

Current Research and Policy
Recommendations for Men Who Have Sex
with Men (MSM) Blood Donor Deferrals

Report: Updated 28 January 2023

Table of Contents



Overview	p. 3
Recommendations	p. 3
Glossary	p. 4
What the Medical and Scientific Communities are Saying	p. 5
The UK Model – Individual Risk Assessment for Blood Donation	p. 8
Research Findings in Brief	p. 9
Empirical Evidence	p. 12
References	p. 20

Overview

This report presents a review of the latest research into the blood donor screening policies that require men who have sex with men (MSM) to abstain for a certain period of time before they can donate.

Taken together, data from current studies support the argument that abstinence-based deferrals are no longer necessary to protect the safety of the blood supply.

The findings show that a policy of assessing every individual donor for the safety of their sexual activity, regardless of their gender or the gender of their sexual partner, would not compromise blood safety, would potentially increase the blood supply and would be a major step in removing discrimination from blood donation.

Based on current research, one of the most equitable individual screening policies, without compromising safety, is the one recently adopted in the United Kingdom (see page 8).

The automatic deferral period for MSM has been recently removed in other countries, such as in the Netherlands, Canada, France, Israel and Greece, or is soon to be removed, such as in Germany (at the next review of blood donation rules). Additionally, the US Food and Drug Administration (FDA) has presented its proposed guidelines to remove the automatic deferral period for MSM in favour of using individual risk-based screening questions. Similar to the UK and Canada, the guidelines propose asking all prospective partners if they have had anal sex with a new or multiple partners within the last three months.

The empirical research on this topic and the history of policies in Australia and overseas are discussed further on in this report.

Recommendations

We recommend the Australian Lifeblood Service adopt the UK model.

Should this not be possible without an Australian review,

We recommend the Australian Lifeblood Service conduct its own review of the medical literature about MSM blood donor deferrals, and if necessary, its own clinical trial with a view to reform.



Glossary

MSM: men who have sex with men (mainly, but not exclusively, gay and bisexual men). In Australia a trans woman in a relationship with a man is also considered part of this group and subject to the same blood donation deferral.

Deferral: refusal by a blood service to accept blood from a potential donor because of the donor's perceived risk of having a blood-borne disease, such as HIV. This can be *temporary* (e.g. 3 months) or *permanent*.

Time-based deferral: refusal to accept blood from a donor for a stipulated period after what is deemed to be a risk activity. For example, men cannot donate for three months after their last sexual contact with another man.

Abstinence-based deferral: synonymous with time-based deferral for men who have sex with men, that is, donation is conditional on abstinence from such sex.

Population-based risk: where risk is calculated based on the proportion of individuals within the general population that are considered to have a particular disease or disorder.

Individual risk assessment: where every potential donor, regardless of the gender of their sexual partner, is assessed for their risk.

Risk-group assessment: where risk is assessed based on a category to which a person belongs (e.g., MSM).

Risk-based screening: where assessment of risk is based on the activity that creates risk, not a surrogate for that activity. For example, screening out all donors who have anal sex with more than one partner rather than all gay and bisexual men.

Gender-neutral screening: a donor screening policy that does not consider the gender of the donor or their sexual partner, only their sexual activity. Similar to *risk-based screening* and *individual risk assessment*.

Donor life cycle: an individual's history of blood donation.



What the Medical and Scientific Communities are Saying

In the early to mid 1980s little was known about how HIV was acquired, detected or transmitted. Public fear, lack of knowledge, and inferior blood screening methods resulted in all men who had sex with men (MSM) being given a lifetime ban from donating blood, irrespective of their sexual activity. Between 1996 and 2000, Australia took the lead and became the first nation to remove a lifetime ban (or 5-year ban depending on the jurisdiction) on blood donation for MSM, in favour of a 12-month (abstinence from sex) deferral period. This Australian initiative was later followed by the United Kingdom, Canada, France, the United States and others. Between 2018 and 2020, deferral periods were reduced further (to 4 or 3 months), including in Australia, as a means of ensuring a stable blood supply in times of need. However, recent data emerging from various nations suggests that a blanket deferral policy for MSM, regardless of duration, is not only exclusionary but also unnecessary.

A number of established researchers on this topic have highlighted the inappropriateness of using the estimated prevalence of HIV among MSM in the general population to justify deferral periods (Germain et al., 2020; O'Brien et al., 2020; Park et al., 2020, Pillonel et al., 2020), with data showing a much lower rate of infection among MSM who donate blood. For example, according to the United States Food and Drug Administration's (FDA) revised recommendations for reducing the risk of HIV infection by blood and blood products, the risk for MSM blood donors is only a quarter of 1% (0.25%).

"...the prevalence of HIV infection in male blood donors who reported that they were MSM was determined to be 0.25%, which is much lower than the estimated 11-12% HIV prevalence in those reporting regular MSM behaviour." (FDA, April 2020)

Further, although shortening the deferral period for MSM was considered to be a risk prior to each policy change, Marc Germain, the Vice-President for Medical Affairs and Innovation, Heba-Quebec, Canada, noted:

"...there is not a single documented case of HIV contamination that can be attributed to the implementation of a temporary deferral policy for MSM." (Germain, 2020, p.437)

Now that several countries have shortened or removed the deferral period for MSM, the emergence of new data shows that removing the deferral period for MSM entirely poses no meaningful risk of HIV infection to blood recipients.

Based on the current research, the United Kingdom has removed the deferral policy for MSM in favour of an individual risk assessment, in which all potential

donors are asked the same sexual behaviour questions. This change came into effect on the 14 June 2021. NHS Blood and Transplant state on their website:

"Following the FAIR (For the Assessment of Individualised Risk) steering group's recommendations and in line with the latest scientific evidence, blood donation has become more inclusive".

"Patient safety is the heart of everything we do. Switching to an individualised check is a fairer and as safe a way to spot infection".

(NHS Blood and Transplant, News: 11 May 2021)

The Netherlands also removed the blanket deferral for MSM on 1 September 2021. Blood Bank Sanquin in the Netherlands state:

"Based on the report of Marcel Verweij and Roland Pierik, and the advice of the medical advisory council of Sanquin, we have concluded that there are no problems with the transfusion safety to be expected if the current blood donor selection policy for homosexual men turns into a more individually focused assessment of risk behaviour." (Wagenigen University & Research, News: 21 March, 2021).

The Health Minister for Israel, Nitzan Horowitz, announced on the 19 August 2021, that all restrictions for MSM blood donors in Israel will be lifted as of 1 October 2021. He clarified that instead of asking donors about same-sex physical relations, all blood donors will be told they need to wait three months "after high-risk sex with a new partner or multiple partners". Horowitz tweeted:

"The discrimination against gay men donating blood is over." He also wrote: "There is no difference between blood and blood. This is a historical step forward for equal rights for the LGBT community in Israel." (Spiro, The Times of Israel, 19 August, 2021).

France lifted the blood donation deferral period for MSM on the 16 March 2022 (Brent, *The Connexion*, 15 March, 2022). The Health Minister for France, Olivier Veran previously tweeted:

"We are putting an end to an inequality that was no longer justified" (AFP, Euronews, 12 January, 2022).

Greece has also changed its policy. The Health Minister for Greece, Thanos Plevris, and deputy Mina Gaga signed a ministerial decree on the 10 January 2022, to remove the blood donor restrictions for MSM. The criteria inhibiting someone from donation will no longer include sexual orientation. The policy

change will come into effect as soon as the change is published in the Government Gazette, Greece's text of laws and decrees. (Kokkindis, *Greek Reporter*, 11 January, 2022).

Canadian Blood Services announced on the 15 December 2021 that it officially asked Health Canada to remove the specific restrictions on blood donations from MSM. The organisation wrote:

"Canadian Blood Services' goal is to stop asking men if they've had sex with another man and instead focus on high-risk sexual behaviour among all donors." (Young, Global News: Health, 15 December, 2021)

The new policy, approved by Health Canada, was implemented in September 2022 (Canadian Blood Services, 2022). The new policy is similar to that implemented in the UK (see page 8). All donors are now asked about "higher-risk" sexual behaviour rather than their sexual orientation or the gender of their sexual partners.

The US has also looked closely at the emerging evidence with the view of using individual risk-based criteria, as opposed to "risk-group" (e.g., MSM). On the 27 January 2023, the US Food and Drug Administration (FDA) released their proposed guidelines, which proposes asking all prospective donors if they have had anal sex with new or multiple partners in the past three months (similar to the UK model, see page 8). The FDA Commissioner Dr. Robert Califf stated:

"Based on the available data, the agency believes the implementation of the proposed individual risk-based questions will not compromise the safety or the availability of the US blood supply. Our approach to this work has always been, and will continue to be, based on the best available science."

(Hassan, CNN: Health, 27 January, 2023)

The new individual assessment criteria implemented in the UK and examples of current peer-reviewed research on blood donation deferral periods for MSM are summarised and discussed in the following sections of the report.

The UK Model - Individual Risk Assessment for Blood Donation

On the 14th June, 2021, the UK moved from an automatic 3-month deferral policy for MSM to assessing a blood donor’s eligibility based on their individual experiences, and not the sex of their sexual partner. This approach, presented by the FAIR (For the Assessment of Individual Risk) steering group (FAIR, 2020), was agreed to by SaBTO, the Advisory Committee on the Safety of Blood, Tissues and Organs (see JPAC, 2021).

All donors will be asked if they have had more than one sexual partner or a new sexual partner within the last 3 months. If the answer is “Yes” then they will be asked if any of this involved anal sex. If the answer is “No”, they can donate. If the answer is “Yes”, they will be deferred. This means all individuals are eligible to donate unless they have had anal sex with someone other than one regular partner of at least 3 months duration (see Figure 1 below).

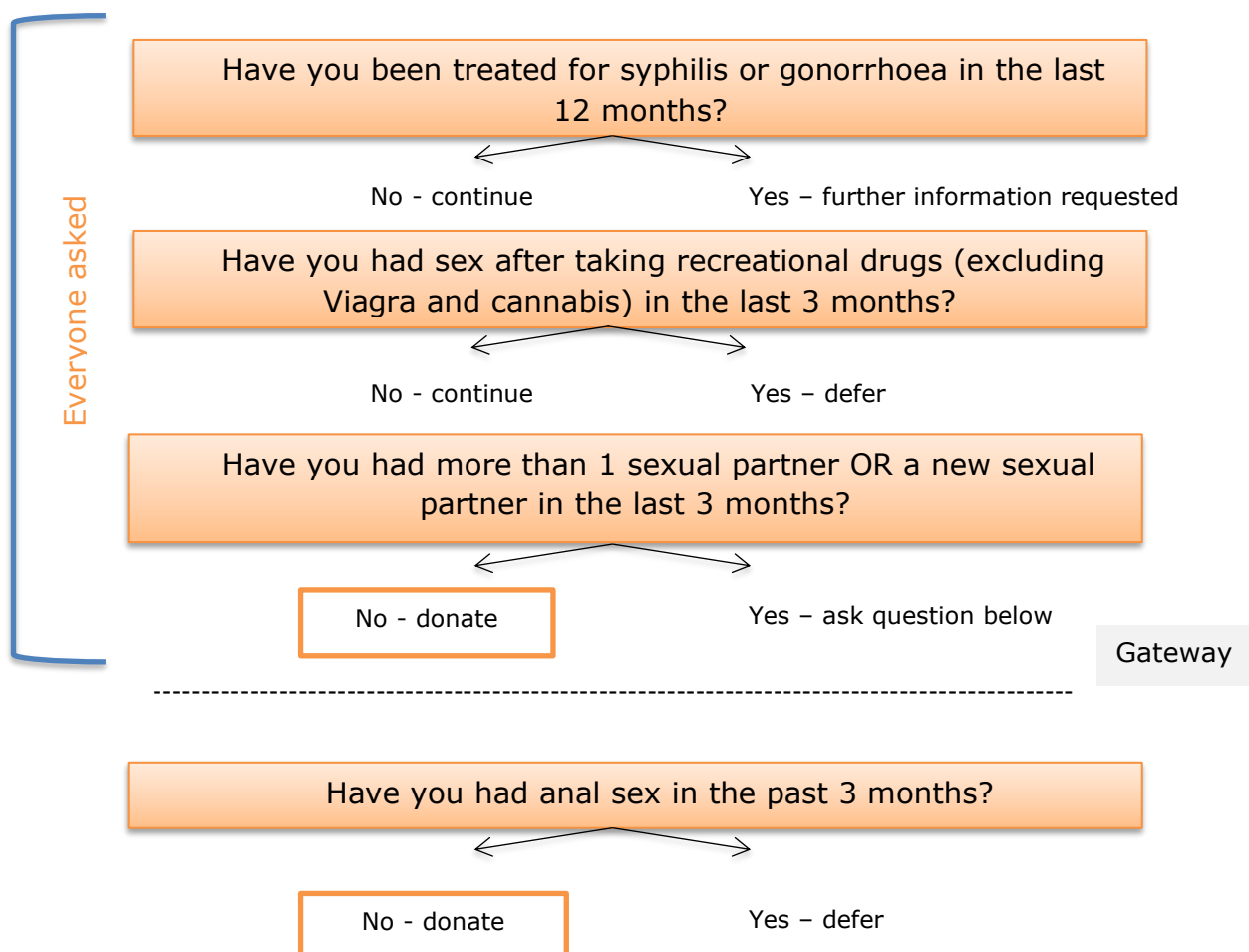


Figure 1. Algorithm for FAIR questions - accepted option A, (FAIR, 2020, Fig 7.1, p. 114)

The individual assessment criteria implemented in the UK means donors will no longer be asked if they have had sex with another man, thus removing the aspect of assessment that was based on previous population-based risk. While the UK is not the first jurisdiction to introduce a gender-neutral risk-based assessment, it is the first among developed English speaking nations, with the aim of making blood donation a fairer and more equitable experience for everyone, while maintaining its safety.

Importantly, this change doesn't just remove the automatic deferral period for MSM individuals. It also means that transgender, gender diverse and non-binary individuals will be assessed in the same way as all other donors. However, all UK donors are currently asked their sex assigned at birth before donating, as certain blood products are safe to manufacture from donors assigned male at birth but not female at birth. Acknowledging that this frequent questioning may not be appropriate for transgender, gender diverse and non-binary individuals, by September 2021, the UK's NHS plans to ask all donors their assigned sex at birth only once upon registering as a blood donor, rather than at each donation session (NHS Blood and Transplant, News: 11 May 2021).

The remainder of this document summarises some of the more recent empirical evidence on this topic that has contributed to this long awaited change.

Research Findings in Brief (for further detail, see pp. 12 – 19)

The following is a brief summary of some of the research findings discussed within this report. For additional studies and further details (e.g. samples, method and more detailed results) refer to the "Empirical evidence" section on page 12.

Caffrey et al. (2022)

Approved by the Canadian Blood Services Ethics Board, this study examines the potential loss in current donors if they were to be presented with the UK's FAIR screening questions. Based on samples from all whole-blood collection sites in Canada, they found that only a small and manageable 1% of current donors would potentially be lost (for example, deferred as a result of having anal sex with someone other than one regular partner of at least 3 months duration). The researchers note that this potential loss in current donors may be largely absorbed by donations from newly eligible gay and bisexual men who have sex with men.

Based on this and other research, Canada removed its deferral period for MSM in favour of a more inclusive gender-neutral individual risk criteria. The new policy went into effect in September 2022.

Pillonel et al. (2020)

This study conducted in France compared a 4-month abstinence period before men who have sex with men (MSM) could donate blood to a 4-month deferral only when these men had more than one sexual partner (the same as the policy for other donors).

The difference between the two groups, in terms of risk of HIV infecting the blood supply, was found to be statistically indistinguishable, supporting the argument of assessing MSM donors in the same way as other donors.

France lifted the blood donation deferral period for MSM on the 16 March 2022.

van Bilsen et al. (2020)

This study from the Netherlands compared the rates of blood borne diseases among monogamous MSM blood donors with those from male donors who were not MSM.

Results showed that none of the monogamous MSM had acquired any of the Class A infections (e.g., HIV, Hepatitis B and C, syphilis) in the preceding 12-months and that evidence of infection of blood borne diseases was overall comparable to male donors who were not MSM.

Following these findings, and a report commissioned by Netherland's Blood Bank Sanquin, the Dutch Government accepted the proposal for the individual assessment of MSM blood donors, with the change having taken effect on 1 September 2021.

Blanco et al. (2020)

This study showed that there was no significant difference in HIV infection risk between Argentina's former abstinence deferral period for MSM and its current "gender-neutral" individual-risk blood donation policy.

The authors conclude that the scientific evidence provided in their study, along with increasing evidence from other countries, support a paradigm shift from "risk group" (e.g., MSM) to gender-neutral "risk practice".

Clement et al. (2021)

This study, involving whole blood donors in Austria, showed that temporary deferrals (like those often used for MSM) can significantly reduce the likelihood of future donations, with the negative effect amplifying over time.

So while the current shortened deferral period of 3 months in Australia may encourage more MSM to donate (albeit a restricted number due to the need to abstain from sex for 3 months), somewhat ironically these donors may be discouraged from donating for the longer term due to the greater potential to experience more frequent temporary deferrals. This would undermine Australia's current efforts to increase the nation's blood supply during times of need, such as during the COVID-19 pandemic.

Clackett et al. (2020)

The data from this Australian study showed that a large percentage of MSM in the sample wished to donate blood, but would not do so if it required a period of abstinence. Over 80% of those willing to donate found the current ban on sexually active MSM from donating blood to be unfair.

These findings suggest that the current deferral policy in Australia for MSM effectively inhibits low-risk MSM from donating blood, due to the fact they would have to abstain from sex for 3 months even with a long-term partner.

Miyashita & Gates (2014)

Based on data from three waves of a nationally representative General Social Survey (GSS) of adults in the US, 3.8% of men reported having sex with a man within the last 12 months.

The study showed that if the deferral period for MSM was removed completely the number of MSM who would likely donate would double. The authors note that based on their estimates the removal of the deferral period for MSM could help save the lives of over a million American people.

Empirical Evidence

Investigating the potential loss of donors when using individual risk assessment screening questions

Caffrey et al. (2022). Behaviour based screening questions and potential donation loss using the “for the assessment of individual risk” screening criteria: A Canadian perspective. *Transfusion Medicine*, Advance online publication. <https://doi.org/10.1111/tme.12888>

One concern about incorporating individual risk assessment is the potential loss of existing donors. For example, asking everyone about anal sex when having multiple sexual partners or a recent sexual partner may disqualify some people who engage in heterosexual sex who, as a group, are considered to be at lower risk of HIV infection in Australia, relative to MSM. This Canadian study examined the likely loss of such donors when applying the UK’s FAIR screening questions.

- Data was collected over three consecutive weeks at all whole blood collection sites in Canada.
- The study applied the UK’s FAIR screening questions, which include those on engaging in anal sex when having multiple partners or a new partner of less than 3 months duration.
- **RESULTS:** Applying the FAIR screening questions, 269 donors out of 27,929 would be deferred. This equates to a donation loss of approximately 1%. Donation loss was higher among younger people (approximately 2% among those aged 17-25) and among first time donors (1.5%) relative to regular donors (0.8%). When considering donation loss based on only the anal sex questions, the deferral rate reduced to 0.7%.
- The authors concluded that the small and manageable loss of donors when applying individual risk assessment screening questions, like the UK’s FAIR criteria, would be largely absorbed by the donations of newly eligible gay and bisexual men who have sex with men. They also note that any small decrease in donations would be outweighed by the positive social impact of a gender-neutral individual risk assessment criteria.

The results of this study were made available to the Canadian Blood Service prior to its recent publication in *Transfusion Medicine*. Since the availability of this data and those from other recent studies, Canada has moved away from its deferral policy for MSM, in favour of a gender-neutral individual risk assessment.

Comparing data for a time-based deferral to a risk-based approach

Pillonel et al. (2020). The evolving blood donor deferral policy for men who have sex with men. Impact on the risk of HIV transmission by transfusion in France. *Transfusion*, 60 (3), 525-534.

- Baseline HIV residual risk was calculated for the period July 2016 to December 2017, with the Incidence Rate – Window period method.
- The risk assessment was conducted with two scenarios (S1, S2). S1- a 4-month deferral, and S2 – a 4-month deferral only in the case of more than one sexual partner (i.e., as was the case for other donors).
- The impact of residual risk was assessed from the surveys on MSM (Prevegay2015 cohort study) and blood donors to estimate a) the increase in MSM donors for each scenario and b) the HIV incidence among these donors.
- **RESULTS:** Adjusting the data, based on the incidence of HIV in the overall MSM population in France, the model estimated the residual risk of HIV transmission by transfusion under S1 (4-month deferral for MSM) was 1 in 6,380,000 donations. In other words, one HIV contaminated donor enters the blood supply every 2 years. For S2 (no deferral for MSM in single-partner relationships in last 4 months), the model estimated the residual risk to be 1 in 4,300,000 donations, which equates to one HIV contaminated donor entering the blood supply in every 1.5 years. In both cases the risk was extremely low.
- Importantly, the difference between S1 and S2 was statistically indistinguishable.

The results of the above study by Pillonel et al. (2020) are discussed below by Professor Marc Germain (Medical Affairs and Innovation, Quebec, Canada), as author of the editorial in the same issue of the *Transfusion* journal.

Germain (2020). Men having sex with men and blood donation. Is there a game changer on the horizon? *Transfusion*, 60 (3), 437-440.

- Germain states “The question is therefore whether the risk posed by allowing MSM in a single relationship would be high enough to pose a significant risk to recipients. The Pillonel model suggests that it would not” (p.438).
- In relation to MSM, he states “...only a small fraction of those who are infected would run the risk of donating during the very short window period; the vast majority would be picked up by serology and/or NAT” (p.438).

- Germain notes that while the Pillonel study may not be a game changer on its own, when considered with other initiatives “it certainly makes accepting sexually active but low-risk MSM much more plausible than previously envisioned” (p. 439).

Switching from time-based deferral to individual risk-based screening

The following study conducted in the Netherlands examined the difference between infection pressure (number of antibody infections) and antibody prevalence in class A (e.g., HIV) and class B (e.g., human herpes virus 8) infections, among MSM and repeat male donors not classified as MSM. The results from this study were part of a proposal submitted to the Blood Bank Sanquin Medical Advisory Board for the removal of the MSM deferral period (which came into effect on 1 September, 2021).

van Bilsen et al. (2019). Infection pressure in MSM and their suitability to donate blood. *Clinical Infectious Diseases*, 68(6), 1001-1008.

- This study compared the antibody prevalence of 10 sexually and transfusion-transmissible infections in the Netherlands among 583 MSM and 583 age-matched repeat male donors, who were not classified as MSM.
- The study used the data from the Amsterdam Cohort Studies (ACS) among MSM, which since 1984 investigates the prevalence, incidence and risk factor of HIV and other sexually transmitted infections. Participants visit the Public Health Service of Amsterdam each 6 months. There they give blood for testing and storage, and complete a questionnaire on their sexual behaviour in the last 6 months and their willingness to donate blood.
- MSM and male repeat donors were screened for antibodies against 5 class A (e.g., HIV, Hepatitis B and C viruses) and 5 class B (e.g., human herpes virus 8, hepatitis E virus, parvovirus B19) infections.
- The infection pressure (IP) was defined as the number of antibody infections with those from Class A (e.g., HIV) given double weight. If antibodies from any Class A infections were detected the IP was classified as high.
- Based on ACS self-report sexual behaviour data covering the preceding 12 months (in line with the then deferral period) MSM were classified as low risk (lr-MSM) or medium-to-high risk (hr-MSM).
- **RESULTS:** Infection pressure (number of antibody infections) was found to significantly correlate with data from the self-report sexual behaviour questionnaire.
- Importantly, data showed that none of the qualified low risk MSM (e.g., men in a monogamous relationship) had acquired any of the Class A infections (HIV, HBV, HCV, HTLV or syphilis) in the previous 12 months and, overall, the antibody prevalence was comparable to both new and repeat male donors not classified as MSM.

The study above highlights the potential for individual risk-based screening to identify low risk MSM for blood donation. It is important to note that at the time of collecting data for this study the Netherlands had a 12-month deferral period for MSM blood donors. In December 2019, after the publication of this study, the Dutch Parliament adopted a motion requesting its blood service re-examine the deferral policy for MSM. In March 2021, at which point the Netherlands had implemented a 4-month deferral policy for MSM, the proposal for individual assessment for MSM donors was accepted. It went into effect on 1 September 2021.

Report commissioned by Netherland's Blood Bank Sanquin

In addition to the submission of empirical data supporting the removal of the blanket deferral period for MSM, researchers Roland Pierik (University of Amsterdam) and Marcel Verweij (Wageningen University) were commissioned by Netherland's Blood Bank Sanquin to write a report weighing up the continued discriminatory behaviour of deferral periods for MSM with the risk of infection to the blood supply. The report (Pierik & Vereij, 2020) examines the dilemma of clashing interests and the legal, ethical and health risks of four different scenarios. Sanquin state that "Based on the report of Marcel Verweij and Roland Pierik, and the advice of the medical advisory council of Sanquin, we have concluded that there are no problems with the transfusion safety to be expected if the current blood donor selection policy for homosexual men turns into a more individually focused assessment of risk behaviour" (Wagenigen University & Research, News: 21 March, 2021).

Park et al. (2020). Blood donation and COVID-19: Reconsidering the 3-month deferral policy for gay, bisexual, transgender, and other men who have sex with men. *American Journal of Public Health: Research and Analysis*, 111(2), 247- 252.

Park et al. (2020) like others (e.g., Germain, 2020; O'Brien et al., 2020, Pillonel et al., 2020) highlight the inappropriateness of using the prevalence of HIV among MSM within the general population to justify deferral periods. New evidence emerging from data based on MSM who donate blood shows the prevalence among this subgroup to be very much lower, with evidence from the United States (FDA, 2020) showing it to be only a quarter of 1% (0.25) in that country. In the article summarised below, Park et al. (2020) argue that individual-risk screening questions for all potential donors may actually reduce non-compliance and be more effective at identifying higher-risk MSM donors.

- In this article Park et al. review historical HIV testing and transmission evidence, and the recent research findings on, and ethical ramifications of, donor deferral periods for MSM. They propose an eligibility screening

protocol that involves individual risk-based screening, which does not effectively exclude donors based on gender identity or sexual orientation.

- They note recent empirical and modelling studies in a number of countries have repeatedly revealed that reducing deferral periods does not meaningfully increase HIV transmission rates (e.g., Goldman et al., 2018; O'Brien et al., 2020; Pillonel et al., 2020).
- Further, research from countries switching from a "deferral-period" approach to a "risk-based" approach (assessing behaviour rather than sex of sexual partner) has found little evidence to support the ongoing use of time-based deferrals.
- For example, Argentina in 2015 implemented a risk-based approach that was "gender neutral". A large cohort study by Blanco et al. (2020) found that despite this change there was no significant difference in the prevalence of HIV among the blood donor population, even though the total number of donors had increased (for more detail, see the summary of this article further below).
- Park et al. (2020) note that current pre-screening questions may contribute to non-compliance due to stigma, confusion and misinformation. They propose that instead of deferral periods, a jargon-free, "risk-based" screening instrument be implemented for all donors. This screening protocol is discussed within their review (see journal details provided above).

Blanco et al. (2020). Gender-neutral donor deferral policies: Experience in Argentina implementing individual risk-assessment policies. *Vox Sanguinis*, 115 (7), 548-554.

In September 2015, the Ministry for Health in Argentina stipulated that blood donation eligibility should be based on "risk-practices", rather than "risk-group", focusing on a "gender-neutral" policy.

- The study by Blanco et al. (2020) examines the prevalence of sexually transmitted infections (STI) in a population of blood donors, pre- and post the change in law. Analysis involved data from donors from a large central region over a 6-year period – 3 years prior to the policy being enforced by law (16 September, 2012 - 15 September 2015) and 3 years after it was enforced by law (16 September 2015 – 15 September 2018).
- A total of 174,074 individuals were enrolled in the study (period 1 – 82,838; period 2 – 91,236). The proportion of male and female donors was similar for both periods. The proportion of first-time/repeat donors was 80%/20% for period 1 and 77%/23% for period two.
- Serological and molecular screening (NAT) were performed on all samples.
- **RESULTS:** Results showed that there were no significant differences in HIV infection between the two time periods (i.e. pre and post the introduction of

the “gender-neutral” policy). Additionally, the no difference observed in HIV infection applied to both female and male donors.

Blanco et al. (2020) conclude that the scientific evidence provided in their study, along with increasing evidence from other countries, support a paradigm shift from “risk group” (e.g., MSM) to gender-neutral “risk practice”. They argue that the “harmonization of deferral criteria for all donors regardless of sexual identity allows to maintain the safety of the blood supply. In this sense, we are sure that the key formula to achieve sustainable and inclusive blood supply systems is to continue working to train specialists in identifying individual risk practices in the blood donor population”. (p. 553)

Reducing deferral periods do not meaningfully increase HIV residual risk

Several countries, starting with Australia, went from a permanent blood donation ban for MSM to a temporary deferral. While the change was thought to be a potential risk at the time “there is not a single documented case of HIV contamination that can be attributed to the implementation of a temporary deferral policy for MSM” (Garmain, 2020, p.437). Data from several countries has shown that reducing the deferral period for MSM does not make a meaningful change in the risk of HIV infection entering the blood supply (for review see Goodman et al., 2018).

O’Brien et al. ’s (2020) study, based on Canadian data and detailed below, found the risk from a 12-month to a 3-month deferral to be very low even under a pessimistic scenario. The authors note that previous risk modelling almost certainly overestimated the risk, as they were based on HIV prevalence among MSM in the general population and were not specific to a subset of MSM who donate blood. These more recent findings, along with more advanced screening methods, suggest that the risk posed by the total removal of the blanket deferral period for MSM is likewise very low.

O’Brien et al. (2020). HIV residual risk in Canada under a three-month deferral for men who have sex with men. *Vox Sanguinis*, 115 (2), 133-139.

- The study employed a deterministic model with stochastic Monte Carlo simulation. Data inputs were based on donor surveillance and surveys, and published data.
- Residual risk was modelled at baseline and for three different scenarios – (1) **most likely** [MSM non-compliance, MSM HIV prevalence rates and MSM HIV incidence rates remain unchanged and newly eligible MSM donors doubles], (2) **optimistic** [MSM non-compliance improves by 50%] and (3) **pessimistic** [MSM non-compliance, MSM HIV prevalence, and MSM HIV incidence all double].

- **RESULTS:** Results revealed that the additional risk posed from going from a 12-month deferral period to a 3-month deferral period is extremely low (even with the pessimistic scenario, for which the risk of HIV infection entering the blood supply was 1 in 16.7 million). For the most likely scenario, the residual risk was 1 in 34.2 million, compared to 1 in 38.0 million with a 12-month deferral (i.e., no meaningful difference).

The authors conclude that since the publication of their findings noted above, Canada had reduced the MSM deferral period to 3 months. They note that a range of projects were funded in Canada to inform future policies that would permit lower-risk MSM to donate blood without a time deferral. On the 15 December 2021, the Canadian Blood Service officially asked Health Canada to remove the specific restrictions on blood donations from MSM. The new policy was approved by Health Canada and was implemented in September 2022.

The negative impact of temporary deferrals on blood donation

Clement et al. (2021). The impact of temporary deferrals on future blood donation behaviour across the donor life cycle. *Transfusion* (online March 2021).

- The study uses data from 123,000 whole blood donors of the Austrian Red Cross who donated at least once over a period of 5.5 years (January 2010 to June 2016).
- The study examined future donation behaviour while taking into account potential endogeneity, depending on donor experience and number of previous deferrals.
- **RESULTS:** Results revealed that temporary deferrals negatively impact future donations, with the effect amplifying over time.
- While results suggest that more experienced donors learn to cope with deferrals, deferrals appear to be extremely detrimental for new donors.
- The authors note "Blood banks should be careful with donor groups who have experienced deferrals in the past because every additional deferral demotivates future donation behavior." (p.1)

The findings from the above study may be particularly applicable to MSM donors who can now donate after 3 months of abstinence, in Australia. Due to the shorter deferral time of 3 months, such donors may experience greater rates of temporary deferrals, should they present to donate in even slightly less time than the 3-month abstinence period. So while the shortened deferral period of 3-months may encourage more MSM to donate (albeit a restricted number due to the need to abstain from sex for 3 months), somewhat ironically these donors may be discouraged from donating for the longer term due to the greater potential to experience temporary deferrals.

MSM willingness to donate blood and the stability of blood supplies.

Clackett et al. (2020). Attitudes and willingness to donate blood among gay and bisexual men in Australia. *Transfusion*, 60, 965-973.

- This study utilised an online cross-sectional survey with the Flux (Following Lives Undergoing Change) cohort of gay and bisexual men living in Australia.
- In the 2018 follow-up of the survey, and after consultation with the NHMRC partnership project with Lifeblood, questions were added about blood donation history and attitude towards the 12-month deferral period for MSM.
- The sample consisted of 1,595 men, with a mean age of 35.4. All had reported having sex with men in the 6 months prior to the survey. As the questions were on future blood donation this sample did not include men who were HIV positive.
- **RESULTS:** Over a quarter of men (28.7%) had donated blood at some time in the past and over three quarters (77.4%) stated that if the deferral policy were changed they would donate in the future.
- Of those willing to donate, the vast majority (90.1%) were unwilling to abstain from sex with men for the 12-month deferral period, with most feeling the policy was homophobic (74.3%) and unfair (80.6%). Most would instead comply with policy and not donate, effectively inhibiting the number of low-risk MSM from becoming blood donors.

Miyashita & Gates (2014). Update: Effects of lifting the blood donation bans on men who have sex with men. Williams Institute, UCLA School of Law.

- The study combined three waves of biennial data (2008, 2010, 2012) from the nationally representative General Social Survey (GSS) of adults in the US. Data showed that 3.8% of men (4.5 million) reported having sex with a man in the last 12 months.
- Using the above data they estimated the number of MSM who would be eligible to donate (based on time deferrals) and would likely donate, and the resulting number of donations.
- **RESULTS:** If the deferral period for MSM were to be completely lifted, the data suggests that the number of MSM who would likely donate would double (360,600) relative to a 12-month deferral (185,800).
- Based on the American Red Cross statement that each blood donation has the potential to be used for life-saving medical procedures on three people, the authors note that their estimates suggest that the removal of the deferral period for MSM could help save the lives of over a million people.

References

- Agence France-Press (2022, January 12). France removes restrictions on gay blood donors. Euronews. <https://www.euronews.com/2022/01/12/france-removes-restrictions-on-gay-blood-donors>
- Blanco, S., Carrizo, L. H., Moyano, R. W., et al. (2020). Gender-neutral donor deferral policies: Experience in Argentina implementing individual risk-assessment policies. *Vox Sanguinis*, 115 (7), 548-554.
- Brent, T. (2022, March 15). France to lift blood donation ban for gay men who have had recent sex. The Connexion. <https://www.connexionfrance.com/article/French-news/Health/France-to-lift-blood-donation-ban-for-gay-men-who-have-had-recent-sex>
- Caffrey, N., Goldman, M., Lewin, A., et al. (2022). Behaviour based screening questions and potential donation loss using the “for the assessment of individual risk” screening criteria: A Canadian perspective. *Transfusion Medicine*, Advance online publication. <https://doi.org/10.1111/tme.12888>
- Canadian Blood Services (2022). Sexual behaviour-based screening. <https://www.blood.ca/en/blood/am-i-eligible-donate-blood/sexual-behaviour-based-screening>
- Clackett, S., Seed, O. R., Prestage, G., et al. (2020). Attitudes and willingness to donate blood among gay and bisexual men in Australia. *Transfusion*, 60, 965-973.
- Clement, M., Shehu, E., Chandler, T., et al. (2021). The impact of temporary deferrals on future blood donation behaviour across the donor life cycle. *Transfusion* (online March 2021).
- FAIR (2020). Can donor selection policy move from a population-based donor selection policy to one based on a more individualised risk assessment? Conclusions from the For the Assessment of Individual Risk (FAIR) group. Retrieved from https://nhsbt.dbe.blob.core.windows.net/umbraco-assets-corp/21001/fair_sabto_20201211.pdf
- FDA (2020, August). Revised recommendations for reducing the risk of human immunodeficiency virus transmission by blood and blood products. US Food and Drug Administration: Guidance Document. <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/revised-recommendations-reducing-risk-human-immunodeficiency-virus-transmission-blood-and-blood>
- Germain, M. (2020). Men having sex with men and blood donation. Is there a game changer on the horizon? *Transfusion*, 60 (3), 437-440.

Goldman, M., Shih, A. W.-Y., O'Brien, S.F., & Devine, D. (2018). Donor deferral policies for men who have sex with men: past, present, future. *Vox Sanguinis*, 113(2), 95-103.

Hassan, C. (2023, January 27). FDA proposal would allow more men who have sex with men to donate blood. CNN Health. <https://edition.cnn.com/2023/01/27/health/fda-msm-blood-donations-draft-guidance/index.html#:~:text=The%20US%20Food%20and%20Drug,more%20gay%20and%20bisexual%20men>

Health Canada (2022, April 28). Health Canada authorizes Canadian Blood Services' submission to eliminate donor deferral period for men who have sex with men. Statement. <https://www.canada.ca/en/health-canada/news/2022/04/health-canada-authorizes-canadian-blood-services-submission-to-eliminate-donor-deferral-period-for-men-who-have-sex-with-men.html>

JPAC (2021). Change notification UK national blood services No. 16-2021. Issued 26 May 2021 by Joint United Kingdom (UK) Blood Transfusion and Tissue Transplantation Services Professional Advisory Committee (JPAC). <https://www.transfusionguidelines.org/document-library/change-notifications/change-notifications-issued-in-2021>

Kokkindis, T. (2022, January 11). Greece lifts ban on gay men donating. Greek Reporter. <https://greekreporter.com/2022/01/11/greece-lifts-ban-gay-men-donating-blood>

Lavietes, M. (2022, January 13). Critics call to end three-month celibacy requirement for gay, bisexual men amid blood shortage. NBC News. <https://nbcnews.com/news/amp/rcna11918>

Miyashita, A. & Gates, G. J. (2014). Update: Effects of lifting the blood donation bans on men who have sex with men. Williams Institute, UCLA School of Law.

NHS Blood and Transplant (2021, May 11). Blood donor selection policy: More people now able to give blood. News and Campaigns. <https://www.blood.co.uk/news-and-campaigns/news-and-statements/fair-steering-group/>

O'Brien, S. F., Gregoire, Y., Pilonel, J., et al. (2020). HIV residual risk in Canada under a three-month deferral for men who have sex with men. *Vox Sanguinis*, 115 (2), 133-139.

Park, C., Gellman, C., O'Brien, M., et al. (2020). Blood donation and COVID-19: Reconsidering the 3-month deferral policy for gay, bisexual, transgender, and other men who have sex with men. *American Journal of Public Health: Research and Analysis*, 111(2), 247-252.

- Pierik & Verweij (2020). Facing difficult but unavoidable choices: Blood safety, donor selection, and MSM deferral. Sequin Blood Supply.
https://www.tweedekamer.nl/kamerstukken/brieven_regering/detail?id=2021Z04493&did=2021D09882
- Pillonel, J., Pelat, C., Tiberghien, P., et al. (2020). The evolving blood donor deferral policy for men who have sex with men. Impact on the risk of HIV transmission by transfusion in France. *Transfusion*, 60 (3), 525-534.
- Spiro, A. (2021, August 19). Health minister announces removal of all blood restrictions for gay men. The Times of Israel.
<https://www.timesofisrael.com/health-minister-announces-removal-of-all-blood-donation-restrictions-for-gay-men/amp/>
- van Bilsen, W. P. H., Zaaijer, H. L., Matser, A., et al. (2019). Infection pressure in MSM and their suitability to donate blood. *Clinical Infectious Diseases*, 68(6), 1001-1008.
- Wagenigen University & Research (2021, March 22). News: Equal treatment of blood donors: Gay men now too assessed on individual behaviour.
<https://www.wur.nl/en/newsarticle/Equal-treatment-of-blood-donors-Gay-men-now-too-assessed-on-individual-behaviour.htm>
- Young, L. (2021, December 15). Canadian Blood Services asks Health Canada to drop ban on gay blood donation. Global News: Health.
<https://globalnews.ca/news/8452710/gay-blood-ban-change-canada/amp>