VoxSanguinis
The International Journal of Transfusion Medicine
International Society of Blood Transfusion
Vox Sanguinis (2013)

SHORT REPORT

DOI: 10.1111/vox.12109

Allowing blood donation from men who had sex with men more than 5 years ago: a model to evaluate the impact on transfusion safety in Canada

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Vox Sanguinis

Received: 28 July 2013, revised 3 October 2013, accepted 3 October 2013

Canada now allows donations from men who had sex with men (MSM) if their last sexual contact with a man was more than 5 years ago. We modelled the impact of this policy on supply and safety. Approximately 4500 new donors will be added and assuming compliance to the new policy remains unchanged, the worst-case scenario predicts the introduction of one HIV-contaminated unit in the inventory every 1072 years. This change will entail negligible additional HIV risk to recipients. A five-year deferral will also protect recipients against the theoretical concern that MSM may represent a group at higher risk of sexually transmitted, emerging blood borne pathogens.

Key words: blood donation, HIV, men having sex with men, temporary deferral.

Introduction

Until recently, men who had sex with other men (MSM), even once since 1977, were not allowed to give blood in Canada, as is the case in most jurisdictions [1]. The agencies responsible for the blood supply in Canada obtained permission from the regulator to allow donations from MSM if their last sexual contact with a man was more than 5 years prior to their donation. This revised policy is the result of a longstanding debate between those who criticized the status quo as being unjustifiable from a scientific perspective and others who fear that any change might jeopardize the safety of the blood supply. Before implementing this change, the following questions were asked: (1) How many new donors will there be under this revised policy? (2) Will there be an increase in the risk posed by transfusion-transmissible diseases, particularly HIV? The following analysis is an attempt to answer these questions, by using a model that we published several years ago, [2] the parameters having been updated to reflect the proposed policy change and the current status of transfusion safety with regard to HIV. We also explain the rationale for the five-year deferral period.

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Methods

The risk model is based on three main parameters: (1) the additional number of units that will be obtained as a result of allowing donations from five-year abstinent MSM, (2) the prevalence of HIV among these units, (3) the proportion of contaminated units that would inadvertently become available for transfusion. We used Monte Carlo simulation to take into account the uncertainties in the model and to obtain the most likely distribution of the predicted risk estimates. The parameters used in the model, their central value and the range that was used in the Monte Carlo simulation are given in Table 1. There were 10 000 iterations for the simulation, using SAS EG version 4.1. The most likely estimates for the model outputs were taken as the mean of the normalized distribution, and the 95% of confidence limits were calculated.

The number of MSM who would become eligible and decide to donate in a given year (N_{1y}), under a five-year deferral policy, is given by the formula:

Table 1 Parameters in the revised HIV risk model, their estimated values and the source of data for these estimates

Parameter	Central value (range[a])	Source and comments
MSM_{tot}: Number of MSM in the population	4·5%[b] (3%–6%)	Germain *et al.* [2]
P_{elig}: Proportion of MSM who would become eligible as a result of a five-year deferral policy	22·5% (15%–30%)	National AIDS Behavioral Survey (1990–91); the National Health and Social Life Survey (1992); the National Survey of Adolescent Males (1995); and the National Household Survey of Drug Abuse (1996). According to these data, the proportion of MSM who had been abstinent for the previous 5 years was 29%. Also, see Davison *et al.* [6]: 62 300 (15·8%) of 394 200 MSM had been abstinent in the previous 5 years
P_{don}: Proportion of newly eligible MSM donors who would decide to donate	3·7%	Germain *et al.* [2]
P_{hiv}: Proportion of newly eligible MSM donors who would be unknowingly HIV sero-positive	0·334% (0·1%–0·6%)	Davison *et al.* [6]: Among 62 300 5-year abstinent MSM, 208 were HIV positive and undiagnosed
$P_{falseneg}$: Proportion of screening tests that give a false-negative result (analytical sensitivity)	1:500 000 (1:1 000 000–1:200 000)	Germain *et al.* [2] Estimate takes into account the redundancy resulting from dual serology and NAT screening for HIV
P_{window}: Proportion of the donations made in the immunosilent phase of infection	0	Window period for HIV cannot extend to 5 years. (This assumes full compliance of newly eligible MSM to the 5-year deferral policy.)
$P_{variant}$: Proportion of donations contaminated with a variant strain of HIV undetectable by current screening tests	1:1 000 000 (1:10 000 000–1:500 000)	No report of any variant HIV strain escaping detection in the context of blood screening. Current serological screening tests reliably detect HIV group O, the only variant strain ever found in North America
P_{tech}: Proportion of false-negative screening test results due to incorrect use of equipment and/or improper carrying out of qualification tests (clinical sensitivity)	1:100 000 (1:1 000 000–1:35 500)	Héma-Québec and Canadian Blood Services unpublished error and accident tracking data, 2005–2012. From a total of 68 040 000 transmissible disease tests, there were 1914 potentially invalid test results (1:35 500). This is considered as the worst-case scenario for $P_{tech,}$ because: (1) There is near-perfect testing redundancy of serology and NAT; (2) Most errors, while representing a deviation from the optimal situation, would not lead to a false-negative test result; (3) Errors were often recognized soon after their occurrence, such that products were removed from the inventory before they could be transfused
P_{errinv}: Proportion of the units placed in inventory erroneously	1:10 000 000 (1:4 000 000–1:100 000 000)	Zero such occurrences in Canada since 2005
$P_{urgent:}$ Proportion of units that are released to inventory on an emergency basis, before being tested for communicable diseases	1:500 000 (1:250 000–1:1 000 000)	Only one such occurrence in recent years in Canada

[a]A triangular distribution of the various parameters is assumed. Ranges were based on extremes of published data, if available, or alternately on best guesses by the authors.
[b]This percentage is applied to the number of men 18 years of age and older in Canada ($n \approx 12\ 113\ 000$).

$$N_{1y} = \mathrm{MSM}_{\mathrm{tot}} \times P_{\mathrm{elig}} \times P_{\mathrm{don}}$$

The number of HIV-contaminated units that would be transfused in a given year (U_{1y}) is obtained as follows:

$$U_{1y} = N_{1y} \times P_{\mathrm{hiv}} \times (P_{\mathrm{falseneg}} + P_{\mathrm{variant}} + P_{\mathrm{window}} + P_{\mathrm{tech}} + P_{\mathrm{errinv}} + P_{\mathrm{urgent}}).$$

We conducted a sensitivity analysis of the effect of P_{tech}, the parameter which has the largest value and therefore the strongest influence on the model results.

Results

Table 2 shows the results of the simulation, where the risk is expressed as how frequently a contaminated unit would inadvertently enter the blood supply in Canada, as a result of the implementation of a five-year deferral for MSM. This might happen as rarely as once every 27 455 years in the scenario with P_{tech} fixed at its lowest value, and as infrequently as once every 1072 years with P_{tech} fixed at the higher end. The model also predicts that there would be approximately 4500 new donors contributing to the blood supply in Canada.

Discussion

The most striking feature of this modelling exercise is that the HIV transmission risk of changing from a lifetime to a five-year deferral of MSM is very close to zero additional risk. This finding is supported by the experience reported by other countries that have adopted even shorter temporary deferral periods [3]. Our model also shows that the gain in newly eligible donors is relatively small, a finding that is not surprising given the small number of MSM who will remain abstinent for more than 5 years. This revised model predicts a lower risk compared to our previous model looking at a one-year temporary deferral [2]. This is because of a downward revision of the estimates for several parameters included in the model, including the proportion of MSM who were abstinent in the previous 5 years (P_{elig}) and, among them, those who would be unknowingly sero-positive (P_{hiv}). We also assume that after 5 years of abstinence, there is no risk of transmission due to the window period. Finally, one critical parameter that was significantly revised is the rate of false-negative results due to incorrect use of equipment and/or improper carrying out of qualification tests for the communicable disease markers (P_{tech}). This parameter depends on the robustness of the blood establishments' quality systems, which have improved over time. Our previous model had relied on data that reflected the situation in U.S. transfusion centres over 15 years ago, whereas the revised estimate is derived from currently observed rates of test errors in Canada obtained from internal error and accident tracking data of the two blood agencies. The projected risk is also lower compared with similar models published by other investigators [4–6]. These discrepancies can be explained mainly by the different assumptions concerning certain key model parameters, primarily about quality system error rates and prevalence of HIV among abstinent MSM. Some parameters in our model, for example, the proportion of 5-year abstinent MSM, are based on relatively old, non-Canadian data, which is one limitation of this study. However, the parameter that has the most significant impact on the model's output, namely P_{tech}, reflects the current Canadian situation. Finally, the model assumes that the compliance of MSM to the revised policy would be no different compared with the lifetime deferral; there is no Canadian data to suggest that it might be otherwise.

Table 2 The HIV risk of allowing donation from five-year abstinent men who had sex with men (MSM) - Results of Monte Carlo simulation (data applicable in Canada)

	***n* (95% interval)**		
	Baseline Scenario	**P_{tech} set at 1:35 500**	**P_{tech} set at 1:1 000 000**
Number of MSM in population ($\mathrm{MSM}_{\mathrm{tot}}$)	545 095 (404 342–685 410)	–	–
Number of newly eligible MSM under 5-year policy[a]	122 431 (80 630–171 872)	–	–
Number of newly eligible MSM who would donate blood in 1 year (N_{1y})[a]	4530 (2983–6359)	–	–
Number of additional HIV-contaminated units that would be made available for transfusion (1 unit every X years)[a]	1:6476 (1:2005–1:16 545)	1:2223 (1:1072–1:4793)	1:12 450 (1:5372–1:27 455)

[a]Results applicable to first year following the implementation of the five-year abstinence MSM deferral policy.

Indeed, investigators from a UK study predicted improved compliance under a one-year deferral [7] with modelled estimates for HIV risk declining in this scenario [8]. It is less clear whether this would also be true with a five-year deferral policy.

The obvious remaining question is: Why a temporary deferral of 5 years and not a shorter one that would still completely protect against HIV window period infections? It is because of the theoretical concern that MSM may represent a group at higher risk of future, unknown emerging blood borne pathogens. This is a highly debatable concept, especially when considering that the transfusion-transmissible agents that have emerged over the last two decades are in no way connected to the MSM behaviour [9]. However, MSM are more likely to acquire sexually transmissible diseases, for example HIV, syphilis and gonorrhoea [10, 11]. In the event of an emerging, sexually acquired, blood transmissible pathogen, MSM might also become a higher risk group for this new infection. It was estimated that a five-year temporary deferral would be enough to recognize the threat and pre-empt any impact on transfusion safety, assuming that the threat will be seen as severe enough to trigger action within this time frame. Indeed, there were instances of emerging, transfusion-transmitted infections, such as Chagas and babesiosis, for which mitigation strategies, while being technically feasible, took longer to implement. Careful monitoring of the effect of the MSM five-year deferral policy will hopefully set the stage for further incremental changes.

Conflicts of interest

The authors declare that they have no conflict of interest.

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