

E-mail Message

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To: DL-RegulatoryAffairs [SMTP:DL-RegulatoryAffairs@redcrossblood.org.au]
Cc: [REDACTED]@tga.gov.au
Sent: 16/10/2013 at 3:53 PM
Received: 16/10/2013 at 3:54 PM
Subject: MSM compliance article

Attachments: Seed et al- Compliance to MSM deferral-Vox Sang (DOI 2013).pdf

Dear [REDACTED],

For your information, please find attached the final pre-published version of the MSM compliance article which has just appeared on the Vox "Early view" site.

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Regards

[REDACTED]

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[REDACTED]
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- Seed et al- Compliance to MSM deferral-Vox Sang (DOI 2013).pdf

Compliance with the current 12-month deferral for male-to-male sex in Australia

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Vox Sanguinis

Background and Objectives In Australia since 2000, donors are deferred for 12 months since last male-to-male sexual contact. There is no estimate of the prevalence of non-compliance (i.e. failure to disclose a risk during the predonation interview which would lead to deferral) with the policy in Australia; however, published studies elsewhere indicate a range of 0.8–11%. We investigated the rate of, timing and motivation for non-compliance.

Materials and Methods A nationally representative sample of donors who had made a recent donation negative for transfusion-transmissible infection testing was surveyed using an anonymous, online instrument. Non-compliance was considered as a 'yes' response to the current screening question. Non-compliers were requested to define the timing of the last sexual contact relevant to their most recent donation. Univariate and multivariate regression analyses were used to define factors associated with non-compliance.

Results Of 14 476 responses from male donors, 34 (0.23%, 95% CI: 0.16–0.33%) were non-compliant of whom 24 (0.17%, 95% CI: 0.11–0.25%) had contact within 6 months of donation. Factors significantly associated with non-compliance included: multiple sexual partners, history of injecting drug use, perception of a lack of privacy during interview and preference for a computer-based questionnaire.

Conclusion Our study confirms high compliance (>99.7%) to the 12-month deferral for male-to-male sex in Australia providing reassuring evidence for the efficacy of the screening question. Issues of 'privacy' and 'discomfort' associated with disclosure suggest the use of validated audio computer-assisted structured interview as a possible option for improving compliance with the donor questionnaire.

Key words: donors, epidemiology, transfusion-transmissible infection.

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Introduction

Deferral of men who have sex with men (MSM) has been the subject of ongoing debate since first application in the early 1980s in response to the observation that HIV disproportionately affected MSM [1–6]. More recently, especially with the improvement in the variety and sensi-

tivity of screening tests for infectious disease, opponents cite permanent deferral for male-to-male sex – which is currently based on risk behaviour, but not sexual orientation as discriminatory against gay and bi-sexual men [7,8]. The majority of blood services worldwide continue to defer donors for male-to-male sexual contact on safety grounds for a period ranging from 6 months to permanent [9]. In Australia, MSM are currently deferred for 12 months since last sexual contact, and this policy has applied nationwide since 2000 [10]. The policy remains

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controversial and has been the subject of several unsuccessful legal challenges, the most recent in 2009 [11].

The rationale for ongoing deferral for male-to-male sex relates to the limitation of tests for transfusion-transmissible infections (TTI) including HIV and HBV which are unable to detect donors with very recently acquired infection [known as the testing 'window period' (WP)]. However, screening questions targeting high-risk behaviours for TTIs (e.g. intravenous drug use or recent high-risk sexual contact) can potentially identify such donors and their deferral prevents TTIs. The efficacy of this strategy is directly dependent on the donor's full and frank disclosure (termed 'compliance') when answering the relevant screening question on the predonation questionnaire. Non-compliance is detrimental to blood safety, and understanding the motivations for and rate of non-compliance among donors provides an important safety metric. Anonymous donor surveys investigating compliance to permanent deferral policies for male-to-male sex have been conducted in a number of countries including the USA [12], UK [13] and Canada [14] with non-compliance ranging from 0.8 to 10.6%. Follow-up interviews with HIV-infected (i.e. test-positive) donors in Australia for the 2000–2006 period indicated a non-compliance rate for male-to-male sex of approximately 27% [15], comparable to a recent UK report of 25% [16]. More recently, the overall non-compliance rate for high-risk behaviours among HIV-, HCV-, HBV- and HTLV-infected donors in Australia declined from 24.4% in 2008 to 12.9% in 2011 [17], which is comparable to the 11% reported in UK donors during 2011 [16]. However, the non-compliance rate among donors testing TTI negative (which would include any in the WP) has not been assessed in Australia.

We previously validated the comparative safety of the current Australian 12-month deferral for male-to-male sex in respect of the risk of HIV transmission [10]. No significant increase in the number of donors with HIV or the proportion with male-to-male sex as a risk was evident when comparing 5-year periods before and after the implementation of the current deferral. The finding from this study that all five HIV-positive donors identified in the 5 years after implementation were non-compliant (i.e. had contact within 12 months and thus should have self-deferred) highlighted that in terms of the risk of collecting an HIV-positive donation, compliance with the deferral policy appears to be more influential than the duration of the deferral itself. This hypothesis has since been supported by other investigators in Sweden [18], France [19] and the UK [20].

The Australian Blood Service nationally applicable donor selection criteria are evidence-based, reviewed annually and approved by the Australian Competent Authority (Australian Therapeutic Goods Administration).

In response to allegations of discrimination, the Blood Service undertook an independent, expert review of sexual-activity-based deferral policies including those for male-to-male sex, sex with a bi-sexual male, sex work/sex with a sex worker and sex with a resident of, or new partner from a high-HIV-risk county. This expert review committee has since recommended that the current 12-month deferral for all these sexual-activity-based deferrals including male-to-male sex could safely be reduced to 6 months. The selection of a 6-month period was principally based on a review of the testing window periods for HIV, HBV and HCV, the predominant sexually transmissible TTIs in Australia. The window periods for tests currently applied in Australia to screen for these TTIs are all well within 6 months allowing for a comfortable 'margin for error' consistent with the public expectation of maintaining a precautionary approach in matters impacting recipient safety. Among additional suggested research by the review committee was an anonymous donor study assessing the rate of compliance with the existing deferral, the results of which should be considered by the Blood Service before any change is implemented [21].

In this report, we describe a subset of data from an online, anonymous survey of volunteer Australian donors who had recently donated a TTI-negative donation. The primary aim of the survey was to provide a reliable estimate of the rate of, and timing in relation to last donation of non-compliance with the current 12-month deferral for male-to-male sex although we also took the opportunity to assess compliance with other sexual-activity-based deferrals and donor attitudes to our current predonation assessment process (to be reported separately).

Materials and methods

Study participants

The study sample comprised 30 274 (14 476 men and 15 798 women) Australian blood donors who had made at least one successful donation within 6 weeks of invitation to the study. For the purpose of this research, a successful donation was defined as having satisfactorily completed the donor assessment process including completion of the predonation questionnaire, formal interview and signature of a legally binding statutory declaration together with negative mandatory TTI test results (see below). To optimise privacy during donation assessment, formal one-on-one interviews are conducted between the donor and assessor in dedicated interview rooms wherever possible. In a minority of collection sessions where a dedicated room is unavailable, a designated area ensuring 'auditory privacy' is required to conduct assessment interviews. This requirement is

audited by collection site managers prior to the commencement of collection sessions.

Donors with positive or incomplete mandatory test results, sample only collections, therapeutic venesections (i.e. patients) and/or autologous collections were excluded from the study. The participant group was a convenience sample stratified against the national blood donor panel on age, gender, donation experience and state of residence to provide a nationally representative sample.

Mandatory TTI testing

All donors in the study were tested for HBsAg, anti-HCV, anti-HIV 1 and 2, anti-HTLV I and II using the Abbott PRISM HBsAg, anti-HCV, HIV 1-2 O plus or anti-HTLV I/II chemiluminescent immunoassays (ChLIA) (Abbott Diagnostics, Delkenheim, Germany). Additionally, all donations were tested for HIV-1 RNA, HCV RNA and HBV DNA individually with the PROCLEIX ULTRIO (HIV-1/HCV/HBV multiplex) assay (Ultrio) on the PROCLEIX TIGRIS (Tigris) automated system (Gen-Probe/Novartis Diagnostics, San Diego/Emeryville, CA, USA) and antibodies to *Treponema pallidum* using the Beckman Coulter PK automated microplate system (Beckman Coulter, Tokyo, Japan) using the *Treponema pallidum* microhaemagglutination test (Fujirebio Inc, Tokyo, Japan).

Survey method

The Blood Service sent a total of 98 044 email invitations to eligible participants inviting them to complete the survey. Among the 98 044 invitations, 16 934 were to first-time donors (7739 men and 9195 women) and 81,110 to repeat donors (39 479 men and 41 631 women). Monthly batches of invites were sent starting from November 2012 concluding April 2013. In addition, an automated reminder email was sent to participants 1–2 weeks after the initial email. These strategies were successful with the study achieving an overall response rate of 31.4%.

The survey instrument was created using Survey Gizmo a secure online research tool. The decision to use an online survey was made in order to reduce project costs and to increase the accuracy of participant responses. Research indicates that validity of responding to sensitive questions is increased when participants feel able to report anonymously [22].

The survey collected information on demographics, perceptions of the current Blood Service interview process and information related to the specific risk factors of interest. In this report, we consider a subset of

responses from the survey, specifically those relating to male-to-male sex and the assessment of the effectiveness of the screening materials and process (similar to the method of Goldman *et al.* [14]). The survey instrument was designed using skip logic such that questions appeared individually, with the response driving the subsequent question posed. The maximum number of questions posed to a participant was 32. The survey was designed such that a valid response was required before the next question was presented. The option for participants to track back through the survey was provided so that an erroneous response could be retrospectively corrected by the donor.

A link to the secure survey was sent as a component of the email invitation from the Blood Service. The survey link was restricted so that it could only be used once to avoid multiple submissions either from the same invitee or from any others that might be forwarded the invitation email. If a donor experienced problems using a restricted survey link, they were given the option to use a generic link. Researchers monitored the number of responses received from restricted links (total responses from restricted links: 30 443, of which 516 were excluded from analyses including 455 where no matching invitation link existed) vs. generic links (total responses from generic links: 347) and are confident that the overall sample reflects an unbiased estimate of donor compliance that has not been affected by multiple submissions.

Consent

Participants were required to read an information statement and had to signal agreement to participation before gaining access to the survey. As the survey was anonymous, the ability to withdraw consent and survey responses was not available. Whilst links to the survey were sent by the Blood Service, responses were collected by the Kirby Institute using Survey Gizmo ensuring anonymity of responses. Statistical analyses of the data were conducted by the Kirby Institute. The survey protocol was approved by both the Australian Red Cross Blood Service and the University of New South Wales Human Research Ethics committees.

MSM survey questions

The current Blood Service predonation questionnaire contains a specific question designed to capture male-to-male sexual contact. This question was included verbatim in the survey with 'yes' responses (i.e. non-compliers) requested to define within the 12-month period the timing of the contact (see below).

Question	Responses
If participant is male:	a. Yes
In the last 12 months, have you had male-to-male sex (that is, oral or anal sex) with or without a condom?	b. No
	If you have answered Yes to the above question, when was the most recent time you had sex with a man <i>prior</i> to your last donation?
	a. Within 1 month
	b. Within 6 months, but not within 1 month
	c. Within 12 months, but not within 6 months

Non-compliance

Male donors who reported male-to-male sexual contact (either oral/anal with or without condom) within 12 months prior to their most recent donation are defined as non-compliant with the current deferral for male-to-male sex. The timing of this non-compliance in relation to their most recent donation was requested to allow an analysis of a potential change to the duration of the deferral to 6 months.

Data analysis and statistical methods

We derived the prevalence (95% confidence intervals) of non-compliance among male donors who had reported having sex with men overall and by donor status (first-time vs. repeat donors). Descriptive statistics were used to compare socio-demographic characteristics for compliant donors including age, state/territory of current residence, country of birth (Australian born vs. not), language spoken at home (English vs. others), level of education (high school vs. less than high school) as well as sexual behaviours, with those who were designated as non-compliant. Chi-square and Fisher's exact (when observed cell counts <5) tests were used to compare the categorical variables. Unadjusted and adjusted odds ratios (AORs) (and 95% confidence intervals) were used with multivariate regression modelling to determine the factors that were more likely to be associated with non-compliance. *P* values <0.05 were considered significant.

Results

Non-compliance rate

Among the 14 476 responses from male donors, 34 (0.23%, 95% CI: 0.16–0.33%) were non-compliant (Table 1). Among first-time donors, 2/1290 (0.16, 95% CI 0.02–0.56%) were non-compliant compared with 32/13 186 (0.24, 95% CI 0.17–0.34%). The difference was

not statistically significant ($P = 0.76$). However, among repeat donors, the prevalence of non-compliance was significantly greater among those who donated two to five times prior to the survey (12/2355, non-compliance: 0.51%) compared with those who donated more than five times (20/10 831, non-compliance: 0.18%, $P = 0.004$).

Timing of non-compliance

Of the 34 non-compliant donors, 24 (71%) responded that the sexual contact occurred within 6 months of their last donation (Table 2). Had a 6-month deferral applied at the time, and assuming no other change in donor behaviour then the non-compliance rate would be 24/14 476 (0.17%, 95% CI: 0.11–0.25%).

Factors associated with MSM non-compliance

Table 3 summarizes results from univariate and multivariate logistic regression analyses of factors associated with non-compliance. After adjusting for other variables, significant association was found between following factors and non-compliance:

- (1) Age: Older donors were less likely to be non-compliant (AOR for donors aged 30–49 years: 0.1, 95% CI: 0.03–0.31, $P < 0.0001$; AOR for donors aged 50 years or above: 0.19, 95% CI: 0.07–0.52, $P = 0.001$).
- (2) Education: Donors with education at a level lower than high school were four times more likely to be non-compliant (AOR: 4.05, 95% CI: 1.47–11.18, $P = 0.007$).
- (3) Perception about personal questions asked: Donors who felt that some questions within the predonation questionnaire were too personal and should not be asked were more likely to be non-compliant compared with others (AOR: 6.76, 95% CI: 1.22–37.34, $P = 0.028$).
- (4) Privacy: When compared with those who felt that privacy was sufficient whilst answering questions in the predonation questionnaire at their last donations, donors who felt that privacy was not enough were 4.8 times more likely to be non-compliant (AOR: 6.99, 95% CI: 2.56–19.11, $P < 0.001$).
- (5) Comfortable raising questions with interviewers: Donors who would not be comfortable were 2.8 times more likely to be non-compliant (AOR: 4, 95% CI: 1.7–9.38, $P = 0.002$).
- (6) Preference for a computer-based questionnaire: Donors who reported that they would prefer a computer-based questionnaire were more likely to be non-compliant compared with those who reported that they would not (AOR: 2.92, 95% CI: 1.36–6.24, $P = 0.006$).

Table 1 Socio-demographic characteristics of self-reported compliant^a and non-compliant^b male donors, by donor status

	First-time donors		Repeat donors	
	Self-reported compliers Number (%)	Self-reported non-compliers Number (%)	Self-reported compliers Number (%)	Self-reported non-compliers Number (%)
Age groups (years)				
≤29	642 (49.8)	2 (100)	2146 (16.3)	21 (65.6)
30–49	447 (34.7)	0 (0)	4578 (34.8)	5 (15.6)
≥50	199 (15.5)	0 (0)	6430 (48.9)	6 (18.8)
State/Territory				
ACT	37 (2.9)	0 (0)	464 (3.5)	0 (0)
NSW	339 (26.3)	0 (0)	3824 (29.1)	15 (46.9)
NT	11 (0.9)	0 (0)	94 (0.7)	0 (0)
Qld	284 (22.1)	0 (0)	2646 (20.1)	7 (21.9)
SA	111 (8.6)	1 (50)	1266 (9.6)	5 (15.6)
Tas	33 (2.6)	0 (0)	382 (2.9)	0 (0)
Vic	326 (25.3)	0 (0)	3260 (24.8)	3 (9.4)
WA	147 (11.4)	1 (50)	1218 (9.3)	2 (6.3)
Country of birth				
Australia	882 (68.5)	1 (50)	10 574 (80.4)	29 (90.6)
Others ^c	406 (31.5)	1 (50)	2580 (19.6)	3 (9.4)
Main language spoken at home				
English	1087 (84.39)	1 (50)	12 638 (96.1)	29 (90.6)
Others	201 (15.61)	1 (50)	516 (3.9)	3 (9.4)
Highest level of education				
High school or more	1045 (81.1)	2 (100)	12 058 (91.7)	26 (81.3)
Less than high school ^d	243 (18.9)	0 (0)	1096 (8.3)	6 (18.8)
Total (as row percentage)	1288 (99.8)	2 (0.2)	13 154 (99.8)	32 (0.2)

^aSelf-reported compliers: Male donors who answered No to the following question: In the last 12 months, have you had male-to-male sex (that is, oral or anal sex) with or without a condom?

^bSelf-reported non-compliers: Male donors who answered Yes to the following question: In the last 12 months, have you had male-to-male sex (that is, oral or anal sex) with or without a condom?

^cIncludes Unknown.

^dIncludes None of the above.

- (7) History of injecting drug use: Donors who disclosed 'ever injecting/being injected drugs not prescribed a doctor/dentist' were more likely to be non-compliant than those who reported that they never injected drugs (AOR: 13.35, 95% CI: 1.4–127.52, $P = 0.024$).
- (8) Number of sexual partners in 12 months prior to last donation: Compared with those who had one or no sexual partner in 12 months prior to last donation, donors with two to four sexual partners were more than 10 times (AOR: 10.5, 95% CI: 4.54–24.31, $P < 0.0001$) and donors who had 5 or more sexual partners were almost 10 times more likely to be non-compliant (AOR: 9.87, 95% CI: 3.02–32.26, $P < 0.001$).

Discussion

Our study is the first to estimate the rate of non-compliance with a 12-month deferral for male-to-male sex. Our

rate of 0.23% among a large sample of male donors is reassuring evidence that the current screening question used in Australia is well understood and there is high 'compliance' with the deferral policy. The high compliance rate (99.77%) is important given accumulating opinion that compliance to the deferral is the most influential factor on the overall HIV transmission risk [10, 18–20].

Our non-compliance rate is substantially lower than published estimates based on anonymous donor surveys investigating compliance to male-to-male sex deferral policies from the USA (1.2%), Canada (0.8–1.4%) and the UK (10.6%). Using an anonymous, mailed survey of male donors from five US collection sites Sanchez *et al.* [12] identified 280/25 168 (1.2%) of respondents who disclosed male-to-male sex since 1977 (i.e. non-compliant with their existing policy of permanent deferral for any male-to-male sexual since 1977). A minority, 92 (0.36%) of the 280 non-compliant donors had donated within the previous 12 months. Goldman *et al.* [14] undertook an

Table 2 Relationship between non-compliance^a and number of sexual partners

	Non-compliant male donors			
	Within 6 months		Within 12 months, but not within 6 months	
	Number	% (95% CI)	Number	% (95% CI)
Number of sexual partners in the 12 months prior to the last donation				
One	8	33.33 (15.63–55.32)	5	50 (18.71–81.29)
2–4	11	45.83 (25.55–67.18)	4	40 (12.16–73.76)
5 or more	5	20.83 (7.13–42.15)	1	10 (0.25–44.5)
Total (% by row)	24	70.6 (52.5–84.9)	10	29.4 (15.1–47.5)

^aMale donors who answered Yes to the following question: In the last 12 months, have you had male-to-male sex (that is, oral or anal sex) with or without a condom?

anonymous, mailed survey of 18 000 Canadian blood donors who donated blood during 2008 to assess the attitudes to current sexual-activity-based questions including male-to-male sex deferral. The authors found that the rate of non-compliance with the male-to-male sex question was 0.8–1.0% in repeat donors and 1.3–1.4% in first-time donors. As a component of a large population based survey of sexual attitudes, Grenfell *et al.* [13] identified a non-compliance rate of 10.6% under the existing permanent male-to-male sex deferral in the UK of whom 2.5% disclosed contact within the last 12 months. This study was used as supporting evidence for a predicted lower non-compliance rate under a proposed 12-month deferral for male-to-male sex which was subsequently implemented by the Blood Services in the UK (excluding Northern Ireland) in November 2011 [23].

All the above studies assessed the rate of non-compliance in the context of a permanent deferral for male-to-male sex, whereas our estimate is derived in the context of a temporary, 12-month deferral since last contact. This may in part explain why our rate is lower since under a permanent exclusion, donors with remote contact, even a single event, are compelled to disclose this and, if so are permanently deferred. Previous studies have identified that donors with remote risk behaviour found disclosure in these circumstances particularly difficult and 'non-compliance' is comparatively higher among these donors [13, 15, 24]. The perception of the policy of permanent deferral for male-to-male sex as 'discriminatory' has also been identified as a potential motivator for non-compliance [13]. Supporting the above, Grenfell *et al.* reported an overall non-compliance rate of 10.6% to the permanent deferral in place at the time; however, only 2.5%

had donated in the previous 12 months. Similarly, in the study by Sanchez *et al.* [12], 1.2% of donors were non-compliant to the permanent deferral for contact since 1977; however, only 0.36% had donated in the past 12 months. Assuming no other change in behaviour, the majority of non-compliers in both studies would become eligible under a 12-month deferral substantially reducing the non-compliance rate to levels approaching our observed rate. Another possible contributor to the lower non-compliance rate observed in our study is the requirement for Australian donors to sign a legally binding statutory declaration as part of the predonation assessment.

To achieve a further reduction in non-compliance, an understanding of the factors associated with non-compliance is required. One factor in our study was the number of prior donations among repeat donors. Whilst intuitively it might be expected that non-compliance would be more likely among first-time donors, we observed the opposite although the difference was not significant. However, when repeat donors were analysed separately grouped into those with '2-5 prior donations' or 'more than 5 prior donations', the non-compliance rate was statistically higher in those with two to five prior donations. We are unable to provide a definitive explanation for this, but one possible reason is that as donors become more 'engaged' and knowledgeable about blood donation and in particular the risks and consequences to blood recipients of non-disclosure, non-compliance becomes progressively less likely. Our regression analysis also identified a number of other significantly associated factors. Non-compliers were more likely to be young (<30 years), less educated and have multiple sexual partners. They were also more likely to consider that screening questions were 'too personal' in nature, that 'privacy' during the interview was insufficient and that they were less comfortable raising questions with interviewers. Perhaps because of these concerns, they had a significant preference for a computer-based questionnaire. Non-compliers were also more likely to have a history of injecting drug use (IDU) which is subject to permanent deferral in Australia. Consistent with our findings, Sanchez *et al.* [12] reported that younger age (mean 36.6 years), multiple partners and IDU were significantly associated with non-compliance in their study. In the UK study of Grenfell *et al.* [13], young age (18–34) and lower education level (incomplete primary or secondary) were factors significantly associated with non-compliance.

Several studies have identified that audio computer-assisted structured interview (ACASI) improves risk behaviour reporting from donors who previously failed to disclose risks during written or face-to-face questionnaires. [25–29] In a recent study of HIV-negative Brazilian donors assessed in parallel using a paper-based questionnaire and

Table 3 Factors^a associated with non-compliance to the 12-month deferral for male-to-male sex

Factors	Unadjusted odds ratio (95% CI)	P value	Adjusted odds ratio (95% CI)	P value
Age group (years)				
≤29	1 (ref)		1 (ref)	
30–49	0.12 (0.05–0.32)	<0.0001	0.1 (0.03–0.31)	<0.0001
≥50	0.11 (0.05–0.27)	<0.0001	0.19 (0.07–0.52)	0.001
Highest level of education				
High school or more	1 (ref)		1 (ref)	
Less than high school ^b	2.1 (0.87–5.08)	0.100	4.05 (1.47–11.18)	0.007
Questions were too personal and should not be asked ^b				
No	1 (ref)		1 (ref)	
Yes	19.57 (4.56–84.04)	<0.0001	6.76 (1.22–37.34)	0.028
Privacy was enough whilst answering questions ^c				
Yes	1 (ref)		1 (ref)	
No	19.64 (9.08–42.48)	<0.0001	6.99 (2.56–19.11)	0.0001
Feel uncomfortable raising question ^c				
No	1 (ref)		1 (ref)	
Yes	9.47 (4.64–19.33)	<0.0001	4 (1.7–9.38)	0.002
Not applicable	0.41 (0.06–3.03)	0.381	0.28 (0.04–2.18)	0.223
Prefer a computer-based donor questionnaire form ^c				
No	1 (ref)		1 (ref)	
Yes	3.56 (1.81–7.01)	0.0002	2.92 (1.36–6.24)	0.006
Number of sexual partners ^d				
None/One	1 (ref)		1 (ref)	
2 to 4	19.41 (9.2–40.93)	<0.0001	10.5 (4.54–24.31)	<0.0001
5 or more ^e	25.89 (9.76–68.69)	<0.0001	9.87 (3.02–32.26)	0.0001
History of ever injecting drug				
No	1 (ref)		1 (ref)	
Yes ^f	7.93 (1.07–58.98)	0.043	13.35 (1.4–127.52)	0.024

^aFactors showing significant associations in adjusted analysis are presented only. Results are further adjusted for the following factors/variables:

Donor status: First time (ref) vs. Repeat; Language spoken at home: English (ref) vs. Others.

Born in Australia: Yes (ref) vs. No; Donor read all/some background material during last donation: Yes (ref) vs. No; Sex worker activity (in 12 months prior last donation): No (ref) vs. Yes; Sex worker contact (in 12 months prior last donation): No (ref) vs. Yes; History of sexual activity with an IDU r (in 12 months prior last donation): No (ref) vs. Yes; History of sexual activity with someone from high-HIV-prevalence country (in 12 months prior last donation): No (ref) vs. Yes; Donated blood to be tested for infection: No (ref) vs. Yes.

^bIncludes donors who reported None of the above.

^cDonors self-reported experience at last donation.

^dDonors self-reported behaviour in 12 months prior to last donation.

^eIncludes donors who answered Not sure when asked how many sexual partner they had in 12 months prior last donation.

^fIncludes donors who answered I do not know when asked whether sexual partner was from a high prevalence country.

^gIncludes donors who answered I do not know when asked whether sexual partner had a history of injecting drug use.

ACASI, the latter identified 120 donors non-compliant for a number of risk factors including 10 who disclosed male-to-male sex [29]. The accumulating evidence that ACASI is an effective tool to improve compliance is a compelling reason to consider it as a possible improvement to our donor assessment procedure. A feasibility study has already been undertaken in Australia; however, a final decision on implementation is dependent on further validation of the effectiveness compared with the current system.

How do we interpret our data in the context of a possible policy change to a 6-month deferral for sexual-activity-based deferrals including male-to-male sex as recommended by

the Australian expert review committee? There are two reasons we believe compliance would marginally improve under a shorter deferral. First, some current non-compliers (i.e. 10/34 or 29% of non-compliers to the male-to-male sex question in this study) become eligible under a 6-month deferral directly reducing the non-compliance rate. Secondly, a shorter deferral will be perceived as more equitable which will reduce the motivation for non-compliant donors who may be doing so in 'protest' against what they perceive as an unfair policy. Importantly, the perception of 'policy equity' needs to be optimized by maintaining Australia's existing approach of a consistent period of

deferral (either 6 months or 12 months) for all sexual-activity-based deferrals.

Our study has several limitations. It is possible that non-compliant donors disproportionately 'opted out' of completing the survey which would tend to underestimate the true rate of non-compliance. Whilst the anonymous nature of the study should minimize this, we concede that our estimates represent minimum estimates of non-compliance. Importantly, all comparable prior studies are subject to the same limitation. Secondly, first-time male donors were slightly under-represented in our sample reflecting their lower response rate (16.7%) compared with 33.4% among repeat donors (data not shown). Given this lower response rate is consistently observed in other Blood Service donor surveys and considering the relatively large sample size of the current survey, we do not believe that this was a significant confounder. Finally, whilst the use of email is convenient and facilitates anonymity, we cannot exclude potential selection bias should donors with email access have different response characteristics than those without email access. We believe that any bias is minimal given a large proportion (66%) of our donors had current email addresses during the invitation period.

Our study confirms high compliance with the 12-month deferral for male-to-male sex in Australia which is reassuring evidence for the efficacy of the screening question as well as the overall donor assessment process. We identified

a number of factors associated with non-compliance which provide a focus for refinements to further reduce the non-compliance rate. Given 'privacy' and 'discomfort' associated with disclosure were key themes, the use of ACASI is a possible option for a revised donor questionnaire; however, this requires local validation.

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Author contributions

All authors contributed to the study design including the content of the online survey tool. Sample size calculations and statistical analysis were undertaken by DPW, DW, TL and HW. DW and SW co-ordinated the sampling plan and invitation of donors. TL co-ordinated response collection and analysis. CS, TL, JL, JP, DPW and DW drafted the article which was reviewed and approved by all authors.

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