

# MSM policy changes around the world and planned Canadian studies of individual donor risk assessments

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September 2017*



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# WHAT I WISH TO COVER

- The evolving situation of MSM eligibility for blood donation, including:
  - The recent announcement in the UK
  - The French initiative with quarantine plasma
- The impact of these changes on blood safety;
- The possible next steps to further advance this contentious issue, in particular:
  - A Canadian initiative to define and implement a research agenda to study other possible approaches to determine the eligibility of MSM



# MSM ELIGIBILITY TO DONATION: AN EVOLVING SITUATION

- 🔴 Countries that have transitioned from a permanent to a temporary deferral:

Country	Deferral period	Year of implementation
Australia	12-month	2001
United Kingdom	12-month	2012
Sweden	12-month	2012-13
Canada	5-year	2013
New Zealand	12-month	2014
France	12-month	2016
United States	12-month	2016
Canada	12-month	2016
Ireland	12-month	2017
United Kingdom	3-month	Late 2017 ?
Japan	6-month	?

# IMPACT ON BLOOD SAFETY ?

- What were the concerns about going from a permanent to a temporary deferral?
  1. An increase in the rate of HIV-positivity among newly eligible donors (i.e. an increase in 'prevalent' infections in the donor pool);
  2. An increase in the number of non-compliant, HIV-infected MSM donors, some of whom might be in the window period on infection (i.e. an increase in 'incident' infections in the donor pool);
  3. The risk posed by unknown, emerging infections that might preferentially target the MSM population;



# The possible consequences of going from a permanent to a temporary deferral

## 1. An increase in the 'prevalent' risk:

- Newly eligible, abstinent MSM would still be at higher risk of HIV compared to never-MSM donors;
- Some of these newly eligible MSM might be unknowingly infected;
- This would increase the number of infected units being collected;
- These infected units would run the risk of being inadvertently made available for transfusion due to quality system failures (test errors, inadvertent release) and emergency releases;

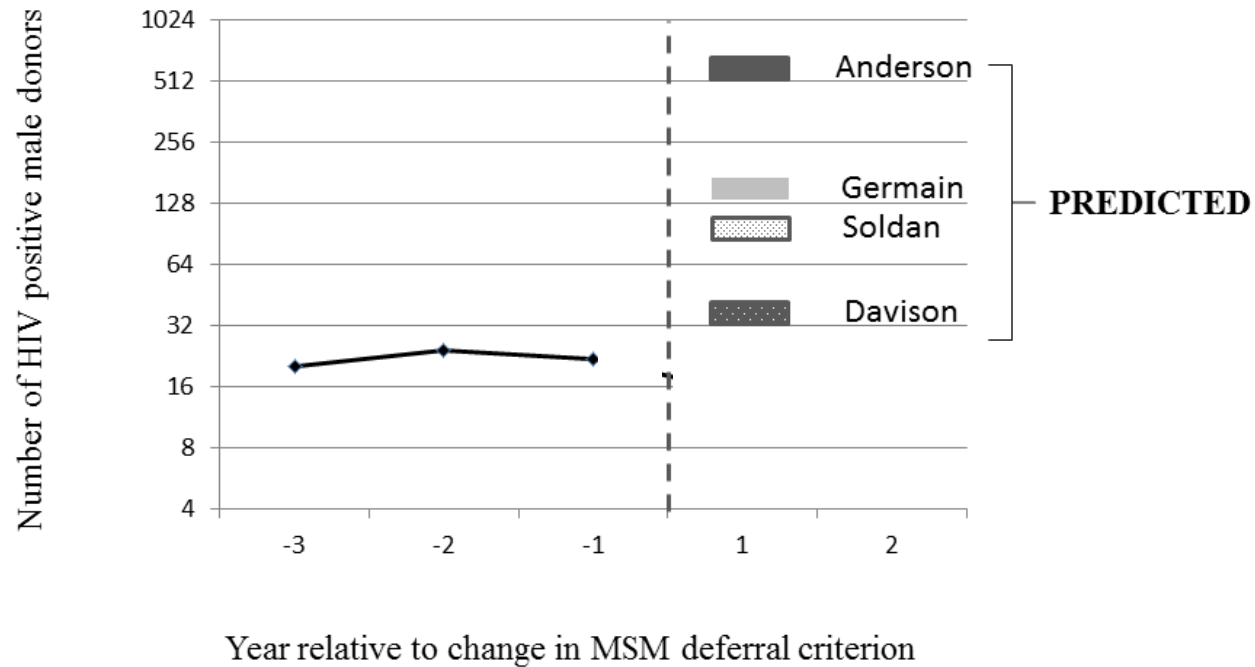
# MODELLING THE IMPACT OF MSM DEFERRAL STRATEGIES

## 🔴 Who tried what and when...

First author	Reference	Year	What was modelled
Dayton, A	BPAC meeting, FDA	2000	Change from permanent to 5-year deferral
Germain, M	Transfusion, vol. 43, p. 25	2003	Change from permanent to 1-year deferral
Soldan, K	Vox Sanguinis, vol. 84, p. 265	2003	Change from permanent to 1-year deferral Change from permanent to no deferral
Anderson, SA	Transfusion, vol. 49, p. 1102	2009	Change from permanent to 5-year deferral Change from permanent to 1-year deferral
Davison, KL	Vox Sanguinis, vol. 101, p. 291	2011	Change from permanent to 5-year deferral
Pillonel, J	Vox Sanguinis, vol. 102, p. 13	2012	Change from permanent to no deferral (if only one MSM partner in last 12 months)
Davison, KL	Vox Sanguinis, vol. 105, p. 85	2013	Change from permanent to 1-year deferral
Germain, M	Vox Sanguinis, Epub	2013	Change from permanent to 5-year deferral

# MODEL PREDICTIONS VERSUS REALITY

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

# Why didn't we observe the predicted increase in HIV prevalence?

🔴 Model parameters may have been greatly overestimated:

- Proportion of MSM in the population?
- Proportion of MSM who are abstinent?
- Proportion of newly eligible MSM who would donate (the first year, anyway)?
- Proportion of newly eligible MSM who would be unknowingly infected?





## 2) What about the possible increase in non-compliance?

- Could a less stringent MSM deferral policy lead to a higher rate of non-compliance?
  - Non-compliant, sexually active MSM are at risk for 'incident' (window period) infections;
  - If this were to happen, the risk HIV transmission by transfusion would certainly increase;
- Did compliance decrease?

## 2) What about the possible increase in non-compliance?

MSM behavior...	Pre- five-year deferral policy (n=9669)	Post-five-year deferral policy (n=6881)
	(% donors)	(% donors)
In last 12 months	<b>0,21</b>	<b>0,19</b>
In last 5 years, but not in last 12 months	<b>0,16</b>	<b>0,24</b>
Since 1977, but not in last 5 years	<b>0,29</b>	0,49
Before 1977	0,13	0,17

**Non compliance to MSM deferral criterion:**

**0,66**

**0,43**

\*Kindly provided by Sheila O'Brien, CBS

# 3) What about other emerging pathogens in the MSM population?

- MSM may be at higher risk for other emerging sexually transmitted infections that could be transmitted by transfusion:
  - ‘HIV-like’ pathogens, that would target MSM as a high risk group;
  - This was the rationale for the ‘prolonged temporary deferral’ (5 years) adopted in Canada in 2013
- However...

# What about other emerging pathogens in the MSM population?

- Emerging pathogens in transfusion over the last 20 years:

Infectious agent	Mode of transmission
Variant CJD	Contaminated foodstuff
Dengue	Mosquito bite
Babesiosis	Tick bite
Chikungunya	Mosquito bite
Trypanosoma cruzi	Triatoma bite
West Nile Virus	Mosquito bite
SARS	Respiratory transmission
Ebola	Contact with blood of biological fluids of infected person
Borrelia burgdorferi	Tick bite
Simian Foamy Virus	Monkey bite
Zika virus	Mosquito bite

- MSM behavior is not a (primary) mode of transmission for any of these infections

# PERMANENTLY DEFERRING MSM FROM BLOOD DONATION: A RAPIDLY VANISHING ACT...

- 🔴 Temporary deferrals have shown:
  - *Zero increase in risk;*
  - *No decrease in compliance*
- 🔴 **A permanent deferral policy for MSM has become very difficult to justify empirically;**

# SOME OTHER INTERNATIONAL INITIATIVES OF INTEREST:

- 🔴 The recent UK decision to go from a 12-month to a 3-month deferral;
- 🔴 The French decision in 2016: allowing donations of plasma for transfusion from MSM with only one male partner in the last 4 months (with quarantine scheme);
- 🔴 Surveillance data from countries that currently have less stringent deferral policies for MSM (Spain, Italy);
- 🔴 Modelling initiatives of the ISBT Working Party on Transfusion Transmitted Infectious Diseases (SRAP Subgroup)

# THE RECENT DECISION TO GO FROM A 12-MONTH TO A 3-MONTH DEFERRAL IN THE UK

## ♦ Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) - Donor Selection Criteria Report (2017):

those substances. After considering the available evidence the working group decided to adopt the same level of tolerance of risk as was done in the 2011 review, i.e. the risk that a potentially infectious donation is not detected on routine screening due to a window period infection is less than one in a million donations. Consideration of other risks to recipients

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### 2 Window period for Blood Borne Infections

Discussion with other international blood services has suggested that a deferral period following a behaviour which may put a donor at higher risk of a BBI should be at least a minimum of 2 infectious window periods. The data available for input into the models did not allow differentiation between a 2 or 3 month deferral period. Hepatitis B has an infectious window period of 30 days, however, there is also an initial period after acquisition which may last up to 15 days when the virus may not be detected but where virus levels may be too low to result in transmission. These values are used when estimating the residual risk of a potentially infectious donation being missed on screening. Given these data it would seem appropriate to recommend a deferral of at least 60 days to take into account two times the infectious window period of HBV plus the initial non-infectious period. The working group decided that a window period of 3 months would protect patients and be operationally feasible. Therefore, the options appraisal/modelling was only done for 3 months and not 2



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The results of the modelling can be seen in Table X and Y. It is estimated that the residual window-period risk of a potentially infectious donations not being detected based on these deferral changes would be between 0.18 - 0.66 per million donations for HIV and between 0.04 - 0.10 per million donations for HCV. As even under the worst-case scenario implementing all selection criteria represents less than a 1 in a million risk to patients these changes are considered tolerable from the standpoint agreed by the SaBTO donor selection working group. Similar residual risk modelling was not carried out for tissue or cell donation,

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relationships. We have failed to find a way to practically separate a sub group of MSM who have oral and or anal sex but are at the equivalent BBI risk as heterosexually active blood donors.

The workgroup have discussed this issue at length. and recognise that in reality this cannot be truly individual, as we cannot assess the potential donor's partner but that

# TEMPORARY DEFERRAL FOR MSM: THE FINAL DESTINATION?

- Will there always be a legitimate concern for window-period infections among sexually active MSM?
- If so, what would be the shortest temporary deferral acceptable?
  - Even the shortest deferral periods will still be perceived as unduly discriminatory by some;
- Are there other viable options that could be more inclusive for MSM without impacting blood recipients safety?



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# A Canadian initiative to further study the issue of MSM eligibility for blood donation

- **June 2016:** the Minister of Health announced that Health Canada would provide Canadian Blood Services with a \$3M contribution to implement an MSM Research Program in partnership with Héma-Québec.
- **Objective of the MSM Research Program:** to ensure the generation of adequate evidence-based research for alternative screening approaches for blood or plasma donors, which could evolve the current deferral policy for men who have sex with men (MSM) while maintaining the safety of the blood supply.
- **The first step of this initiative:** a two-day meeting in January 2017 with national and international stakeholders to identify research priorities for closing knowledge gaps that impact donor eligibility for MSM, Canadian Blood Services and Héma-Québec held.
- **Spring 2017:** Request for proposals sent out in the Canadian research community; results announced in **July 2017**

# Identified research priority #1/3:

- Research to inform the development of an **individual risk assessment** donor policy (behavioral based) or to strengthen the existing policy (population based).

Questions to be addressed:

- How to identify a low-risk population of MSM eligible to donate?
- How to formulate an acceptable donor questionnaire that would prevent deferral of low-risk MSM?
- What would be the feasibility of a gender-blind deferral policy?
- Level of donor compliance vis-à-vis donor questionnaire?

# Identified research priority #2/3:

- Research to evaluate **operational feasibility of potential donor deferral policies and their acceptability.**

Questions to be addressed in this area:

- What factors influence the way donors answer screening questions?
- How do we ensure appropriate interpretation of the question and truthful answers?
- How can we improve comprehension of information?
- What is the public acceptance of risk?

# Identified research priority #3/3:

- **Risk modeling and surveillance** to assess the risk associated with alternative donor selection policies. Questions to be addressed in this area may include but are not restricted to:
  - What data are required to improve existing modeling strategies?
  - Are there any other factors that should be considered in the model?
  - How would one test the model?

# Some examples of the projects that were funded

- ◆ **A longitudinal analysis of behavioural and biological risk among men who have sex with men in metro Vancouver (PI: Lachowsky, Nathan)**
- ◆ **Sex Now 2018: A national survey on blood donation and undiagnosed blood borne infections (PI: Lachowsky, Nathan)**
- ◆ **Attitudes, behaviours, and acceptability related to current and future blood donation policy: a qualitative study of gay, bisexual and other men who have sex with men in Vancouver, Toronto, and Montreal (PI: Grace, Daniel)**
- ◆ **Operational impact of individual risk assessment options (PI: O'Brien, Sheila)**
- ◆ **Assessing alternative CBS blood donor deferral screening policies for men who have sex with men (PI: Brennan, David)**
- ◆ **Evaluation of the acceptability and feasibility of a fractionation plasma donation program in the Montreal MSM community. (PI: Otis, Joanne)**





# Some examples of the projects that were funded

- ◆ **ACB and MSM - it's not an oxymoron: a research project that explores the importance of ACB people in MSM blood donation research (PI: Dryden, OmiSoore)**
- ◆ **Assessing unintentional creation of bias against MSM as a function of exposure to blood donor screening questionnaire and assessing sexual behaviour risk factors of those successfully passing blood donor screening (PI: Fisher, William A.)**
- ◆ **Safety, Acceptance, Fairness & Equality(SAFE project): Acceptable risk and donor selection (PI: Ditto, Blaine)**
- ◆ **Mathematical modelling - comparing HIV risk between MSM donation strategies (PI: O'Brien, Sheila)**
- ◆ **Estimating the probability of HIV risk in MSM donor policies through biobehavioural and mathematical modeling studies (PI: Hart, Trevor)**

# CONCLUSIONS

- There is definitely a trend toward less stringent MSM deferral policies;
- A temporary deferral appears to pose zero additional risk to transfusion safety (12-month or even less?) ;
- It remains to be seen whether even more inclusive policies could be adopted without incurring any significant risk to recipients;
  - *Behavioral (non-abstinence) based criteria?*
  - *Stay tuned to hear more about the Canadian initiative!*
- This politically charged issue is likely to remain highly controversial;

# Questions?

# THANK YOU!



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