

THE IMPACT OF MSM POLICY CHANGES AROUND THE WORLD:

What Happened, Why, and What Next?

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BACKGROUND

- 🔥 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 (pending regulatory approval)
Japan	6-month	?

BACKGROUND

- 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 dire predictions 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

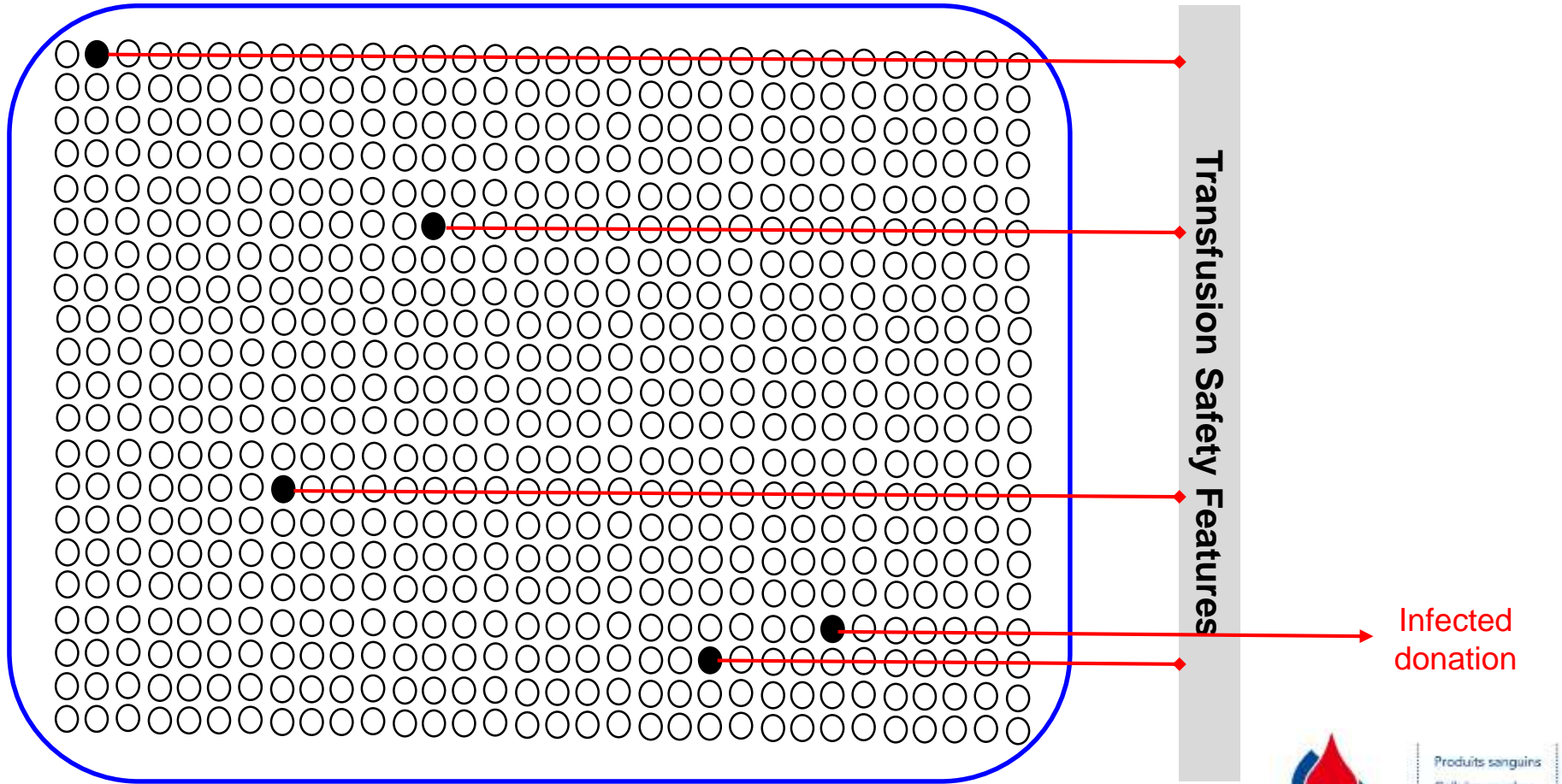
MODELLING THE IMPACT OF MSM DEFERRAL STRATEGIES

- Common features of most models:
 - How many new donors would become eligible and donate under the revised policy?
 - How many of these donors would be infected with HIV?
 - **How many of these infected units would end up being transfused? (because of errors, test failures, etc.)**

MSM RISK MODELS; A SIMPLIFIED VISUAL REPRESENTATION

DONORS (RESTRICTIVE MSM DEFERRAL POLICY)

RECIPIENTS

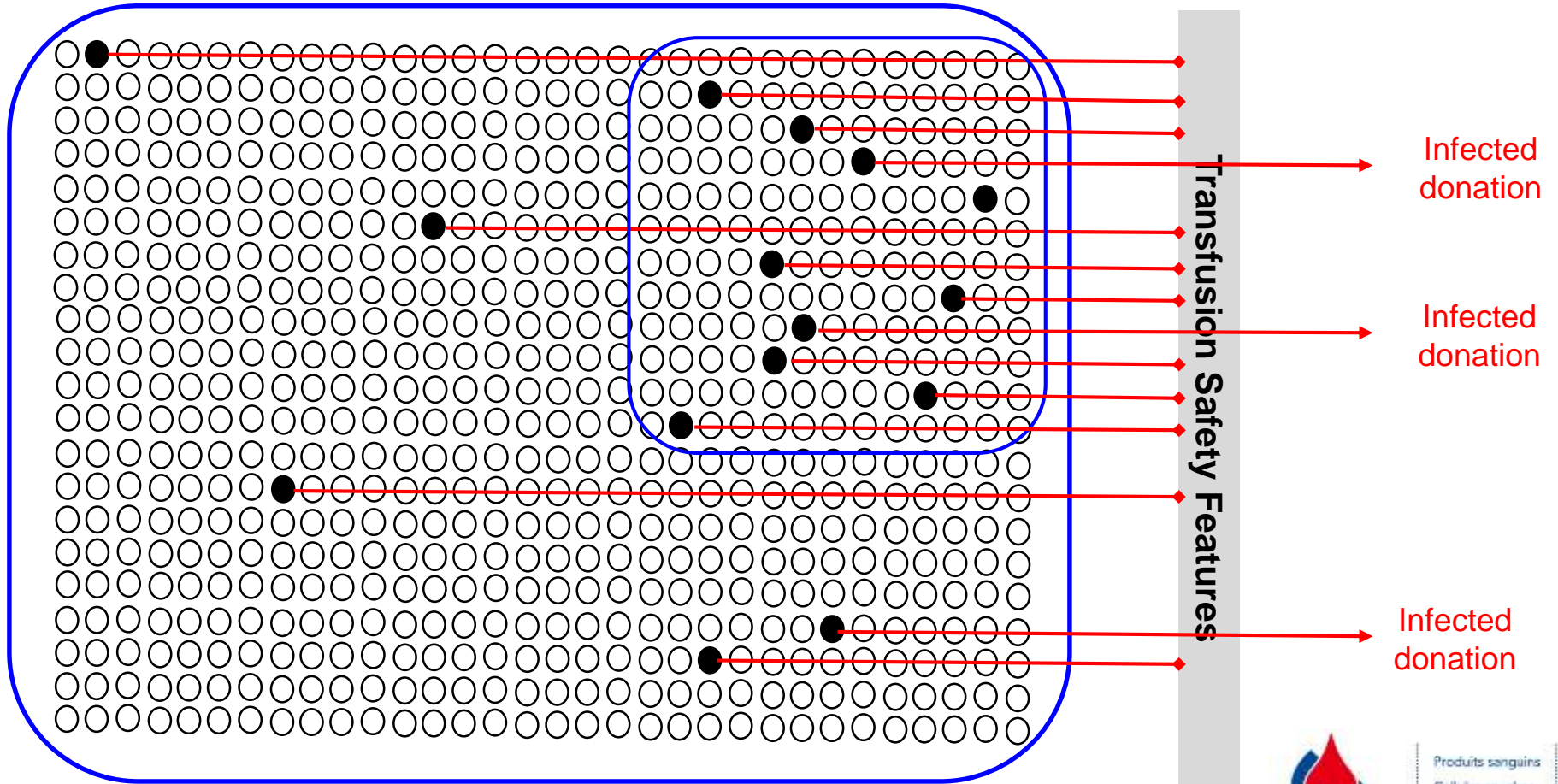


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MSM RISK MODELS; A SIMPLIFIED VISUAL REPRESENTATION

DONORS (LIBERAL MSM DEFERRAL POLICY)

RECIPIENTS



WHAT HAVE THE MODELS PREDICTED?

- Variable but very small additional risk to recipients

- Some examples:

- Germain et al. (Vox sanguinis, 2013)

Impact of a five-year deferral policy in Canada:
One additional HIV contaminated unit every 6,500 years

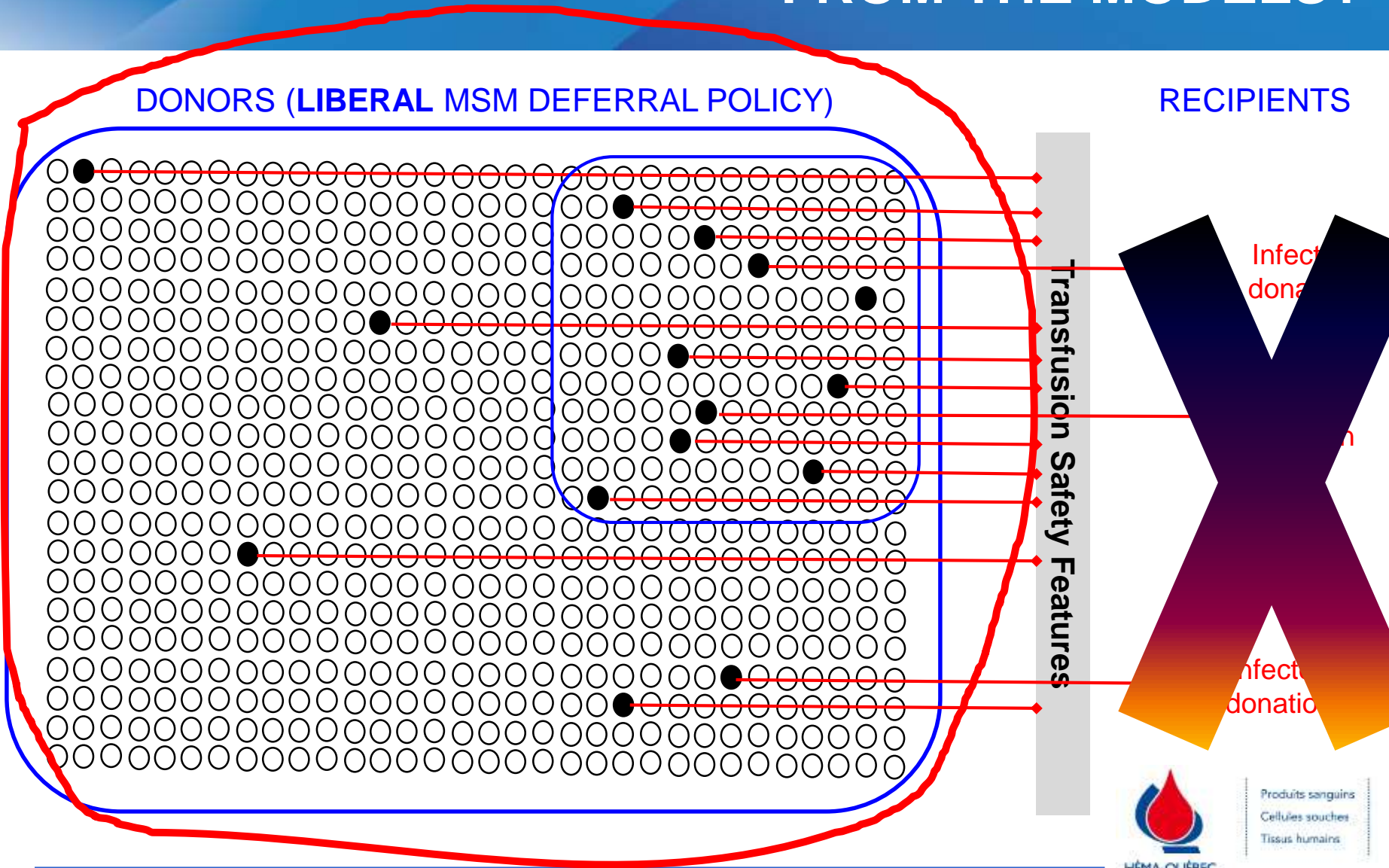
- Anderson et al. (Transfusion, 2009)

Impact of a one-year deferral policy in the U.S.:
One additional HIV contaminated unit every 5 years

CAN WE LOOK AT OTHER PREDICTIONS FROM THE MODELS?

DONORS (LIBERAL MSM DEFERRAL POLICY)

RECIPIENTS



MODEL PREDICTIONS VERSUS REALITY

TABLE 2. Predicted and observed rate of HIV in the male donor population of three countries that changed from a permanent to a temporary deferral

	Countries that changed from a permanent to a temporary deferral			Total (% relative increase)
	UK (England and Wales)	Australia	Canada	
Total adult male population	17,472,092	7,724,348	12,113,000	
Baseline number of HIV-positive male donors; mean of 3 years preceding the policy change	16	3	3	22 (ref.)
Predicted number of HIV-positive male donors in first year after implementation of temporary deferral for MSM*				
Soldan model ⁵	66	25	15	106 (382%)
Germain models ^{4,10}	103	42	18	163 (641%)
Anderson model ⁶	467	202	105	774 (3418%)
Davison models† ^{7,9}	24	7	7	38 (73%)
Observed rate of HIV-positive male donors after the policy change; mean of 2 years after the policy change	10	3	3	16 (-27%)

* The predicted number is the sum of the baseline number plus the additional number of HIV-positive male donors that would result from the revised policy according to the various models.

† In the models by Davison and coworkers, the adult male population considered at risk included only those less than 45 years old, that is, approximately 62% of the total adult male population.

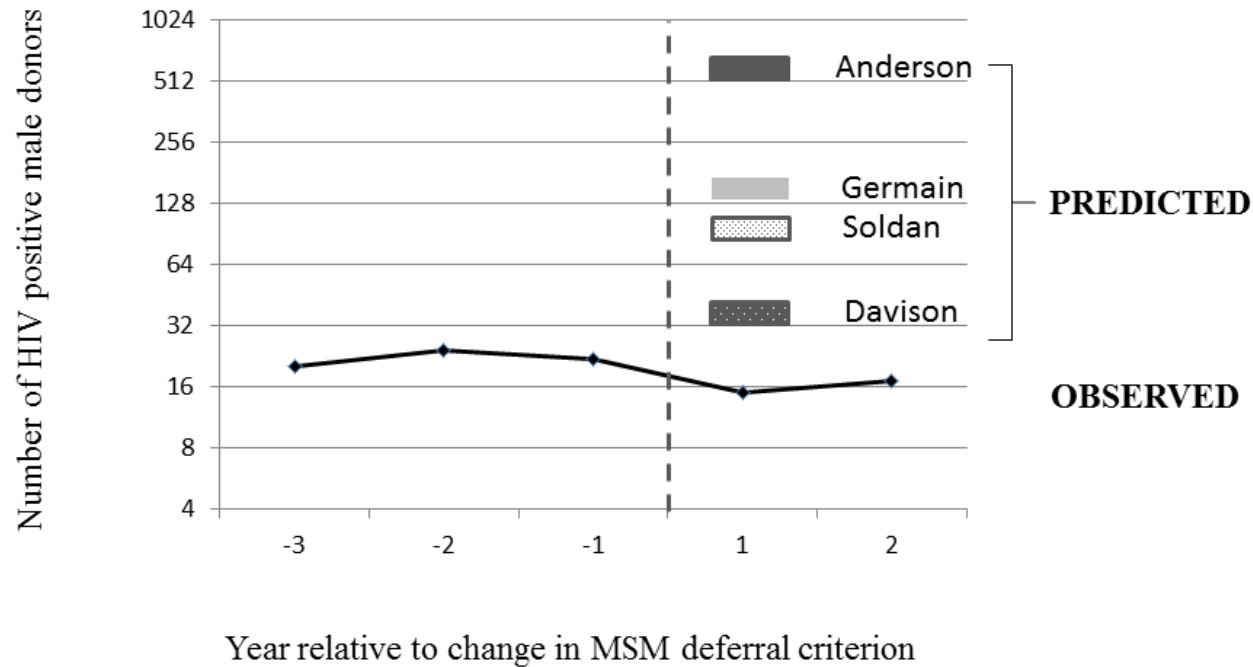


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MODEL PREDICTIONS VERSUS REALITY

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 Mar 7. doi: 10.1111/trf.13541. [Epub ahead of print]

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?

COMPLIANCE SURVEY RESULTS IN CANADA (Canadian Blood Services)*

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

COMPLIANCE SURVEY RESULTS IN CANADA

- Rate of non-compliance is low;
- No evidence that the rate increased following the implementation of a temporary deferral;
- Similar findings reported elsewhere (UK)
- If more non-compliant MSM donors were to donate, and if these donors were at higher risk for HIV, there should be an increase in HIV prevalence;
 - ‘Window period’ cases would be the rare exception: most recent infections would be identified by serology/NAT, yet;
 - No increase in HIV prevalence was observed;
 - Also, no increase in ‘yield cases’ (NAT+/Ab-)

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 or biological fluids of infected person
Borrelia burgdorferi	Tick bite
Simian Foamy Virus	Monkey bite

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

What about other emerging pathogens in the MSM population?

- Let's imagine a new, HIV-like pathogen:
 - Transmissible through transfusion;
 - High risk of transmission through MSM behavior;
 - Lower risk of transmission through heterosexual contact;
- Given that **12-month abstinent MSM who come to donate blood are at no higher risk of HIV**, compared to the general donor population, then:
 - This same group of MSM should also not be at higher risk this other HIV-like pathogen;
- In other words, 12-month abstinent MSM who come to donate blood are at very low risk for any MSM-associated infection;

SUMMARY OF THE EXPERIENCE OF COUNTRIES THAT WENT FROM A PERMANENT TO A TEMPORARY MSM DEFERRAL

- 🔴 Models had predicted a significant increase in HIV prevalence in the donor pool;
 - *There was no such increase and the rate of HIV remained very low and stable;*
- 🔴 No increase in non-compliance was observed;
- 🔴 The increase in the risk to recipients is even lower than expected and is in fact zero;
- 🔴 **Based on these considerations, a permanent deferral policy for MSM has become very difficult to justify.**

IS THIS THE END OF THE ROAD? (IF NOT, WHAT'S NEXT?)

🔴 Shorter temporary deferral periods?

- This option (6-month) was recently considered in Australia but was not adopted;

🔴 Other options?

- The so-called 'behavior-based' deferrals
- For example: allowing donations from MSM in a stable, single relationship



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What are the relevant international initiatives to monitor ?

- **United States:** Implementation of the 12-month deferral (2016?);
- **France:** Implementation of two new policies (2016?):
 - A 12-month MSM deferral for whole blood donation;
 - Allow donations of plasma for transfusion from MSM with only one male partner in the last 4 months (with a plasma quarantine scheme).
- Surveillance data from countries that currently have less stringent deferral policies for MSM:
 - Spain
 - Italy
- Studies among low-risk, sexually active MSM populations?
- New modelling initiative:
 - ISBT Working Party on Transfusion Transmitted Infectious Diseases (SRAP Subgroup);
 - Revised models that will give more weight to compliance

CONCLUSIONS

- There is definitely a trend toward less stringent MSM deferral policies;
- Temporary (12-month) deferrals appear to pose no risk to transfusion safety;
- It remains to be seen whether even less stringent policies could be adopted without incurring any risk to recipients;
- This politically charged issue is likely to remain highly controversial;

Questions?

THANK YOU!



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