CME

No evidence of a significantly increased risk of transfusion-transmitted human immunodeficiency virus infection in Australia subsequent to implementing a 12-month deferral for men who have had sex with men

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BACKGROUND: Male-to-male sex is the predominant route of human immunodeficiency virus (HIV) transmission in Australia and since the early 1980s blood services in Australia have deferred donors for this practice for at least 5 years. This retrospective analysis assesses the impact on HIV prevalence of implementing an abridged 12-month deferral for male-to-male sex.

STUDY DESIGN AND METHODS: The prevalence of HIV among blood donors for 5-year periods before (Period 1) and after (Period 2) implementing the revised 12-month deferral was compared. Using deidentified data from postdonation interviews with HIV-positive donors the proportion disclosing male-to-male sex as a risk factor was compared for the two periods.

RESULTS: Twenty-four HIV-positive donations were identified among 4,025,571 donations in Period 1 compared with 24 among 4,964,628 donations in Period 2 ($p = 0.468$). The proportion of HIV-positive donors with male-to-male sex as a risk factor in Period 1 was 2 in 15 (13.3%), which was not significantly different from the proportion in Period 2, 5 in 16 (31.25%; $p = 0.22$). All five men who have sex with men risk HIV infections during Period 2 were from donors whose risk was within the 12-month criterion for acceptability, who would have been deferred had they provided a complete history.

CONCLUSIONS: We found no evidence that the implementation of the 12-month deferral for male-to-male sex resulted in an increased recipient risk for HIV in Australia. The risk of noncompliance to the revised deferral rather than its duration appears to be the most important modifier of overall risk.

Effective donor selection measures combined with of state-of-the-art testing have ensured that Australia has one of the safest blood supplies in the world in respect of transfusion-transmissible viruses.[1-3] The importance of deferral measures focusing on preventing donation by "high-risk" individuals was first illustrated in the early 1980s before universal human immunodeficiency virus (HIV) antibody screening when Busch and colleagues[4] demonstrated a marked decline in the "per-unit" risk of HIV infection in the United States coinciding with the progressive implementation of donor selection measures. One important component of effective donor selection is predonation questioning of donors to identify and defer those who have engaged in high-risk behavior for transfusion-transmissible viral infections.[2,3,5] Questions underpinning specific donor deferral criteria should be clear, concise, and based on the latest epidemiologic evidence to avoid the perception of discrimination.[5-7]

In 1983 it was confirmed that HIV could be transmitted by blood transfusion and that male-to-male sex was an

ABBREVIATIONS: ACT = Australian Capital Territory; MSM = men who have sex with men; NSW = New South Wales; RR = residual risk; WP = window period.

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important mode of transmission.[8] In the absence of a specific screening test for HIV many blood services,[8,9] including those in Australia,[10] commenced deferring donors who disclosed a history of male-to-male sex.[8,9] The rate of HIV notifications in Australia peaked in 1988 and gradually declined, reaching its nadir in 1999. Since then this trend has reversed with a noticeable increase in the number of HIV diagnoses in recent years.[11] Epidemiologic data confirm that in Australia HIV continues to be transmitted primarily through sexual contact between men and that the recent increasing trend in HIV notifications is predominantly associated with men who have sex with men (MSM).[11,12] Recent mathematical modeling has identified that MSM pose the greatest risk to the Australian blood supply in terms of the potential to transmit HIV infection to blood recipients.[13] In Australia, MSM are currently deferred from blood donation if the exposure occurred within the previous 12 months in accordance with the Australian Red Cross Blood Service (the Blood Service) *"Guidelines for the Selection Of Blood Donors."* Importantly, contrasting the situation elsewhere (including North America[14,15] and the United Kingdom[16]) the duration of deferral for MSM in Australia is the same as that applied to those disclosing similar risk activities through heterosexual contact. Such "harmonization" of approach in respect of high-risk sexual contact has been jointly advocated by the AABB, American Red Cross, and America's Blood Centers.[17]

Because of legislative constraints the current 12-month deferral for MSM was implemented throughout Australian state and territory jurisdictions in a stepwise manner between 1996 and 2000. Japan, Argentina and Hungary also currently have a 12-month deferral period.[14,18] South Africa currently has a 6-month deferral (A. Bird, personal communication, June 2010). Many other industrialized countries have longer deferral periods. For example the United Kingdom currently has a lifetime deferral for MSM, the United States, and Canada currently have an indefinite deferral for MSM since 1977, and New Zealand currently has a 5-year deferral period for MSM.[14,18] Italy and Spain currently have no specific deferral for MSM although questions targeting high-risk sexual exposure are included in their respective predonation questionnaires.[16]

Despite a lack of data, there continues to be ongoing debate about the impact of MSM deferral periods, particularly the value of retaining a period in excess of 12 months given the significant improvement in donor screening tests.[9,16,19-22] Critics have labeled the existing policies, but particularly the lifetime ban, as scientifically unjustified[17,22] and discriminatory.[21] A recent unsuccessful legal challenge to the existing Australian MSM deferral policy[23] and a current challenge against the policy of the Canadian Blood Services[24] highlight the controversial nature of the MSM deferral. Despite the controversy, regulators in the United States, Canada, and the United Kingdom have resisted relaxing their existing deferrals principally citing modeling data.[25,26] This modeling data predict that the risk of an HIV infectious donation entering their respective blood supplies would increase should they allow a change to a 12-month MSM deferral period. The premise is that a change in eligibility criteria would be expected to increase the number of HIV-positive donors presenting and that the recipient infection risk would be a function of increased accidental release of infectious units.

However, more recently, preliminary data from Italy examining the impact of discontinuing Italy's MSM deferral in 2001 indicates that the proportion of HIV-infected donors with MSM as a disclosed risk did not significantly increase in the postimplementation period.[27] Moreover, recent refinements to the modeling for the US blood supply indicate a substantially lower risk than originally predicted.[15,21,28] Fueling further debate, the modeled estimate for the risk of releasing an HIV-infectious unit by reducing the MSM deferral in the United States to 12 months is approximately 2.6 times less than the corresponding (currently accepted) risk of HIV transmission associated with the use of pooled whole blood–derived platelets (PLTs; which comprise 12.5% of those supplied) versus apheresis PLTs.[15,29]

This retrospective analysis assesses the impact of implementing a 12-month MSM deferral policy on the prevalence of HIV among donors and male-to-male sex as a disclosed risk factor.

MATERIALS AND METHODS

MSM deferral policy

Before the formation of the Australian Red Cross Blood Service as a national blood service in 1996, state and territory blood services were administered by Red Cross divisions. The implementation date of the 12-month MSM deferral in Australia therefore varied between states and territories due to differences in state-based legislation. Table 1 summarizes the existing MSM deferral policies and changeover dates for each jurisdiction.

Population

The Blood Service collects and processes all allogeneic blood donations in Australia. The study population comprised all donations collected by each individual jurisdiction (refer Table 1) in the 5-year period preceding the implementation of the 12-month MSM deferral (n = 4,025,571 donations—Period 1) and the 5-year period postimplementation (n = 4,964,628 donations—Period 2).

HIV testing

Depending on the jurisdiction, before June 6, 2000, all donations were screened using one of the following HIV-1

TABLE 1. Implementation dates for the previous and current MSM deferral policies by state and territory

Australian state/territory	Existing MSM deferral	12-month* deferral implemented
South Australia	1980†	April 1, 1996
Queensland	PD‡	February 1, 1999
Western Australia	1980†	February 12, 1999
Northern Territory	5 years§	February 12, 1999
Victoria	5 years§	October 27, 1999
Tasmania	1977¶	October 27, 1999
ACT	1980†	October 9, 2000
NSW	1977¶	October 9, 2000

* Twelve-month deferral from last male-to-male sexual contact.
† Donor permanently deferred if any male-to-male sexual contact since 1980.
‡ Permanent deferral for all donors who have ever engaged in male-to-male sex.
§ Five-year deferral from last male-to-male sexual contact.
¶ Donor permanently deferred if any male-to-male sexual contact since 1977.

and -2 antibody assays: Genelavia MIXT HIV-1/2 antibody enzyme immunoassay (EIA; Sanofi Diagnostics Pasteur, Marne-la Cocquette, France), Abbott HIV-1/2 antibody EIA (Abbott Diagnostics, Abbott Park, IL), or PRISM HIV-1/2 chemiluminescent assay (Abbott Diagnostics). From June 6, 2000, all jurisdictions used the PRISM HIV-1/2 or PRISM HIV O Plus chemiluminescent assay. In addition, from June 6, 2000, all donations were screened for the presence of HIV-1 RNA with an HIV-1/hepatitis C virus (HCV; multiplex) assay and an HIV-1 discriminatory assay (Procleix, Chiron Blood Testing, Emeryville, CA). The Procleix multiplex assay was performed on individual donations from South Australia, Western Australia, and the Northern Territory and on pools of 24 (until 2005) and subsequently 16, for donations from all other jurisdictions. During both periods, donations that tested repeatedly reactive on an HIV-1 and -2 antibody screening assay were confirmed as positive by HIV Western blot performed by an external reference laboratory. Confirmation of any HIV RNA–positive/HIV antibody–negative "nucleic acid testing (NAT)-yield" donors required the detection of RNA by an alternative RNA assay on the index sample and/or subsequent HIV antibody seroconversion.

Postdonation interviews

Pre-2000 procedure

HIV screening test repeat-reactive donors were contacted by phone and/or registered mail and offered confirmatory testing, counseling, and a confidential interview. Consent was obtained to record deidentified data and those donors who did not wish to participate in further testing or counseling were referred to their family doctor or directly to an infectious disease specialist. Donors whose follow-up testing confirmed the presence of HIV infection were referred to their local doctor for clinical assessment and referral to an appropriate specialist. Where HIV-positive donors were interviewed by the Blood Service before referral, this was performed individually by medical officers or Blood Service–trained nurse counselors. Each interview was conducted in person or by telephone, as soon as practicable after the index donation (usually within 2-4 weeks). A questionnaire (which varied in content dependent on the state/territory) was used to elicit epidemiologic data and potential risk exposures for HIV. Where discrepancies were apparent between the information disclosed at the initial predonation interview and the subsequent risk factor assessment, the reasons for these were discussed. All potential HIV-infective risk factors were recorded.

Post-2000 procedure

From 2000 onward, the follow-up of HIV-positive donors was performed as described by Polizzotto and colleagues.[3] The major difference to the pre-2000 protocol was the use of a nationally standardized questionnaire. Briefly this involved inviting each confirmed-positive donor to participate in an interview to elicit epidemiologic data and potential risk factor exposures. Consent was obtained to record deidentified data. Interviews were conducted by Blood Service–trained counselors or medical officers in person or by telephone depending on donor or interviewer preference.

Analysis of potential risk factors

The postdonation interview records of each individual HIV-positive donor were reviewed for all potential HIV risk factors. Risk factors were categorized in accordance with the method described by Polizzotto and co-authors.[3] In some cases more than one potential risk factor was disclosed and therefore it was not possible to attribute infection to any single risk factor.

Statistical analysis

Rates of HIV-positive donations (per million donations) were compared pre- and post-MSM deferral changes using Poisson regression. The proportion of repeat donations (combined and among males only) and positive donations in which the donors reported their HIV exposure to be male-to-male sex were compared before and after deferral changes using Fisher's exact test. p values of less than 0.05 were considered significant.

RESULTS

HIV prevalence

After the implementation of the 12-month MSM deferral policy, the prevalence of HIV-positive donations did not significantly change among either the total number of

donations or the donations from males (Table 2). Twenty-four HIV-positive donations were identified among 4,025,571 donations in Period 1 compared with 24 among 4,964,628 donations in Period 2 (incidence rate ratio, 0.81; 95% confidence interval [CI], 0.46-1.43; p = 0.468). Among only male donors, 16 were identified in Period 1, and 13 in Period 2 (incidence rate ratio, 0.66; 95% CI, 0.32-1.37; p = 0.266). The overall (male and female combined) proportion of HIV-positive repeat donors increased from 7 of 24 in Period 1 to 14 of 24 in Period 2 (p = 0.08), and in male repeat donors, from 4 of 16 in Period 1 to 9 of 13 in Period 2 (p = 0.07). [Correction added after online publication 21-Jul-2010: The number of donors has been corrected.] Among males the difference was entirely due to an increase in one jurisdiction, New South Wales (NSW)/Australian Capital Territory (ACT), where the number increased for zero in Period 1 to six in Period 2, although this was not significantly different from the increase in males in all other jurisdictions, from four in Period 1 to five in Period 2 (p = 0.10). Notably, one of the six NSW male donors in Period 2 was HIV antibody negative, HIV-1 RNA positive (NAT yield) indicating very recent infection.

Risk factors (Table 3)

Of the 24 HIV-positive donors identified during Period 1, 20 consented to a follow-up interview. Among these 20, 15 donors disclosed HIV-associated risk factors with three identifying two risk factors. In Period 2, 24 HIV-positive donors were identified with 20 consenting to follow-up interview. Of these 20, 16 donors disclosed HIV risk factors, two identifying two risk factors. If it is assumed that one donor with undisclosed male-to-male sex but a history of anal warts engaged in male-to-male sex then the proportion of HIV-positive donors with male-to-male sex as a risk factor in Period 1 was 2 of 15 (13.3%), which was not significantly different from the proportion in Period 2, 5 of 16 (31.25%; p = 0.22). Notably, all five donors disclosing male-to-male sex as a risk in Period 2 would have been deferred from donation had they disclosed this risk at the time of donation (since it occurred within the previous 12 months).

DISCUSSION

This retrospective analysis examines the HIV prevalence in Australian blood donors and risk factors among those found to be HIV positive, before and after the implementation of a 12-month deferral for MSM in Australia. The paucity of such empirical data has previously been cited as a barrier to assessing the safety implications of relaxing MSM deferral policies.[14,15,30]

If the change to a 12-month deferral for male-to male sex in Australia had resulted in previously ineligible HIV-positive donors attending to donate, an increase in the prevalence of HIV-positive donors and/or the proportion

TABLE 2. Comparison of HIV prevalence before and after implementation of a 12-month deferral for MSM in Australia

	5 years before deferral change								5 years after deferral change							
	Total donations	Male donations	HIV-positive donors: male			HIV-positive donors: female			Total HIV-positive donors	No donations	Male donations	HIV-positive donors: male			HIV-positive donors: female			Total HIV-positive donors
Jurisdiction	(Period [P1])		FTD	RD	Total	FTD	RD	Total		(Period [P2])		FTD	RD	Total	FTD	RD	Total	
NSW/ACT	1,088,042 (09/10/95-08/10/00)†	553,813	3	0	3	1	0	1	4	1,621,007 (09/10/00-08/10/05)	825,170	1	6*	7	1	1	2	9
VIC/Tas	1,048,143 (27/10/94-26/10/99)	549,541	1	1	2	1	0	1	3	1,326,559 (27/10/99-26/10/04)	695,515	0	1	1	0	0	0	1
Qld	956,121 (01/02/94-31/01/99)	513,819	5	2	7	1	2	3	10	1,062,387 (01/02/99-31/01/04)	570,927	2	1	3	3	1	4	7
WA/NT	467,153 (12/02/94-11/02/99)	247,031	1	1	2	2	1	3	5	527,679 (12/02/99-11/02/04)	279,037	0	1	1	1	2	3	4
SA	466,112 (01/04/91-31/03/96)	242,145	2	0	2	0	0	0	2	426,996 (01/04/96-31/03/01)	221,824	1	0	1	1	1	2	3
National total	4,025,571	2,106,350	12	4	16	5	3	8	24	4,964,628	2,592,473	4	9	13‡ (p = 0.27)	6	5	11	24§ (p = 0.47)

* Includes one NAT-yield donor (i.e. HIV antibody negative/HIV-1 RNA positive).
† Day/month/year.
‡ Comparison of HIV prevalence in male donations before and after deferral implementation.
§ Comparison of HIV prevalence in total donations before and after deferral implementation.
FTD = first-time donors; NT = Northern Territory; RD = repeat donors; SA = South Australia; Tas = Tasmania; VIC = Victoria; WA = Western Australia.

TABLE 3. Potential infective risk factors* identified in HIV-positive donors before and after implementation of a 12-month deferral for MSM in Australia

Risk factor	5-year preimplementation period	5-year postimplementation period	p value
IV drug use	3 (20.0)	1 (6.25)	
Partner or contact with infective risk	4 (26.7)	4 (25.0)	
Sex with individual from overseas	2 (13.3)	3 (18.8)	
Sex with sex worker	1 (6.7)	1 (6.25)	
Receipt of blood product	2‡ (13.3)	0 (0)	
Other blood contact	1 (6.7)	3 (18.8)	
Tattooing or piercing	1 (6.7)	0 (0)	
Surgery or endoscopy	1 (6.7)	1 (6.25)	
Male-to-male sexual contact (MSM)	2§ (13.3)	5¶ (31.3)	0.22**
Residence in high-risk country	1 (6.7)	0 (0)	
Total donors with risk factors	15†	16†	

* Disclosed during personal interview conducted subsequent to the HIV-positive result as described under Materials and Methods.
† Data are reported as number of donors reporting risk factor (%). For the preimplementation period, 20 of 24 HIV-positive donors were interviewed and 15 of 20 reported one or more risk factors. For the postimplementation period 20 of 24 HIV-positive donors were interviewed and 16 of 20 reported one or more risk factors. For each risk factor, percentages are the percentage of total donors reporting a risk factor who reported each specific risk. Note: donors could report more than one risk factor.
‡ Transfused overseas.
§ Includes one donor in whom male-to-male sex was not disclosed but highly suspected by the interviewer based on a history of anal warts.
¶ All five donors were "noncompliant" since the risk activity disclosed occurred within 12 months of donation. This would have led to their deferral if disclosed at the time of donation.
** Comparison of the proportion of donors identifying male-to-male sex as a risk exposure as a proportion of all HIV-positive donors where at least one risk exposure was disclosed.

of HIV-positive donors with MSM as a risk factor would be expected. Modeling[25,26,28,31] has predicted an increase in the prevalence of HIV-infected individuals attending to donate with a consequent increase in the (residual) risk of HIV transmission.[14,19]

After the implementation of the 12-month MSM deferral policy, the prevalence of HIV-positive donations did not significantly change among either the total number of donations or the donations from males (Table 2). However, there was a nonsignificant increase in the overall (male and female combined) and male-only proportion of HIV-positive repeat donors from Period 1 to Period 2. Importantly, lookback on prior donations from the repeat donors failed to identify any positive recipients (data not shown). As well the change did not reflect a national trend among blood donors as it was due to a nonsignificant increase in only one jurisdiction (NSW/ACT). National surveillance data reported that the rate of newly acquired HIV infection in NSW (which represents 56% of all HIV diagnoses in Australia) increased by almost 20% (and 41% Australia-wide) between 2000 and 2005, a period that corresponds closely to Period 2 for all jurisdictions except South Australia.[32] Against this background of increasing HIV incidence in the population at large, one might expect that both the donor HIV prevalence (measured by the overall rate of HIV positive donations) and the incidence (measured by HIV seroconversion in repeat donors) might also increase. Supporting the efficacy of the Blood Service donor education and selection criteria for HIV, neither trend appears to be evident on a national basis among blood donors. As noted the prevalence data in this report failed to show a significant increasing trend among all donors. In a separate Australian analysis of donor HIV incidence trends measured by the rate of HIV seroconversion in repeat blood donors, Seed and colleagues[33] reported a low and stable incidence rate in the range 0 to 0.4 per 100,000 donations, with no discernible trend for the Period 2000 to 2006.

To investigate whether the change to a 12-month deferral for MSM in Australia resulted in an increase in the *proportion* of HIV-positive donors with male-to-male sex as a risk factor, the records of confidential interviews conducted with HIV-positive donors[3] exploring potential risk factors were retrospectively analyzed. While the analysis showed an increase in the proportion of HIV-positive donors declaring MSM as a risk in the period subsequent to the implementation of the 12-month MSM deferral policy (Period 2) compared to the period before implementation (Period 1), this increase was not significant. However, the possibility that this increase, albeit not significant, was due to the change in the MSM deferral policy attracting additional HIV-positive donors cannot be excluded. These findings are consistent with the experience in Italy where Velati and coworkers[27] also found a nonsignificant increase in the proportion of HIV-positive donors with MSM as a disclosed risk, after discontinuing their MSM deferral policy in 2001.

The finding that all five HIV-positive donors in Period 2 who disclosed male-to-male sex as a risk were "noncompliant" according to the revised MSM deferral policy is very important; that is, their nondisclosed risk activity occurred within 12 months of donation. Had they disclosed this at the time of donation it would have led to their deferral and mitigated the risk of collecting an HIV-positive donation. In other words, the failure of the MSM deferral question itself to exclude these donors was unrelated to the duration of the deferral per se but rather a failure of the donor to correctly recall or, more likely, disclose the risk behavior. The exact reason for nondisclosure in these five cases was not able to be determined

from the interview records. However, a previous Blood Service[3] study with some overlap in study participants identified several motivational factors for noncompliance among viral-positive, accepted blood donors including temporal remoteness of the risk, perception that laboratory testing rendered disclosure unnecessary, and consideration that the question did not apply to episodes involving condom use. Importantly, the authors noted that no positive donor had donated for the purpose of obtaining testing (so call "test-seeking" behavior). Several other studies based on anonymous donor surveys[30,34-36] or retrospective interview of viral-positive donors[3,37,38] have identified the importance of such "nondisclosure of deferrable risk" on the efficacy of deferral policies. The overall incidence of nondisclosure among *all donors* is difficult to estimate but available studies suggest a rate of 0.2% to 2%.[34-36] In the context of MSM, Sanchez and colleagues[30] in the United States reported that in a survey of more than 25,000 male donors 1.2% of current donors were MSM since 1977 (i.e., were donating despite being ineligible). The comparative UK figure for nondisclosure among MSM appears even higher. A UK national survey of sexual attitudes and lifestyles identified that at least 7% of MSM respondents (who are subject to permanent deferral from blood donation) reported donating blood after sex between men.[39] In relation to the risk of HIV in blood donors, a recent report to the UK Advisory committee on the safety of blood, tissues, and organs noted that approximately 20% of all HIV-positive donors and 40% of incident (seroconverting) donors later reported sex between men as a probable route of infection.[39] In a previous Blood Service study, Polizzotto and colleagues[3] identified that 22% of donors who tested positive for a transfusion-transmissible viral infection subsequently disclosed risk exposure that would have resulted in their deferral if reported during the predonation interview. In a recent study of nondisclosure among donors with a history of intravenous (IV) drug use O'Brien and colleagues[34] reported that 0.2% donors surveyed overall, but almost 10% of HCV-positive donors failed to disclose a history of IV drug use despite a lifetime deferral applying in Canada. The consensus interpretation of these studies is that some degree of nondisclosure is inherent in the process of predonation screening.

The level of compliance to any existing MSM deferral policy is also paramount in the context of the precision of the risk modeling undertaken to assess the risk of changing the policy. In the most recent predictive modeling for the United States, Anderson and colleagues[28] identified the percentage of donors with an undisclosed MSM risk within the previous 5 years (one of the possible revised MSM deferral options) who were already donating was the most influential factor affecting the quantity of additional HIV-infectious donations predicted to enter the blood supply. This underscores the importance of maximizing the compliance rate among existing donors in the context of risk minimization.

We interpret our findings to indicate that the overall sensitivity (in terms of excluding HIV-positive donors) of the MSM deferral question is less dependent on the duration of deferral than the level of compliance with it. Therefore, we contend that the five noncompliant donors identified after the change in deferral policy represent the "baseline" level of noncompliance inherent in the system.

The HIV residual risk is almost entirely associated with donations taken from donors in the very early phase of infection (the so called "window period" [WP]).[40] Importantly, as highlighted by Vamvakas[22] all cases of HIV infection result in the development of detectable HIV antibody, p24 antigen, and/or HIV RNA within 12 months.[41-43] The implementation of HIV-1 NAT in Australia in 2000[44] reduced the estimated HIV WP from approximately 22 days (for the existing HIV antibody assay) to approximately 9 days.[45] Thus a 12-month deferral for MSM provides for a substantial safety margin. As discussed, the key issue is compliance to the policy, which ensures that any HIV-positive donors with a recent MSM risk will "self-defer" thus removing the risk to the blood supply. Indeed it was the improvement in HIV testing methods by the early 1990s, which underpinned the original Australian policy change. Likewise the reduction in the HIV WP from combined antibody and RNA testing is cited by AABB, American Red Cross, and America's Blood Centers in their joint statement advocating for a change in the MSM deferral policy in the United States to 12 months:[19] ". . . current duplicate testing using NAT and serological methods allow detection of HIV-infected donors between 10 and 21 days of exposure. Beyond this window period, there is no valid scientific reason to differentiate between individuals infected a few months or many years previously."

In terms of the residual risk of HIV infection in Australia, modeled estimates indicate a declining trend since commencement of the 12-month MSM deferral in the first jurisdiction in 1996. A 1994-1995 study by Whyte and Savoia[46] estimated the residual risk in Victorian donors to be approximately 1 in 1.3 million. The HIV residual risk estimate for more than 450,000 Australian repeat donations (representing approx. 50% of the national total) collected during 1997 in Victoria, South Australia, Tasmania, Queensland, and the Northern Territory declined to approximately 1 in 4.6 million.[47] In the inaugural national study covering all Australian jurisdictions, Seed and colleagues[48] estimated the HIV residual risk during 2000 to 2001 (after HIV NAT commenced) to be approximately 1 in 3.4 million. In a subsequent study for the 3-year Period 2000 to 2003, the risk had declined further to approximately 1 in 7.3 million.[1] While these are modeled estimates, it should be noted that only a single transfusion-transmitted HIV case has been recorded in Australia (1998 in Victoria) since universal HIV testing

commenced in 1985.[49] Notably the implicated donation was made by a female, repeat donor who had recently begun a new relationship with an immigrant from a high-HIV-prevalence country who subsequently tested positive for HIV antibody. Taken together, these data indicate that the overall recipient risk for HIV (as measured by the modeled residual risk estimates, rate of seroconversion, and rate of observed breakthrough infections) was not adversely impacted by the implementation of the 12-month MSM deferral.

There are several limitations to this analysis. First, during the 10-year period covered by this study a number of blood safety–related interventions were implemented. These interventions may have affected the blood donor HIV prevalence, thereby obscuring any impact due to the MSM deferral change. Second, during the study period there was a "sliding" implementation of the revised MSM deferral, which resulted in differing observational periods in each jurisdiction. Third, there has been a trend to earlier HIV diagnosis in Australia,[12,50] which may have resulted in an increased "self-deferral" rate among HIV-positive individuals resulting in a decline in the number of HIV-positive donors presenting to donate. A fourth limitation relates to the previously noted trend of declining HIV residual risk (RR) estimates. Finally, the modeling method and key assumptions used to estimate RRs have been refined over time and therefore caution is required when comparing RRs from different periods.

Notwithstanding these limitations there is no evidence that the implementation of the 12-month MSM deferral resulted in an increased recipient risk for HIV in Australia. However, because the epidemiology of HIV differs between countries and donor populations, this finding may not necessarily translate to other donor populations. Given the advances in HIV testing methods which have substantially reduced the WP to less than 10 days, the risk of noncompliance to the MSM deferral rather than its duration appears to be the most important modifier of overall risk in the Australian context. Thus understanding the reasons for noncompliance and implementing appropriate strategies to minimize this should provide the most effective approach to further reduce the already very small HIV residual risk in Australia.

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CONFLICT OF INTEREST

The authors declare they have no conflicts of interest relating to the manuscript submitted to **TRANSFUSION**.

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