

## E-mail Message

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**From:** [REDACTED]@redcrossblood.org.au  
**To:** [REDACTED]@tga.gov.au  
**Cc:** [REDACTED]@tga.gov.au, [REDACTED]@redcrossblood.org.au, DL-RegulatoryAffairs [SMTP:DL-RegulatoryAffairs@redcrossblood.org.au]  
**Sent:** 9/05/2013 at 11:43 AM  
**Received:** 9/05/2013 at 11:44 AM  
**Subject:** Submission for proposed changes to the GSBD for Sexual Activity-Based Deferrals (Blood Service Ref: RR13-047 )

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**Attachments:** RR13-047 Submission.pdf  
 Submission paper for sexual activity based deferrals 02 May.pdf

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Dear [REDACTED],

Further to my letter of 26 April 2013 detailing the review of the Guidelines for the Selection of Blood Donors (GSBD), please find attached the submission for proposed changes to the GSBD in relation to sexual activity-based deferrals.

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A copy will also be sent by post, including a copy of the references.

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Regards

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 Australian Red Cross Blood Service  
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P: [REDACTED] I F: 08 6213 5949 I M: [REDACTED]

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- RR13-047 Submission.pdf - Submission paper for sexual activity based deferrals 02 May.pdf



**Australian Red Cross  
BLOOD SERVICE**

<b>FOR THE ATTENTION OF</b>  [REDACTED] Cell and Tissue Therapy Unit Biological Science Section Office of Scientific Evaluation Therapeutic Goods Administration PO BOX 100 WODEN ACT 2606	<b>COPY TO</b>  [REDACTED] Inspection Group Manager – Blood, Tissues, Cellular Therapies & Medicines B Office of Manufacturing Quality Therapeutic Goods Administration PO Box 100 WODEN ACT 2606
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**Submission for proposed changes to the Guidelines for the Selection of Blood Donors (GSBD) for Sexual Activity-Based Deferrals (Blood Service Ref: RR13-047 )**

**Date of submission: 9 May 2013**

<b>Summary Information</b>
Current Guidelines: A 12 month deferral is applied for the following sexual activity-based activities <ul style="list-style-type: none"><li>• male-to-male sex</li><li>• bisexual contact (a woman who has had sex with a man who has had sex with a man)</li><li>• sex worker</li><li>• sex worker contact (sex with a male or female sex worker)</li><li>• sexual contact with a new partner who has lived in a high HIV risk country</li><li>• sexual contact while in a high HIV risk country</li></ul>
Proposed Guidelines: In 2011, an independent, expert review committee recommended that the current 12 month sexual activity-based deferrals could safely be reduced to 6-months. This was conditional on supportive evidence that 'compliance' to the existing deferrals is high. Having established this from the results of the recently completed 'Donor Accuracy Survey', it is proposed that the 12 month deferral for the above sexual activity-based behaviours be reduced to 6 months.
The proposal has been endorsed by the Blood Service Donor and Product Safety Advisory Committee, Clinical Microbiologist and Clinical Governance Committee.
Please refer to the attached paper

Notifying Officer(s)	Contact details
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# Submission for Proposed Changes to the Guidelines for Selection of Blood Donors (GSBD) in relation to Sexual Activity-Based Deferrals

## 1. ESTABLISHING THE CONTEXT

The Australian Red Cross Blood Service ('Blood Service') has a responsibility to ensure that the risk to Australian blood recipients is as low as reasonably achievable. In this regard, the Blood Service exercises due discretion on who it will accept to donate blood. Currently, it imposes a 12 month deferral for sexual activity-based behaviours including:

- male-to-male sex
- bisexual contact (a woman who has had sex with a man who has had sex with a man)
- sex worker
- sex worker contact (sex with a male or female sex worker)
- sexual contact with a new partner who has lived in a high HIV risk country
- sexual contact while in a high HIV risk country

The Blood Service continues to receive a large number of complaints in relation to these sexual-activity-based deferrals, in particular deferral for male-to-male sex. The main focus of most of these complaints has been that the Blood Service discriminates against some sections of the community, particularly homosexually-active men. There have been three anti-discrimination cases in relation to the male-to-male sex deferral policy. These were the Victorian Civil and Administrative Tribunal (1998), Human Rights and Equal Opportunity Commission (2007) and the Tasmanian Anti-Discrimination Tribunal (2009). In the Victorian Civil and Administrative Tribunal case, it was ruled that the Blood Service's deferral policy on male-to-male sex was not discriminatory. The case brought to the Human Rights and Equal Opportunity Commission was dismissed with the President of the Commission commenting that the Blood Service's donor deferral policy was reasonable and objective and necessary to safeguard the blood supply. In the Tasmanian Anti-Discrimination case, the tribunal found that the complainant had not been discriminated against and that the Blood Service had the right to ensure that the risk to the blood supply is low.

Despite these past endorsements of the Blood Service's position, future success in defending against such complaints will be contingent on whether the evidence base remains valid. In addition, there is an organisational obligation for the Blood Service to review the currency of its deferral policies on a regular basis, taking into account new scientific evidence and international best practice. As a result of this process some donor deferrals will be reduced, others lengthened, and some remain unchanged. In 2010, the Blood Service commissioned an independent review into sexual activity-based deferrals - *Review of Australian Blood Donor Deferrals Relating to Sexual Activity* ("the Review").<sup>[1]</sup> The Review committee comprised of experts in relevant fields including epidemiology, infectious diseases, HIV medicine, medical ethics, transfusion medicine in addition to donor and patient advocates. At the time, similar reviews into sexual activity-based deferrals, in particular deferral for male-to-male sex, had already been undertaken or were being considered in other countries including the USA, UK, New Zealand, Canada and by the Council of Europe (CoE). The Review in Australia considered submissions from the public, international donor deferral policies, evidence-based risk analysis for scenarios with deferral changes and pertinent Australian and overseas studies before it delivered its recommendations to the Blood Service in March 2012. The Review found that there was no evidence to support increasing the period for the sexual activity-based deferrals. In fact it found that there was

sufficient scientific evidence to support decreasing all of the sexual activity-based deferrals listed above from 12 months to 6 months without compromising the safety of blood and blood products in Australia. In making the recommendation, the Review took into consideration the current testing technologies used by the Blood Service to screen donations. It also considered the potential impact of an unknown emerging infection on the length of deferral periods. In respect of this it noted '*...As there is no scientific basis to determine a suitable length of time to allow for symptoms or detection of an unknown infection, the committee decided it was not appropriate to include this when determining duration of deferrals*'.

The Review stipulated that the Blood Service should conduct an anonymous donor study to determine the compliance of donors with sexual activity-based deferrals before implementing the recommendation for a reduction to 6 months. At the time of the Review there had been no such study undertaken in Australia to assess the accuracy of responses to pre-donation questions i.e. non-compliance in donors who test negative for transfusion-transmissible infections (TTIs). Importantly, a change in the deferral period may result in a change in the non-compliance rate which could either negatively or positively impact the TTI risk.

**The Review has recommended a reduction in the duration of the following sexual activity-based deferrals from 12 months to 6 months, contingent on a study on donor compliance:**

- **male-to-male sex**
- **bisexual contact (a woman who has had sex with a man who has had sex with a man)**
- **sex worker**
- **sex worker contact (sex with a male or female sex worker)**
- **sexual contact with a new partner who has lived in a high HIV risk country**
- **sexual contact while in a high HIV risk country**

The importance of the rate of non-compliance and its impact on the overall TTI risk was highlighted by a Blood Service study assessing the HIV transmission safety of the current 12-month deferral for male-to-male sex.[2] In the 5 year period after the deferral was reduced to 12 months all five HIV positive donors identified declared male-to-male sexual-contact within 12 months at their post donation follow up interview (i.e. were non-compliant). Had they complied and self-deferred, then the number of HIV positive donors identified would have been lower under the 12-month deferral than under the longer, pre-existing deferral period which varied (5 years or permanent) dependent on state/territory.

The authors concluded that in terms of HIV transmission risk, the level of compliance to the deferral was more influential than the duration of the deferral. This principle has since been confirmed by others, including a Swedish group who modelled different deferral durations and compliance rates to assess the relative safety of various male-to-male sex deferral durations. Their modelling indicated that a 6-month deferral with a 99% compliance rate resulted in a lower overall HIV transmission risk than a permanent deferral with a 95% compliance rate.[3] A more recent UK NHSBT modelling analysis also suggests that a risk reduction is achievable under a shorter deferral. Their modelling demonstrated a decline in HIV risk of 19% under a scenario where compliance to the deferral improved from 95% to 97.5%.[4]

While the rate of non-compliance among TTI-positive donors in Australia is known to be in the range 12-25% the rate among TTI-negative donors has not been measured.[5] Therefore

in line with the Review's recommendations and subsequent to approval from the Blood Service Human Research Ethics Committee, the Blood Service commenced an anonymous donor study - *Assessing the accuracy of the pre-donation questionnaire: a national survey of blood donors in Australia* (hereafter the *Donor Accuracy survey*) in November 2012. The study was completed in April 2013. The main aim of this study was to estimate the number of TTI-negative donors who failed to report sexual activity-based behaviours that would have deferred them from donating blood for 12 months had they disclosed these at the pre-donation interview (i.e. non-compliance). Based on overseas studies assessing non-compliance to male-to-male sex deferrals, the rate of non-compliance in TTI-negative donors was predicted to be in the range 0.8% to 10.6%.[6-8]. In Canada where donors who disclosed male-to-male sex since 1977 are permanently deferred, a study [5] found that the rate of non-compliance to their male-to-male sex question was 0.8 to 1.0% in repeat donors and 1.3 to 1.4% in first-time donors. In the UK study [6] where a permanent exclusion for male-to-male sex applied at the time, the non-compliance rate was 10.6%.

The results from the Donor Accuracy survey (refer section 5) indicate that the non-compliance rate in Australian donors for the six sexual activity-based deferrals assessed is low (range 0.05 to 0.29%). The rate for the male-to-male sex question (0.23%) was substantially lower than that reported overseas (0.8-10.6%). This is both pleasing and important in the context of the overall risk from non-compliant donors which would therefore be comparably lower than overseas. It is important to note that it is not possible to predict with any accuracy the behaviour of donors under any new policy – in this case a reduction to 6 months deferral. However it would be highly unlikely that compliance would worsen under a shorter deferral period given more donors would become eligible and that recall of the timing of last sexual contact should be more accurate in a shorter time period. Ultimately, the only definitive method of assessing non-compliance under a revised policy is to repeat the Donor Accuracy survey at an appropriate interval post implementation.

In line with the recommendations of the UK Department of Health's Advisory Committee on the Safety of Blood, Tissue and Organs (SaBTO), this is the approach currently being undertaken by the UK NHSBT to confirm that non-compliance has not worsened under their 12-month male-to-male sex deferral implemented in November 2011. The study by Grenfell and colleagues[8] identified a non-compliance rate of 10.6% under the existing permanent deferral of whom 2.6% disclosed contact within the prior 12 months. Extrapolating from this predicted a non-compliance rate under a 12-month deferral in the UK of approximately 2.6%. This prediction is to be tested by a soon-to-be commenced Donor Accuracy survey of existing UK blood donors.

**The Blood Service's survey on donor compliance has found a comparatively low non-compliance rate among Australian donors. While it is not anticipated that this would differ greatly in practice, the only way to establish this would be through a post-implementation survey.**

*Current and Proposed Guidelines*

Currently the Guidelines for the Selection of Blood Donors (GSBD) states that donors who have had the following sexual activity behaviours are deferred for 12 months; the proposed change is to reduce the deferral period to 6 months:

Donor Event	Category	Use NBMS Code	Explanation/Clarification	Action	Autologous	Recall Requirements		
						Fresh Components	Clinician Notification	Plasma for Fractionation (CSL)
<b>Declaration questions: If the donor rescinds his/her previous answer to any of the Donor Declaration questions, a DAPS MO needs to be consulted.</b>	Male to male sex	T339	If a man has had sex with another man, including safe sex with a condom within the last <b>12 6</b> months.	Defer for <b>12 6</b> months after last sexual contact. Collect UR samples if recall required	Accept	Yes, and collect UR samples	DAPS MO to assess UR test results	Category 1
	Bisexual contact	T340	If a woman has had sex with a man who has had sex with a man, defer for <b>12 6</b> months after last sexual contact with the bisexual male, regardless of when the male to male sex took place (unless the woman's sexual partner is a current Blood Service donor).	Defer for <b>12 6</b> months after last sexual contact. Collect UR samples if recall required	Accept	Yes, and collect UR samples	DAPS MO to assess UR test results	Category 1
	Sex worker	T342	If a person has worked as a sex worker	Defer for <b>12 6</b> months after cessation of sex work. Collect UR samples if recall required	Accept	Yes, and collect UR samples	DAPS MO to assess UR test results	Category 1
	Sex worker, contact	T345	Sexual partners of sex workers	Defer for <b>12 6</b> months after last sexual contact. Collect UR samples if recall required	Accept	Yes, and collect UR samples	DAPS MO to assess UR test results	Category 1
	Sexual contact, new partner who has lived overseas	T344	If a donor has had sex with a new partner who has lived for a cumulative total of 12 months in a high risk area for HIV in the last 10 years. • See Part 5 Geographical	Defer for <b>12 6</b> months from initial sexual contact. Collect UR samples if recall required	Accept	Yes, and collect UR samples	DAPS MO to assess UR test results	Category 1

Donor Event	Category	Use NBMS Code	Explanation/Clarification	Action	Autologous	Recall Requirements		
						Fresh Components	Clinician Notification	Plasma for Fractionation (CSL)
			Considerations for areas where HIV is endemic. • See Part 1 Guide to DQF; Section A Q16 (New & Returned), Section B Q20 (For All Donors), Section C Q7 (Donor Declaration).					
	Sexual contact, while overseas	T344	If a donor, while overseas, has had sex with a resident in a high-risk area for HIV. • See Part 5 Geographical Considerations for areas where HIV is endemic.	Defer for <del>12</del> 6 months from the last sexual contact. Collect UR samples if recall required	Accept	Yes, and collect UR samples	DAPS MO to assess UR test results	Category 1

Equivalent changes will also be required to the Donor Declaration and the guide to the Donor Declaration in the GSBD. The proposed changes to the Donor Declaration questions are noted on the next page. Also included is a proposed change to question 4 to increase the donors' understanding of the question.



# C Donor declaration

To the best of your knowledge, have you EVER: Comments (staff use only)

- |   |     |    |    |
|---|-----|----|----|
| 1. Thought you could be infected with HIV or have AIDS?   | Yes | No | E2 |
| 2. "Used drugs" by injection or been injected, <b>even once</b> , with drugs not prescribed by a doctor or dentist? | Yes | No | E3 |
| 3. Had treatment with clotting factors such as Factor VIII or Factor IX?  | Yes | No | E4 |
| 4. Had a <b>positive</b> test <del>which showed you had</del> for hepatitis B, hepatitis C, HIV or HTLV?            | Yes | No | E5 |

## In the last 12 months have you:

- |  |                |               |   |
|--|----------------|---------------|---|
| 5. Had an illness with swollen glands and a rash, with or without a fever?   | Yes            | No            | E1                                      |
| 6. Engaged in sexual activity with someone you might think would answer "yes" to any of questions (1-5)?                         | Yes            | No            | E6                                      |
| <del>7. Had sexual activity with a new partner who currently lives or has previously lived overseas?</del>                       | <del>Yes</del> | <del>No</del> | <del>E7</del>                           |
| <del>8. Had sex (with or without a condom) with a man who you think may have had oral or anal sex with another man?</del>        | <del>Yes</del> | <del>No</del> | <del>F0</del>                           |
| <del>9. Had male to male sex (that is, oral or anal sex) with or without a condom?<br/>(Females please tick "I am female")</del> | <del>Yes</del> | <del>No</del> | <del>E9</del><br><del>I am female</del> |
| <del>10. Been a male or female sex worker (e.g. received payment for sex in money, gifts or drugs)?</del>                        | <del>Yes</del> | <del>No</del> | <del>F1</del>                           |
| <del>11. Engaged in sexual activity with a male or female sex worker?</del>  | <del>Yes</del> | <del>No</del> | <del>F2</del>                           |
| <del>12</del> 7. Been imprisoned in a prison or been held in a lock-up or detention centre?                                      | Yes            | No            | F6                                      |
| <del>13</del> 8. Had a blood transfusion?  | Yes            | No            | F8                                      |
| <del>14</del> 9. Had (yellow) jaundice or hepatitis or been in contact with someone who has?                                     | Yes            | No            | F8                                      |

## In the last 6 months have you:

- |   |                |               |   |
|---|----------------|---------------|---|
| <del>10. Had sex (with or without a condom) with a man who you think may have had oral or anal sex with another man?</del>        | <del>Yes</del> | <del>No</del> | <del>F0</del>                           |
| <del>11. Had male to male sex (that is, oral or anal sex) with or without a condom?<br/>(Females please tick "I am female")</del> | <del>Yes</del> | <del>No</del> | <del>E9</del><br><del>I am female</del> |
| <del>12. Been a male or female sex worker (e.g. received payment for sex in money, gifts or drugs)?</del>                         | <del>Yes</del> | <del>No</del> | <del>F1</del>                           |
| <del>13. Engaged in sexual activity with a male or female sex worker?</del>   | <del>Yes</del> | <del>No</del> | <del>F2</del>                           |
| <del>14. Had sexual activity with a new partner who currently lives or has previously lived overseas?</del>                       | <del>Yes</del> | <del>No</del> | <del>E7</del>                           |
| 15. Been injured with a used needle (needlestick)?  | Yes            | No            | F3                                      |
| 16. Had a blood/body fluid splash to eyes, mouth, nose or to broken skin?   | Yes            | No            | F4                                      |
| 17. Had a tattoo (including cosmetic tattooing), body and/or ear piercing, electrolysis or acupuncture (including dry-needling)?  | Yes            | No            | F5                                      |

## *Current Standards*

The Council of Europe *Guide to the Preparation, Use and Quality Assurance of Blood Components*, 14<sup>th</sup> edition (CoE *Guide* –v14) has no specific deferral period for these sexual activity behaviours. However, the table of conditions leading to permanent deferral (rejection) on page 63 of the CoE *Guide* – v14 includes “Persons, whose sexual behaviour puts them at high risk of acquiring severe infectious diseases that can be transmitted by blood.”

The CoE *Guide* – v14 also states on page 66 that “If there was contact with an infectious disease, the deferral period should equal the incubation period, or if unknown, the nature of the contact and the deferral period has to be determined by the responsible physician.”

In addition, the example of a donor questionnaire on pages 77 and 78 includes the following:

- Have you ever accepted payment for sex in money or drugs?
- For men: have you had sex with another man?
- For women: to the best of your knowledge has any man with whom you have had sex in the past 12 months had sex with a man?
- During the past 12 months have you had sexual contact with someone who received or has received payment for sex in money or drugs?

The recently published Council of Europe Resolution CM/Res (2013)3 on sexual behaviours of blood donors that have an impact on transfusion safety (adopted by the Committee of Ministers on 27 March 2013) does not specify deferral timeframes. Instead it supports a risk based approach and provides the ability for Blood Services to decide on a temporary deferral policy for sexual behaviours, provided that the Blood Service can demonstrate that the sexual behaviour does not put the donor at high risk of acquiring severe infectious diseases that can be transmitted by blood.

The Australian Regulatory Guidelines for Biologicals, Appendix 4 – Guidance on donor selection, testing and minimising infectious disease transmission via therapeutic goods that are human blood and blood components, human tissues and human cellular therapy products states: “A donor whose sexual practices put them at increased risk of acquiring infectious diseases that can be transmitted by blood, cells or tissues” are “ineligible for 12 months from last contact” However, currently this is a guidance only and not a mandated standard for blood. Consideration of changes to this document in light of the results of the Review and donor compliance survey may be appropriate.

### *Previous TGA discussion / correspondence*

The *Review of Australian Blood Donor Deferrals Relating to Sexual Activity* and the Donor Accuracy Survey have been discussed at Blood Service – TGA liaison meetings on 25 May 2012 and 21 December 2012.

## **2. RISK ANALYSIS**

### ***Risk to donors***

Reducing sexual activity deferral period to 6 months will have no impact on the safety of donors.

## Risk to recipients

### Risk impact of deferral period

Minimising recipient risk correlates directly with selecting an appropriately 'safe' deferral duration. In defining the 'minimum' deferral periods for sexual activity-based deferrals there are a number of important principles including;

1. Selecting a period sufficient to cover the testing 'window periods' (for TTI's subject to donation testing), or incubation periods (for TTIs without mandatory testing).
2. Selecting deferral periods focusing on recent risk behaviour which need to be discrete, easily recalled time durations (e.g. 6 or 12 months).
3. Consideration of the potential for a so-called 'magnet' effect in which individuals engaging in high risk behaviour donate blood in order to obtain their infection status with the most sensitive test available.
4. The potential for a novel TTI to emerge which shares a common transmission route with an existing TTI

The *Review* carefully considered the appropriate length of deferral periods before making the recommendation that 6 months was sufficient for known TTIs. The following is extracted directly from their final report (Section 6.1.2 *Length of deferral periods* - pp 41-42).

**Table 10. Minimal deferral periods for TTIs**

Agent	Testing window period (WP)		Incubation period Mean days (range)	Upper WP/Incubation period estimate (days)	Minimum deferral period with required safety margin (days) <sup>a</sup>
	NAT Mean days (range)	Serology Mean days (range)			
HIV	5.6 (5.0-6.4)[21]	22 (6-38)[22]		38	76
HAV			28 (10-50)	50	100
HBV	23.9[60]	HBsAg 38 (95% CI 33-43.7)[23]		44	88
HCV	3.1[60]	66 (38-94)[24]		94	188
HTLV		51 (36-72) [25]		72	144
<b><i>T. Pallidum</i> (syphilis)</b>		28 <sup>b</sup> [26]		28	56

<sup>a</sup>Current Blood Service policy with respect to deferral duration requires adding a safety margin to testing window periods/incubation periods to ensure safety of the blood supply. The safety margin agreed with the TGA requires a doubling of the uppermost range or confidence interval of the testing window period/incubation period. <sup>b</sup>IgM antibodies detected at 14 days, IgG antibodies detected at 28 days

- Length of deferral needs to consider window periods for both NAT and serological testing. Despite being shorter, one cannot rely on window periods alone due to individuals who may have chronic infection (e.g. HIV 'elite controllers' who may test negative for nucleic acid but will have a positive serological test. Therefore best practice demands that the deferral period is based on the uppermost limit of the serological testing window period or incubation period in order to maximise the potential to detect all TTI positive donors.

- After considering the data in table 10, it is apparent that a deferral period based on the testing window period of HCV would be sufficient to cover the testing window periods for all of the infections. The committee agreed that six months should be the minimum period of deferral as this period of time allows for a safety margin that doubles the uppermost antibody testing window period for HCV (94 days) in accordance with the current TGA-approved guidelines. It is suggested that this period of deferral should be consistently applied to all donors considered at risk of sexually-transmitted TTIs.
- Based on the epidemiological risk of incident infections for known TTI's, reducing the deferral period from 12 to 6 months will not impact the current safety of the blood supply as any unknown incident infections acquired through sexual activities would have occurred outside the testing window period and will therefore be detected through routine screening conducted by the Blood Service.
- In the event that sufficient evidence of appropriate quality becomes available to exclude the risk of sexually transmitted HCV<sup>i</sup>, the committee found that the duration of the deferral could be further reduced to 100 days based on the epidemiological evidence regarding the incubation period for HAV.
- The committee considered whether the potential for sexual transmission as a route of infection in an unidentified new or emerging pathogen should impact the duration of current deferrals for sexual activity. Making predictions for length of deferral for emergent pathogens is difficult due to the very nature of being an unknown event. With unknown variable to consider (i.e. rate of transmission, recovery rates, duration of asymptomatic infection period). In addition, sexual transmission is not the only potential route of new infections and may not be the route of the next emerging infection. In contrast to the delayed identification of TTIs in the 1980s, it is anticipated that improvements in laboratory and clinical surveillance systems will provide more reliable information regarding early identification of new pathogens, their route of transmission and those at risk who should be deferred from donating.
- In the event of new evidence, the policy for the duration of sexual activity-related deferrals should be reviewed.

#### *Risk impact of non-compliance rate*

While defining the appropriate deferral period is imperative, as noted previously the level of compliance to the selected deferral period is arguably even more important. Without achieving both optimally there is the possibility that recipient risk could be adversely impacted.

The results of the Donor Accuracy study (refer section 5) confirm a low rate of non-compliance among Australian donors under the current 12-month sexual activity-based deferrals. While it is impossible to predict with absolute certainty the non-compliance rate under a 6-month deferral, as noted previously it is counter-intuitive to anticipate that it would worsen for several reasons:

- First, accurate recall of recent risk behaviour and timing of last sexual contact would be expected to improve, not worsen under a shorter deferral period.

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<sup>i</sup> Subsequent to the publication of the *Review* committee's final report two prospective studies (Witt et al. *Clin Infectious Disease* 2013 and Terrault et al *Hepatology* 2013) of incident HCV were published identifying sexual transmission as an independent risk factor for HCV acquisition particularly for men engaging in unprotected receptive anal intercourse. Thus a deferral period considering the HCV window period remains appropriate.

- Second, more donors become eligible (i.e. those whose last sexual contact was between 6 and 12 months) and thus non-compliance by this group is no longer necessary and the overall non-compliance rate reduced.
- Third, the move to a shorter deferral period should be perceived as supportive of evidence-based deferral policies, thus reducing the motivation for non-compliance among donors who may be donating in 'protest'.

While the recent modelling in the UK and Sweden support the potential for the overall TTI risk decline should the non-compliance rate improve, ultimately the only method to validate the outcome of the proposed policy change is to assess it post-implementation.

### ***Risk to sufficiency***

It is expected that the proposed changes will only have a marginal improvement to sufficiency.

### ***Risk to staff safety***

There is no additional risk to safety of staff given our policy of observing 'Universal Precautions'.

### ***Risk to reputation***

In the interest of maintaining a safe blood supply, the Blood Service has an obligation to defer blood donors who fail to meet the selection criteria. Despite this, the Blood Service has had to defend three cases in which it has been accused of discriminating against individuals in relation to the male-to-male sex deferral policy. All three cases found that the Blood Service had a right to safeguard the blood supply.

The Blood Service has received numerous complaints from potential donors who are affected by the 12-month deferral period as well as from the public. These individuals have lobbied for reduction for sexual activity-based deferrals. We expect that the reputation of the Blood Service will be enhanced as the public will perceive that the Blood Service has listened to the community, commissioned an independent expert review to examine the scientific evidence for the deferral periods and ultimately accepted the recommendation from the review. This reinforces the Blood Services' stated commitment to evidence-based deferral policies.

Furthermore, as recommended by the *Review* (p 48) the Blood Service has established a Donor Deferral Advisory Panel (sexual activity-based deferral) 'consisting of experts in communication, social marketing and public relations, biomedical specialists, and members of communities affected by deferral policies to provide advice in developing communication strategies that address the reasons for deferral and importance of compliance'. The advisory panel is chaired by an external expert and is expected to meet bi-annually (face to face) with the inaugural meeting in July 2013. The Panel will advise the Blood Service on optimal communication of the current proposal to amend the deferrals to 6-months as a priority agenda item.

### ***Other risk***

Some recipients and the members of the public may regard the change in the deferral policy as a risk to the blood supply as there are yet unknown infectious agents which may have a longer incubation period before an infected person develops signs and symptoms of disease. While this is a genuine concern, as noted by the *Review* there is no scientific method to determine incubation periods for as yet unknown agents. However, the Blood Service

conducts active surveillance for pathogens of concern to the blood supply as part of the EREED (Emerging, Re-emerging, Emerged, Infectious Disease) framework. Examples of pathogens under current/recent management include;

- dengue outbreaks in N. Queensland
- malaria in Greece
- WNV outbreaks in Europe
- novel coronavirus hCoV-EMC
- H7N9 in China.

**The proposed reduction of the current sexual activity-based deferral period from 12 to 6 months is not predicted to have any negative impact on recipient safety, while reaffirming to the community that the Blood Service is committed to evidence-based donor selection criteria.**

### 3. INTERNATIONAL PRACTICE

#### *United States*

The US has an indefinite deferral for sex workers and males who have had male-to-male sex since 1977. Donors who have had sex with a sex worker and female donors who have had sex with a man who has had male-to-male sex are deferred for 12 months.

#### *Canada*

Canada imposes an indefinite deferral for sex workers, donors who have had male-to-male sex since 1977 and donors who have had sex with someone who was born in or lived in Africa since 1977. The Canadian Blood Service is in discussion with its regulator to reduce the deferral period for donors who have had male-to-male sex from indefinite deferral to 5 years.

Donors who have had sex with a sex worker and female donors who have sex with a male who has had male-to-male sex, are deferred for 12 months.

#### *United Kingdom*

Prior to 2011, the UK had an indefinite deferral for donors who have ever had male-to-male sex. Following a comprehensive review by SaBTO, the English, Welsh, Scottish and Northern Ireland governments accepted the SaBTO recommendation to move to a 12-month deferral commencing in November 2011. However, the Blood Services did not change their indefinite deferral policy for sex workers. All other sexual activity has a 12 month deferral - i.e. female donors who have sex with a man who has had male-to-male sex, sex with a sex worker and sex with someone from a country with high HIV prevalence.

The Blood Service of the Republic of Ireland (Irish Blood Transfusion Service or (IBTS) retained their existing permanent deferral for male-to-male sex.

#### *New Zealand*

New Zealand changed both its male-to-male sex and sex worker deferral from permanent to 5 years in 2008. However, sex workers only within New Zealand are deferred for 12 months. All other sexual activity has a 12-month deferral, including female donors who have had sex

with a man who had male-to-male sex, sex with sex worker and sex with someone from a country with high prevalence of HIV.

*Other*

It is important to note that South Africa, Japan, Italy, Spain and Mexico have less stringent deferral policies for donors who have had male-to-male sex. Japan and South Africa both have 6-month deferrals while Italy, Spain and Mexico have no specific deferral for male-to-male sex.

**Table 1.** Comparison of deferral periods for MSM, bisexual contact, sex worker and sex worker contact in UK, USA, Canada ,France , New Zealand, Italy and Japan[9]

	USA	Canada	UK (excluding ROI)	France	New Zealand	Japan	Italy
Male who has had male-to-male sex	Indefinite	Indefinite	Indefinite until 2011 changed to 12 months deferral	indefinite	5 year deferral	Was 12 months deferral until April 2011 when it became 6 months deferral	No deferral if monogamous or 4 months if occasional
Female who has sex with a male who has had male-to-male sex	12 months deferral	12 months deferral	12 months deferral	12 months deferral	12 months	12 months	4 months if occasional or indefinitely if recurrent
Sex worker	Indefinite	Indefinite	Indefinite	Not stated	1 year if within New Zealand, 5 years if outside New Zealand	12 months	indefinite
Sex with sex worker	12 months	12 months	12 months	indefinite	12 months	12 months	4 months if occasional or indefinite if recurrent

**An increasing number of blood services world-wide have moved from an indefinite deferral period to a finite deferral period – generally 12 months but in some cases longer (e.g. 5 years), shorter (e.g. 6 months) or even no set deferral period at all.**

## **4. LITERATURE REVIEW**

### **Seed et al (ref 2)**

Establishes safety of 12 month deferral in relation to HIV transmission risk in Australia and highlights the importance of compliance in determining the final risk level. The authors conclude that the compliance level has more bearing on the risk than does the duration of the deferral period itself.

### **Sanchez et al (ref 6)**

First anonymous survey of US blood donors assessing non-compliance to US indefinite male-to-male sex deferral. 25,000 male donors surveyed by mail from 5 collection sites with a non-compliance rate of 1.2%.

### **Goldman et al (ref 7)**

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 to the male-to-male sex question was 0.8 to 1.0% in repeat donors and 1.3 to 1.4% in first-time donors.

### **Grenfel et al (ref 8)**

As a component of a large population based survey of sexual attitudes, identified a non-compliance rate of 10.6% under the existing permanent male-to-male sex deferral in the UK of whom 2.6% disclosed contact within the last 12 months. Extrapolation from this predicts a non-compliance rate under a 12 month deferral of approximately 2.6%.

### **Davison et al (ref 4)**

The risk of HIV transmission for England and Wales (2005-2007) was modelled under a 12 month or permanent deferral for male-to-male sex with varying assumptions for HIV incidence and compliance to the policy. The authors highlight that under a 12 month deferral with improved compliance the risk could be reduced by up to 29%. These findings confirm the Blood Service assertion (from ref 2) that compliance is more influential than deferral duration on overall risk.

## **5. DONOR ACCURACY SURVEY**

In order to estimate the non-compliance rate to existing sexual activity-based questions on the donor questionnaire the Blood Service, in partnership with the Kirby Institute surveyed donors who had recently donated. Sample size calculations indicated the need for a large survey (approximately 30,000 respondents) to achieve the required statistical power.

Between November 2012 and April 2013 a nationally representative sample of allogeneic donors who had made at least one successful donation within the past 6 weeks was emailed a personalised link inviting their participation in an anonymous, online survey. Successful donation was defined as having satisfactorily completed the donor assessment process including the pre-donation questionnaire, formal interview and signature of a legally binding statutory declaration together with negative mandatory TTI test results for HIV, HBV HCV, HTLV and treponemal antibodies. 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 stratified against the national blood donor panel on age, gender, donation experience and State of residence to provide a nationally representative sample.



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.

## Results

A total of 98,044 e-mails were successfully delivered to eligible donors during the study period. Of these 30,790 (14,706 males and 16,084 females) completed the survey, a creditable response rate of 31.4%. After excluding 516 non conforming responses there were 30,274 (14,476 male and 15,798 female) available for analysis. Of these, 3,543 (11.7%) responses from first time donors and 26,731 (88.3%) from repeat donors.

The survey responses for each of the seven sexually activity-based screening questions on the current DQF were analysed separately and are summarised in the table below.

**Table 2.** Non-compliance rates for individual questions

Survey question	No. responses	No. non compliers (%)	% non compliance rate (95%CI)	No. with last contact within 6 months (%) <sup>a</sup>
<b>Male donors:</b> In the last 12 months have you had male to male sex (that is, oral or anal sex) with or without a condom?	14,476	34	0.23 (0.16-0.33)	24 (0.17)
<b>Female donors:</b> In the last 12 months have you had sex (with or without a condom) with a man who you think may have had oral or anal sex with another man?	15,798	29	0.18 (0.12-0.26)	23 (0.15)
In the last 12 months have you been a male or female sex worker (e.g. received payment for sex in money, gifts or drugs)?	30,274	16	0.05 (0.03-0.09)	13 (0.04)
In the last 12 months have you engaged in sexual activity with a male or female sex worker?	30,274	88	0.29 (0.23-0.36)	63 (0.21)
In the 12 months before your last donation, did you have sex with a new partner (i.e someone you had not previously had sex with) who had lived overseas for 12 months or more during the previous 10 years in a country in the list below?	30,274	50	0.17 (0.12-0.22)	Not assessed

In the last 12 months, did you have sex in an overseas country that is included in the list below? Which of the following most appropriately describes this person you had sex with?	30,274	77	0.25 (0.2-0.32)	Not assessed
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<sup>a</sup> The rate in this column represents the predicted rate of non-compliance under a 6-month deferral assuming no change in the behaviour of currently compliant donors

### Key findings

1. This large survey of over 30,000 Australian blood donors confirmed that non-compliance to sexual activity-based questions is comparatively low, in the range 0.05 to 0.29%. There was no statistically significant difference in the non-compliance rates for first time and repeat donors. Overall these findings are reassuring and support the effectiveness of the current screening questions.
2. In respect of the male-to-male sex question, the subject of the majority of international research and controversy, our observed non-compliance rate of 0.23% (95%CI: 0.16-0.33) is markedly lower than the published studies which range from 0.8-10.6%. One possible reason for our lower rate is that this study is the first to assess non-compliance under a 12 month deferral whereas all other studies to date measured non-compliance where a permanent deferral for male-to-male sex applied. Intuitively the non-compliance rate would be predicted to be lower under the 12 month deferral as donors with remote male-to-male sexual contact are eligible and therefore have no need to disclose activity beyond 12 months. In contrast, where a permanent exclusion for any male-to-male sex applies there may be increased motivation for non-compliance either deliberately or because of a lack of accurate recall.
3. Among females, the rate of non-compliance to the 'sex with a bisexual male question' was similarly low, 0.18% (95% CI: 0.12-0.26%).
4. The non-compliance rate among donors disclosing sex work is very low, 0.05% (95%CI: 0.03-0.09). Likewise the rate for donors accessing sex workers is also low, 0.29% (0.23-0.36%).
5. The non-compliance rates to the questions concerning sex with a new partner (in the last 12 months) or past resident (12 months or more in the past 10 years) from a high prevalence HIV country were also both low, 0.17% (0.12-0.22) and 0.25% (0.2-0.32) respectively.
6. Overall, the low rate of non-compliance with all current sexual activity-based questions is a very positive outcome. While not guaranteeing that such low levels would be maintained should we implement a 6 month deferral, on balance we would predict non-compliance to remain unchanged or improve marginally. The primary rationale for this prediction is that some current non-compliers (i.e. those with sexual contact between 6 and 12 months) become eligible under a 6 month deferral and thus are no longer non-compliant. This acts to reduce the non-compliance rate. For example, reference to table 1 indicates that 10/34 donors currently non compliant to the male-to-male sex question would become compliant under 6 month question as their contact occurred between 6 and 12 months. Further, where the screening questions are perceived to be inequitable (e.g. deferral for male-to-male sex and sex work) the shorter deferral sends a positive message that the Blood Service is committed to ongoing policy review in light of new evidence. This should reduce the motivation for non-compliant donors who may be doing so in 'protest' against what they perceive as an unfair policy.

## Limitations of the study

We surveyed a representative sample of our donors and therefore the probability of inviting non-compliant donors should be proportionate. However, we cannot exclude the possibility that some non-compliers intentionally chose not to complete the survey (i.e. 'opted out') or alternatively completed the survey without disclosing their non-compliance.. Therefore, the estimates we report are the minimum rates, and the maximum non-compliance for the sexual activity-based screening questions assessed is unknown. Importantly, this limitation is common to all the published studies assessing non-compliance and therefore the observation that the relative non-compliance rate in Australian donors is comparatively lower is valid.

## 6. CONCLUSION

This proposal to amend the sexual activity-based deferrals from 12 to 6 months since last contact is supported by;

- An independent, expert Review committee recommendation made subsequent to a comprehensive analysis of all the issues at hand which supported the safety of a 6 month deferral (subject to a supportive 'compliance' research study).
- A large, anonymous donor survey to estimate the level of compliance to the current Australian policies which identified an internationally low level of non-compliance.
- International practice with a trend to shorter deferral periods based principally on improved TTI testing methods (e.g. 6-month deferrals for male-to-male sex in South Africa and Japan).
- The Blood Service EREEID framework which optimises identification and management of pathogens with a potential to impact the proposed deferrals.

Ultimately, the proposal is not predicted to have any negative impact on recipient safety, while reaffirming to the community that the Blood Service is committed to evidence-based donor selection criteria. The establishment of the Donor Deferral Advisory Panel provides an ideal conduit for optimising communication of any revised policies.

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On behalf of the Donor and Product Safety Policy Unit

**Date**

May 2013

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