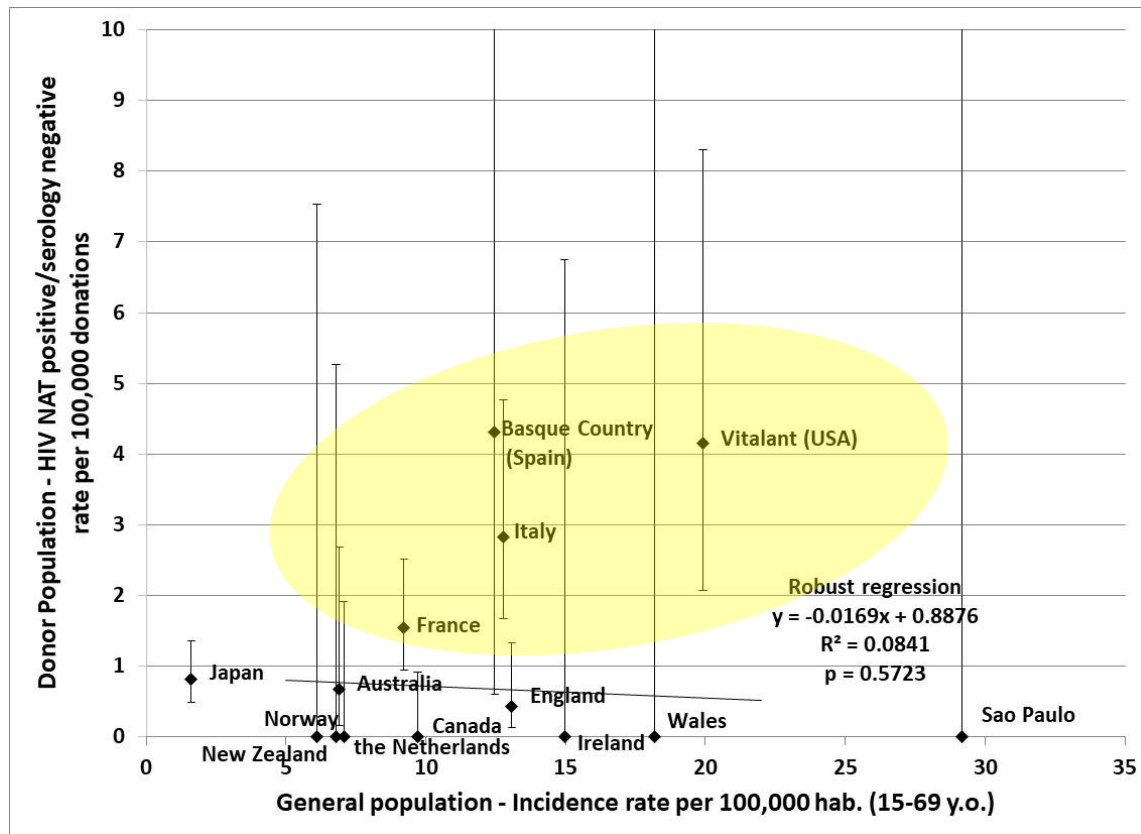
Germain M et al. An international comparison of HIV prevalence and incidence in blood donors and general population: a **BEST** Collaborative study. Vox Sang. 2021 Apr 9. doi: 10.1111/vox.13107. Online ahead of print.



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WHAT ABOUT COUNTRIES WITH NO TIME-BASED DEFERRALS FOR MSM?



MSM AND QUARANTINED PLASMA FOR TRANSFUSION IN FRANCE

Thanks to **Pierre Tiberghien** (EFS)

- Program initiated in June 2016 (extension of existing quarantine plasma program);
- MSM eligible if no more than one sexual partner in last 4 months (same policy applied to heterosexual donors);
- Plasma donation quarantined for at least 2 months until a new donation is given and tested negative;
- Apheresis donations on fixed sites.



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MSM AND QUARANTINED PLASMA FOR TRANSFUSION IN FRANCE

- Three years of data (June 2016 – June 2019):
 - **1063** plasma donations from **456** donors;
 - High deferral rate (11,4% for sexual risk factors);
 - Infectious markers:
 - ✓ **1 HIV** positive donation (Ab and NAT; recency test: negative)
 - ✓ **0 HCV / 0 HBV** positive donations
 - ✓ **9 syphilis** Ab positive donations (2 in return donors)
 - ✓ **1 HAV RNA** positive donation
- Conclusions:
 - Low accrual;
 - Infectious markers different from general donor population;
 - Uncertain representativity compared to the targeted MSM population



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MSM AND QUARANTINED PLASMA FOR TRANSFUSION IN ISRAEL

THE JERUSALEM POST

CORONAVIRUS ISRAEL NEWS ISRAEL ELECTIONS WORLD NEWS MIDDLE EAST

Gay men allowed to donate blood through Magen David Adom in new policy

The move was made possible by significantly more sensitive tests that screen for HIV and can identify infection soon after it occurs.

By JUDY SIEGEL-ITZKOVICH JANUARY 10, 2018 14:04



4-MONTH QUARANTINE



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MSM AND BLOOD DONATION – THE BRAZILIAN ‘NATURAL EXPERIMENT’

Thanks to **Luiz Amorim** (Hemorio)

- 🔴 June 2020: The Brazilian supreme court rules that prospective blood donors cannot be questioned about their sexual orientation; questions on sexual practices have to be ‘gender neutral’;
- 🔴 Blood establishments complied (as of June 15, 2020) but continued to ask about certain risk factors (to all donors, regardless of their gender):
 - Number of sex partners in the last 6 months;
 - Casual sex partner;
 - Use of PrEP.



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MSM AND BLOOD DONATION – THE BRAZILIAN ‘NATURAL EXPERIMENT’

- Impact on infectious disease markers (very preliminary data, from Hemorio):

Marker		Before	After	P
HBV NAT	N	123,435	109,580	
	n	32	28	
	Positivity rate (per 1000)	0.259	0.255	0.96
Syphilis	N	123,435	74,035	
	n	2679	1586	
	Positivity rate (%)	2.68	1.59	0.68
HIV NAT	N	123,435	109,580	
	n	55	71	
	Positivity rate (per 1000)	0.45	0.65	0.037



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MSM AND PLASMA FOR FRACTIONATION

- All donations are tested; the only remaining risk is the window period risk;
- Plasma donations can be frozen and quarantined until the donor is retested, thus completely eliminating the window period risk;
 - Such a program will be initiated later this year in Canada (Canadian Blood Services) in two pilot sites;
 - MSM will still be subjected to a risk assessment (no PreP; only one sexual partner)
- The fractionation process inactivates viruses;



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THE ACCEPTABILITY OF A QUARANTINE PLASMA PROGRAM FOR MSM

Caruso J, Germain M, Godin G et al. 'One step closer': Acceptability of a programme of plasma donation for fractionation from men who have sex with men. Vox Sang 2019;114(7):675-686

Conclusion: The findings suggest some interest in the programme of plasma donation for fractionation, but this is significantly tempered by the fact that differential treatment for MSM would continue and that their demands regarding access to whole blood donation are still unmet.

Plus:

- Complexity
- Costs



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MSM DONATING PLASMA FOR FRACTIONATION WITHOUT A QUARANTINE SCHEME

	DEFERRAL MODEL	MOST LIKELY	OPTIMISTIC	PESSIMISTIC 1	PESSIMISTIC 2
HIV positive donations per 1,000,000 donations	3-month deferral	3.80	3.73	8.99	11.47
	No deferral	5.34	5.04	16.56	20.53
Probability of getting a pool with a viral load	3-month deferral	0.004343	0.004180	0.011823	0.015233
	No deferral	0.005190	0.004573	0.016660	0.020733
Mean copies per pool after NAT and PRT (copies/pool)	3-month deferral	9.7141×10^{-8}	9.7466×10^{-8}	4.8291×10^{-6}	9.7525×10^{-8}
	No deferral	3.5337×10^{-6}	2.9617×10^{-6}	3.2736×10^{-6}	3.2350×10^{-6}
Maximum copies per pool after NAT and PRT (copies/pool)	3-month deferral	1.5965×10^{-6}	1.7089×10^{-6}	0.01678	2.2153×10^{-6}
	No deferral	0.00292	0.00393	0.01590	0.01458

Houle-Aubé E. et al. HIV Residual Risk In Canada For Apheresis Source Plasma Donation Without Deferral For Men Who Have Sex With Men. (Submitted for publication)

THE UK ANNOUNCEMENT

- ◆ December 2020: Recommendations from the **SABTO FAIR** (For the Assessment of Individualised Risk) group recommendations;
 - “...a move from a **population-based 3 month deferral for all MSM** to a donor selection policy based on deferral of potential donors with higher risk behaviours...”
 - “...all potential donors who have ever had sex will be asked if they had a **new sexual partner or more than one sexual partner in the last 3 months**. If ‘yes’, donors will be asked if they had anal sex with their partner(s) regardless of whether they consistently used condoms. From this, donors who have had one sexual partner who was not new in the last 3 months are eligible to donate irrespective of gender...”
- ◆ To be implemented in Summer 2021



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MEANWHILE AT SANQUIN...

2021 #9

March 19, 2021

Sanquin Announces Changes to MSM Deferrals in a Move to an Individual Risk-based Approach

This week Sanquin, the national blood provider for the Netherlands, informed the Minister of Health, Welfare[,] and Sport that the blood bank is revising its deferral policies for men who have sex with other men (MSM). The revision will happen in two phases beginning in September 2021.

Sanquin will begin allowing blood donations from MSM “in lasting monogamous relationships.” According to an announcement from the organization, “a further extension will be prepared to allow MSM outside of a relationship to be admitted as a blood donor by the end of 2022, without the current deferral [period] of four months. In so doing, Sanquin sets equal treatment as the starting point for its admission policy.”



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Some final considerations

- 🔴 Going from ‘time-based’ to ‘behavior-based’ deferrals for MSM: a ‘paradigm shift’
- 🔴 Allowing sexually active MSM: will it increase the risk for recipients?
 - Current residual risk of HIV transmission by transfusion is extremely low, even in countries allowing MSM to donate (lower than 1;1,000,000)
 - French risk assessment of HIV-Residual Risk:
 - Baseline (12-month deferral): 1 in 6,380,000 donations
 - 4-month deferral : 1 in 6,300,000 donations
 - Behavior-based deferral: 1 in 4,300,000 donations
 - ‘Real world’ data will be available soon (Brazil, UK, Netherlands)
 - Situation may differ between countries
 - More modelling should be done
- 🔴 Other issues to be considered:
 - Compliance
 - PreP

Pillonel J et al.
Transfusion
2020;60:525-534



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CONCLUSIONS

- 🔴 MSM deferral policies internationally: “The Times They Are a-Changin...”
- 🔴 The pressure will likely mount from interest groups; we are all under the obligation to evaluate future options, some of which are:
 - Status quo
 - ‘Wait and see’
 - Rely on models and allow donations from sexually active MSM (while excluding high risk behaviors)
 - A stepwise approach: First, allow sexually active MSM to donate plasma for transfusion (under quarantine) or for fractionation (without quarantine)
 - Other?
- 🔴 We should always have the goal of maintaining a very high level of safety for recipients



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Questions?

THANK YOU!



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