




# The impact of blood donation deferral strategies on the eligibility of men who have sex with men and other sexual risk behavior in Australia

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## Abstract

**Background:** In Australia, a man cannot donate blood if he has had sex with another man within the past 3 months. However, this policy has been criticized as being discriminatory as it does not consider lower risk subgroups, and led to calls for modifications to the policy that more accurately distinguish risk among gay, bisexual, and other men who have sex with men (GBM).

**Study Design and Methods:** We used data from a nationally representative survey to estimate the proportion of GBM aged 18–74 years old who would be eligible to donate under current criteria and other scenarios.

**Results:** Among the 5178 survey participants, 155 (3.0%) were classified as GBM based on survey responses. Among the GBM, 40.2% (95% CI 28.0%–53.7%) were eligible to donate based on current criteria, and 21.0% (95% CI 14.5%–29.5%) were ineligible due to the 3 months deferral alone. Eligibility among GBM, all men, and the population increased as criteria were removed. Under the new Australian plasma donation criteria, 73.6% (95% CI 64.4%–81.1%) of GBM, 68.4% (95% CI 65.5%–71.2%) of all men, and 60.8% (95% CI 58.8%–62.8%) of the full population were estimated to be eligible. Only 16.1% (95% CI 8.6%–28.1%) of GBM knew that the male-to-male sex deferral period is 3 months.

**Abbreviations:** AIDS, acquired immunodeficiency syndrome; GBM, gay, bisexual and other men who have sex with men; GNA, gender neutral assessment; HIV, human immunodeficiency virus; HTLV, human T-lymphotropic virus; IRA, individualised risk assessment; PrEP, HIV pre-exposure prophylaxis; TGA, Therapeutic Goods Administration; TTI, transfusion transmissible infection; WP, window period.

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**Discussion:** Changing the deferral criteria and sexual risk evaluation would lead to a higher proportion of GBM being eligible to donate blood. Knowledge of the current GBM deferral period is very low. Improved education about the current criteria and any future changes are required to improve blood donation rates.

#### KEYWORDS

bisexual, blood, blood donation, deferral criteria, eligibility, gay, GBM, HIV, men who have sex with men, MSM, perceptions, PrEP, prevalence, sexual risk behavior, transfusion medicine

## 1 | INTRODUCTION

To ensure both the safety and sufficiency of the blood supply, continuous evaluation and refinement of the criteria for blood donation are required. It is also increasingly recognized that these criteria must be inclusive and avoid deferrals of population groups without a justifiable scientific rationale,<sup>1</sup> while not compromising donor and recipient safety.

In the early 1980s, the onset of the AIDS epidemic led many countries, including Australia, to implement policies that required the permanent deferral from blood donation of individuals determined to be at higher risk of transmitting HIV. This included any man who had a history of sex with another man. Since then, improvements in HIV testing have allowed for the reduction of male-to-male sex deferral periods for blood donation. The most recent change in Australia was in 2021, when the deferral was reduced from 12 to 3 months, aligning more closely with the HIV test window period (WP; the early infection period during which HIV is present in the blood, but cannot be detected by a test).<sup>2,3</sup> Despite this change, the current policy still results in deferral of a potentially substantial proportion of GBM who may not be at increased risk of HIV acquisition, particularly those in long-term monogamous relationships, and those who have only participated in oral sex, despite these being associated with a negligible HIV risk.<sup>4</sup>

Further, current deferrals apply equally to transfusable component donation and plasma for further manufacture where the risk of transfusion transmissible infections (TTIs) is mitigated by the processing of plasma products, rendering this exclusion not based on appreciable risk. However, in May 2023 the Therapeutic Goods Administration (TGA) approved an application from Australian Red Cross Lifeblood (Lifeblood), Australia's blood collection agency, to allow most donors with higher risk sexual activities to donate plasma for fractionation, with the only remaining exclusion being recent sex (i.e., within the past 3 months) with someone with hepatitis B, hepatitis C, HIV or HTLV.<sup>5</sup> This update has been approved by state and

federal governments and the plasma manufacturer and implementation is being planned.

Male-to-male sex remains the major HIV risk exposure in Australia, accounting for 68% of new HIV notifications in 2021.<sup>6</sup> Nevertheless, with just 552 HIV notifications with a first ever diagnosis in 2021,<sup>6</sup> population rates are very low, and current donor screening protocols have a HIV WP of less than 1 week.<sup>2,3,7</sup> On this basis, the rationale for the 3 month deferral continues to be questioned in Australia as well as in other comparable countries.<sup>8,9</sup>

Excessive deferral periods for GBM pose a risk of non-compliance or wider donation refusal due to the perception of the policy as unjustifiable and discriminatory.<sup>8</sup> This perception may discourage eligible GBM and their advocates from donating blood. A less restrictive policy may not only increase the pool of eligible donors, but also encourage more GBM, and those in favor of a more inclusive policy, to donate blood.<sup>10–12</sup>

To enhance access to blood donation, several countries have introduced “gender neutral assessment” (GNA), or “individualized risk assessment” (IRA) to assess HIV risk, aiming for an equitable approach.<sup>13–15</sup> We refer to these approaches as GNA given they assess the sexual activity regardless of the HIV risk in the population group. GNA applies deferrals after higher-risk sexual behaviors, usually defined as anal sex with a new partner or with more than one partner in the last 3 months. To determine these behaviors, GNA entails asking all donors a set of detailed sexual history questions, which may result in eligible donors feeling uncomfortable and/or refusing to answer, potentially decreasing total donation participation (refusal to answer results in deferral).<sup>16,17</sup> Furthermore, GNA still excludes GBM with new or multiple sexual partners and those who take HIV pre-exposure prophylaxis (PrEP), as well as a proportion of the heterosexual population who are currently eligible to donate<sup>16</sup>; yet partner numbers and/or anal sex are not considered a significant risk factor for HIV in Australian heterosexual populations because the background HIV prevalence is low.<sup>4,18</sup>

While changes to blood donation policies are necessary to provide more risk-based assessment for GBM, it is important to carefully consider the potential impact of new policies on the donor pool. Changes must be evidence-based and prioritize blood safety. A balanced approach must maximize inclusivity while minimizing donor loss. To improve understanding of the impact that further changes to sexual risk deferral criteria may have on the donor pool, we used data from a national survey to estimate impacts on eligibility under selected scenarios related to sexual activity. We also assessed knowledge of the male-to-male sex deferral period.

## 2 | MATERIALS AND METHODS

We conducted a nationally representative cross-sectional survey via the Life in Australia™ probability-based panel. To be eligible to participate in the survey, respondents had to be resident in Australia and aged 18 years or over, consistent with blood donation age requirements. Detailed methods for this survey, assignment of eligibility, and ethical approval have been previously described.<sup>19</sup> Using the same methods, eligibility for blood donation among the Australian general population, all men, and GBM aged 18–74 years old was assessed under the scenarios described in Table 1. Reasons for selecting

**TABLE 1** Deferral scenarios.

Scenario	Changes to current criteria (as of November 2023) <sup>19</sup>	GBM/sexual activity related criteria	Rationale
1	No change	GBM are ineligible to donate if they have had sex with another man in the last 3 months, or if they have taken HIV PrEP (within 12 months as assessed in survey, the current whole blood deferral, although plasma PrEP deferral is currently 3 months) <sup>19</sup>	Current policy setting
2	Three-month male-to-male sex deferral removed if GBM have had no new partner in past 12 months	GBM are eligible to donate blood if they have had sex with another man in the previous 3 months and have had no new partner within the previous 12 months, and are not taking PrEP <sup>a</sup>	More closely resembles the individualized risk assessment which has been adopted internationally, where monogamous GBM are generally deemed eligible, but PrEP deferrals remain. This scenario may be considered for whole blood donation in Australia
3	Three-month male-to-male sex deferral removed	GBM not on PrEP are eligible to donate blood if they have had sex with another man within the previous 3 months, regardless of whether they have had a new partner	To evaluate the impact of the three-month male-to-male sex deferral alone on eligibility among GBM. This scenario is not being considered for whole blood donation in Australia because of the increased risk of HIV in higher risk subpopulations of GBM
4	Three-month male-to-male sex and PrEP deferral removed	GBM are eligible to donate blood if they have had sex with another man within the previous 3 months, regardless of whether they have taken PrEP	To evaluate the impact of the three-month male-to-male sex and the PrEP deferral on eligibility among GBM. This scenario is not being considered for whole blood donation in Australia but indicates the gain in GBM that may be achieved by the Australian “plasma pathway”
5	All sexual activity deferrals removed (except for 3-month deferral for sex with someone known to be positive for a blood borne virus)	All sexual history questions (i.e., questions about recent sex partners, payment for sex in money, gifts or drugs, countries of residence of new sex partners, and PrEP use) removed, but ineligible if have had sex within last 3 months with someone who has tested positive for hepatitis B, hepatitis C, HIV or HTLV	Resembles the Australian “plasma pathway” which is awaiting implementation, giving an indication of the total gain from removing sexual activity for plasma donation. This scenario is not considered for whole blood donation in Australia, due to higher risks

<sup>a</sup>New partner is defined as someone with whom they have had sexual activity (oral or anal sex, with or without a condom). Note that in Australia, a similar policy is being considered, but in this case only anal sex with new or multiple partners within the past 3 months would result in deferral. Due to questions asked in the survey, only sexual activity defined as oral or anal sex with a new partner within 12 months could be assessed.

these scenarios are also described in the table. For the purpose of this analysis, we defined GBM as survey respondents who identified as male and who had had sex with a man within the previous 3 months, or identified as gay, bisexual, or “other term.”

### 3 | RESULTS

Of 5178 respondents who completed the survey, most online (96.5%), and a small proportion via phone (3.5%), 155 (3.0%) were classified as GBM, as shown in Figure 1. Just over half the total sample (55.8%,  $n = 2889$ ) reported previously attempting to donate blood, with 8.5% ( $n = 439$ ) having done so overseas, and 51.4% ( $n = 2660$ ) in Australia. By “attempting” we mean presenting to donate blood, thus this figure includes both those who successfully donated and those who were deferred. Current donors (donated blood within the last 2 years) formed 9.1% of the sample ( $n = 469$ ), 35.9% ( $n = 1861$ ) were lapsed donors (donated blood in Australia over 2 years ago), and 54.3% ( $n = 2811$ ) were non-donors (never donated blood in Australia). A further 0.7% ( $n = 37$ ) had indeterminate donor status. Within the GBM sample, 44.5% ( $n = 69$ ) had ever attempted to donate blood, with 6.5% ( $n = 10$ ) having attempted to donate blood overseas, and 40.6% ( $n = 63$ ) having attempted to donate blood in Australia. Current donors formed 3.9% of the GBM sample ( $n = 6$ ), 27.7% ( $n = 43$ ) were lapsed donors,

67.7% ( $n = 105$ ) were non-donors, and 0.7% ( $n = 1$ ) had indeterminate donor status.

Population eligibility estimates among the scenarios assessed are displayed in Table 2. Overall, 57.3% (95% CI 55.3%–59.3%) of the sample were eligible to donate blood under current criteria. Among men, 62.6% (95% CI 59.6%–65.6%) were eligible, and 40.2% (95% CI 28.0%–53.7%) of GBM were eligible. Eligibility among these groups increased as criteria were removed. Numbers are not provided with the population estimates, as the percentages are based on weighted Australian population results.<sup>19</sup> For reference, raw eligibility estimates are displayed alongside the weighted estimates. Prevalence of sexual risk related exclusion factors are displayed in the Table S1.

Table 3 displays the response rates corresponding to each available option in response to the question “How long do you think the deferral period is after having male-to-male sex?” A higher proportion of GBM answered this question correctly (16.1%, 95% CI 8.6%–28.1%) compared to all men (10.8%, 95% CI 8.7%–13.3%) and the full sample (10.3%, 95% CI 9.0%–11.8%).

### 4 | DISCUSSION

Our results demonstrate that the current blood donation criteria in Australia result in notably lower eligibility rates among GBM (40.2%) compared to the overall male population (62.6%) and the general population (57.3%). These findings highlight the disparity in blood donation

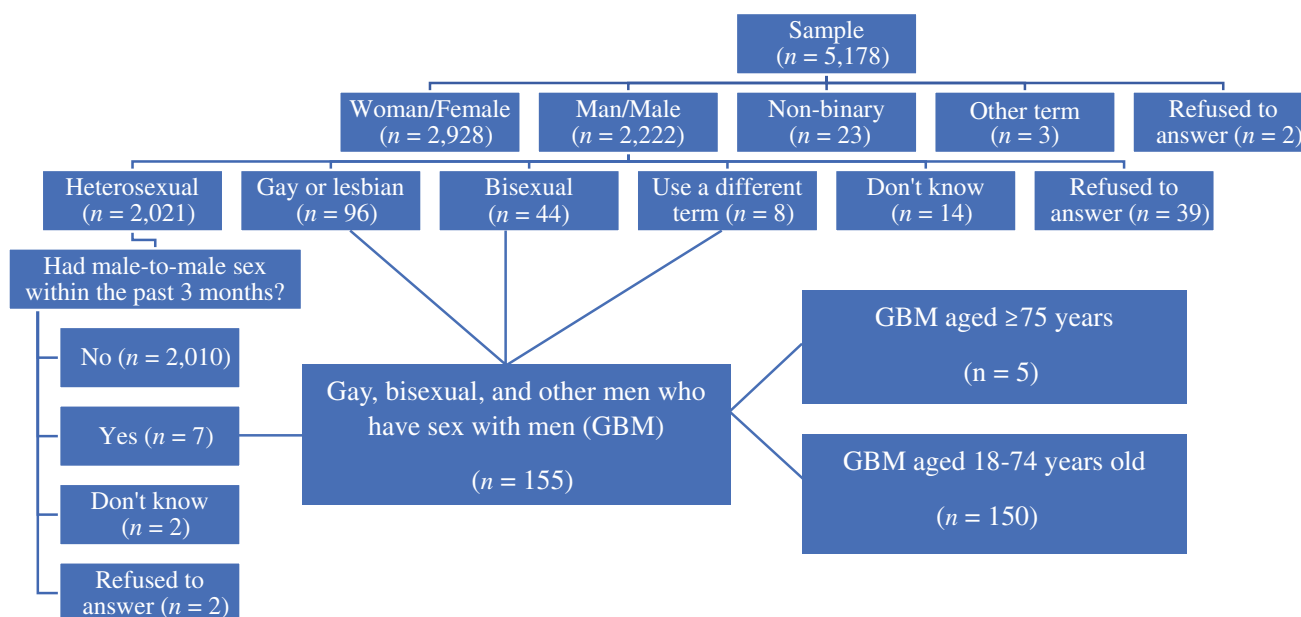


FIGURE 1 Flow diagram to show gay, bisexual, and other men who have sex with men portion of the survey sample. [Color figure can be viewed at [wileyonlinelibrary.com](http://wileyonlinelibrary.com)]

TABLE 2 Population eligibility estimates.

Scenarios	Changes to current criteria (as of November 2023) <sup>19</sup>	Population eligible estimates (%; 95% CI)		
		All	All men	GBM only
Scenario 1	No change	57.3 (55.3–59.3)/10,256,700	62.6 (59.6–65.6)/5,508,800	40.2 (28.0–53.7)/215,874
	Population eligible estimate (weighted %; 95% CI)/number of people eligible <sup>a</sup>			
	Population eligible estimate (raw %; 95% CI)	56.2 (54.7–57.6)	60.8 (58.6–62.9)	23.3 (17.2–30.8)
Scenario 2	GBM eligible if have had no new partner in past 12 months (i.e., monogamous GBM not on PrEP)	57.6 (55.6–59.6)/10,310,400	63.3 (60.2–66.2)/5,570,400	47.8 (36.0–60.0)/256,686
	Population eligible estimate (weighted %; 95% CI)/number of people eligible <sup>a</sup>			
	Population eligible estimate (raw %; 95% CI)	56.6 (55.2–58.0)	61.8 (59.6–63.9)	35.3 (28.1–43.3)
Scenario 3	Three-month male-to-male sex deferral removed	58.1 (56.1–60.2)/10,399,900	64.4 (61.4–67.3)/5,667,200	61.5 (50.6–71.4)/330,255
	Population eligible estimate (weighted %; 95% CI)/number of people eligible <sup>a</sup>			
	Population eligible estimate (raw %; 95% CI)	57.0 (55.6–58.5)	62.8 (60.7–65.0)	49.3 (41.4–57.3)
Scenario 4	Three-month male-to-male sex and PrEP deferral removed	58.5 (56.5–60.5)/10,471,500	65.1 (62.1–68.0)/5,728,800	67.9 (57.6–76.7)/364,623
	Population eligible estimate (weighted %; 95% CI)/number of people eligible <sup>a</sup>			
	Population eligible estimate (raw %; 95% CI)	57.4 (56.0–58.8)	63.6 (61.4–65.7)	56.7 (48.6–64.4)
Scenario 5	All sexual activity deferrals removed	60.8 (58.8–62.8)/10,883,200	68.4 (65.5–71.2)/6,019,200	73.6 (64.4–81.1)/395,232
	Population eligible estimate (weighted %; 95% CI)/number of people eligible <sup>a</sup>			
	Population eligible estimate (raw %; 95% CI)	59.3 (57.8–60.7)	66.1 (64.0–68.2)	60.7 (52.6–68.2)

<sup>a</sup>Based on Australian Bureau of Statistics 2021 estimated residential population (ERP) of 17.9 million, and 8.8 million men aged 18–74 years old.<sup>21</sup> For the GBM population, we used our GBM proportion of the sample (3.0%), translating to a population of 537,000. We considered using other recent estimates of the Australian non-heterosexual population, but these had different definitions of non-heterosexual.<sup>25,26</sup>



TABLE 3 Perceived deferral period after having male–male sex.

How long do you think the deferral period is after having male-to-male sex?	Population, aged 18–74 years old (% , 95% CI)		
	GBM	Men	All
3 months	16.1 (8.6–28.1)	10.8 (8.7–13.3)	10.3 (9.0–11.8)
1 year	14.5 (9.2–22.2)	12.3 (10.3–14.7)	10.3 (9.1–11.7)
5 years	3.6 (1.4–8.6)	2.9 (2.0–4.3)	2.6 (2.0–3.4)
Permanent	17.5 (11.2–26.2)	13.3 (11.3–15.5)	12.7 (11.3–14.1)
No deferral	10.3 (4.1–23.5)	12.0 (9.9–14.4)	12.3 (11.0–13.8)
Don't know	36.7 (25.4–49.7)	47.0 (43.9–50.2)	50.4 (48.3–52.4)
Refused to answer	1.4 (0.4–4.6)	1.7 (0.9–3.1)	1.5 (0.9–2.3)

eligibility rates between GBM and other population groups under the current criteria. Whilst the current 3-month male-to-male sex deferral still allows a significant proportion of GBM to donate, our survey estimates that 21.0% of GBM were ineligible due to the male-to-male sex criterion alone. Notwithstanding, the current criterion does not consider whether GBM are in a long-term monogamous relationship and still excludes people reporting oral sex with another man despite this being associated with a negligible risk,<sup>4</sup> therefore improvements can be made. Lifeblood had planned to remove oral sex as a risk factor, however, is now considering an overall shift to a GNA approach, similar to scenario 2 for whole blood. This would effectively remove any GBM-specific deferral.<sup>20</sup>

When GBM who had engaged in sexual activity with another man within the preceding 3 months were considered eligible, provided they had not acquired a new partner in the past 12 months (scenario 2), their eligibility rate rose to 47.8%. If Australia were to shift to a GNA, individuals, including GBM, would be deemed eligible if they have not had anal sex with a new partner or multiple partners within the past 3 months. Unfortunately, we did not collect the data in our survey to estimate accordingly, and our data is limited to new partner within 12 months. Furthermore, we cannot differentiate between oral and anal sex. Therefore, our estimate for scenario 2 is likely a more conservative estimate than the true eligibility rate under a GNA. Removing the three-month GBM deferral from the criteria (scenario 3) resulted in a sizeable increase among the GBM population (from 40.2% under the current criteria to 61.5%), a modest increase among all men (from 62.6% to 64.4%), and a slight increase among the general population (57.3%–58.1%). The rate of eligibility among GBM increased further to 67.9% when the “PrEP” deferral was also removed (scenario 4).

In scenario 5, we removed all sexual activity questions which resulted in the highest rates of eligibility for each population assessed. While this scenario would not be considered for whole blood donation, it is acceptable for plasma for

further manufacture, due to the plasma processing TTI mitigation. Thus, this scenario provides an estimate of the number of GBM and the total population who will become eligible under this new ‘plasma pathway.’ Of note, without the sexual activity restrictions, eligibility among GBM was in fact higher than both the general population and males overall (73.6% among GBM, 68.4% among all men, and 60.8% among the general population). This is likely because the GBM population in this survey is a younger cohort than the full survey sample and overall ineligibility increased with age. The 2021 Census counted approximately 17.9 million Australians within the 18–74 age range,<sup>21</sup> so our survey estimates that the “plasma pathway” and removal of all sexual activity questions from the plasma donor questionnaire, will allow approximately 626,500 additional people to become newly eligible to donate plasma. The total donation-eligible pool is also demonstrated to increase under the other scenarios assessed, but this does not consider donor loss from discomfort with the questions for GNA or newly deferred individuals who are currently eligible.

Regarding the knowledge of the male-to-male sex deferral duration, a slightly greater percentage of GBM correctly identified the current deferral period as 3 months compared to men and the entire sample, but the confidence intervals are wide thereby limiting further interpretation. However, GBM were also more likely to overestimate the duration, as a larger proportion of them selected 1, 5 years, or permanent deferral in comparison to both men and the broader sample. Each of these timeframes have been correct at some point, suggesting that these misperceptions may have arisen due to lack of awareness regarding criterion changes. Concerningly, 36.7% of GBM, and approximately half of the male respondents (47.0%) and the whole sample (50.4%) said they do not know the deferral length. While GBM appear to be more knowledgeable about the deferral period, lack of knowledge and overestimations of the timeframe are widespread. This suggests that many GBM think they are ineligible to donate when they are in fact eligible, a misconception which may act as a deterrent,

discouraging them from donating blood if eligible. Both the current criteria, and any changes to the questionnaire or criteria require public health education and campaigns to educate not only donors and GBM, but also the general population to ensure that those who are eligible to donate come forward, and to increase their understanding of why certain personal questions are being asked.

There are limitations to this study. From March 2020 until after the survey was conducted in November 2021, Australia imposed COVID-19 restrictions. The restrictions may have led to behavioral changes that altered eligibility. For example, there was reduced sexual contact among gay and bisexual men during lockdowns which might have increased the number of GBM eligible under the current deferral criteria.<sup>22</sup> Furthermore, our lack of data on new partners, multiple partners, and anal sex within the previous 3 months limits our ability to estimate the proportion of GBM, men, and the general population to donate blood under GNA. While we have data on new sexual partners within the past 12 months, the data does not differentiate between oral, vaginal, or anal sex partners. We considered adjusting the data using data from other studies (the ADVANCE study in the US),<sup>23</sup> and the FLUX study in Australia,<sup>24</sup> however these studies are not representative of the Australian population. This study also highlights the issues with weighting data, especially among smaller sub populations as the weighting is designed to be representative of the Australian population and is likely to be different for a sub-population such as GBM. There is a considerable difference in rates of eligibility between the raw and weighted GBM population estimates. We also have a small sample size of 155, which leads to larger confidence intervals. However, despite these limitations, this study provides a valuable insight into the positive impacts on the donor-eligible pool when certain sexual risk criteria are relaxed, while considering all other blood donation eligibility criteria assessed.

Our findings demonstrate the estimated donation gains from further modifications to blood donation eligibility criteria in Australia. These changes would increase the proportion of eligible GBM, and others, affected by sexual activity deferrals. While changes to blood donation policies are necessary to increase inclusivity, it is important to consider the potential impact of new policies on the donor-eligible pool. Changes to the criteria may require changes to existing questions and/or additional questions relating to recent sexual activity which some people might feel uncomfortable answering. Further research is required to improve our understanding of comfort in answering such questions among current donors, and comfort in answering the questions and willingness to donate blood among those who are currently ineligible but who would become eligible under new policies.

A balanced approach that seeks to achieve inclusivity while minimizing the loss of eligible and current donors is needed. Any change should be implemented carefully to minimize any unintended impact on the donor-eligible pool. Public health education and awareness campaigns will be pivotal in ensuring that both eligible donors, including GBM, and the general population understand the necessity of certain questions and criteria, thereby reducing stigma and promoting greater participation in blood donation.










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Investigators VH and RT are employed by Lifeblood, and investigator BM's position at the University of Queensland is co-funded by Lifeblood. Investigator YM derives income from the NHMRC Partnership Project grant. The authors declare they have no other conflicts of interest relevant to the manuscript submitted to *Transfusion*.

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## SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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