Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

REQUEST FOR ADVICE

ADVISORY COMMITTEE ON BIOLOGICALS **MEETING 3**

19 September 2013

AGENDA ITEM 4.2
Proposed changes to the Guidelines for Selection of Blood Donors in relation to sexual activity-based deferrals

Purpose of application	To seek advice on changes to the donor deferral period for individuals who engage in certain sexual behaviours
Summary of Issue	The Australian Red Cross Blood Service (ARCBS) has requested approval of a variation to the *Guidelines for Selection of Blood Donors*, which would allow the donor deferral period for individuals who engage in certain sexual behaviours to be relaxed from 12 months to 6 months
Questions for ACB	The committee is requested to provide advice on the following specific issues: 1. Does the Committee agree that there is sufficient evidence to support relaxing the blood donor deferral period in relation to sexual activity-based behaviours for currently identified 'high risk' groups? 2. If the Committee considers that there is insufficient evidence to support relaxing the deferral period for some or all high risk groups, what additional evidence should be sought? 3. Since compliance with providing correct answers to pre-donation questions is highlighted as critical to the mitigation of TTIs, does the Committee have sufficient confidence in the Blood Service's survey outcomes to demonstrate that Australia has a significantly lower level of non-compliance compared with overseas results? Does the Committee feel the Blood Service has properly accounted for the differences in survey results? If not, what further analysis would the Committee recommend the Blood Service undertake to address this matter? 4. Does the Committee feel that there would be an increase in donations with this reduced deferral period? The committee is (also) requested to provide advice on any other

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TGA Health Safety Regulation

	issues that it thinks may be relevant.
Attachment	**Agenda item 4.2 Proposed changes to the Guidelines for Selection of Blood Donors in relation to sexual activity-based deferrals** Attachment 1. Australian Red Cross Blood Service Submission, May 2013 Attachment 2. Deferral of males who had sex with other males Attachment 3. Review of Australian Blood Donor Deferrals Related to Sexual Activity (May 2012) Attachment 4. The Kirby Institute, Transfusion-transmissible Infections in Australia, 2012 Surveillance Report

[redacted]

4 September 2013

Bill Turner, Head of the Office of Scientific Evaluation

Delegate of the Secretary under regulation 39D
of the Therapeutic Goods Regulations 1990

Advisory Committee on Biologicals Meeting 3

Meeting date: 19th September 2013 **Agenda Item: 4.2**

Proposed changes to the Guidelines for Selection of Blood Donors in relation to sexual activity-based deferrals

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BACKGROUND

The Australian Red Cross Blood Service (ARCBS) has requested TGA approval of a variation to their Technical Master File, specifically to the Guidelines for Selection of Blood Donors, which would allow the donor deferral period for individuals who engage in certain sexual behaviours to be relaxed to six months (**Attachment 1**). The ARCBS Technical Master File currently demonstrates compliance to standards including *Therapeutic Goods Order No. 88: Standards for 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*. The standard currently stipulates ineligibility to donate for 12 months from last contact for 'a donor whose sexual practices put them at increased risk of acquiring infectious diseases that can be transmitted by blood, cells or tissues'.

Since 2000, the ARCBS has imposed a 12 month deferral[1] on blood donations from individuals who have participated in sexual behaviours including:

- Male to male sex (MSM)
- Bisexual contact (women having sex with MSM)
- Sex work
- Sex worker contact (sex with a male or female sex worker)
- Sex with a new partner who has lived in a high HIV risk country
- Sexual contact while in a high HIV risk country

Current international donor deferral criteria

Internationally, donor deferrals for sexual activity-based behaviours range from indefinite deferrals for MSM in the United States and several European countries, 5 years in Canada and New Zealand, 12 months in the United Kingdom (Table 1, from Benjamin et al, 2011, **Attachment 2**), to 6 months in South Africa (since 2006) and Japan (since 2011). The technical recommendations from the WHO Guidelines on Assessing Donor Suitability for Blood donation (2012) advise that individuals whose behaviour put them at high risk of transfusion transmissible infections should be deferred permanently.

South Africa moved to a policy of six month deferral for sexual activity-based behaviours in October 2006 after introducing single donor NAT testing for HIV. The prevalence of HIV

[1] Prior to 20 May 2013, when this deferral period was put in Therapeutic Goods Order No. 88, the ARCBS established deferral periods (in consultation with the TGA) and they were not referenced in legislative instruments.

in South Africa is significantly greater than in Australia, and HIV is predominantly heterosexually transmitted. They do not report any significant changes in donor epidemiology or TTI with HIV, HBV, HCV or syphilis since the change in deferral policy.

Japan implemented a six month deferral in 2011, also citing increasingly sensitive screening using NAT tests. There are no published data on changes in the risk or frequency of transmission of sexual activity related TTIs in Japan since the change although the prevalence of HIV among donors has increased.

Risk of transfusion-transmitted HIV in Australia

Current estimates indicate that the residual risk of TTI with HIV or HCV in Australia are less than 1:1,000,000 per unit transfused; for HBV the residual risk is about 1:538,000 units transfused[2]

The Kirby Institute developed a mathematical model for a Review of Blood Donor Deferrals Related to Sexual Activity (2012) commissioned by the ARCBS (**Attachment 3**). The model estimated the relative risk of failing to detect a new (incident) HIV infection in a potential donor who engaged in one of the 'high risk' sexual behaviours. The model was based on a number of assumptions, which included that there was 100% compliance with donor deferral criteria, that the donor donated twice a year, and that the donor was not infected 12 months previously. The reference case (relative risk of 1) was a heterosexual male donor with a new female partner in the last 12 months. The model indicated that although the risk of an undetected HIV infection in a man in a monogamous relationship with a HIV negative man was zero, the relative risk of an undetected infection where the donor's partner may not be monogamous, even if confirmed HIV negative in the previous 6-12 months, was 59.5 (95% uncertainty boundaries 16.4-219.8) times greater than the reference case.

The model applied to brothel-based female sex workers indicated a relative risk of undetected HIV infection of 7.7 (95% UB 0.9-31.1) compared to the reference case, but the authors commented that the risk in other female sex workers could be higher. The risk of undetected HIV infection in a potential donor who had sex with an overseas sex worker was estimated at 43.2 (8.0-212.4) compared to the reference case, and the risk for a heterosexual donor with a new partner from a high HIV prevalence country was estimated at 19.5 (9.0-39.8) times greater than the relative risk of infection of a donation from a the reference case. The risk for a heterosexual donor who has casual sex while travelling in a country with high HIV prevalence was estimated to be 2.3 (0.5-9.0) times greater than for a heterosexual male with a new female partner in Australia. There are no data indicating how the residual risk of HCV, HBV, HTLV or syphilis may change with a change in policy, as there is less available data to guide estimates for values included in the model for these TTI.

The ARCBS proposal presented the findings of an anonymous survey of successful donors (screening tests negative for the identified TTI) to determine the compliance of donors with sexual activity-based deferrals ("The Donor Accuracy survey"). The survey had a response rate of 31.4%, and indicated that around 1.2% of HIV-negative Australian donors failed to report sexual activity-based behaviours that would have resulted in 12 month deferral if the behaviour was disclosed at the pre-donation interview of their most recent donation. They concluded that the low 'non-compliance' rate with the donor deferral questionnaire supported the proposal to relax the deferral period. It is possible that 'non-

[2] Australian Red Cross Blood Service: Residual risk estimates for transfusion-transmitted infections 2012 <http://www.transfusion.com.au/adverse_events/risk/estimates>

compliance' rates among the large group of non-responders may differ from responders. The ARCBS also acknowledges that there is no way of knowing if the low non-compliance rate will be maintained with a shorter deferral period.

Overall non-compliance with deferrals among TTI-positive donors between 2008 and 2011 was estimated at 12-25% (The Kirby Institute, 2012, **Attachment 4**). This figure includes non-compliance with deferrals for injecting drug use and known previous positive tests for TTI. Non-compliance with sexual activity-based deferrals ranged from 0-11.1% over the period 2008-2011. HBV infections and HCV infections were most frequently detected.

Additional risk mitigation steps that could be implemented to improve current blood safety controls

Several international jurisdictions discuss implementation of pathogen-reduction technologies. These are currently available for some blood components, but not for whole blood or red blood cells.

Italy and Spain apply gender-neutral questions about sexual behaviours. Canadian research indicates that universal implementation of alternate criteria based on behaviours is nonspecific and would lead to deferral of many current donors (Goldman, 2011).

The ARCBS proposal indicated that there are insufficient resources to consider expanding the donor questionnaire to allow for more detailed assessment of individual risk.

DISCUSSION

Summary of key and significant issues

The ARCBS proposed the change in deferral period to support their commitment to evidence-based deferral policies. The ARCBS deferral policies have been challenged as discriminatory on three separate occasions since 1998 (Victorian Civil and Administrative Tribunal, 1998; Human Rights and Equal Opportunity Commission, 2007; and Tasmanian Anti-Discrimination Tribunal, 2009). The Victorian and Tasmanian tribunals ruled in favour of the ARCBS, and the HREOC application was dismissed without a hearing. The ARCBS acknowledges that the likely effect on total blood donations is unlikely to be significant.

The WHO Blood Regulators Network (BRN) is a group of international regulatory authorities, including the TGA, with responsibility for the regulation of blood, blood products and related in vitro diagnostic devices in their individual jurisdictions. A key principle of the BRN is that the safety of transfusion recipients should be the first priority of the regulating authority. Under current Australian regulations, there have been no cases of transfusion transmitted HIV since 1998.

Current screening tests for HIV, HBV, HCV, HTLV and syphilis in donated blood are robust. The ARCBS has applied NAT testing for HIV, HCV and HBV of individual donations since July 2010. As the residual risks of transfusion transmitted infection are very low, changing the deferral period is unlikely to have a significant effect on the risk of window period donations.

The risk of transfusion transmitted HIV from donations provided by members of the risk groups considered in the ARCBS proposal is considerably greater than the risk of TTI from donations currently accepted.

The independent Review canvassed opinion from a number of stakeholder groups including recipients of regular blood transfusions, and gay and lesbian group advocates. Critics of the current Australian criteria observed that the lack of provision for safe sex practices, HIV test results and low risk behaviours unfairly excluded individuals at low risk of TTI from donating. Other submissions expressed concern that transfusion recipients will not be adequately protected by changes in deferral periods and that the current screening questionnaire may not be reliable enough to defer individuals with increased risk of exposure to TTI.

There is a potential issue that the term "men who have sex with men", or MSM, may be used as a catch-all term for a range of high risk practices. Gay advocates have argued that not all MSM engage in high-risk practices, and some practices that may decrease risk, for example "serosorting" (engaging in sexual activities with partners having the same HIV status), are increasingly common.

The ARCBS has a donor interview process that reassesses the individual donor risk of TTI at each proposed donation. They propose regular surveys of adherence to donor selection criteria. Research from the ARCBS and internationally indicates that the residual risk of TTI will be most influenced by adherence to donor deferral recommendations. If changes to deferral periods or donor questionnaires are implemented then significant attention should be paid to reviewing donor adherence to deferral criteria.

CONCLUSION/CONSULTATION

The data suggest a reduction in the donor deferral period from 12 months to 6 months for persons included in groups identified with sexual behaviours for an increased risk for TTIs may be achieved without a reduction in the safety of the blood supply, provided there is compliance with the blood donor deferral questionnaire.

A relaxation in the donor deferral period from 12 months to 6 months may lead to an increase in the rate of donations (currently undetermined) from the groups with sexual behaviours for an increased risk for TTIs. However it is also possible that the change will result in an increased rate of TTI positive donations, based on ARCBS data that in Australia, the rate of non-compliance with deferrals among TTI-positive donors is estimated at 12-25% (The Kirby Institute, 2012, **Attachment 4**) while 1.2% of TTI-negative Australian donors admitted non-compliance with a 12 month deferral period for sexual activity-based behaviours (The ARCBS, 2013, **Attachment 3**).

Questions for ACB:

1. Does the Committee agree that there is sufficient evidence to support relaxing the blood donor deferral period in relation to sexual activity-based behaviours for currently identified 'high risk' groups?

2. If the Committee considers that there is insufficient evidence to support relaxing the deferral period for some or all high risk groups, what additional evidence should be sought?

3. Since compliance with providing correct answers to pre-donation questions is highlighted as critical to the mitigation of TTIs, does the Committee have sufficient confidence in the Blood Service's survey outcomes to demonstrate that Australia has a significantly lower level of non-compliance compared with overseas results? Does the Committee feel the Blood Service has properly accounted for the differences in survey results? If not, what further analysis would the Committee recommend the Blood Service undertake to address this matter?

4. Does the Committee feel that there would be an increase in donations with this reduced deferral period?

ATTACHMENTS

Attachment 1: Australian Red Cross Blood Service Submission, May 2013

Attachment 2: Deferral of males who had sex with other males (Benjamin et al., 2011)

Attachment 3: Review of Australian Blood Donor Deferrals Related to Sexual Activity (May 2012)

Attachment 4: The Kirby Institute: Transfusion-transmissible Infections in Australia-2012 Surveillance Report

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").[1] 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 rage 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 to1.0% 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:

						Recall Requirements		
Donor Event	**Category**	**Use NBMS Code**	**Explanation/Clarification**	**Action**	**Autologous**	**Fresh Components**	**Clinician Notification**	**Plasma for Fractionation (CSL)**
Declaration questions: **If the donor rescinds his/her previous answer to any of the Donor Declaration questions, a DAPS MO needs to be consulted.**	Male to male sex	T339	If a man has had sex with another man, including safe sex with a condom within the last ~~12~~ 6 months.	Defer for ~~12~~ 6 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 ~~12~~ 6 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 ~~12~~ 6 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 ~~12~~ 6 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 ~~12~~ 6 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 ~~12~~ 6 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

						Recall Requirements		
Donor Event	**Category**	**Use NBMS Code**	**Explanation/Clarification**	**Action**	**Autologous**	**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 ~~12~~ 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, **even once**, 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 positive test ~~which showed you had~~ 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
~~7. Had sexual activity with a new partner who currently lives or has previously lived overseas?~~	~~Yes~~	~~No~~	~~E7~~
~~8. Had sex (with or without a condom) with a man who you think may have had oral or anal sex with another man?~~	~~Yes~~	~~No~~	~~F0~~
~~9. Had male to male sex (that is, oral or anal sex) with or without a condom?~~	~~Yes~~	~~No~~	~~E9~~
~~(Females please tick "I am female")~~	~~I am female~~		
~~10. Been a male or female sex worker (e.g. received payment for sex in money, gifts or drugs)?~~	~~Yes~~	~~No~~	~~F1~~
~~11. Engaged in sexual activity with a male or female sex worker?~~	~~Yes~~	~~No~~	~~F2~~
~~12~~ 7. Been imprisoned in a prison or been held in a lock-up or detention centre?	Yes	No	F6
~~13~~ 8. Had a blood transfusion?	Yes	No	F8
~~14~~ 9. Had (yellow) jaundice or hepatitis or been in contact with someone who has?	Yes	No	F8

In the last 6 months have you:

10. Had sex (with or without a condom) with a man who you think may have had oral or anal sex with another man?	Yes	No	F0
11. Had male to male sex (that is, oral or anal sex) with or without a condom?	Yes	No	E9
(Females please tick "I am female")	I am female		
12. Been a male or female sex worker (e.g. received payment for sex in money, gifts or drugs)?	Yes	No	F1
13. Engaged in sexual activity with a male or female sex worker?	Yes	No	F2
14. Had sexual activity with a new partner who currently lives or has previously lived overseas?	Yes	No	E7
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*, 14th 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	Upper WP/Incubation period estimate (days)	Minimum deferral period with required safety margin (days)[a]
	NAT Mean days (range)	Serology Mean days (range)	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
***T. Pallidum* (syphilis)**		28[b][26]		28	56

[a]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. [b]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 form 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[i], 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 form 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.

[i] 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 EREEID (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 <u>negative</u> 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 (%)[a]
Male donors: 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)
Female donors: 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

[a] 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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VoxSanguinis
The International Journal of Transfusion Medicine
ISBT International Society of Blood Transfusion
Vox Sanguinis (2011) **101**, 339–367

INTERNATIONAL FORUM

DOI: 10.1111/j.1423-0410.2011.01489.x
Vox Sanguinis

Deferral of males who had sex with other males

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Donor history questionnaires for the determination of blood donor eligibility are a critical layer of blood safety. Early in the course of the AIDS epidemic in North America homosexual men with multiple partners were identified as one of the segments of the population with the highest risk of infection. Voluntary deferral of this group from blood donation led to a dramatic decrease in transfusion-transmitted HIV even before testing was introduced. In the early 1980s blood donors were deferred in England, the US and other nations, if they were 'homosexual males with multiple partners'. After the implementation of HIV testing in 1985, the majority of the HIV-positive donors identified revealed 'men having sex with men' (MSM) behavior, leading the US Food and Drug Administration (FDA) to recommend indefinite deferral of all men who 'have had sex with men, even once since 1977'; many other regulators and jurisdictions have enacted similar criteria.

Three decades later, despite the recognition of other modes of transmission, MSM donors are still among the population segments with the highest prevalence and incidence of HIV in countries around the world.

No other donor eligibility criterion has generated as much controversy or public discourse [1,2]. Proponents for change point out that in many countries other key components of blood safety such as donor testing and blood center process control have improved vastly, reducing the contribution of donor questioning to safety. Gay advocates in particular argue that donor selection policies based on MSM are discriminatory against gay and bisexual men in that they amount to a *de facto* permanent exclusion on the grounds of sexual preference, and are unfair, as other groups with similar risks of HIV infection are allowed to donate blood after shorter time-period deferrals designed to cover the seroconversion window. On the opposite side of the discussion, recipient advocacy groups and regulators are understandably adverse to any change that is not centered on improving safety. Recipient groups argue that they have suffered greatly due to transmission of HIV and HCV by transfusion, and they will be the bearers of any increase in risk that may result from policy changes. Because both MSM and recipients are vulnerable groups that have suffered in the past, the debate over possible changes in criteria has ethical, societal, and emotional dimensions not seen in discussions concerning other donor selection criteria.

Of particular concern to blood operators is the prospect that young eligible donors may be dissuaded from donating blood to institutions that are perceived to act in a discriminatory and unfair fashion. This International Forum seeks to describe approaches to this issue and challenges to the status quo, in a snapshot in time. Since it is extremely difficult to obtain data to evaluate the possible impact of policy changes made to address concerns expressed by advocacy groups, comparison of international practice is particularly valuable, since we may learn from approaches implemented in other jurisdictions. We received responses from 24 respondents representing countries on six continents. In most, but not all, the MSM policy is determined at the national level.

The following questions were asked of the respondents:

Question 1

(a) What are your current national deferral policies for men who disclose having sex with other men and when were they implemented?

(b) Is your MSM deferral (e.g. indefinite, 12 months, etc.) consistent with that for other similar risk behaviors? (e.g. sex with an HIV-positive heterosexual partner, rape victim) (Please provide examples).

(a) National deferral policies

Most countries (13 of 24 – Table 1) currently employ a permanent or indefinite deferral for any MSM behavior, or MSM behavior since 1977. Six countries use definite period deferrals (Table 2), ranging from 5 years in New Zealand, to 12 months in Australia, Brazil, Japan and the Czech Republic, to 6 months in South Africa. Interestingly, New Zealand has recently reduced its deferral from up to 10 to 5 years, South Africa from 5 years to 6 months and Japan reports that it intends to reduce its 12 month deferral to 6 months in 2011, with the introduction of improved NAT testing. Australia implemented a reduced deferral period of 12 months over a decade ago, where the previous deferral period had either been indefinite or 5 years depending on jurisdiction. Five countries have no national deferral policy for MSM, however the circumstances differ in each: In

Table 1 Deferral periods that countries which do indefinitely defer males who have had sex with males (MSM) apply to prospective blood donors who reveal other risks of exposure to HIV

	United States	Canada	Mexico	Germany	Norway	Sweden	United Kingdom	France	Slovenia	Estonia	Egypt	Hong Kong	China
Male who has had sex with other males (MSM)	[a]Indefinite	Indefinite	Indefinite	Indefinite	Indefinite	[b]Indefinite	Indefinite	Indefinite	Indefinite	Indefinite	Indefinite	Indefinite	Indefinite
I.V. drug abuse	Indefinite	Indefinite	Indefinite	Indefinite	Indefinite	Indefinite	Indefinite	Indefinite	Indefinite	Indefinite	Indefinite	Indefinite	Indefinite
Received money or drugs in exchange for sex	Indefinite	Indefinite	Indefinite	Indefinite	Indefinite	Indefinite	Indefinite	Not stated	Indefinite	Indefinite	Indefinite	Indefinite	Indefinite
Sex with HIV-infected heterosexual partner	12 months	Indefinite	Indefinite	4 months	6 months	12 months	12 months	4 months	Indefinite	12 months	Indefinite if extramarital. 6 months if marital	Indefinite	12 months
Sex with a heterosexual sex worker	12 months	12 months	12 months	4 months	6 months	Indefinite	12 months	Indefinite		6 months	Indefinite	12 months	12 months
Female who has had sex with an MSM male	12 months	12 months	Indefinite	4 months	6 months	12 months	12 months	12 months		6 months	Indefinite	12 months	12 months
Rape (female victim, male assailant)	12 months	6 months	12 months	[c]4 months and anonymous self exclusion	[d]Deferral	12 months	[e]4 months	Not stated		6 months	12 months	[f]No policy	[f]No policy
Rape (male victim, male assailant)	12 months	Indefinite	12 months	[c]4 months and anonymous self exclusion	[d]Deferral	Indefinite	[g]Indefinite	Not stated		6 months	12 months	[f]No policy	[f]No policy
Incarceration for > 72 h	12 months	12 months	Indefinite	4 months	No deferral	No deferral	No deferral	Not stated		12 months	12 months	[f]No policy	[f]No policy
History of Gonorrhea or Syphilis	12 months	12 months	12 months	Indefinite	Indefinite for Syphilis; Other 12 months	Syphilis: 1 year; Gonorrhea: 3 months	Syphilis: indefinite; Gonorrhea: 12 months	Syphilis: 12 months; Other 4 months		Syphilis: indefinite; Gonorrhea: 6 months	Syphilis: indefinite; Gonorrhea: 12 months	Indefinite	Indefinite
Blood exposure (e.g. needlestick, tattoo from unlicensed establishment)	12 months	6 months	12 months	4 months	6 months	[h]6 months	[e]4 months	4 months		6 months	6 months	12 months	12 months

Table 1 (*Continued*)

	United States	Canada	Mexico	Germany	Norway	Sweden	United Kingdom	France	Slovenia	Estonia	Egypt	Hong Kong	China
Multiple heterosexual sex partners	No deferral	[i]6 months	Indefinite	Indefinite	6 months	[j]3 months	No deferral	4 months	No deferral	No deferral	Indefinite	No deferral	Indefinite
Recent new heterosexual partner	No deferral	[i]6 months	[k]No influence on deferral	[c]4 months and anonymous self exclusion	6 months	[j]3 months	No deferral	4 months	No deferral	No deferral	Indefinite	No deferral	No deferral
Safe sex practices (e.g. condom use, monogomous relationships)	No influence on deferral	No influence on deferral	[k]No influence on deferral	No influence on deferral	No influence on deferral	No influence on deferral	No influence on deferral	[l]Considered	No influence on deferral	No influence on deferral	Indefinite	No influence on deferral	No influence on deferral
Casual sex	No deferral	[i]6 months	12 months	[c]4 months and anonymous self exclusion	6 months	[j]3 months	No deferral	4 months	No deferral	6 months. If lifestyle, indefinite	Indefinite	No deferral	No deferral
Comment													

[a]The word 'indefinite' is used here to include both permanent and indefinite deferrals.
[b]Under consideration, see text.
[c]Each donor has to review the risk for transmissible diseases and complete an anonymous self exclusion process.
[d]Deferral for rape is based on risk assesssment.
[e]With negative tests for HIV, HBV, HCV, HTLV and syphilis.
[f]Deferral would be at least 12 months if history is revealed.
[g]This may be reviewed, exceptions are allowed.
[h]Sex partner is a 12 month deferral.
[i]6 months if 'sex with someone whose sexual background you don't know'.
[j]3 months after 1st engagement with a new sex partner.
[k]Interviewing MD determines risk.
[l]Considered in determining deferral for heterosexual risk partners.

Table 2 Deferral periods that countries which do not indefinitely defer males who have had sex with males (MSM) apply to prospective blood donors who reveal other risks of exposure to HIV

	Brazil	Czech Republic	South Africa	New Zealand	Australia	Japan	Italy	Spain	Poland	Russia	India
Male who has had sex with other males (MSM)	12 months	12 months	6 months	5 years	12 months	[a]12 months	[b,g]No deferral	No deferral	[c]No deferral	No deferral	[d]Not defined
I.V. drug abuse	Indefinite	[e]Indefinite	Indefinite	Indefinite	Indefinite	12 months	Indefinite	Indefinite	Indefinite	Indefinite	Indefinite
Received money or drugs in exchange for sex	12 months	12 months	6 months	[f]1 year if in New Zealand	12 months	12 months	Indefinite	Indefinite		Not determined	[d]Not defined
Sex with HIV-infected heterosexual partner	12 months	12 months	6 months	12 months	12 months	12 months	[g]4 month or indefinite	12 months		Indefinite	Indefinite
Sex with a heterosexual sex worker	12 months	12 months	6 months	12 months	12 months	12 months	[g]4 month or indefinite	12 months		Not determined	[d]12 months
Female who has had sex with an MSM male	12 months	12 months	Not asked	12 months	12 months	12 months	[g]4 month or indefinite	12 months		Not determined	Not defined
Rape (female victim, male assailant)	12 months	Not defined	[h]6 months	No specific deferral in place	No specific deferral	12 months	4 months	12 months		Not determined	Not defined
Rape (male victim, male assailant)	12 months	Not defined	[h]6 months	5 years	12 months	12 months	4 months	12 months		Not determined	Not defined
Incarceration for > 72 h	Indefinite	6 months	Depends	No specific deferral in place	12 months	No criteria	4 months	No policy	6 months	Not determined	Not defined
History of Gonorrhea or Syphilis	12 months	12 months	12 months	Syphilis: indefinite; Gonorrhea: 4 weeks	12 months	Syphilis: indefinite; Other 1 year	Syphilis: indefinite; Gonorrhea: risk dependent	12 months	Syphilis: indefinite; Gonorrhea: 12 months	Syphilis: indefinite; Gonorrhea: not determined	12 months
Blood exposure (e.g. needlestick, tattoo from unlicensed establishment)	12 months	6 months	6 months	6 months	12 months	12 months	4 months	4–6 months	6 months	12 months	6 months
Multiple heterosexual sex partners	12 months	12 months	6 months	No deferral	No deferral	12 months	[g]4 month or indefinite	12 months		No deferral	Not defined

Table 2 (*Continued*)

	Brazil	Czech Republic	South Africa	New Zealand	Australia	Japan	Italy	Spain	Poland	Russia	India
Recent new heterosexual partner	4 months	No deferral	6 months	No deferral	No deferral	No deferral	4 months	12 months		No deferral	Not defined
Safe sex practices (e.g. condom use, monogomous relationships)	No influence on deferral	No influence on deferral	No influence on deferral	No influence on deferral	No influence on deferral	No influence on deferral	[b]Condom use considered not protective	[i]Considered		No influence on deferral	Not defined
Casual sex	12 months	12 months	6 months	No deferral	No deferral	12 months	[g]4 month or indefinite	12 months		No deferral	Not defined
Comment											

[a]Will become 6 months in April 2011.

[b]No deferral only if declared monogamous.

[c]Donors not subject to detailed questions. 'Information on infectious diseases for blood donors' and the questionnaire do not mention MSM.

[d]There is no national policy. Interviewer may determine unsafe practices and defer indefinitely.

[e]12 months in the absence of drug dependence.

[f]5 years if occurring outside of New Zealand.

[g]4 months if occasional, Indefinite if recurrent.

[h]Victim and partner: Acceptable 6 months after the assault and tests negative for HIV, HCV, HBV & syphilis.

[i]Monogomous sex and condom use are considered safe, provided that other unsafe sex practices have not incurred.

India, there are no national polices in place but local interviewers are expected to defer donors considered to be at increased risk, which may include MSM. In Poland and Czech Republic, donors are not subjected to direct questioning but are provided with information on infectious disease risks and are expected to confirm that they have read and understand this information and do not consider themselves having been exposed to infection risk. MSM is not mentioned as a specific risk factor in Poland, but is defined as a risk factor by the national blood transfusion society in the Czech Republic. Russia has recently reversed a national policy requiring deferral of MSM donors following pressure at the Government level from gay advocacy groups. We are not told of the risk of HIV transmission in Russia and it is unclear that the effect of this change is being assessed. Italy converted from an indefinite deferral for MSM, to deferral based on risk factors (new or multiple partners) regardless of sexual preference in 2001. In contrast, Spain has always used behavioral risk factors, including the number of sex partners, new partners, casual sex and condom use, rather than eliciting a history of MSM.

(b) Consistency of MSM and other deferral criteria

Intravenous drug abuse leads to a indefinite deferral in all but one jurisdiction (Japan), while those accepting money or drugs for sex (sex trade workers) are generally indefinitely deferred in countries with an indefinite deferral for MSM, as well as Italy and Spain (see Table 1), presumably based on historical practice and the general concept that these risk factors are lifestyle choices that are likely to be recurrent. In contrast, behaviors that may engender similar or greater risk of HIV transmission with each occurrence, such as heterosexual sex with a known HIV infected partner are a 1 year deferral or as short as 4 months in most countries, and are often inconsistent with MSM policies. Countries with fixed period MSM deferrals tend to have fixed period sex worker deferrals as well, maintaining consistency.

Question 2

Do you use risk behavior-based criteria such as number of sex partners, recent new partners, casual sex, anal or oral sex, 'safe-sex' or condom use, etc. as criteria for deferral for any donors? If so, describe.

Use of risk based criteria for heterosexual donors

Heterosexual behavioral risk factors such as number of partners, new partners, casual sex or use of condoms are not considered in the evaluation of donor eligibility in the US, UK, Hong Kong or Slovenia. However many other countries with lifetime, fixed period or no MSM bans ask questions about heterosexual behavioral risk to varying degrees. Affirmative answers usually lead to a 3–6 month deferral period. For example, Canada currently defers prospective donors for 6 months for sex with a partner whose sexual background is unknown, although this has recently been removed as a requirement for blood as determined by the Canadian Standards Association; many European countries (Sweden, France, Norway, Italy, Spain) consider whether a donor has new, multiple or unknown recent sexual partners. Sweden defers a donor for 6 months following a tattoo or piercing, however the sexual partner of this donors is deferred for 12 months. Australia and New Zealand, two countries with fixed period MSM bans, report not using new or multiple partners as deferral criteria, while only France responded that regular condom use was considered in determining donor deferral. Although not solicited in the questionnaire, the United Kingdom reported a 12 month deferral for donors who reported sex with a partner from 'high heterosexual risk areas'.

Question 3

Has there been a recent (within 5 years) review of policies in your jurisdiction triggered by

(a) regulatory guidelines or advisory committees
(b) court findings or court cases
(c) stakeholder, public or political pressure regarding your deferral for MSM and what were their conclusions (how have they affected policy)?

Review of policies

(a) Regulatory guidelines or advisory committees

Internal Blood Service and/or external reviews have taken or are currently taking place in several countries. In the US, the major blood suppliers, including AABB, America's Blood Centers and the American Red Cross have taken the public position that the 'current lifetime deferral for men who have had sex with other men is medically and scientifically unwarranted' with the recommendation that the deferral criteria 'be modified and made comparable with criteria for other groups at increased risk for sexual transmission of transfusion-transmitted infections.' Despite multiple public reviews by the FDA over the last 10 years, no change in US regulatory policy has occurred. The Swedish National Board of Health and Welfare has since 2006 tried to enact a fixed period deferral (6–12 months), but the Swedish Medical Products Agency strongly disagrees, arguing that if plasma is sent for fractionation into medicinal products, a lifetime permanent deferral for MSM is indicated. Blood Services have continued to enforce a lifetime ban and now await the outcome of an international working group organized by the European Directorate for the Quality of Medicines and Healthcare (EDQM).

(b) Human rights commissions or court cases

Direct challenges to the policy on the basis of human rights are reported by South Africa, where gay advocates argued

that the risk of heterosexual transmission far exceeds that of homosexual transmission. The Human Rights Commission that was central to the post-Apartheid reconciliation process, failed to rule on the issue and the Blood Service moved to a limited 6 month deferral period, founded on internal reviews and the recent introduction of single donor NAT testing. New Zealand and Australia report complaints to their respective Human Rights Commissions. In New Zealand, mediation resulted in the complaints being dropped, following a national review process. In Australia, the Tasmanian Anti-discrimination Tribunal ruled against the complainant, finding that 'the conduct of the Blood Service did not constitute direct or indirect discrimination', while the Australian Human Rights and Equal Opportunities Commission ruled that a complaint of discrimination was 'misconceived'. In Canada, a provincial superior court recently ruled in favor of the Blood Service, noting that 'blood donation is not a right but a gift that CBS or any blood collector is not obligated to accept; that blood donors have a duty to answer all screening questions honestly, even if they don't agree with the question; and that the MSM deferral policies are not discriminatory, but are based on health and safety considerations.'

While most rulings have favored the Blood Services' right to determine donor selection policies to protect the blood supply, a recurring theme is that this engenders a responsibility to regularly review policies in the light of the best scientific information and with input from all parties in the community. Indeed, the Canadian court found in a non-binding observation that, while the safety of patients is paramount, the gradually increasing duration of the lifetime deferral for MSM since 1977 is potentially problematic and demands constant reassessment by the blood suppliers.

(c) Stakeholder, public, or political pressure

Most countries report advocacy by gay groups for removal of donor selection based on MSM behavior. This has taken many forms, including urging the boycott of blood drives at schools and university campuses, petitions and protests. In the US, Congressional leaders have increasingly taken up the issue and formal letters have been submitted to the FDA questioning the basis of current policy. In Russia, protests led directly to the removal of MSM as a criterion by the Russian Ministry of Health and Social Development. The impact in other countries may be less dramatic in the short term, however it is unlikely that the pressure will diminish without the issue being adequately addressed, if not resolved.

Question 4

If there have been changes to your MSM deferral policies in the last 5 years, what impact have they had on HIV prevalence and incidence in your donor population?

Recent changes and their impact

As mentioned in above, national blood programs in several countries including Japan, New Zealand and South Africa, have recently further reduced their fixed deferral periods, indicating an increasing comfort level with fixed deferrals. In addition, Australia has recently reported data from their less recent policy change indicating it was not associated with an increase in recipient risk, and their background rate of detection of HIV-infected donors remains very low at approximately 1:207 000 donations [3]. No evidence of testing seeking behavior is apparent. In South Africa, a rising number of HIV positive donors have been documented, however, these have been attributed to increased recruitment of populations with high heterosexual HIV risk, rather than MSM risk. South Africa initiated its Haemovigilance Programme in 2001 and reported about two HIV transmitted infections a year up to 2005. Since the introduction of NAT testing there has not been any HIV transfusion transmitted infection reported to the Haemovigilance Programme in five years between 2005 and 2010, however risk models suggest that this is likely to occur.

In contrast, the outcome of changes in countries such as Brazil, Czech Republic, India, Poland and Russia are less clear. In Italy, the outcome of the decision in 2001 to remove the indiscriminate lifetime MSM ban is currently documented by unpublished institutional data from the Italian National Blood Centre and the Italian Society for Transfusion Medicine and Immunohematology, suggesting no significant change in the incidence and prevalence of HIV in blood donors between 1999 and 2008, while previous reports have inferred an incremental increase over time, with incident cases being predominantly male repeat donors [4]. We await the full publication of these data for clarity.

The current situation in Spain is cause for concern: Although there is no deferral for MSM behavior, donors are questioned by health care professionals about multiple behavioral risk factors including new or multiple sex partners of either sex or casual sex. Blood Service epidemiological data have shown a recent increase in the HIV seropositivity rate and NAT HIV window-period donations, with the majority of cases occurring among repeat male donors, many of whom report a history of MSM and undisclosed high risk behavior. These data suggest a degree of test-seeking behavior by this population, especially following the introduction of NAT testing which, together with major changes in population demographics due to a massive influx of immigrants in recent years, are leading public health officials to consider the institution of a 12 month deferral for MSM behavior.

Question 5

Do you attribute the changes noted in question 4 to the MSM policy changes or to changes in the HIV prevalence and incidence in the general population of your geographical area? What are the current major risk factors for HIV in your general and donor populations?

Major risk factors for HIV transmission in the general and donor population

MSM is the predominant mode of HIV transmission in the general population of the majority of reporting countries, and prevalence amongst this group may be 40–60-fold higher than that of the general population. Notable exceptions are Russia, Poland and Estonia where intravenous drug abuse, and Italy and South Africa where heterosexual contact predominates. Immigrant HIV-infected individuals and heterosexual transmission in areas of high HIV prevalence are increasingly important in many countries. In South Africa heterosexual spread is the predominant mode of transmission, accounting for infection in approximately 11% of the general population.

In conclusion: Blood Services are obligated to provide the safest possible blood products to patients. To meet this obligation, most respondents include MSM behavior in the criteria for determination of donor eligibility. A rising tide of protest by gay advocates claiming discrimination and inequity now threatens the ability of operators to collect blood in schools, university campuses and work places. While the courts have generally upheld the right of Blood Services to employ donor history questions about MSM behavior in order to ensure patient safety, many countries are reviewing the scientific basis of MSM deferrals. As result of these reviews, a growing number of countries have moved to increasingly brief, fixed-period deferrals, often with the incorporation of some behavioral risk questioning. The lack of solid evidence to support the safety of complete abolition of MSM-based deferrals and concerns about donor untruthfulness regarding sexual risk and test-seeking behavior remain as the greatest challenges confronted by blood operators and regulators, the ultimate guardians of blood safety. Consequently, in order to address these issues, all policy changes need to be transparent and require both donor and public education to ensure that risk does not increase due to inadvertent devaluation of the donor history questionnaire as a valid and effective layer of safety. Nevertheless, current international experience argues for the safety of fixed period deferrals for MSM, especially when fortified with judicious behavioural risk questioning that may in addition provide further protection as the worldwide heterosexual HIV epidemic expands.

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C. R. Seed, H. Yang, J. Lee & A. J. Keller

Question 1

(a) The current Australian Red Cross Blood Service (the Blood Service) national policy for men who have had sex with another man (MSM) is 12 months deferral from last sexual contact. This deferral was implemented in a stepwise manner in Australian state and territory jurisdictions between 1996 and 2000 because of legislative constraints. By October 2000, all Australian states and territories had implemented the current national policy. Notably, a recent, retrospective analysis of the impact of the deferral concluded that there was no evidence that it led to an increased risk of transfusion-transmitted HIV in Australia [1].

(b) Yes. We apply the same deferral period of 12 months for similar risk behaviors such as sexual contact with a sex worker or a HIV-positive heterosexual partner. Similarly, a donor with a new partner from a HIV risk area (defined as a country with HIV prevalence of 1% or greater) is deferred for 12 months.

Question 2

Multiple partners or casual sex are not used as criteria for deferring donors. Since 'safer sex' practices (e.g. condom use) reduce but do not eliminate the transmission risk they do not obviate the need for deferral. Thus our current male to male sex question; 'Within the last 12 months: Had male to male sex (that is, oral or anal sex) with or without a condom?' clearly indicates that condom use does not equate to 'safe' sex and still leads to deferral.

Question 3

(a) The Blood Service 'Guidelines for the selection of blood donors', which includes all the donor deferral questions, is reviewed annually in accordance with Australian regulatory requirements.

(b) There have been three unsuccessful challenges to the policy of deferring donors who have engaged in male to male sex considered by Australian quasi-judicial bodies; two in the last 5 years.

In May 2009, the Tasmanian Anti-Discrimination Tribunal, in the case Michael Cain v The Australian Red Cross Society [2], found that the conduct of the Blood Service in deferring Mr Cain as a donor did not constitute either direct discrimination or indirect discrimination. The Tribunal found that the reason for the policy ''is the fact that people who engage in male-to-male sex have, as a group, a high risk of HIV transmission'' (paragraph 551).

In 2007 the President of the Human Rights and Equal Opportunity Commission (HREOC) found that a complaint that the conduct of the Blood Service in deferring donors who had engaged in male to male sex had breached human rights under the Human Rights and Equal Opportunity Commission Act was misconceived, and declined to hear the complaint. The President of HREOC considered that the criterion applied by the Blood Service to this particular donor deferral policy was reasonable and objective and based on the need to safeguard the blood supply.

Despite these cases upholding the legislative validity of the current deferral it is incumbent on the Blood Service to continually evaluate donor selection policies based on new information. Therefore the Blood Service will be coordinating an independent review of sexual-activity based donor deferral criteria (targeted for completion during 2011) which will include reviewing the policy for MSM.

(c) The Blood Service continues to receive written and verbal communication from donors and members of public about the MSM deferral policy. Despite the unsuccessful legal challenges noted previously, many respondents continue to assert that the current policy discriminates against male homosexual individuals. The Blood Service donor selection policies are underpinned by its primary obligation to protect blood recipients. Accordingly, our position regarding the MSM policy is that it will continue until there is clear evidence that the policy could be revised without any increased risk to the blood supply and the patients who depend on it.

Question 4

There have been no changes to the MSM deferral policies in the last 5 years. However, there has been refinement of the wording of the 'male to male sex' question. The wording of the question is now more explicit with regard to the exact nature of the sexual practice concerned, and became effective July 2010. Therefore any impact on HIV prevalence and incidence is yet to be determined but will be closely scrutinized.

Question 5

Epidemiological data confirms that in the Australian general population HIV continues to be transmitted primarily through sexual contact between men and that the recent increasing trend in HIV notifications is predominantly associated with MSM [3,4]. Of the 281 cases of newly

acquired HIV infection reported in 2008, the reported exposure category for 243 (84·3%) was MSM [3].

Confidential interviews with HIV positive blood donors indicate that MSM was disclosed in 27% of HIV positive donors in the period 2001–2006. In contrast to the general population it does not predominate with several other risk factors including; sex with an individual from overseas (20%), contact with infected blood (20%) and sex with a sex worker (13%) also disclosed [5]. The 27% figure above includes some cases where the history of MSM was not disclosed at initial interview by the Blood Service, but only in the course of later discussions. Therefore it is possible that this figure is under-reported compared to the general population surveillance data.

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S. Biagini & S. Wendel

Question 1

(a) According to a Brazilian national guideline [1] implemented in December 2002, MSM who declare such sexual activities in the previous 12 months are deferred from donating blood. There have been a number of changes and guidelines [2] issued since 2002, but all kept the same 12-month deferral period.

(b) Yes, our MSM deferral period is consistent with that in other risk situations as the risk of a rape victim; people who received money in exchange for sex; an HIV positive heterosexual partner; a casual partner; multiple heterosexual partners; and cocaine users (inhalation). Donors who reveal IV drug use are indefinitely deferred. We do not consider condom use as safe sex practice since we have concerns about its appropriate use.

Question 2

Yes, we use it. We apply the following deferral period: if a donor refers more than three partners a year deferral (12 months); casual sex (12 months); and recent new partner (4 months). We do not ask about types of sexual intercourse (anal, oral sex or 'safe-sex').

Question 3

No, there has been no change in policies in Brazil in the past 6 years, although a new guideline is actually under public consultation and will probably become effective by mid 2011.

Question 4

Not applicable.

Question 5

Not applicable.

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M. Goldman, J. Murray & D. Devine

Questions/Answers

Question 1

(a) In Canada, we have an indefinite deferral for men who have sex with other men, even one time since 1977. This policy has been in place since the mid 1980s. The criterion was first listed in a specific AIDS information pamphlet given to donors prior to phlebotomy, and was added to the donor health assessment questionnaire by the late 1980s.

(b) MSM and intravenous drug use (IVDU) account for approximately 50% and 20% of prevalent HIV infections in Canada respectively, and have similar deferral criteria [1,2]. Sex with an HIV positive partner similarly results in an indefinite deferral. Heterosexual risk factors vary in their level of risk and time period of deferral (please see Table 1). For example, commercial sex workers, i.e. individuals who have received money or drugs in exchange for sex are indefinitely deferred. Other HIV risk deferrals are of shorter duration, but are also believed to be associated with less risk of HIV transmission. For example, the deferral for a female who has had sex with an MSM is 12 months. In modeling studies, the risk of acquiring HIV associated with this behaviour has been calculated to be considerably less than that associated with MSM [3–5].

Question 2

In general, we do not use criteria such as number of sex partners or new partners. We do have a question 'In the past 6 months, have you had sex with someone whose sexual background you don't know?' This question predates the addition of more specific questions about having sex with someone who has accepted money or drugs for sex or has taken illicit drugs intravenously. Our data assessing risk factors in HIV positive donors and HIV rates in returning donors temporarily deferred for this criterion suggests that this question does not identify a separate risk category for HIV infection. Therefore, the value of this question is uncertain and it has recently been removed from the second edition of the Standards for Blood and Blood Components published by the Canadian Standards Association.

Question 3

In 2001, CBS and Héma-Québec the two blood operators in Canada, co-sponsored a Consensus Conference on Optimizing the Donor Selection Process. The conference was open to the public and included presentations from scientific experts, as well as presentations on ethics and law, and perspectives from high interest groups, including patient advocacy organizations. The advisory panel made no recommendations specifically to change MSM criteria, but advocated for a continued assessment of donor criteria based on evolving data [3]. Subsequent review of policies has been stimulated by this recommendation, by pressure from various advocacy groups, and by the commitment of our organisation to base donor criteria on evidence and best practice, whenever possible [4].

In 2006, CBS commissioned the McLaughlin Centre for Population Health Risk Assessment at the University of Ottawa to conduct a risk assessment of donor deferral for MSM [5]. In April 2007, CBS engaged in structured consultative meetings, lead by an independent facilitator, with high interest groups. These included both members of our National Liaison Committee, which represents many patient advocacy groups such as The Canadian Hemophilia Society, and groups advocating for change, such as The Canadian AIDS Society and The Canadian Federation of Students. The goals of these discussions were to explore and understand positions and identify potential gaps to inform the decision making of the Board of Directors. It was clear from these discussions that patient stakeholder groups were concerned that any criteria change would lead to an increased risk for either known or unknown emerging pathogens. Other special interest groups would prefer risk based behaviour questions and did not necessarily find that a shortened deferral period was an acceptable alternative.

In 2007, the Canadian Blood Services Board of Directors, taking into account both the McLaughlin Centre for Population Health report and the results of the public consultation, determined that CBS would maintain the current policy for MSM deferral, while actively gathering knowledge to close information gaps identified through the risk assessment and the consultation process. The Board felt that it was not prudent to move forward until they were fully convinced that a change to the policy would not affect recipient safety. With respect to filling the information gaps, CBS has committed a substantial sum to fund research relevant to this policy, in partnership with the Canadian Institutes for Health Research (CIHR), the Canadian federal research organization.

Canadian Blood Services' Office of Public Affairs created a LGBTTQ (lesbian, gay, bisexual, transgendered, two-spirited, and queer) working group, whose mission is to make recommendations about policy, facilitate linkages and foster understanding between the LGBTTQ community, the Canadian Federation of Students, CBS and patient recipient stakeholders.

There has been a recent court decision in Ontario, Canada regarding whether the MSM deferral criteria is justifiable

from a legal rights perspective [6]. In this case, the litigant, a sexually active gay man living in Canada, donated blood on several occasions between 1990 and 2002, and denied that he had had sex with another man since 1977 on each occasion. When these circumstances came to the attention of CBS in 2002, through an anonymous e-mail, CBS went to court to learn his identity and sued him for negligent misrepresentation. The litigant then counter-sued CBS and the Attorney General of Canada (acting on behalf of CBS's regulator, Health Canada), claiming the MSM criteria discriminated against him under the *Canadian Charter of Rights and Freedoms*. The judge ruled in CBS's favour, finding the litigant negligently misrepresented himself. She also ruled that because CBS is not a government organization, the *Charter* does not apply to CBS or to its donor screening process. Of greater interest to the international transfusion medicine community, the judge ruled that blood donation is not a right but a gift that CBS or any blood collector is not obligated to accept; that blood donors have a duty to answer all screening questions honestly, even if they don't agree with the question; and that the MSM deferral policies are not discriminatory, but are based on health and safety considerations. The judge expressed reservations about the length of the deferral period for MSM. She acknowledged there is an absence of consensus on the ideal deferral period, but also indicated it is important CBS, as the expert, be given deference in determining the appropriate deferral period and the pre-requisites for change [6].

There have been no recent changes in Standards or regulations in Canada regarding this issue.

Question 4

There have been no changes to our MSM deferral policies in the last 5 years.

Question 5

The prevalence and incidence of HIV in our donor population has been stable and extremely low over the last decade, with from 1 to 8 HIV positive donors found annually. The prevalence of HIV was 0·80 per 100 000 donations in 2009 (5·69 and 0·33 per 100 000 donations for first-time and repeat donors, respectively). Since 2003, 70% of HIV positive donors have been male. Risk factors found in HIV positive donors who agree to participate in interviews include MSM, female donor with MSM sexual partner, heterosexual contact with someone who had HIV/AIDS, and heterosexual contact with someone who has injected street drugs or taken money or drugs for sex (unpublished data, Sheila O'Brien, Director, Epidemiology and Surveillance CBS). The number of donors is too small to conduct a detailed statistical analysis.

The prevalence of HIV in the general population in Canada has been steadily increasing due to improved survival and new infections [1,2]. The current major risk factors for new infections are MSM (44%) followed by IV drug use (17%), heterosexual/non-endemic (20%), and heterosexual/immigrant from endemic country (16%). There has been little change in the distribution of risk factors in the last 5 years. According to the Public Health Agency of Canada, the prevalence rate of HIV/AIDS in the Canadian population is estimated at 0·18%, or 180 per 100 000 population, and approximately 26% of these individuals are unaware of their infection.

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Z. Yongming

Answer 1

(a) Our current national deferral Policies on MSM are demonstrated in Health Examination Criteria on Blood Donors (GB18467-2010). Since the Criteria are still in the approval process, current estimates are that they will be implemented in 2011.

(b) Our MSM deferral is consistent with that for other similar risk behavior. For example, Criteria 6.1.19 requires that MSM, multiple sexual sex partners, and I.V. drug abusers are excluded from donation indefinitely. Criteria 6.2.15 requires that those who have sexual contact with an individual at high risk of blood transmissible diseases are deferred for 12 months.

Answer 2
We do not use risk behavior-based detailed criteria for deferral of donors in either the or the new questionaire tools.

Answer 3
In recent years, there have been many research projects on homosexuality in China, and MSM is especially considered as one of the high risk behaviors for HIV infection threatening the public health. Laws or regulatory guidelines have not previously been drafted. Items regarding deferral for MSN donors are expected to appear in the forthcoming Health Examination Criteria on Blood Donors (GB18467-2010).

Answer 4
So far we do not have any supporting data, and have no idea about what the impact MSM deferral on HIV prevalance and incidence in our donor populations has been.

Answer 5
With the increase in the prevalence and incidence of HIV in our country, MSM is presumed to be the current major factor for HIV transmission in our general and donor populations based on the information from the Chinese CDC.

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P. Turek

(1) Legal requirement is to defer from blood donation '*persons, whose sexual behavior put them into increased risk of an acquisition of severe infectious diseases transferrable via blood*'. In practice MSM are temporarily (12 month) deferred from blood donation. This policy is defined in an official recommendation of the national blood transfusion society. This recommendation is based on sequential reassesment of epidemiological data.

MSM deferral policy/criteria are consistent with those in other similar sexual risk behavior.

(2) Before blood donation a candidate donor is informed about sexual activities which put him/her at increased risk of HIV infection and a general recommendation/plea 'not to give blood in case of increased risk' is addressed to the donor. During donation detailed risk behavior-based questions are not asked, the only topic-related questions asked are:

- have you read a donor information carefully? and
- do you consider yourself as a person at increased risk according to the donor information?

(3) Donor deferral policy (incl. risk sex behavior) is reassessed by expert committees at regular intervals as political pressure from the homosexual community is ongoing. Legally binding requirements are formulated in general terms and they need not to be reformulated.

(4) There was no major change in donor deferral policy within last several years in the Czech Republic.

(5) The incidence and prevalence of HIV is increasing slightly in both the donor population and in the general population. Actual rates are luckily very low and do not allow correlations to be performed. MSM contact is a major risk factor for HIV infection in the general population (over 60% of cases) and also in blood donors (MSM contact is usually not divulged at the time of donation but is admitted following the detection of HIV infection. in the Czech Republic).

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F. M. Moftah

Question 1
MSM are deferred, since 2007. It is consistent with men with HIV.

Question 2
One criterion only, high risk sex behavior.

Question 3
No.

Question 4
Not measured.

Question 5
Unsafe sex.

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R. Kullaste

Question 1

(a) Men who disclose having sex with other men are permanently deferred. It was implemented as national policy in 2005.

(b) Yes, we believe so. Indefinite deferral is applied to multiple casual sex and for 'sex workers' (money or drugs in exchange for sex).

Question 2

Yes, we use some: casual sex once – 6 months deferral, sex with HIV-infected heterosexual partner – 12 months deferral, sex with heterosexual sex worker – 6 months deferral.

Question 3

(a) no (b) no (c) yes, our MSM community has applied to the Ministry of Social Affairs for changing of the deferral policy. This occurred quiet recently and the discussion is still ongoing. No changes are planned so far.

Question 4

No changes to our MSM deferral policy has been made during last 5 years.

Question 5

It is estimated that the major current risk factor for HIV in general population is intravenous drug use. The main risk factor in the donor population is not clearly understood.

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Question 1

(a) Our current national policy in France for male donor candidates who disclose having sex with other men is permanent deferral. This policy has been implemented as a current practice since 1983 and integrated in the national regulation in 2009, in the 'Arrêté' of January 12 fixing the criteria for blood donor selection.

(b) The permanent deferral is based on epidemiologic studies showing the higher HIV prevalence and incidence among MSM in France. HIV prevalence among MSM was estimated to be in the range of 7–18%. The comparison of the mid-point of this range (13%) with the prevalence estimate in the heterosexual population aged 18–69 (0·2%) shows that HIV prevalence among MSM is about 65 times higher. With an HIV incidence estimated to be 1% in the MSM population in 2008, this incidence is 200 times higher in MSM than in the French-national heterosexual population, 18 times higher than in IDUs, and nine times higher in non-French nationals [1].

The permanent period of deferral is consistent with other similar risk behavior.

Question 2

We effectively use behavior risk criteria such as number of sex partners, casual sex, protected sex (condom use), as criteria for deferring donors. We don't use the precise terms 'oral or anal sex', although our questionnaire makes clear that only MSM risk behaviors are considered and not 'WSW' (women sex with women) practices.

Question 3

The current national regulation issued in January 2009 foresees an annual review of the policies defining donor selection. The first review took place earlier in 2010 and the outcome has been to keep unchanged the national policy and regulation for donor selection criteria for the coming year. This review is conducted under the aegis of the Ministry of Health with the contribution from experts, notably from the Blood Establishment (EFS) and the Competent Authority (AFSSaPS).

Question 4

Our MSM deferral policies have not changed in the last 5 years. Nevertheless, risk models have been made to assess the consequences of potential changes. In France, we used a model to estimate the impact on the HIV residual risk of a change in strategy in which MSM would be only deferred if they have had more than one sexual partner in the last 12 months. Depending on the scenario used this new strategy would result in an overall HIV residual risk of between 1 in 3 000 000 donations, close to the current risk (1 in 2 440 000 donations during the 2006–2008 period), and 1 in 650 000 donations. The worst case scenario corresponds to a mean of three donations potentially infected with HIV each year in France in addition to the current estimate of one donation infected with HIV each year. Based on these numbers, the incremental risk of this change in policy concerning MSM would probably be low; nevertheless, considering the worst case scenario, it could be judged to be unacceptable. However, these estimates do not take into account the possible better compliance of MSM with a less stringent policy.

Question 5

As indicated above, there has been no change in the last 5 years. However, we know relatively well the current major risk factors in the general and the donor populations

in France, and then we can compare the proportion of MSM in the two populations. Despite the permanent deferral of MSM from donating blood, we estimate that nearly half of the current risk of HIV transmission by transfusion in France can be attributed to MSM who do not comply with the policy. Although HIV incidence has been estimated to be much lower among MSM blood donors than among the MSM of the general population, the proportion of donors infected by male-to-male sex among donors newly infected with HIV was as high as the estimated proportion of MSM among people newly infected with HIV in the general population (48%): in 2008, an estimated 6940 persons became infected with HIV in France of whom 3320 were MSM [1]. The similarity of the proportion of MSM for blood donors and the general population would have been expected if the criteria for the donor selection were the same for all potential donors. However, the policy for heterosexuals is only temporary deferral based on risky behavior (4 months after the end of the high risk situation). Therefore, the percentage of blood donors who are MSM infected with HIV should be much lower than that of the general population.

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E. Seifried & M. M. Mueller

Question 1

MSM disclosure leads to an indefinite deferral in Germany. This has been implemented in the national guidelines since the beginning of 1980s.

(a) Blood donors with a significantly higher (compared to the whole population) transmission risk of severe infectious diseases like HBV, HCV or HIV infection, but not restricted to these examples, will be deferred for an indefinite period. However, not all potential examples are listed in the national guidelines. Each donor is seen by a physician before donation in Germany and the donor history is reviewed. In addition, each donor has to state anonymously (via a barcode depicting his/her donation number) whether his/her donation can be used for transfusion. This 'statement' is read electronically and products will be destroyed, if the donor excludes him/herself via the anonymous self-exclusion barcode.

Question 2

We use a confidential 'anonymous self-exclusion' procedure as stated in answer 1b (above). Each donor receives an instruction leaflet with more than 10 examples for a higher risk of hepatitis or HIV transmission including multiple heterosexual sex partners, sex with sex workers, sex tourism, one-night stand, etc. This leaflet includes two barcodes. In a green field stating 'o.k.' and 'my blood can be used', the barcode allows full use of the donation. In a red field with 'my blood cannot be used', the second barcode will prevent any use for transfusion. The donor chooses one barcode and puts it onto the donation sheet. The barcodes itself are only distinguishable from each other by the software once they are peeled off the original leaflet. The nurses and physicians at the donation site only make sure that a barcode is affixed on the donation sheet. Any 'my blood cannot be used' barcode results in destruction of all products coming from this donation.

Question 3

No.

Question 4

No impact.

Question 5

The current major risk factor for HIV infection in the general population is MSM (67% of new HIV infections in Germany in 2009 for which the source of infection is known [1]; incidence for a positive test for HIV about 1 in 29 000 of the whole population). For the donor population, this risk group is deferred. HIV positive test results in regular blood donors are only found in rare situations in Germany (about 1 sero-conversion in more than 125 000

donations [2]). Therefore, the current major risk factors for the donor population are difficult to define, since the absolute numbers are low.

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L. C. Kit

Question 1

Male donors who disclose a history of having sex with other men are deferred permanently for blood donation. This policy has been implemented since the 1980s at the beginning of the HIV epidemic.

Our MSM deferral policy is consistent with that for other similar risk behaviors, e.g. I.V. drug abuse, received money or drugs in exchange for sex and sex with HIV-infected heterosexual partner are all permanently deferred.

Question 2

No, we do not ask direct questions about donor life-style such as number of sex partners, recent new partner, casual sex, anal or oral sex, 'safe-sex' and/or condom use, etc. in our blood donation questionnaire. We are of the opinion that it is very difficult to provide a clear and evidence-based definition of each of these criteria for determining suitability of potential donors to give blood without causing potential disputes or challenges from concerned individuals or social groups.

Question 3

In Hong Kong, we do not have regulators but an Expert Panel on Blood and Blood Products Safety to regulate blood safety policy and implementation. Membership of the Panel comprises of lawyer, clinical and laboratory haematologists, HIV&t AIDS specialists, microbiologist, and epidemiologist and transfusion experts. The Expert Panel has recently at a meeting in September 2010 reviewed the latest international developments in MSM donor deferral policies including the FDA's response to the AABB, American Red Cross and American Blood Centres' joint statement on the policy in US [1] and the Australian Red Cross Blood Service's article published in Transfusion titled '*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*' [2]. The Panel considered that the current permanent deferral policy continued to be applicable in the local setting in Hong Kong.

Question 4

There have not been any changes in our MSM deferral policies in the past 5 years.

Question 5

Summarised in Table 1 below are the cumulative data from 2001 to 2009 of blood donors who were found to be confirmed anti-HIV positive and their risk factors, if known. It is noted that a high proportion of confirmed HIV positive male blood donors (51·2%) had history of MSM activities.

For the general population in Hong Kong, according to the latest statistics released by the Department of Health (Table 2) [3], homosexual contacts accounted for 36·2% of the reported cases in the second quarter of 2010 and 30·2% cumulatively since the establishment of the reporting system.

Table 1 Cumulative data of HIV blood donors from 2001 to 2009

Gender	Male	Female
Total number	41	5
Age range	16–57	19–44
Risk factor revealed	36	4
Homosexual	18	1
Bisexual	3	0
Heterosexual	15	3
Other risk factors identified	0	0

Table 2 Summary update (30th June 2010) of the HIV/AIDS cases reported to the Department of Health, the Hong Kong Special Administrative Region

	April to June 2010		Cumulative	
	HIV	AIDS	HIV	AIDS
Sex				
Male	74	13	3724	975
Female	31	3	925	166
Ethnicity				
Chinese	66	12	3088	886
Non-Chinese	39	4	1561	255
Route of transmission				
Heterosexual contacts	33	8	2054	700
Homosexual contacts	31	5	1217	239
Bisexual contacts	7	1	188	45
Injecting drug use	4	0	288	46
Blood/blood product recipients	0	0	79	24
Perinatal	1	0	25	7
Undetermined	29	2	798	80
Total	105	16	4649	1141

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R. N. Makroo

Answer 1

(a) There are as yet no defined national policies on this subject however different institutes follow their own institutional guidelines in this regard. These are largely consistent with the policies followed for other similar high risk behaviors like intimate contact with seropositive patients.

(b) Yes it is. For example, individual who give history of having sex with a commercial sex worker in the past is deferred indefinitely.

Answer 2

Although there are no set deferral criteria currently being followed in India, history of any such high risk behavior is considered for deferral.

Answer 3

No. However, homosexuality (gay marriages) has been legalized lately under Article 377. Government of India.

Answers 4 and 5

No recent changes in the national policy have been made.

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Question 1

(a) The current policy envisages that the deferral of applicant/regular blood donors due to personal behaviors that possibly increase the risk of transmission of viral infections cannot be based on the blood donor's sexual orientation, but needs to be based on declared/detected risk/high risk behaviors, regardless of sexual orientation. This selection criterion has been implemented nationwide since April 2001 by a decree of the Ministry of Health which changed the previous provisions establishing permanent deferral of male blood donors who declared having had sex with other males.

(b) MSM deferral criteria are consistent with those for other similar risk behaviors. The same deferral criteria are applied to any blood donor, both male and female, regardless of sexual orientation. They are based on the declaration/evidence of:

- risk behaviors (e.g. occasional sex with a new partner implies 4-month deferral after the sexual intercourse);
- high risk behavior (e.g. usual/recurrent sex with multiple new partners implies permanent deferral).

Question 2

Deferral criteria based on sexual behaviors are not specifically applied to MSM but to any blood donor, both male and female. A recent new partner or occasional sex (both homosexual and heterosexual) evokes a 4-month deferral, and 'safe sex', implying the use of condom, is not a reason for reducing any deferral period. The specific type of sexual intercourse (oral, anal, etc.) is not assessed because any type of sex with a new/previously unknown partner is considered at risk for blood donation.

The number of multiple sex partners/events that determine a permanent deferral is not defined in the questionnaire. The physician in charge of blood donor selection is responsible for adjudicating low vs. high risk behaviors (e.g. occasional vs. usual/recurrent behaviors).

Question 3

The current policy was adopted in 2001 and no revisions have been issued so far. A few blood establishments tend to apply more stringent criteria for MSM, occasionally causing strong protests from gay associations claiming social discrimination and involving parliamentary debates; in the latter the current policy has always been sustained in a bipartisan way.

Question 4

No changes have been introduced in MSM deferral policies over the last 5 years.

Question 5

Surveillance systems of HIV infections in the general population have been in place in Italy since 1987, and of blood donors since 1988.

A similar trend has been observed in the blood donor population: the incidence and prevalence rates were, respectively, $5{\cdot}1 \times 10^5$ and $29{\cdot}3 \times 10^5$ in 1988, $2{\cdot}1 \times 10^5$ and $12{\cdot}9 \times 10^5$ in 1999, $2{\cdot}1 \times 10^5$ and $18{\cdot}5 \times 10^5$ in 2008 [National Blood Centre and Italian Society of Transfusion Medicine and Immunohaematology – data publication in progress]. This shows that the incidence rate of HIV positive blood donors before and after the blood donor deferral policy in place until 2001 has not changed. Furthermore, the residual risk of transfusion transmission of HIV infection in Italy has been shown to be similar to other European Countries[1].

Current major risk factors observed in the new HIV infections in the general population have substantially changed over time. Indeed, the proportion of cases in intravenous drug addicts has moved from 74·6% in 1985 to 7·7% in 2008, whereas new HIV infections attributed to sexual risk behaviors (heterosexual and homosexual) have become the majority, increasing from 7·8% to 75·7% of the total cases, with a hetero/homosexual ratio of 2/1[2].

The risk factor distribution in the blood donor population is quite similar according to the data collected since 1996 in the Lombardy region (which is the Italian region with 15% of the national population and with the highest HIV incidence rate in the general population) and to the data collected nationwide by the National Blood Centre starting from 2008 to 2009. This data [National Blood Centre and Italian Society of Transfusion Medicine and Immunohaematology – data publication in progress] shows that sexual risk behaviors are responsible for 89–94% HIV positive blood donors with known risk factors and that the hetero/homosexual ratio ranges between 1·8 and 2·8:1.

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K. Tadokoro

Question 1

(a) A male donor is deferred who has had sexual contact with another male(s) within 1 year. This was implemented in 1995. Question 14 in the questionnaire relating to risk behaviors is as follows;

In the past 1 year, have you

(1) had sexual contact with unknown partner(s)?
(2) Male donors only: had sexual contact with another male?
(3) been diagnosed positive for HIV (AIDS) test?
(4) been an intravenous drug user?
(5) had sexual contact with anyone fitting above (1)–(4)?

The deferral term will be shortened from 1 year to 6 months from April 2011, corresponding to the increased sensitivity of new screening tests with NAT.

(b) Yes, it is consistent with other that for other similar risk behaviors.

Question 2

number of sex partners; depends on the situation
recent new partners no deferral

casual sex: 1 year deferral,

A history of anal or oral sex or condom use in MSM sex does not influence the deferral.

Question 3

There has been no review in these 5 years.

Question 4

There has been no change in the deferral policy. Rate of HIV positive donors has been increasing in parallel to that in the general populations, although it was 1·929/100 000 in 2009 and lower than the previous year.

Question 5

No relating answer.

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A. Bravo-Lindoro, A. D'Artote-González & V. Torras Giner

Question 1

(a) In Mexico, our current national deferral policies obligate the deferral of donors with a history of MSM of donor since January 29th 1988 [1].

(b) Indefinite deferral applies to MSM, heterosexual persons with several sexual partners, prostitution, and those who have had sexual contact with anyone who has had a positive test for HIV. For other sexual risk behaviors like rape, causal sex, more than one sexual partner, sex with a prostitute, the deferral time is 12 months.

Question 2

Criteria such as a history of several sex partners, recent new sexual partners, casual sex and anal or oral sex are used as risk behavior factors in order to defer donors for 12 months.

Specific Mexican standards for blood transfusion do not consider safe sex and condom use in order to approve a person as a blood donor [2]; at the moment this is a controversial issue in our blood services.

Question 3

(a) At the present time, no official changes have been made, however new standards are now in the process of approval. MSM criteria deferral will remain the same. In our country there is an advisory committee that holds regular meetings with professionals from different institutions and reviews national policies every 5 years or less. if it is necessary.

(b) We have not had any jurisdiction court cases.

(c) There has been sporadic public pressure from MSM groups. The national committee decided that indefinite deferral for MSM should remain because in México 97% of blood is donated by family replacement donors and most are first time donors, for this reason many donors deny their high risk behavior. When we follow up confirmed HIV positive donors they have not not disclosed their high risk behavior, neither during the medical evaluation nor by the autoexclusion procedure. The '*Banco Central de Sangre del Centro Medico Nacional Siglo XXI IMSS*' has found that 52·5% (out of 116 HIV positive confirmatory donors/227,163 total donors) recognized that they have had high-risk sexual behavior on subsequent followup.

We have more than 530 blood banks and only a few of them (< 20%) are able to test blood by NAT [3].

Question 4

We have not changed our MSM deferral policies in the last 5 years.

Question 5

Mexico has a prevalence of HIV of 0·3% in the general population and had a estimated population of 220,000 people infected with AIDS in 2009 (60% of MSM, 23% heterosexual women, 6% clients of sex workers, 5% heterosexual men, 3% sex workers, 2% loss of liberty persons and 1% intravenous drugs users) [4].

We believe that the most important risk factor in HIV transmission in blood donors and the general population in our country remain associated with the sexual transmission. At moment, MSM is the most important risk.

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P. Flanagan

(1) a. Men who have sex with men are deferred from donation for a period of 5 years following their most recent episode. Sex is specifically defined as 'oral or anal sex with or without a condom'. This deferral was introduced in April 2009 in accordance with the recommendations arising from an Independent Expert review of behavioural criteria in New Zealand (1). Prior to this the deferral had been set at 10 years.

b. The independent expert review identified inconsistencies between the deferral period for different risks. In particular the deferral period for MSM was significantly longer than that applied to people who have lived in countries known to have a high risk of heterosexual transmission of HIV infection (e.g. Sub-Saharan Africa). This was seen to be a concern, particularly so if the rationale for the prolonged exclusion of MSM relates to risks associated with failure to identify 'prevalent' as opposed to 'incident' infections. The review recommended that a consistent approach should be applied for these 'primary' risks. A 5 year deferral now applies for both MSM, sex work outside of New Zealand and people who have lived in countries considered to be high risk for HIV infection (defined as an adult prevalence of 1% or more). The only exception to this is injecting drug use which continues to result in a permanent deferral. Secondary risks, i.e. sex with an individual identified as having a primary risk of HIV, results in a 12 month deferral.

(2) This issue was carefully examined by the independent expert group. In principle, it is acknowledged that a risk framework that more accurately assesses individual risk will be preferable to the current approach where decisions are made on broad risk behaviours. Unfortunately however at this stage no convincing and validated system for individual risk assessment exists. The MSM deferral defines 'sex' as 'oral or anal sex with or without a condom'. Other than this no attempt is made to assess individual risk and in particular no framework for risk assessment exists for heterosexual sex.

Table 1 HIV Incidence and prevalence rates for New Zealand donors

	First time tested donors		Previously tested donors	
Year	Number	Rate per 100 000 donors	Number	Rate per 100 000 donors
2006	2	8·7	1	1·3
2007	1	4·76	0	0
2008	0	0	0	0
2009	0 (1)[a]	0 (5·52)	0	0
2010 (to end August)	1	7·1	0	0

[a]Donor deferred because of recent tattoo but sample taken for testing.

(3) The independent expert review was undertaken in 2007. The review was triggered by a series of complaints from gay men concerning the deferral policies. This included a number of complaints made to the New Zealand Human Rights Commission (HRC). The HRC complaints have all been withdrawn following mediation, the robustness of the review process having contributed significantly to this outcome. The key policy changes arising from the review are identified above.

(4) HIV positivity rates in New Zealand donors are shown in Table 1. Numbers are low but at this early stage there is no indication of any change in frequency of HIV positivity following introduction of the 5 year deferral period in April 2009.

(5) Reports of HIV in New Zealand are monitored by AIDS New Zealand. Data is available on the University of Otago AIDS New Zealand website (2). Currently approximately 50% of new reports of HIV infection relate to MSM, these infections are largely contracted in New Zealand, and 33% relate to heterosexual transmissions of which the majority are contracted overseas. Five of the six donors identified as HIV positive in Table 1 were male. Two of the five reported MSM and a further two a link to sub-Saharan Africa.

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Question 1

(a) The current Norwegian national guidelines for transfusion medicine require indefinite or life-long deferral of men who disclose a past or present history of having sex with other men. This national deferral policy has been practiced since the beginning of 1986, i.e. approximately 25 years. However, formal guidelines were not in place until a couple of years later.

(b) Indefinite deferral applies to intravenous and inhalant drug abusers as well as sex workers/prostitutes. This is consistent with a deferral policy for high risk groups. On the other hand, a transient deferral period of 6 months applies to donors after their last sexual contact with an HIV-, HBV- or HCV-infected person. Women may be accepted as donors 6 months after their last sexual contact with men having sex with other men. Six months deferral is also given after the last sexual contact with a sex worker/prostitute or an intravenous or inhalant drug abuser. Indefinite deferral applies to people from countries with at high prevalence of serious transfusion mediated infectious diseases. Rape victims are normally given 6 months deferral. However, this depends on the type of rape as spousal or marital non-consensual sex may be considered as rape. Male sexual assault of another male is a special case which may have to be considered separately depending on the situation (Victimized as a child? Repeated assaults?). Thus, rape victims are not a homogenous group, and special assessment of rape may be necessary. Additional criteria may apply.

Question 2

Norwegian regulatory guidelines do not use risk behaviour-based criteria related to the type or form of sexual contact. Only new sexual contact or sexual contact with high risk groups are considered when assessing transmission risk. Recording detailed sexual histories may prevent people from volunteering as blood donors, especially as this is often pointed out by many donors. In addition, people's perception of 'safe sex' may vary considerably and therefore be counterproductive when assessing real transmission risk.

Question 3

Norwegian regulatory authorities and their advisory committees review theirs guidelines regularly and frequently, and changes are rapidly implemented to fit the current threat of microbial transmission risk. However, there have been no amendments or changes in MSM deferral policies within the last 5 years (see Question 1) triggered by any of the bodies mentioned or by pressures from stakeholders or from public or political pressures. This does not mean there is no pressure from stakeholders as the issue is often discussed on various web blogs, Facebook campaigns and in the media. The political pressure is vague, although occasional attempts to push for acceptance of males who have sex with other males as blood donors do occur. However a serious public discussion of risk factors along with levels of safety is missing.

Question 4

This question is not applicable as no changes have been implemented during the last 5 years regarding the Norwegian MSM deferral policies (see Question 1).

Question 5

The first part of this question does not apply to Norway (see Questions 1 and 4). The current major risk factor for HIV in the general population is the high prevalence of HIV in some immigrant populations in which the majority of patients were infected before arrival in Norway. Thus a list of HIV prevalence per country is given in the regulatory guidelines and countries are grouped according to this list and other criteria. Different rules for donor eligibility apply for each group of countries so that donor suitability is based on real risk assessment and not discriminatory regulations against immigrant populations. This is in line with the current MSM deferral policy.

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Question 1

(a) Following the access of our country to the European Union in 2004, the Polish Minister of Health issued the Decree of April 18th 2005 regarding recommendations for blood collection from donors and donor candidates (adjustment to Commission Directive 2004/33/EC of 22

March 2004 implementing Directive 2002/98/EC of the European Parliament and the Council).The Polish regulations currently in force include only one *indirect* reference to blood donation deferrals for men who disclose having sex with other men (MSM) namely that permanently deferred from donating blood are '*Persons whose sexual behavior puts them at high risk of acquiring severe infectious diseases that can be transmitted by blood*' Similar recommendations had already been in force in the Polish Blood Transfusion Service (BTS) since the late 80s.

(b) According to numerous behavioral studies, sexual behavior of the MSM population frequently puts such persons in a position of higher risk, therefore routine blood transfusion practice usually permanently defers members of this population from blood donation. Every case however needs to be considered individually and accordingly, it is sometimes acceptable to qualify a donor who declares to have a long-term relationship with only one partner (monogamous relationship).

Question 2

Prior to blood donation every person who volunteers to donate blood is required to get acquainted with a document '*Information on infectious diseases for blood donors*'. In this document the following risk behaviors are itemized:

(1) Recent or previous history of injectable drug abuse
(2) Sexual contacts with persons who use injectable drugs
(3) Sexual contacts with numerous partners
(4) Sexual contacts with new acquaintances
(5) Sexual contacts in exchange for money
(6) Sexual contacts with persons tested positive for AIDS, syphilis, HBV and HCV.

In this document there is a definite recommendation *not to donate blood* in case of individual increased risk.

Next, the person is required to complete a *Donor Questionnaire* which, among others, includes the following questions:

(1) Have you read and understood the content of document *'Information on infectious diseases for blood donors'*?
(2) In light of the content of this document *'Information on infectious diseases for blood donors'*? do you consider yourself having been exposed to infection risk?

Question 3

(a) and (b). Within the last 5 years there has been no review of policies in the Polish jurisdiction triggered by regulatory guidelines, advisory committees, court findings and court cases.

(c). As consequence of relatively frequent deferrals of members of MSM population, the Polish blood transfusion service is submitted to strong pressure from homosexual societies, gay activists and some human rights organizations. The issue therefore is under permanent scrutiny and discussion. According to our current knowledge, this has not affected the MSM policy.

Question 4

As no changes in the MSM deferral policy have been introduced during the last 5 years, there was no opportunity to draw any conclusions in the subject of legal policy having impact on HIV prevalence and incidence in the donor population of our country.

Question 5

As mentioned above, no changes to our MSM deferral policies have been introduced therefore no implications of such changes can be reported.

As concerns major HIV risk factors for the general Polish population, approximately 50% of all HIV/AIDS infections since epidemic onset in 1985 were ascribed to injectable drug abuse. As of 2001, a significant shift in main risk factors for HIV/AIDS infection was observed; the majority of HIV infected persons were heterosexual, with no history of injectable drug abuse and were infected via high risk sexual behavior. Recently, an alarming increase in the number of HIV infections in the MSM population has been observed. Most HIV/AIDS infected persons (84%) fall within the 20–49 age range; which is approximately the same age range for most blood donors (National AIDS Center Agenda of the Polish Ministry of Health).

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(1) Currently there is no official documented deferral policy for MSM risk behavior in Russia. On the14th of September, 2001 the Russian Ministry of Health issued an order regarding medical examination of blood donors. Among the absolute contraindications to donate, the first point was 'AIDS, HIV carriage and groups of high risk (homosexuals, drug addicts, prostitutes)'. Since 1993 homosexual relationships between consenting adults in private are no longer considered a crime in Russia. Since 1999 the Russian psychiatry profession no longer

Table 1 Donors, donations and HIV-positive donors in Russia in 2001–2008

	2001	2002	2003	2004	2005	2006	2007	2008
Blood donors	2 229 659	2 097 064	2 047 373	2 031 747	1 939 593	1 802 957	1 800 995	1 831 224
Plasma donors	160 766	177 709	191 319	200 818	222 663	236 572	255 678	276 222
Blood donations	3 019 703	2 904 055	2 843 616	2 774 947	2 654 877	2 413 889	2 367 513	2 367 932
Plasma donations	672 867	759 708	811 547	864 581	909 477	945 984	1 032 828	1 098 685
All donations	3 692 570	3 663 763	3 655 163	3 639 528	3 564 354	3 359 873	5 459 021	3 466 617
HIV – positive donors	1690	1894	1939	1981	1597	1673	1378	1560
Population (millions)	146·3	145·2	145·0	144·2	143·5	142·8	142·0	141·1

considers homosexuality as a mental illness as it adopted the international classification of mental illnesses. On 16th of April 2008 the Russian Ministry of Health deleted the words 'and groups of high risk (homosexuals, drug addicts, prostitutes)' from above-mentioned order. In practice, there are a very few people who disclose their MSM status in the blood center. Since 2008 they are allowed to donate.

(2) The word 'sex' is absent in our blood donor questionnaire. I am reminded of a famous episode from the TV show US-Soviet Space Bridge when an American asked a question about sex in the Soviet Union, and a Soviet lady proudly answered 'There is no sex in the USSR!'. In fact, she said 'There is no sex in the USSR... there is love', but the last words were cut off of the broadcast, as the show was not being aired live. This created a still-popular catchphrase. In the Soviet mindset the word 'sex' is considered dirty by many, nearly synonymous with pornography [1].

(3) Activists at Gay Russia campaigned against the ban mentioned in Question 1. They undertook several pickets and wrote letters to the Ministry of Health and Social Development as well as to the Russian General Prosecutor asking for the repeal of the ban because it contradicted the Russian Constitution and federal legislation.

(4) We have no data about the prevalence and incidence of infections among donors. Russian official statistics collect the number of donors which are deferred after blood screening per year. HIV was found in about 200 blood donors in 1998, 372 in 1999, 493 in 2000 and more than 1000 in each year in the XXI century (Table 1).

Probably MSM deferral policy have no influence on HIV prevalence and incidence in our donor populations.

(5) In the general population about 50% of new HIV transmissions are heterosexual and another 50% are due to drug use. In the donor population, the current major risk factor is heterosexual transmission.

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(1) a. Since 2006, when Slovenia implemented the European COMMISSION DIRECTIVE 2004/33/EC of 22 March 2004 implementing Directive 2002/98/EC of the European Parliament and of the Council as regards certain technical requirements for blood and blood components, donors revealing a history of MSM are indefinitely deferred according to the technical part of these recommendations (1–3). Before this time, MSM donors were not allowed to donate according to the 8th European Council Guide to the preparations and Quality assurance (4). It is obligatory for all donors regardless of the type of donation (whole blood or apheresis procedure) to fill in the Medical Questionnaire before every donation in order to fulfil the donation criteria or to exclude oneself before or after the donation. Every donor is interviewed by a medical doctor who is responsible for making a final decision about a donation.

b. Besides this deferral for MSM behaviour, an indefinite deferral is also implemented for a person who has received money for sex, has been a sexual partner of an HIV-positive person or MSM, or who is a drug user.

(2) A history of other risky sexual behaviours and practices (such as number of sexual partners, recent new partners, casual sex, anal or sex, 'safe-sex' or condom use, etc., including a history of rape) are not regularly solicited in our Medical Questionnaire. If the donor has any doubt about donation criteria he/she is invited to consult the medical doctor who is responsible for the donation and who must be present on site. The deferral time depends on the type of risk behaviour and the period after the

risk contact. Deferral times are not uniformly prescribed. The donor is usually provided with advice to proceed with the testing for hepatitis B C, and HIV. If the risk of being infected is very high the donor is advised to see a specialist for infectious diseases, which is a part of our health care insurance system.

(3) Since the introduction of the EU directives in 2006, there have been no new guidelines introduced into the blood donation criteria regarding the MSM deferral policies.

The news about the inclusion of MSM donors within European and USA countries is regularly checked, as the pressure from MSM organisations and the general public is also growing in Slovenia. Since the European Court decided that the right of safe blood was above the right to donate, MSM organisations have stopped their pro-donation activities.

(4) The impact has not been evaluated scientifically. Since HIV testing was introduced (anti -HIV1/2/0 and p24 Ag in 1986, single donation HIV-1 RNA NAT in 2007) in Slovenia, an average of 1–2 donors have been found to be positive for HIV (Slovenia has around 98 000 donations per year) (5). There were only a few MSM donors who have attempted to donate in spite of our published policies. A lot of effort has been undertaken to educate the general population, with the assistance of the Red Cross.

(5) There are no data on the impact of the new MSM policy. According to the annual report of the National Health Institute, the MSM population is the highest HIV-risk group in our country (6). As the number of HIV positive persons is growing in the general population, the Ministry of Health and other health care organisations are involved in the prevention and detection of risky sexual behaviour to provide the population with preventive care and knowledge.

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Question 1

(a) The South African National Blood Service (SANBS) defers males who have had sex with another male for 6 months from the last male to male sexual activity. The deferral period for MSM was reduced to 6 months on 1 October 2006. Prior to this, the deferral period for blood donation for MSM was 5 years. In October 2005 (1 year earlier) the South African National Blood Service (SANBS) and the other Blood Service in South Africa, the Western Province Blood Service (WPBTS), implemented individual donation nucleic acid testing (ID NAT) to screen all blood donations for HIV, HCV and HBV. All blood donations in South Africa are from voluntary non-remunerated donors. Taking into account the analytical sensitivity of the Procleix Ultrio ID NAT System (particularly its ability to detect low level HIV viremia in the pre-seroconversion window period), as well as data available on the minimal infectious dose for HIV transmission, it was decided to align the deferral period for MSM with the deferral period for other risk behaviour such as more than one sex partner, casual sex etc.

(b) Yes. The 6 months deferral period is also applicable for other High Risk behaviours such as:

- Received money or drugs in exchange for sex
- Sex with infected heterosexual partner
- Sex with a heterosexual sex worker
- Multiple heterosexual sex partners
- Casual sex
- New sexual partner in the past 6 months

Question 2

Yes. The behaviours mentioned in (1b) above are classified, as with MSM deferral, in a high risk behaviour category and individuals who have engaged in such behaviour are deferred for 6 months. Structured one-on-one donor interviews have been implemented which aim to improve the understanding of the donor questionnaire and the relationship between risk behaviour and HIV infection. The Donor Questionnaire includes standard risk questions relating to HIV test-seeking behaviour, possible exposure to multiple partners, prostitution, casual sex, sexual assault, sexually transmitted diseases or sex with partners with an unknown sexual history. In the Self Exclusion Questionnaire, Risk behaviour and HIV/AIDS questions are worded as follows:

2.3 In the past 6 months have you had sexual activity with or without a condom?

- With more than one sex partner?
- With a regular sex partner excluding your spouse?
- Had sex with someone whose sexual background you do not know?

2.4 In the past 6 months have you

(a) Had sexual activity with a prostitute or anyone else who takes money or drugs or other favours for sex?
(b) Received money, drugs or other payment for sex?
(c) Been a victim of sexual assault?

2.5 Male Donors

- In the past 6 months have you had anal or oral sex with another man with or without a condom?

2.6 In the past 12 months have you had a sexually transmitted disease (STD) e.g. syphilis, gonorrhoea, genital ulcers, VD or 'drop'?

Question 3

(a) No (b) No (c) Yes. The medical and technical divisions within SANBS reviewed the MSM deferral policy and a decision was made to align MSM deferrals with the other high risk behaviour deferrals. The deferral period was changed from 5 years to 6 months, based on the implementation of ID-NAT.

In 2005, discussions and meetings were held between SANBS and Gay & Lesbian groups. Gay & Lesbian Groups considered that SANBS was discriminating against them as a group and approached the South African Human Rights Commission on the issue. No ruling was forthcoming and the outcome of the discussions did not affect MSM deferral policy. One of the considerations was that that the decision to defer MSM donors should be based on South African data relating to HIV prevalence (amongst MSM) and not on data from other countries. It was proposed that a study should be conducted by the Human Sciences Research Council of South Africa on the prevalence of HIV in Gay & Lesbian groups. A study may be conducted within the next year and, based on the results (or if any other new data becomes available), SANBS will again review its deferral policy on MSM.

The South African Department of Health has also indicated that no group should be discriminated against and that research studies should be conducted.

Question 4

As indicated in question 1, the deferral period for MSM was reduced from 5 years to 6 months on 1 October 2006. The number of HIV positive blood donors has increased significantly since October 2006 (from 0·1% in 2005 to 0·21% in 2010) however, we are almost certain that, on further analysis, this will be shown to be related to heterosexual transmission since SANBS now has a policy to recruit donors who are more representative of the general South African population. SANBS has previously shown that the prevalence of HIV is significantly higher in the donor cohorts who are now being actively recruited.

South Africa has a National Haemovigilance Program as well as a well developed National Lookback Program. It is notable that, in the almost 5 years since the introduction of ID NAT, there has not been a single reported case of transfusion transmitted HIV. Over this period more than 3·6 million donations, screened by ID NAT and by standard serological screening (ChLIA on the ABBOTT PRISM), have been transfused. The prevalence of HIV in the general South African Population is approximately 11% and the overall prevalence in the donor population, in spite of the Donor Questionnaire, is 0·21% (up from 0·10% in 2006). It is almost certain that this increase in prevalence in blood donors is predominantly through heterosexual (HIV Clade C) transmission (refer to the recent publication: 'Sexual risk behaviours and HIV-1 prevalence among urban men who have sex with men in Cape Town, South Africa' [2]. In this survey, there was an overall HIV prevalence in MSM of 10·4%. This is similar to the overall (National) prevalence of HIV in South Africa (10·9%) but, pertinently, is significantly higher than that in the general population of the Western Cape Province (3·8%) (Ref: South African National HIV Prevalence, Incidence, Behaviour and Communication Survey (http://www.hsrcpress.ac.za).

Question 5

As outlined under question 4, the changes in HIV prevalence in blood donors can be attributed mainly to changes in prevalence and incidence in the general population (heterosexual transmission). A major risk factor for HIV (in both the general and blood donor population in South Africa) appears to be related to the number of sex partners (multiple sex partners).

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(1) Currently, Blood Centres in Spain do not ask blood donors questions about their sexual orientation.

Consequently, there is no established policy in relation to the deferral of potential male donors who have sexual relations with other men (MSM).

(2) In Spain, although there is no MSM blood donor deferral policy, blood centres health care professionals ask many questions during the blood donor interview which are related to practices that can result in acquiring HIV infection. This policy is in agreement with European Directives [1] and Spanish Blood Donation Laws [2] and has been reinforced by the Ministry of Health via the publication of a specific guide for blood donor selection [3]. These questions are mainly related to the detection of risky activities and are applied to both men and women. To protect against the risk of HIV transmission, blood donors in Spain are deferred indefinitely either if they have had sex for money, drugs or any kind of compensation (prostitution), sex with people with residence in countries with a high prevalence of HIV, intravenous use of illegal drugs or if they are HIV/AIDS carriers. Presenting blood donors who have had sex with HIV carriers/patients or IV drug users, sex with more than one partner at a time, either of the same or different gender, or sex with an occasional partner, are deferred for 12 months.

(3) Current Blood Donation regulations were enforced in 2005 [2]. This law do not mention MSM risk as a cause of temporary nor indefinite deferral. The law states, in a general manner, that blood donors with a sexual behaviour that encompasses a high risk of contracting severe transfusion transmitted infectious diseases have to be deferred indefinitely. During the last 5 years there have been no changes in Spanish blood donor deferral policies due to either social or regulatory pressure.

(4) Although policies have not changed during the last 5 years, epidemiological data from Spanish blood centres have registered a steady increase in the serological positivity rate as well as in the number of HIV window period cases detected by NAT, and especially so during the last 3 years. There has been a substantial increase in the prevalence of HIV, which was 8·5/100 000 donations in 2009, compared to 4·5/100 000 in 2000 (data provided by the Spanish Ministry of Health) and to European data, i.e. an average of 1/100 000 [3]. In addition, the rate of window period HIV-NAT found during this period was 1/349 436 donations, which is even higher than HCV-NAT window period cases (1/502 424).

(5) Between 2008 and 2009, a total of 299 HIV positive cases were detected out of 3 609 212 donations (8·3/100 000 donations). Fifty seven percent were repeat blood doors. By gender, 88% were male and only 12% female. With respect to the kind of risks detected, 74% of HIV donors disclosed having an MSM risk after being found positive in the blood donor testing, 22% revealed promiscuous heterosexual behaviour and, in 27%, the risk factor was not disclosed. This data have caused great concern on the part of the Spanish Blood Bank community and the Spanish Ministry of Health, which is drafting a new regulatory policy. The new blood donor deferral criteria will exclude MSM donor candidates for a period of up to 12 months. The temporary deferral time is also being discussed by the Council of Europe.

Spain has an intermediate prevalence of HIV in the general population, which contrasts with this high prevalence among blood donors. As recently published by Suligoy *et al.* [4], the prevalence of HIV in blood donations was highest in Eastern Europe, followed by Central Europe and Western Europe. Among the Western European Countries, Spain, Italy and Israel had the highest prevalence.

In Spain, there is a great deal of discussion regarding the necessity of MSM deferral, and social pressures have been a constant issue from the very beginning of the HIV epidemic. The gay community in Spain has always exerted great pressure to prevent blood banks from questioning blood donors about MSM behaviour. However, the HIV rate has increased most during the last 3 years, paradoxically after the implementation of HIV NAT in all blood centres. What seems to be clear is that many people are using blood donation as a way of discreetly taking an HIV test and, perhaps, the increased amount of information about new tests implemented in blood centres have prompted this situation leading to more people searching for NAT testing.

With respect to MSM practices, Blood Centres Directors in Spain think that more stringent donor deferral policies must be established in accordance with the vast majority of European countries. The safety of blood with respect to the transmission of infectious diseases is guaranteed by European laws which regulate both the selection of donors, through pre-donation questionnaires, and serological screening [1]. However, variability in the epidemiology of human immunodeficiency virus (HIV) infection in different countries, as well as some differences in the selection of donors, could influence the efficacy (regarding the safety of blood) of these processes [3]. Only Spain and Italy have more liberal policies with respect to MSM. In Spain, this policy does not seem appropriate to address this kind of risk.

Together with the change in the MSM blood donor deferral policy, the Spanish Ministry of Health is making great efforts in the education of gay communities, which is perhaps the best and most comprehensive approach to dealing with HIV transmission through transfusion.

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(1) a. Permanent deferral, implemented in the early 1980s a year or two before anti-HIV tests became available in 1985.

b. A risk modelling study trying to resolve this question has been performed in Sweden, although there are still no data published from that study.

(2) Having sex (vaginal, anal or oral) for the first time with a new partner results in 3 months deferral. This rule is in place to prevent individuals that often change sex partners to donate blood. Use or not use of condoms does not influence length of deferral.

(3) The Swedish National Board of Health and Welfare (NBHW) has since 2006, due to political pressure, tried to implement at first a 6 months deferral, and when not succeeding with that, a 12 months deferral for MSM since last sex contact. The Swedish Medical Products Agency (MPA) however disagrees, and demands a continuous permanent deferral if blood components from donations are to be sent to a fractionator for production of medicinal products. At present NBHW has postponed their new rule of only 12-months deferral until 10th of June 2011, pending the result of an international working group named 'The subordinate ad-hoc working group of the CD-P-TS on risk behaviours having an impact on blood donor management' (see: http://www.edqm.eu). NBHW has also decided to include several other sexual risk behaviours in a general 12-months deferral; behaviours that until now have had none or only 6 months deferral period. As an example the sex partner of an individual that has been pierced or tattoed must wait 12 months before eligible for blood donation, while the person getting pierced or tattoed only have to wait 6 months!

(4) Not applicable.

(5) Four hundred and eighty-six new HIV-infected individuals were reported in Sweden during 2009 (http://www.smittskyddsinstitutet.se/upload/Publikationer/epi-arsrapport-2009.pdf). Out of these, 134 were infected via MSM behaviour, 221 heterosexually, 27 through intravenous drug abuse, and nine mother-to-child transmissions during pregnancy and delivery. In 95 cases data concerning the route of transmission were lacking. The two largest groups reported as HIV-positives are immigrants with heterosexual transmission before moving to Sweden and MSM within Sweden. During the last 10 years there is a trend with raising numbers of HIV transmissions in Sweden due to MSM activity.

Since start of testing 1985, 68 blood donors or applicant donors has been found to be HIV-infected. MSM transmission has been reported for 37 and heterosexual transmission for 29; for the remaining two, information of the way of transmission is lacking.

During 2005–2009 10 blood donors or applicant donors (all male) have been found HIV-positive; at least three of these with MSM as a risk factor and the others infected heterosexually.

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(1) a. The current national deferral policy is that a permanent deferral is applied to any potential male donor if he has ever had oral or anal sex with another man, even if a condom or other protective was used. The current policy was implemented in February 1991.

b. This is consistent with the permanent deferral for homosexual rape (although this may be waived in exceptional circumstances e.g. a donor who was sexually abused as a child), sex workers and IV (recreational) drug users. However a 12 month deferral is applied to a donor after sex (even if they used a condom or other protective) with a partner:

who is or the donor thinks may be HIV positive.

who has ever received money or drugs for sex (a prostitute).

A female donor who has a male partner who has ever had oral or anal sex with another man, even if they used a condom or other protective will be deferred for 12 months.

Heterosexual rape attracts a 4 month deferral with additional testing. If the Hepatitis C NAT and Hepatitis B Core antibodies are negative (as well as usual mandatory tests for HBV, HCV, HIV, HTLV and syphilis) the donation is accepted.

(2) The only risk-based criteria we use relate to men having oral or anal sex with men.

(3) There is a current review of our policies on donor deferral to protect the blood supply from HIV. This is being performed by the Advisory Committee on the Safety of Blood Tissues and Organs. This committee provides advice to the UK Departments of Health. The advice that the committee has requested and will review includes:

- Information about the frequency of infected donations and how people found to be infected probably acquired their infection.
- The results of a study to estimate the risk of HIV infectious donation entering the blood supply, under both current exclusion criteria and different scenarios of donor selection.
- Estimates of the relative risks of sexually-transmitted infections, including unknown and emerging infections, for donors with 'high risk' sexual behaviours.
- Analysis of survey data about sexual behaviours of respondents who self report as blood donors, which includes a small, targeted study of MSMs
- There is also work in progress on knowledge on attitudes towards donor exclusion ad deferral and compliance of MSMs. This includes work on potential effects on compliance should donor selection criteria change.

They are due to report with recommendations to the UK Departments of Health in January 2011. This may include recommendations for change in the guidance or for further research.

(4) The policy of deferral for MSM was first implemented in September 1983 as a deferral for 'homosexuals with multiple partners'; this was altered to 'practicing homosexuals' in late 1984 and 'any man who had sex with another man since 1977' in 1987. This became a permanent deferral for MSMs in February 1991 (i.e. our current guidance).

(5) The current major risks for HIV are firstly (74% of cases where the cause was known) heterosexual sex, either in high risk countries (e.g. Africa or Thailand) or with partners who had a sexual contract in high risk countries (43% of cases overall), sex in other countries or with other high risk partners, and secondly MSM.

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(1) a. The current national deferral policy in the United States requires indefinite deferral for any man disclosing sex with another man, even once since 1977. This policy was first instituted by the Food and Drug Administration (FDA) in 1983 and is formalized in guidelines published in 1992 [1].

b. This policy is consistent with the deferral interval for donors who disclose other lifestyle choices that may expose them to recurrent risks, such as prostitution and intravenous drug use. The policy is inconsistent with deferral policies for isolated risk experiences, even if they occasionally expose the donor to a higher risk of disease transmission, e.g. having sex with an HIV infected person or with a prostitute. Such risk behaviors elicit a 1-year deferral.

(2) US policies do not consider information on numbers of sexual partners, occasional partners or the descriptions of particular sex acts for determination of eligibility for volunteer blood donation. The donor questionnaire does not ask whether the donor engaged in casual sex, anal or oral sex, or whether the donor used a form of barrier protection during a sexual encounter. For donors revealing a history of MSM, descriptions of risk behavior include oral and anal sex and are considered to have the same level of risk.

(3) Pressures to change the current policy have increased steadily, particularly over the past 10 years. In 2001 the FDA Blood Products Advisory Committee (BPAC) reviewed the issue and heard a recommendation from the AABB and America's Blood Centers (ABC) to decrease the current lifetime deferral period for MSM behavior to a 1 year deferral interval. The committee failed to endorse these recommendations by a narrow margin. Four years later in 2005, the American Red Cross (ARC) joined with ABC and AABB in reiterating the need for reconsideration of the policy in light of the proven benefit of nucleic acid tests at detecting and preventing the transfusion of HIV infected units early in the course of infection when diagnostic tests for antibody are negative. In response to mounting pressure, the FDA hosted a 1 day workshop in 2006 on behavior-based deferrals in the age of nucleic acid testing. At that conference the ARC, ABC and AABB testified that 'the deferral period for men who have had sex with other men should be made consistent with deferrals for those behaviors judged to increase the risk of infection via heterosexual routes'. Shortly thereafter, the FDA chose to reaffirm their continued support for a lifetime deferral for MSM through a web-based press release [2].

In recent years, opposition to the FDA's stance has arisen from several critical groups, including students and academia, gay rights advocacy groups, and members of the United States Congress. Some universities have discontinued campus blood drives in protest of the policy. In early 2010, two US Senators called for hearings and a substantial group of senators and congressman petitioned the FDA for change. In June 2010, the US Department of Health and Human

Services Advisory Committee on Blood Safety and Availability (ACBSA) hosted a 2-day public hearing to gather information from interested groups on both sides of the issue [3]. The ARC/ABC/AABB joint position was once again placed into the record [4]. Patient groups, including the Committee of Ten Thousand, an advocacy group for persons with bleeding disorders living with HIV/AIDS, argued against changes to current policies, while the Gay Men's Health Crisis proposed multiple approaches to deferral interval schemes that would be seen as less discriminatory, and would treat similar behaviors in a consistent manner whether the donors were male or female. At the conclusion of the hearing, the ACBSA declined to recommend that the lifetime deferral be lifted, but agreed that the policy should be amended after sufficient research into the risks and benefits of change has been compiled. At this time, the lifetime ban remains in effect.

(4) There have been no changes in the general MSM deferral policies of the United States in the prior 5 years.

The prevalence and incidence of HIV in the US donor population between 1999 and 2008 has been assessed by ARC, an organization that collects about 42% of the blood supply. The overall prevalence of HIV among female donors has slowly declined to approximately 5 per 100 000 donations in 2008, while the prevalence in male donors has remained stable at 14–17 per 100 000 donations, and was approximately twofold higher than that of females. The incidence of HIV among repeat donors, however, increased from 1.5 per 100 000 person-years (py) in 1999–2000 to 2.2 per 100 000 py in 2007–8 ($P < 0.05$), with the increase seen mostly in young males of African American descent in the Southern regions of the US. The residual risk of window period associated HIV transmission was calculated at 1:1 149 000 donations and at least four HIV transfusion transmission cases have been documented since the inception of NAT in 2001 [5].

(5) The US has not changed their deferral policy and changes in the donor population mirror the changing demographics in the general population, suggesting the failure of questions to eliminate donors at risk of infection. The number of individuals living with HIV infection in the US continues to rise and was calculated at 1.1M in 2006, although the number of new cases each year remains relatively constant at approximately 56 000 per year [6]. An estimated 79% of individuals are thought to be aware of their infection. Since the early 1980s, MSM have consistently represented the majority (53% in 2008) of persons living with HIV in the US, and are 44 times more likely to be infected than heterosexual men. The number of new infections among MSM has risen steadily since the 1990s, as has heterosexual transmission, while infections among other risk groups other modes have declined. In 2008, one in five homosexual men in 21 major US cities were infected.

Among men, 64% of newly infected persons are MSM. Intravenous drug use and high risk heterosexual contact account for 16% and 13% of the new cases respectively. By contrast, 72% of newly infected women engaged in high-risk heterosexual behavior and 26% use intravenous drugs. Thirty-five percent of persons infected with HIV in the US are white, but 46% are African-American, a group that comprises only 12% of the population. Studies show that there is a correlation between socioeconomic status and high risk behavior: high risk behavior tends to increase as income declines, while awareness of the disease and preventive measures increases with higher levels of education [6].

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Review of Australian BLOOD DONOR DEFERRALS RELATING TO SEXUAL ACTIVITY

May 2012

An independent review commissioned by the Australian Red Cross Blood Service

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Review Committee

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Acknowledgements

The committee sought information and advice from additional people throughout the review process and wish to formally acknowledge Associate Professor David Wilson (The Kirby Institute) for conducting the statistical analyses described in the report. Dr Clive Seed and Dr Anthony Keller (Australian Red Cross Blood Service) provided the committee with information regarding protocols and the management of blood donation in Australia. Darryl Maher (CSL Biotherapies) provided information on the processes involved in plasma fractionation, and Marion Hemphill (Legal Counsel, Australian Red Cross Blood Service) provided information on legal issues surrounding donor deferral.

Preparation of the report

This report was prepared and edited by Dr Veronica Pitt (The Alfred hospital and Monash University). The statistical analyses described in the report was provided by Associate Professor David Wilson (The Kirby Institute).

Executive Summary

This review was undertaken by the committee on the understanding that the primary concern of the Australian Red Cross Blood Service is to maintain the safety of blood and blood products provided in Australia in compliance with current Australian legislation (including regulatory legislation and anti-discrimination laws) and that public safety is paramount. While it is accepted that interventions involving blood transfusion are not free from risk, the Blood Service has a legal and social responsibility to ensure blood transfusions are as safe as possible.

Whilst this review specifically focused on donor deferral based on sexual activity, the committee supports that a similar evidence-based process should be undertaken for other donor deferral criteria to ensure that donor selection policies in Australia are aligned with current scientific evidence.

Members of the public were invited to make submissions to the review committee addressing concerns and providing suggestions regarding Blood Service deferral criteria relating to sexual activity. The committee considered each of the submissions received, as well as the findings and observations from previous anti-discrimination challenges involving the Blood Service, and is acutely aware of the concerns and impacts of the deferral process on different parts of the community. Discrimination based on sexual preference is an ongoing issue in society and the committee strongly endorses the continued need to address unfair discrimination in our society through appropriate legislation and social change.

Length of deferral period

The committee found there is sufficient evidence to support reducing the current deferral period of 12 months to six months for all sexual activity-based deferral criteria without compromising the safety of blood and blood products in Australia. The effectiveness of deferral periods relies on donor compliance. Changes to the length of deferral periods should consider the impact on donor compliance and whether changing to a reduced deferral period is likely to have any positive or negative impacts on compliance. The committee recommends that the Blood Service considers the results of a compliance study (currently in progress) before implementing the recommendation to reduce the deferral period. The following key points were considered by the committee when considering the appropriate length of deferral periods:

- The safety of blood and blood products is the paramount consideration in terms of the obligations of the Blood Service and public expectation.
- The Blood Service screens all donated blood using a combination of nucleic acid tests (NAT) and serological tests to detect human immunodeficiency virus (HIV), hepatitis B (HBV) and hepatitis C (HCV), and serological tests are used to detect human T cell lymphotropic virus (HTLV) and syphilis (*Treponema pallidum*).
- Each test has a testing 'window period' where recently acquired infections will not be detected. It is important that individuals recently exposed to infection do not provide a donation during the window period to avoid the risk of failure to detect transfusion-transmissible infections (TTIs) in donated blood.

- The length of deferral periods for TTIs should be based on available evidence for window periods and the minimum time required to ensure all positive donations will be detected by NAT or serological tests or both. As individuals with chronic infection may only be detected through serology tests, the length of time for any deferral period will depend on the window period for serological tests which are always longer than their NAT counterparts.
- The serology test to detect HCV has the longest testing window period with an estimated upper range of 94 days. A deferral period based on detection of HCV could be consistently applied to all sexual activity-based deferral criteria as it allows sufficient time to detect all of the relevant sexually-transmitted infections (STIs).
- A deferral period of six months incorporates an empirical safety margin that approximately doubles the length of time of the upper estimate of the HCV testing window period (i.e. 2 x 94 = 188 days). This safety margin is applied by the Blood Service in accordance with current guidelines for prevention of transmission of infectious disease approved by the Therapeutic Goods Administration.
- A reduced deferral period could be considered by the Blood Service in future if further research indicates HCV is not sexually transmitted and no longer needs to be considered in the duration of sexual activity-based deferrals.
- The committee also considered the potential impact of unknown emerging infections on the length of deferral periods. 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 committee suggests the Blood Service conducts further research regarding the effectiveness and appropriate length of time for safety margins currently incorporated into deferral periods (i.e. in addition to the time thresholds for test window periods).
- There is no evidence to support an increase in the length of the donor deferral period.
- This policy should be reviewed as further evidence becomes available.

Ongoing donor deferral

An independent assessment of epidemiological evidence of risk was undertaken by the committee. Based on the available evidence and expert opinion the committee assessed the sexual activity-based deferral policies currently used by the Blood Service as appropriate but wishes to highlight the following points for further consideration by the Blood Service.

Men who have sex with men

- The committee acknowledges there is a subgroup of men who have sex with men (MSM) who are at low risk of infection, such as MSM in monogamous relationships. Making definitive statements about a partner's sexual behavior is a limiting factor for all potential blood donors and the information they provide is not always accurate; consequently there is an unknown risk of HIV associated with all sexual partners. The main point of concern from the evidence-based risk assessment is the risk of acquiring HIV from a non-monogamous partner in an MSM relationship is significantly greater than the risk of acquiring HIV from a

non-monogamous partner in a heterosexual relationship because the risk of transmission of HIV is greater in the MSM community. The committee agreed the significant difference in risk means that removing the deferral for MSM in monogamous relationships would introduce an unacceptable risk to the ongoing safety of the blood supply. However, the committee agreed the deferral period for MSM, including those in monogamous relationships, could safely be reduced to six months.

Sex workers

- Evidence indicates that Australian sex workers are at a lower risk of acquiring or transmitting STIs compared to other heterosexual individuals. However, the available evidence only applies to the subgroup of the sex worker population that is brothel-based female sex workers. The committee found that removing deferral of all sex workers is not currently supported by the available evidence and would introduce an unacceptable risk to the blood supply. However, the deferral period could safely be reduced to six months.
- Despite recent research assessing the risk of STIs in Australian sex workers, there is still a paucity of evidence regarding the risk of infection in individuals that receive payment for sex who are not brothel-based sex workers. The committee identified this as an area requiring further research that could be supported by the Blood Service and used to inform donor deferral policies in future.

Sexual partners of individuals who have ever received clotting factors

- The committee considered the current safety of plasma-derived products in Australia and suggests the Blood Service, in collaboration with CSL Biotherapies, explore whether a time threshold can be identified for individuals receiving clotting factors in Australia that would indicate the risk of being infected with blood-borne viruses is comparable to the average population. Where the evidence supports such a time threshold, the Blood Service should reconsider deferral of sexual partners of individuals treated with products since this time.
- In addition, the committee identified there may be individuals who have only ever received recombinant (not human-derived) clotting factors whose sexual partners do not pose a risk to the blood supply. It is suggested that the Blood Service explore the feasibility of identifying this group as potential donors.

Communication strategies to improve compliance with deferral criteria

The committee supports the obligation of the Blood Service to ensure the ongoing safety of blood and blood products in Australia. It is essential that public confidence in the blood supply is maintained and the committee believes the Blood Service has the responsibility to raise public awareness regarding blood donation processes and the evidence underpinning deferral policies in order to facilitate appropriate self-deferral and compliance with current deferral criteria.

The committee encourages the Blood Service to consider establishing an advisory panel 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 reasons for deferral and the importance of compliance. A systematic review of interventions used to increase donor compliance should also be conducted to

provide an evidence-based approach for implementing strategies to improve compliance with deferral criteria.

Submissions received from the public highlighted the following key areas the Blood Service should consider providing information about when developing future communication strategies:

- Evidence-based information specifically targeted at communities affected by deferral criteria. Tailored information regarding blood donation, the risk of TTIs related to sexual activity, and the relationship between testing window periods and donor deferral should be provided to each of these groups.
- Information regarding limitations of laboratory tests used to screen donated blood for TTIs. In particular, the existence of testing 'window periods' (when recently acquired infections will not be detected) and the importance of dual testing (NAT and serological tests) in order to detect individuals with chronic infection.
- The rationale for length of deferral periods. This should incorporate the evidence for window periods of serological tests used by the Blood Service to screen for STIs that can be transfusion-transmissible.

Further research

In undertaking this review, the committee identified the following areas of research the Blood Service should consider for future policy decisions regarding sexual activity-based donor deferral.

- The level of compliance with donor deferral criteria in Australia is currently unknown and may impact the efficacy of a reduced deferral period. Evidence regarding donor compliance should be sought from anonymous surveys of donors and the wider community. Qualitative research should be conducted to understand reasons for non-compliance, to help predict likely changes in compliance if deferral policies are changed, and to inform communication strategies to improve compliance with deferral criteria.
- Deferral policies developed by the Blood Service currently require an empirical safety margin that is approximately double the length of time of the relevant testing window period. The evidence supporting this is unclear and the Blood Service is encouraged to seek further evidence regarding the effectiveness and appropriate length of time for safety margins applied to window periods in the detection of transfusion-transmissible infections.
- Current controversy exists regarding sexual transmission of HCV. The committee suggests the Blood Service should obtain a systematic review of all available evidence regarding transmission of HCV to determine whether sexual activity is a risk factor, particularly in MSM. If necessary, the Blood Service should support primary research activities to determine whether HCV needs to be considered in future reviews of sexual activity-related deferral policies.
- Research regarding HIV transmission and condom use is ongoing and a number of large prospective cohort studies are currently in process. It is anticipated these studies will make important contributions to understanding HIV transmission and risk behavior and will further inform future evaluations of donor deferral policies.

- Pathogen reduction technologies are used in the treatment of plasma products. Development of pathogen reduction technologies for the treatment of red blood cells is an ongoing area of research that is being closely monitored by the Blood Service. Evaluations of these new technologies will need to be undertaken to assess the potential benefits for TTI risk reduction as well as the potential costs of implementing these systems in Australia.
- There is increasing demand for plasma-derived products in Australia. The Blood Service may wish to consider the opportunity to increase the donor pool by allowing individuals that are currently deferred to donate plasma only. This would require further investigation in collaboration with CSL Biotherapies and would need to consider the potential risk of TTIs in donated plasma and the risk of transmitting infection to recipients based on their use of different plasma-derived products.

ABBREVIATIONS

BBV	blood-borne virus
Blood Service	Australian Red Cross Blood Service
CSW	commercial sex worker
DNA	deoxyribonucleic acid
FSW	female sex worker
HAV	hepatitis A virus
HBV	hepatitis B virus
HCV	hepatitis C virus
HIV	human immunodeficiency virus
HTLV	human T-cell lymphotropic virus
IDU	injecting drug use
MSM	men who have sex with men
NAT	nucleic acid test
PRT	pathogen reduction technology
RNA	ribonucleic acid
STI	sexually transmissible infection
T. pallidum	*Treponema pallidum*
TGA	Therapeutic Goods Administration
TTI	transfusion-transmissible infection

1 INTRODUCTION

1.1 Australian Red Cross Blood Service

The Australian Red Cross Blood Service (herein referred to as the Blood Service) was established in 1996. The primary policy objective for the Australian blood sector described in the National Blood Agreement is to provide an adequate, safe, secure and affordable supply of blood products, blood related products and blood related services in Australia (http://www.nba.gov.au/policy/pdf/agreement.pdf).

The manufacture of all homologous blood components by the Blood Service (i.e. where the donor gives blood for the general blood inventory and not for a specific patient) is regulated by the Therapeutic Goods Administration (TGA) under Part 4 of the Therapeutic Goods Act 1989. Manufacturing licences are granted by the TGA subject to satisfactory compliance audits. The Council of Europe Guide to the preparation, use and quality assurance of blood components provides the primary standard [1].

Blood donations are processed by the Blood Service into fresh components for transfusion (e.g. red blood cells, platelets and plasma). In addition, plasma is provided to CSL Biotherapies as a starting material for the manufacture of plasma-derived blood products (e.g. albumin, clotting factors and immunoglobulins).

Around 3% of the Australian population donate blood through the Blood Service each year (approximately 560 000 donors) with an average of about 1.3 million donations per year for the 2005-2010 period.[2] Blood donation has always been voluntary and unpaid in Australia. It is estimated that Australia needs in excess of 27 000 blood donations per week (approximately 1.4 million donations per year) to meet current patient needs.

1.2 Safeguarding the blood supply

The current focus on risk minimisation in blood components is a consequence of the discovery of transmission of human immunodeficiency virus (HIV) and hepatitis C virus (HCV) by contaminated blood products in the early 1980s and early 1990s, respectively. The public's confidence in the safety of the blood supply was severely shaken in the wake of the HIV contamination scandals in France and Canada, resulting in a paradigm shift toward optimal blood component safety and recipient safety. Government policy makers and their regulatory authorities subsequently favoured decisions based on the 'precautionary principle' founded on the concept that '… for situations of scientific uncertainty, the possibility of risk should be taken into account in the absence of proof to the contrary.' Importantly, the effectiveness of Australia's response to the HIV epidemic, particularly protection of the blood supply, is considered exemplary.[3]

Australia was among the first countries to implement universal HIV antibody screening of donors in early 1985, and only a single case of HIV transmission by transfused blood has been recorded since. Despite immediate implementation of anti-HIV screening as soon as the test was available, over 120 people (predominantly haemophilia patients) that received clotting factors manufactured from

pooled donor plasma were infected with HIV.[4] A further 150 recipients received fresh blood components from donors subsequently found to be HIV positive, a rate of 9.3 per million people.[5] This rate was substantially lower than other developed countries including Canada (1148 infected recipients with a rate of 45.2 per million)[6] and the USA (rate 23.3 per million).[7]

In order to maintain the quality and safety of blood and blood products in Australia, a four tier combination approach to safety currently applies:

1 Through pre-donation public education using the http://www.donateblood.com.au website, the media, and the Blood Service National Contact centre. Donors are informed of eligibility criteria for blood donation and the reasons for deferral from donation through brochures and handouts in collection facilities.

2 Individuals whose behaviours or actions result in them having an increased risk of acquiring blood-borne infection are excluded by specific screening questions asked prior to donation.

3 State-of-the-art tests are undertaken on donated blood to identify prospective donors with pre-existing infections and r**e**gular donors acquiring new infections.

4 Where available, physical or chemical measures are applied to inactivate viruses and other infectious agents (these are collectively termed pathogen reduction technologies or PRT). Presently PRT are only used for manufactured plasma products and are not available for red cells and whole blood. Research and development for PRT for fresh blood components is ongoing.

1.3 Sexual activity-based donor deferral criteria

Australian blood donors are required to complete a questionnaire every time they donate to assess their risk of exposure to transfusion-transmissible infections (TTIs). The questionnaire is reviewed in a private and confidential interview with the donor, and those assessed as being at high risk of recent exposure are deferred from donating to minimise the risk of introducing infectious diseases into the blood supply.

Part C of the donor questionnaire (Donor Declaration) contains a series of questions specifically related to TTIs that are sexually transmitted. These include HIV, hepatitis B virus (HBV), HCV, human T cell lymphotropic virus (HTLV), and syphilis *(Treponema pallidum*). Donors who disclose relevant risk behaviour are 'deferred' from donation either temporarily or indefinitely. Donor selection is directly dependent on the compliance of donors to answer questions on the donor questionnaire and in confidential private interviews with full and frank disclosure.

Risk of exposure to TTIs through sexual activity is currently assessed by the Blood Service using the questions below.

To the best of your knowledge have you:

1 In the last 12 months, had an illness with swollen glands and a rash, with or without a fever?

2 Ever thought you could be infected with HIV or have AIDS?

3 Ever ‘used drugs’ by injection or been injected, **even once**, with drugs not prescribed by a doctor or dentist?

4 Ever had treatment with clotting factors such as Factor VIII or Factor IX?

5 Ever had a test which showed you had hepatitis B, hepatitis C, HIV or HTLV?

6 In the **last 12 months** engaged in sexual activity with someone you might think would answer ‘yes’ to any of questions 1-5?

7 To the best of your knowledge have you, since your last donation or in the last 12 months, had sexual activity with a new partner who currently lives or has previously lived overseas?

Within the **last 12 months** have you

1 Had male to male sex (that is, oral or anal sex) with or without a condom?

2 Had sex (with or without a condom) with a man who you think may have had oral or anal sex with another man?

3 Been a male or female sex worker (e.g. received payment for sex in money, gifts or drugs)?

4 Engaged in sexual activity with a male or female sex worker?

The reliance on the donor’s knowledge about their sexual partners contrasts with other blood exposure risk activities like tattooing or body piercing, which are assessed directly from the donor’s own behaviour. In the case of sexual activity-based deferrals, overall accuracy is highly dependent on the donor’s knowledge of the risk in their sexual partners. As it is not considered operationally practical with current resources to perform tailored individual assessments of individual donors prior to every donation, ‘group’ risks of TTIs are used for deferral criteria. This is consistent with international practice and other donor deferral criteria such as the geographically-based deferral of individuals from UK considered at high risk for variant Creutzfeldt-Jakob disease (vCJD).

1.4 Ethical considerations

The primary duty of a blood service is to produce a safe and sufficient resource of blood and blood products and failure to do so would be considered a breach of its duty of care.

The main objection to a policy of deferral is the concern that such policies discriminate against minority groups within the community. It prevents certain groups from accessing the social and moral benefits of blood donation and, more importantly, there is concern that deferral policies stigmatise groups of individuals as being ‘unclean’ and ’less worthy’. In practice, this means groups such as sex workers and men who have sex with men (MSM) (including those in long-term monogamous relationships) cannot donate blood unless they alter their sexual practices. This presents a significant challenge to an individual’s right to privacy and sexual preference.

In ethical terms, discrimination represents a failure to treat people as equals. The principle of equality, applied in the context of blood donation, requires that all potential donors be treated equally unless there is a relevant material difference.

1.5 Legal considerations

Anti-discrimination law in Australia requires a complainant to establish that discriminatory conduct took place within employment, education, or the provision of goods or services. Central to legal challenges involving blood services is whether they constitute a 'service' to donors. In Australia it has been argued the Blood Service only provides a 'service' to blood recipients and that donors themselves are providing a 'gift' to the Blood Service. It follows that not accepting a potential donor's blood is not refusing a service, but is rather the Blood Service exercising discretion in the interests of maintaining a safe blood supply. The judicial system acknowledges that blood services are not limited to the provision of donated blood to recipients, as they also provide a service to blood donors through providing locations and facilities for individuals to donate blood as well as undertaking processing and distribution of blood to hospitals and providing health advocacy. With respect to individual donors, it is important to recognise that the law does not give anyone the right to donate, and central to any legal argument is the fact that blood services have the legal responsibility to ensure any risk of unsafe blood is as low as reasonably achievable.

There have been three unsuccessful legal challenges in Australia that have argued the Blood Service policy of deferral for MSM is discriminative on the grounds of sexuality and lawful sexual activity:

1 1998 Victorian Civil and Administrative Tribunal

2 2007 Human Rights and Equal Opportunity Commission

3 2009 Tasmanian Anti-Discrimination Tribunal

In 1998 in the case of *Norman v. The Australian Red Cross Society*, the Victorian Civil and Administrative Tribunal (VCAT) found that the conduct of the Blood Service in deferring donors who had engaged in male to male sex in the specified period on the donor questionnaire did not constitute discrimination.

In 2007 the President of the Human Rights and Equal Opportunity Commission (HREOC) found that a complaint that the conduct of the Blood Service in deferring donors who had engaged in male to male sex had breached human rights under *the Human Rights and Equal Opportunity Commission Act 1986* was misconceived. He declined to hear the complaint. The President of HREOC considered that the criterion applied by the Blood Service to this particular donor deferral policy was reasonable and objective and based on the need to safeguard the blood supply.

Most recently, in May 2009, the Tasmanian Anti-Discrimination Tribunal in the case of *Michael Cain v. The Australian Red Cross Society* found that the conduct of the Blood Service in deferring Mr Cain as a donor did not constitute either direct or indirect discrimination. The Tribunal considered the alternative policy suggested by Mr Cain, to allow low risk MSM to donate, however this was not considered a viable option based on reliable evidence that it would lead to an increased risk of HIV transmission. The Tribunal found that the reason for the policy 'is the fact that people who engage in male-to-male sex have, as a group, a high risk of HIV transmission'[8] and that it is beyond question that the Blood Service is bound to keep the risk to the blood supply as low as possible.

These findings are consistent with other recent international legal challenges such as *Freeman v. Canadian Blood Services 2006*, where blood donation was acknowledged as a gift (not a right) that

blood services are not obligated to accept. It was also accepted in this case that deferral of MSM was not discriminatory and was based on safety of the blood supply and donor recipients.[9]

Whilst all cases in Australia to date have ruled in favour of the Blood Service, it is the responsibility of the Blood Service to regularly review deferral policies to ensure they are supported by scientific evidence and are in accordance with anti-discrimination laws in Australia.

2 TERMS OF REFERENCE

A review committee was formed comprised of a group of experts and an independent chair. The Review Committee was selected by agreement between the chairperson and the Blood Service and was comprised of suitably qualified experts.

2.1 Review committee terms of reference

The principle tasks of the review committee were:

1 To review the ongoing appropriateness of exclusion of donors on the basis of current and/or past sexual activity to ensure the ongoing safety of blood and blood products provided in Australia.

2 Where a form of screening dependent on sexual activity is considered appropriate, to recommend how exclusions from donation should be structured.

Particular emphasis should be given to the following.

a The appropriateness of ongoing exclusion of men who have sex with men and in particular:

  i Whether it is possible to define sexual activities that should result in exclusion from donation.

  ii The level of protection afforded by regular condom use and whether this is sufficient in the context of transfusion transmission to avoid exclusion.

  iii Whether (in the context of routine blood donation operations) it is possible to consistently identify a set of criteria by which individuals might be identified as at greater risk of acquiring blood-borne infections than that of the wider population.

  iv The appropriate period (if any) of any exclusion.

b Consideration of possible additional approaches to protect the donated blood supply from the risks associated with HIV acquired through heterosexual activity, with a particular emphasis on risks associated with sexual activity with people living in or from geographic areas of high prevalence.

c The relative risk of male-to-female versus male-to-male sex.

d The appropriateness of excluding current and former sex workers and the appropriate period of any exclusion.

e Whether the potential for sexual transmission as a route of infection in an as yet unidentified (i.e. new or emerging) pathogen should impact the duration of current deferrals for sexual activity.

f Advise on the development of effective communication tools to improve overall compliance with the sexual activity-based donor criteria and to explain their ongoing use.

2.2 Items not addressed in this review

2.2.1 Human herpesvirus-8

Human herpesvirus (HHV)-8 is the causative agent of Kaposi's sarcoma and may also cause other tumours such as primary effusion lymphoma and multicentric Castleman's disease. It can be transmitted through sexual contact. Epidemiological research has demonstrated that transfusion transmission of HHV-8 is possible, however evidence indicates the risk from blood products is extremely low and experts feel it is insufficient to justify specific intervention for HHV-8.[10] For this reason, HHV-8 was not included in the evidence-based review of sexual activity-related deferral criteria.

2.2.2 Deferral criteria not related to sexual activity

Several deferral policies that are not related to sexual activity and are therefore beyond the scope of the current review were identified by the committee as potential areas for future review. These include:

- From 1 January 1980 through to 31 December 1996 inclusive, have you spent (visited or lived) a total time which adds up to 6 months or more in England, Scotland, Wales, Northern Ireland, the Channel Islands, the Isle of Man, or the Falkland Islands?
- Ever "used drugs" by injection or been injected, **even once**, with drugs not prescribed by a doctor or dentist?

3 BACKGROUND TO SEXUAL ACTIVITY-BASED DONOR DEFERRAL IN AUSTRALIA

3.1 Transfusion-transmissible infections

The first case of transfusion-transmitted HIV in Australia was reported in July 1984.[11] At that time, Australia had one of the highest rates of transfusion-related AIDS in the world.[6] Australia was among the first countries to implement universal blood donor screening for HIV-1 antibodies, as soon as the test became available in April 1985.

On the basis of an increased risk of HIV transmission the Blood Service has been deferring donors who declare a history of male-to-male sex since the mid 1980s; the current 12 month deferral period was implemented nationally in 2000.

In 1992, approximately 18% of the 1570 people with haemophilia in Australia tested positive for HIV and these infections were attributed solely to the use of plasma-derived products manufactured in Australia.[6] The last reported case of HIV/AIDS infection through blood transfusion in Australia occurred in 1998 during routine surgery conducted at The Royal Children's Hospital in Melbourne. The source of infection was an asymptomatic female donor who had recently been exposed to HIV through sexual activity with a new partner from Africa. This is the only case of post-transfusion HIV reported since the introduction of universal HIV antibody testing.

Prior to the discovery of HCV in 1988 and the subsequent implementation of universal donor screening and HCV antibody testing in February 1990, many Australian haemophilia patients were infected by plasma-derived products. First generation HCV antibody testing reduced the risk of transmission by blood products by approximately 70%, which was further reduced by second generation antibody testing implemented in 1991. The number of cases of post-transfusion HCV fell significantly after HCV antibody testing commenced, with only 13 cases reported after 1995 and none since HCV RNA testing commenced in 2000.[12]

3.2 Epidemiology of TTIs in Australia

The Kirby Institute (formerly the National Centre in HIV Epidemiology and Clinical Research) is funded by the Australian Government Department of Health and Ageing and is affiliated with the Faculty of Medicine, the University of New South Wales. The institute is responsible for monitoring and evaluating patterns of transmission of specific blood-borne viral and sexually transmissible infections for public health in Australia. This work is overseen by the Ministerial Advisory Committee on AIDS, Sexual Health and Hepatitis. Australian epidemiological data regarding blood-borne viral and sexually transmissible infections are regularly updated and made available to the public through annual surveillance reports (http://www.med.unsw.edu.au/nchecrweb.nsf/page/Annual+Surveillance+Reports). Data presented in this section and throughout this report are based on the 2011 Annual Surveillance Report.[13] In addition, 2011 saw the first annual publication of a collaborative report from The Kirby Institute and the Blood Service, 'Transfusion-transmissible infections in Australia. 2011 Surveillance Report'[2]

that provides an up to date summary of epidemiological data and trends of TTIs in Australian blood donors (see section 3.4).

3.2.1 Human immunodeficiency virus

HIV is a blood-borne virus most commonly transmitted through sexual intercourse with an infected person. It is also transmitted through parenteral exposure (through piercing the skin or mucous membranes) and vertically from infected mother to child.

An estimated 21 391 people were living with diagnosed HIV infection in Australia at the end of 2010. The annual number of new HIV diagnoses over the past five years has remained relatively stable at around 1000 cases per year.[13]

HIV transmission in Australia occurs primarily through sexual contact between men, accounting for 66% of new diagnoses in 2006-2010. Of 1297 cases of HIV infection newly diagnosed in 2006-2010, for which exposure to HIV was attributed to heterosexual contact, 60% were in people from high prevalence countries or their partners.[13]

3.2.2 Hepatitis A virus

Hepatitis A virus (HAV) is transmitted by ingestion of contaminated food or water or direct contact with an infected person. It is usually spread via the fecal-oral route of transmission but rare cases of transmission by blood transfusion have been reported. HAV infection has an incubation period of around six weeks. There is a short period of time where the virus is in the bloodstream for a week before and the week after the onset of jaundice.

The population rate of reported diagnoses of acute HAV infection in Australia has been approximately 1.4 per 100 000 population or less between 2006 and 2010, except for an outbreak in 2009, which saw the rate rise to 2.5 per 100 000 population.[13] Infections have resulted from exposure to contaminated food or water,[14] however, there have also been a number of HAV outbreaks among MSM in Australia.[15-17]

3.2.3 Hepatitis B virus

HBV is a blood-borne pathogen, transmitted parenterally by exposure to blood or sexual contact with an infected person, and perinatally from mother to child. Serum, semen and saliva can be infectious for HBV. Unlike HIV, HCV, HTLV and syphilis, HBV can be prevented by vaccination.

An estimated 170 000 people were living with HBV in Australia in 2010 and there were 335 deaths attributed to chronic HBV infection.[13]

HBV infection disproportionately affects people from low- and middle-income countries and estimates of prevalence in culturally and linguistically diverse populations within Australia are generally consistent with prevalence in their countries of origin.[18]

Based on reported cases, HBV transmission in Australia continues to occur predominantly among people with a recent history of injecting drug use (IDU).[13] Both MSM and sex workers are at increased risk of infection, particularly if engaging in unprotected sex.[18]

Notifications of newly acquired HBV infection underestimate the true incidence of the infection, while notifications of unspecified or chronic cases underestimate the burden of disease related to HBV infection. The system is also poor in reporting country of birth and Aboriginal and Torres Strait Islander status. [18]

3.2.4 Hepatitis C virus

HCV is most commonly transmitted by parenteral exposure (piercing the skin or mucous membranes).

In 2010 an estimated 297 000 people in Australia had been exposed to HCV; an estimated 76 000 had cleared the infection and 168 000 were living with chronic HCV infection.[13]

Based on reported cases, HCV transmission in Australia continues to occur predominantly among people with a recent history of IDU. Controversy exists regarding sexual transmission of HCV. A recent Australian study suggested there was increased susceptibility to HCV in a population of HIV positive MSM,[19] although it is possible the source of infection may be due to an overlap of IDU in this population.

3.2.5 Human T lymphotropic virus

HTLV can be transmitted vertically from mother to newborn or through heterosexual contact. There are few data on the prevalence of HTLV infection in the general Australian population with blood donor rates being the best available estimate (see section 3.4).

3.2.6 *Treponema pallidum* (syphilis)

Syphilis is a disease caused by the bacterium *Treponema pallidum*, which is transmitted predominantly by sexual activity.

The rate of diagnosis of infectious syphilis increased sharply in the male population from 5.2 to 12.1 per 100 000 population between 2005 and 2007. The rate has declined to 8.9 in 2010. The increases in infectious syphilis have largely occurred among MSM.[13]

T. pallidum is inactivated by refrigeration at 4°C which virtually eliminates the risk of transmission by refrigerated components (whole blood and red cell concentrates). The plasma fractionation process incorporates pathogen reduction steps which also effectively eliminates *T. pallidum.* However *T. pallidum* survives in platelets (stored at room temperature) and fresh frozen plasma (snap frozen), constituting a risk of transfusion transmission.

3.3 Routine screening for TTIs in donated blood

The Blood Service routinely tests all donations for HBV, HCV, HIV, HTLV and syphilis (*T. pallidum*).

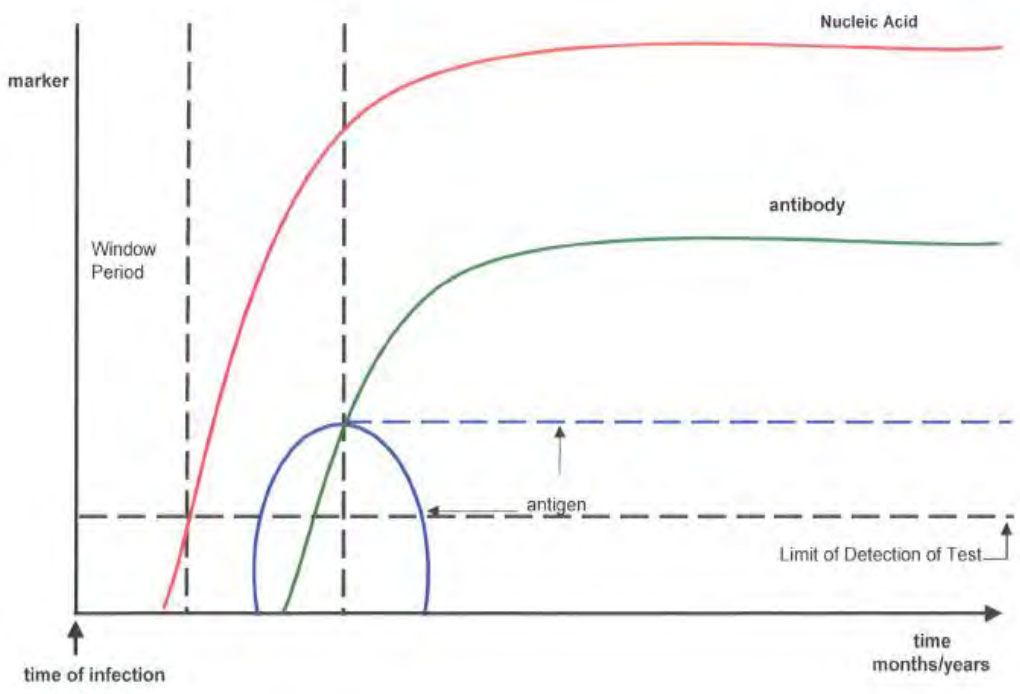
3.3.1 Window periods

A significant threat to the safety of the blood supply is the risk of failing to detect a TTI in donated blood. It is important to understand that the risk varies dependent on the duration of infection in the donor concerned. Individuals with established (termed ‘prevalent’) infections may be

symptomatic or aware of their positive status and therefore self-defer from donating. However, for those unaware of their infection status, deferral is based on risk behavior identified in the pre-donation questionnaire. In the event an individual with an established infection does successfully donate, screening of their donation will almost always lead to a positive result for either nucleic acid tests (NAT) or serology tests (or both). Donors with new (termed 'incident') infections are likely to be asymptomatic and depending on how recently they acquired the infection, may not have sufficient levels of virus or antibodies to allow detection in standard screening assays used by the Blood Service.

Despite improvements in tests used to detect TTIs in recent years, testing is not 100% effective. This is largely due to the existence of a 'window period', the time between acquiring an infection and being able to detect the presence of infection through testing (Figure 1). The window period varies depending on the test being applied and whether it detects the actual virus (e.g. detection of viral RNA or DNA by NAT) or an indirect marker of the virus (e.g. detection of antibodies that are produced in response to the virus). Window periods can also vary for cases of atypical infection, immunocompromised patients and new or different virus variants.

Figure 1. Viral markers and the window period in the early stages of infection [20]



For HIV, HBV and HCV, the Blood Service employs a dual testing strategy combining serological testing (for antibodies or antigen) and NAT for detection of HIV-1 RNA, HCV RNA and HBV DNA. The rationale for combining NAT and serology is that while NAT is able to detect recently infected individuals earlier, serological testing can identify chronically infected individuals more accurately. NAT for HTLV and *T. pallidum* has not been implemented for donor testing due to the effectiveness of the antibody tests for these agents in reducing the risk of transfusion transmission. The estimated window periods for tests currently applied by the Blood Service are presented in Table 1.

Table 1. Estimated window periods (range) in days for NAT and serology testing of blood donations

	HIV	HBV	HCV	HTLV	*T. pallidum*
NAT	5.6 (5.0-6.4) [21]	23.9[a] (20.9-27.8)	3.1[a] (2.8-3.4)	Not applicable	Not applicable
Serology	22 (6-38) [22]	38 (33-43.7) [23]	66 (38-94) [24]	51 (36-72) [25]	14-28 days [26]

[a] http://www.transfusion.com.au/blood_products/testing/NAT_FAQ#NATQ01

3.4 Epidemiology of TTIs in Australian blood donors

The blood service monitors trends in both prevalence (i.e. frequency of infection in first time donors) and incidence (i.e. recently acquired infections in repeat donors) based on blood donation testing results. Further to these results, viral positive donors are invited to participate in confidential interviews to determine the likely route of transmission. The first annual surveillance report of TTIs in Australia incorporates anonymous donor data from all donors who donated blood between January 2005 and December 2010.[2]

The presence of any TTIs in blood donations was 16.9 per 100 000 donations in 2010.[2] The prevalence of TTIs in blood donors is comparatively lower than the general population in Australia with first time donors showing higher prevalence of TTIs than regular or repeat donors. Current data indicates HBV is the most common infection found in first time blood donors, followed by HCV.

Table 2. Prevalence of TTIs among blood donors [2]

TTI	Prevalence (infection detected in first time donors)
HBV	86.02 per 100 000 donations
HCV	78.25 per 100 000 donations
HIV	1.81 per 100 000 donations
Syphilis	0.34 per 100 000 donations

HCV had the highest incidence rate among previously negative repeat donors (1.44 per 100 000 donations). HBV incidence is around 0.66 per 100 000. The majority of donors with HIV infection were repeat donors (0.24 per 100 000).

The prevalence of HTLV infection remains very low in Australian blood donors and there was only one incident case among previously negative repeat donors during 2005-2010.

The rate of active syphilis infections detected among first time donors has gradually increased in recent years and the incident rate for previously negative repeat donors is around 0.15 per 100 000 donations.

3.4.1 Risk factors for TTIs identified in blood donors

Blood donations that test positive for TTIs are the subject of 'lookback' investigations undertaken by the Blood Service to trace the fate of blood components from the donor's prior donations. Where a risk of infection exists, donor recipients and their treating clinicians are notified. Positive donors are also invited to participate in a confidential interview in order to determine the likely source of exposure to infection. Current analysis of risk factors for donors indicates that most donors with HBV infection were born overseas and the most frequent risk factor is ethnicity or country of birth.[2] Similar results have been seen for HTLV infection in blood donors. Unlike HBV, the majority of HCV positive blood donors are born in Australia with injecting drug use reported as the most common risk factor for exposure. The most common routes of exposure for HIV in positive donors is male-to-male sexual contact (40%), and sexual partners with known risk or known to be positive for any TTI (40%).[2] Analysis of risk factors for donors who have tested positive for active syphilis is not available. These findings are consistent with previous work conducted by Polizzotto et al in identifying potential risk exposures in positive blood donors from 2000 to 2006.[27]

3.4.2 Residual risk for TTIs in donated blood

There were no cases of transfusion-transmitted HIV, HCV, HTLV or syphilis infections reported during 2008-2010. There were two probable cases of transfusion-transmitted HBV infection reported during 2009 associated with blood components from the same HBV infected donor.

Based on its annual surveillance data from blood donation testing, the Blood Service estimates the risk of transmission (termed 'residual risk') per unit transfused for each TTI and publishes this data annually (http://www.transfusion.com.au/adverse_events/risks/estimates). The most recent estimates are based on data collected during 2009-2010 and indicate the residual risk per unit transfused is less than one in a million for HIV, HBV, HCV, HTLV and *T.pallidum*.

3.5 Rationale for current sexual activity-based donor deferral criteria

The rationale for deferral based on sexual activity is dependent on the prevalence of a transfusion-transmitted infectious agent among the donor's sexual partner(s) rather than the sexual practice itself, as this is what defines the comparative risk of acquiring infection.

The current duration for sexual activity-related deferral is 12 months as it covers the incubation period, the window period for testing, and allows an additional safety margin for detecting HIV, HBV, HCV, and HTLV. The current standard of practice for safety margins applied by the Blood Service is to double the most conservative scenario for detecting an infection (i.e. double the length of time of the uppermost threshold for a testing window period or double the length of an incubation period for the appearance of symptoms).

Management of deferral of individuals by the Blood Service depends on whether sexual contact is ongoing (i.e. with a current sexual partner) or in the past (i.e. with a past, non-current partner). In this context, oral sex as well as penetrative vaginal and anal sex all constitute sexual or mucosal contact. However, kissing and mutual masturbation do not constitute sexual or mucosal contact. 'Safer sex' practices such as condom use reduce, but do not eliminate, the risk of transmission therefore sexual activity-related deferral criteria apply even where condoms are used.

The current Blood Service eligibility criteria relating to sexual activity state that a potential donor is deferred for 12 months, if they:

- **Are a man who has had sex with another man (oral or anal sex with or without a condom).**

  Rationale: In Australia, over 80% of HIV positive individuals report a history of male-to-male sex. In this context, the use of condoms or number of partners does not alter the deferral period, oral sex as well as penetrative or receptive anal sex constitutes sexual or mucosal contact, and kissing and mutual masturbation do not result in deferral. HIV is sexually transmitted and a male who has had oral or anal sex with another man has an increased risk of window period transmission and undiagnosed HIV infection that may be undetectable by testing.

- **Are a woman who has had sex (oral, vaginal or anal sex with or without a condom) with a man who the donor thinks may have had oral or anal sex with another man.**

  Rationale: The higher HIV prevalence associated with MSM and sexual transmission of HIV means this group is at increased risk of window period transmission and undiagnosed HIV infection which may be undetectable by testing.

- **Had sex with someone who has ever 'used drugs' by injection or been injected, even once, with drugs not prescribed by a doctor or dentist.**

  Rationale: Intravenous drug use is highly associated with an increased risk of HBV, HCV, HTLV, and HIV as well as other infectious agents. These viruses are sexually transmitted therefore sexual partners are at increased risk of window period transmission and undiagnosed HIV infection that may be undetectable by testing.

- **Had sex with someone who, in the last 12 months, has had an illness with swollen glands and a rash, with or without a fever.**

  Rationale: These are symptoms indicative of 'seroconversion' illness associated with early HIV infection that may be undiagnosed and undetectable by testing.

- **Had sex with someone with HIV/AIDS, human T-lymphotropic virus (HTLV) or HCV.**

  Rationale: Sexual transmission is an important route of infection in HIV and HTLV, and is a potential risk factor for HCV. Therefore sexual partners of infected individuals are at increased risk of window period transmission and undiagnosed infection.

- **Had sex with someone with hepatitis B, unless the donor has a high level of immunity.**

  Rationale: HBV is sexually transmitted therefore sexual partners of infected individuals are at increased risk of undiagnosed infection unless protected by pre-existing immunity to the virus.

- **Had sex with someone who has ever had treatment with clotting factors such as factor VIII or factor IX.**

  Rationale: Those who have received clotting factors (e.g. haemophilia patients) in the past are at increased risk for HIV infection therefore sexual partners are also at increased risk.

- **Had sex with a new partner from a high HIV risk area or had sex with any partner currently living in a high HIV risk area.**

  Rationale: Some geographical areas have a high rate of HIV infection in the general population. An HIV risk area is defined as a country with a high or rapidly increasing estimated adult HIV/AIDS incidence rate (>1%). HIV is sexually transmitted; therefore sex with a new partner from a high risk HIV area or sex with any partner currently living in a high risk HIV area has an increased risk of window period transmission and undiagnosed HIV infection that may be undetectable by testing. Deferral of this group is consistent with findings regarding the only case of HIV transmission since testing commenced in Australia where the implicated donor was a female who had a new sexual relationship with a male partner from Africa.

- **Worked as a sex worker (i.e. received payment for sex in money, gifts or drugs) or had sex with a sex worker.**

  Rationale: Sex workers have multiple sexual partners with unknown history and may be at higher risk of acquiring HIV, HBV, HTLV and syphilis. Sex with a sex worker therefore increases the risk of acquiring TTIs. Deferral is not restricted to clients of sex workers but includes all sexual partners of the sex worker. The use of condoms and the number of partners does not affect the deferral period.

4 REVIEW METHODS

4.1 Public submissions

Members of the public were invited to make submissions to the review committee addressing concerns and providing suggestions regarding the current donor deferral criteria relating to sexual activity. A call for public submissions appeared in all major newspapers across Australia in September 2010 as well as on the website www.bloodrulesreview.com.au .

Details were collected from each submission regarding who the submission was made by (i.e. an individual or on behalf of an organisation) and the location of the sender. The committee identified a list of potentially relevant organisations that had not responded to the call for submissions and these were approached separately and invited to make a submission to the review (APPENDIX A: Organisations approached for public submissions).

A qualitative synthesis of all public submissions received was carried out using a thematic analysis approach. Individual submissions were analysed to identify the main themes presented in the text. A systematic assessment of all submissions was conducted to identify each of the different themes presented as well as cumulatively recording any repetition of themes across separate submissions.

4.2 Review of current international policies

We used the Google search engine and the 'Advanced search' facility to conduct internet searches to identify websites for donor blood services in member countries of the Organisation for Economic Co-operation and Development (OECD, APPENDIX B: Countries reviewed for blood donor policies related to sexual activity). International blood service websites were searched to identify current policies related to sexual activity-based donor eligibility. We also used Advanced Google searching with the name of each country incorporated with terms used to describe blood donation (e.g. blood donation, blood donor, blood collection), and terms used to describe donor selection (e.g. guidelines, criteria, policy, selection, deferral, or exclusion) in order to further identify information on current international donor policies.

An overview of current international policies was conducted based on the following information: name of country, policies relevant to sexual activity and donor eligibility (including length of deferral time, if any), timing of policies (date the policy was established, date the policy was last reviewed and whether the policy was endorsed or changed at this time), and evidence resources linked to the policy.

We attempted to obtain all relevant information in English and employed freely available translation software applications on the internet (e.g. Yahoo! Babel Fish, Google Translate) to ascertain information on sexual activity-related policies described in non-English sources.

4.3 Previous and ongoing reviews to inform international policies

We conducted a systematic search of electronic literature databases MEDLINE, EMBASE, and *The Cochrane Library* using a combination of medical subject headings (MeSH) and free text terms that relate to sexually-transmitted blood-borne infections and blood donation (APPENDIX C: S). Searches were limited to identify publications from 1980 onwards.

Titles and abstracts of citations identified by the searches were screened for relevance. Citations identified as potentially relevant to the topic area were retrieved in full-text. Articles describing a formal review of donor policies related to sexual activity were identified and their findings summarised and presented to the committee for discussion.

The process of identifying international policies and previous reviews conducted to inform these policies also led to the identification of several reviews that are currently in process. Further information regarding the current status of any ongoing reviews was sought from relevant government and blood authority websites (e.g. Council of Europe Expert Committee on Blood Transfusion, UK Advisory Committee on the Safety of Blood, Tissue, and Organs (SaBTO)).

4.4 Evidence-based risk analysis for scenarios with changes to deferral criteria

A scientifically rigorous approach to determine the impact of changes to deferral policies would be to conduct a prospective controlled study of transfusion recipients. The feasibility of such a study is unlikely due to the unethical risk of infection for transfusion recipients. Even if a parallel study of donor samples were conducted without involving transfusion recipients (i.e. blood donor samples were collected for study purposes only), the low risk of infected donations means a significantly large sample size would be needed in order to detect a difference between groups in the study. The resource implications for these types of studies are significant and alternative methods to estimate the impact of policy changes have been sought using mathematical modeling. This involves estimating the risk of an infectious donation being collected during the window period that is in the early stages of infection and not detectable by screening tests.[28]

Several studies have attempted to estimate the impact of changing donor deferral criteria and the risk of sexually-transmitted TTIs entering the blood supply.[29-32] These studies have mainly focused on the impact of reducing the deferral period for MSM and the estimated risk of an HIV-infected donation.

The review committee sought expert input from The Kirby Institute for infection and immunity in society to calculate the average risk of failing to detect a new (incident) infection in a potential blood donor based on a number of different scenarios involving high risk groups that are currently deferred from donating. The calculations are based on established mathematical transmission modeling methods and are used to estimate average and relative risks of failing to detect incident infections for various risk groups.[33, 34] A scenario involving heterosexuals with a new partner (not from a country with high HIV prevalence) was included as a reference group that could be at risk of infection but are not currently deferred from donating blood. The separate scenarios requested for analysis by the committee are outlined in section 4.4.1 below.

4.4.1 Description of scenarios

The review committee provided the following descriptions of potential donor scenarios to epidemiological and biostatistical experts at The Kirby Institute. The average risk of failing to detect a new infection in each scenario was estimated based on current epidemiological evidence of sexually transmitted TTIs:

1 MSM
   - A MSM (no further specification)
   - B MSM in a monogamous relationship
     - i both partners monogamous
     - ii partner may not be monogamous, confirmed negative status within past 12 months
     - iii partner may not be monogamous, infection status unknown

2 Sex workers
   - A Sex worker within Australia
   - B Male who has had sex with an Australian-based female sex worker

3 Heterosexuals
   - A Countries with high HIV prevalence (>1%)
     - i Individuals who have had sex with someone currently living in a high prevalence country
       - a Sex worker
       - b Not a sex worker
     - ii Individuals who have had sex with a new partner who has previously lived in a high prevalence country (cumulative total 12 months in past 10 years)
   - B Individuals who have had sex with a new partner (not from a high prevalence country)

4.4.2 Scenario analyses

A mathematical model, based on standard transmission risk equations and the best available data, was used to estimate the risk of failing to detect a newly acquired transfusion-transmissible infection (TTI) for different scenarios.

Given the relative paucity of epidemiological and behavioural data for TTIs other than HIV, it was decided that the different deferral scenarios would be investigated thoroughly for HIV as a case study. Although some quantitative differences in risk and qualitative ranking of deferral conditions would exist for the relative risks of other TTIs, it is expected that the general conclusions would be consistent if other case studies could have been examined to the extent of HIV.

The length of deferral periods in the scenario analyses were based on allowing sufficient time after risk exposure to guarantee that either HIV RNA or HIV antibody will be detectable. In the context of the risk of HIV transmission by transfused blood components, the effectiveness of a 12 month

deferral period for MSM has been demonstrated previously in Australia.[35] Consequently, scenarios were chosen based on current deferral periods (12 months) or less to estimate the impact of decreasing the current deferral period.

Individuals that are infected are asked not to donate and therefore it is assumed that no-one with a diagnosed infection would attend to donate and there is almost complete compliance with current donor guidelines.

It is important to note that the risk of an undetected 'incident' infection is distinct from an estimate of the risk of a detected infection (in magnitude and relative to other comparative scenarios). The model calculations of the risk of failing to detect an incident infection was determined as the probability of newly acquiring infection in an interval prior to donation less than the duration of the window period of the diagnostic test. Specifically, the probability of newly acquiring infection in the window period is based on the product of (i) the probability of not being infected up to the start of the window period and (ii) the probability of acquiring infection in the window period. In order to calculate (i) it is necessary to define a reference starting point. For these calculations it was assumed that a potential donor was not infected 12 months prior to donation; this reference assumption was applied across all scenario risk groups to enable comparison in relative risks. The average probability of transmission or not, over a period of time, was calculated using a Bernoulli equation based on the expected number of exposure events, proportion of events that are protected by a condom, efficacy of condoms, average incidence and prevalence in partners, and the probability of transmission per discordant act. All parameters in the risk equations were defined to have best estimates and minimum and maximum uncertainty bounds based on confidence intervals from calculations or plausible limits. An uncertainty analysis was conducted by sampling 1000 parameter sets, using Latin hypercube sampling, from across parameter space and estimating the resultant variation in risk.

4.4.3 Data collection

The following data were required to calculate risk estimates for each scenario described in section 4.4.1. Data was primarily collected from Australian studies describing the incidence and prevalence of sexually-transmitted TTIs and reported trends in risk behaviours. Both local and international studies of disease transmission were considered for data relating to sexual transmission between discordant couples. The Blood Service provided all data relevant to testing window periods currently applicable to blood donation screening in Australia.

Variables relevant to sexually-transmitted TTIs:

- Average incidence and prevalence of TTIs in sexual partners (e.g. MSM, sex workers, heterosexuals)

Variables relevant to sexual activity:

- Frequency of sexual activity per partnership per year (i.e. expected number of exposure events)
- Probability of transmitting infection per sexual act
- Condom use

- Condom efficacy

Variables relevant to blood donation:

- Testing window periods based on current tests applied by the Blood Service (i.e. NAT and serology testing)

4.4.3.1 Australian studies

The committee consulted the following sources for epidemiological evidence regarding sexually-transmissible TTIs and sexual risk behavior in the Australian setting:

- Annual surveillance reports for HIV, viral hepatitis and sexually transmissible infections in Australia (The Kirby Institute)
- Gay Community Periodic Surveys (National Centre in HIV Social Research)
- Health in Men study (The Kirby Institute)
- Law and Sexworker Health Project (The Kirby Institute)
- Australian Study of Health and Relationships (Australian Research Centre in Sex, Health and Society)

Study authors were contacted for unpublished data or further information when required. The reference lists of publications from the above studies were also searched to identify studies with relevant data for the scenario analyses. We conducted forward citation searches in the Web of Science® database (Thomson Reuters) for studies that were more than five years old in order to identify more recent publications with relevant data. Finally, we sought advice from experts to suggest studies that would provide relevant data for each scenario.

Risk estimates in the scenario analyses were based on the most recent epidemiological data or behavioural data observed in past years. Prediction or investigation of potential future changes in epidemiology of TTIs in Australia, sexual behaviour, or donor compliance was not undertaken.

4.4.3.2 Sexual activity and risk exposure for TTIs

The efficiency of sexual transmission of TTIs varies by mode of exposure (e.g. male-to-female versus female-to-male, penile-vaginal sex versus penile-anal sex). The probabilities of transmission per sexual act and per partnership for various TTIs have been estimated but are most rigorous for HIV. Transmission probabilities for different modes of exposure have been estimated from numerous research studies, with different study designs and conducted in different settings. Evidence regarding transmission rates per couple interaction and per sexual act was taken from cohort studies of sero-discordant couples or those at high risk of seroconversion such as MSM, sex workers, or IDUs. Probability of HIV transmission per coital act considers transmissions that occur at the earlier stages of infection (i.e. within the first 12 months of a partner seroconverting) as donors with partners who have known established infection should be screened out in accordance with current donor guidelines. The best evidence from conducted syntheses of available data was used to inform transmission risks in the model calculations. A summary of risk estimates and algorithms for calculating risk has been described elsewhere by Fox et al.[36]

4.5 Recommendations to the Blood Service

The review committee considered findings of the evidence-based scenario analyses to assess the appropriateness of the current deferral criteria and whether any potential changes to deferral policies could be made that would maintain an acceptable level of risk of TTIs in the Australian blood supply.

For each of the current deferral criteria described in the terms of reference (see section 2), the committee considered the following factors:

- Risk of sexually-transmitted TTIs in the relevant population
- Potential risk of failing to detect incident HIV infections in the relevant population
- Risk of acquiring an infection from a partner in the relevant population
- Potential impact of changes to deferral criteria on blood safety
- Potential impact of changes to deferral criteria on the donor pool
- Potential impact of changes to deferral criteria on blood product availability
- Ethical implications of changes to deferral criteria
- Legal implications of changes to deferral criteria and anti-discrimination legislation.

5 REVIEW FINDINGS

5.1 Public submissions

Thirty-four submissions to the review committee were received comprising 25 submissions from individuals and nine submissions received from organisations. Individual submissions were received from a range of people who identified themselves as regular blood donors, recipients of blood transfusions, MSM in monogamous relationships, or sex workers. The remaining 30% did not specify any group they identified themselves as being part of. The nine organisations that made submissions included HIV/AIDS organisations and those representing the interests of sex workers, Christians, the gay, lesbian, bisexual and transsexual community, and anti-discrimination. A submission was also received from the Royal College of Pathologists of Australasia. Half of the submissions did not specify the location of the sender, however some of the submissions indicated they had been sent from NSW, WA, VIC or TAS. Table 3 provides a summary of the submissions received.

Table 3. Summary of public submissions

Individual or organisation	Description	Location
Individual	Blood donor	-
Individual	Blood donor	NSW
Individual	Blood donor	Victoria
Individual	Blood donor	WA
Individual	Blood donor	WA
Individual	Blood donor and recipient	WA
Individual	Blood recipients	-
Individual	Blood recipients	-
Individual	MSM	TAS
Individual	MSM monogamous	-
Individual	MSM monogamous	-
Individual	MSM monogamous	-
Individual	-	-
Individual	-	-
Individual	-	-
Individual	-	-
Individual	-	-
Individual	-	-
Individual	-	NSW

Individual or organisation	Description	Location
Individual	-	WA
Individual	Research project	VIC
Individual	Sex worker	-
Individual	Sex worker	-
Individual	Sex worker	-
Organisation	AIDS Council of NSW	NSW
Organisation	Australasian Society for HIV Medicine	NSW
Organisation	Australian Christian Lobby	ACT
Organisation	Australian Federation of AIDS organisations	NSW
Organisation	Office of the Anti-Discrimination Commissioner	TAS
Organisation	Royal College of Pathologists of Australasia	NSW
Organisation	Scarlet Alliance, Australian Sex Workers Association	NSW
Organisation	Spectrum: The University of Newcastle Queer Collective	NSW
Organisation	Tasmanian Gay & Lesbian Rights Group	TAS

The submissions were qualitatively analysed using QSR International's NVivo 8 software (NVivo qualitative data analysis software; QSR International Pty Ltd. Version 8, 2008). The majority of the submissions (19/34) addressed eligibility criteria regarding MSM. The second most frequent criterion addressed was the deferral of sex workers (8/34). A small proportion of submissions also addressed donor eligibility for individuals who have had sex with people from a country with high prevalence of HIV (4/34), or individuals that have had sex with MSM (2/34), IDU (2/34), sex workers (2/34) or someone who has received Factor VIII or Factor IX (2/34). None of the submissions addressed criteria regarding individuals who have had sex with someone who has HBV, HIV, AIDS, HTLV, HCV or who displayed symptoms of infection.

The following results largely relate to eligibility criteria for MSM and sex workers which is consistent with these groups being addressed in majority of the submissions received. The main themes have been categorised and are summarised below.

5.1.1 Criticisms of current eligibility criteria

Current eligibility criteria were criticised for being applied at a group level (i.e. based on sexuality or occupation) rather than at the level of individual sexual activities. The current criteria were observed as lacking provisions for safe sex practices, HIV test results, or behaviours that are likely to reduce the risk of TTI within deferred donor groups. This limitation means that individuals who are at low risk of TTI within these groups are still deferred from donating.

Donor selection processes in Italy and Spain were offered as cases that support removal of MSM deferral.

5.1.2 Support for current eligibility criteria

There were three main themes identified when classifying comments that supported the current eligibility criteria: 1) safety of the blood supply is maintained because of the current eligibility criteria, 2) MSM are identified as a group at increased risk of TTIs in Australia and should be deferred based on this increased risk, and 3) the potential legal implications if changes to the criteria resulted in an increased risk of exposure to TTIs for transfusion recipients.

5.1.3 Issues of concern

The submissions included a number of themes relating to the concerns individuals or organisations expressed when discussing the appropriateness of current eligibility criteria. These included concern about the protection of transfusion recipients, unfair discrimination of low risk individuals in the donor selection process, and the overall sustainability of the blood supply to meet increasing demands for blood donations. The history of viral transmission through transfusion of blood recipients in Australia remains a cause for concern when considering changes to eligibility criteria, as is the risk of transmission of new and emerging pathogens. The reliability of the screening questionnaire to defer individuals with increased risk of exposure to TTIs was queried. Some were concerned that changes to the current criteria may be made in response to pressure from 'lobby' groups rather than following an objective evaluation.

5.1.4 Perceptions and beliefs

The submissions contained several recurring themes that reflected the perceptions and beliefs held by the authors. These included beliefs that current eligibility criteria were not based on evidence. Some expressed their belief that blood donation is not a human 'right'. There were also perceptions that risks for TTIs were comparable between heterosexuals and MSM and that routine testing of blood donations carried out by the Blood Service was sufficient to detect the presence of TTIs without the need for donor deferral.

5.1.5 Suggestions for donor selection process

Several submissions included specific suggestions for donor selection. These included the availability of pre-donation testing for TTIs as well as asking more detailed questions regarding unsafe sexual activities such as condom use, number of partners, and previous testing for TTIs. It was suggested the duration of deferral periods should reflect the 'window periods' of tests currently applied by the Blood Service to detect TTIs in blood donations and there should be consistency in the length of deferral applied to donor selection policies.

5.2 Review of current international policies

Internationally, South Africa has the shortest deferral period of six months for MSM however Japan has recently reduced its current 12 month deferral policy to six months.[37]

Across Europe, EU member states are required to permanently defer individuals whose sexual behavior puts them at high risk of acquiring infectious diseases that can be transmitted by blood (EU Directive on Blood Safety 2004/33/EC Annex III point 2.1). MSM deferral policies vary across member states however there is no national policy for MSM deferral in Italy or Spain. UK changed from permanent deferral to 12 month deferral for MSM in 2011.[38]

Most, but not all, countries have permanent deferral policies for sex workers. Similar to Australia, New Zealand has a 12 month deferral for sex workers however sex workers from outside New Zealand are deferred five years.

Several countries temporarily defer individuals who have recently had a new sexual partner (i.e. France, Switzerland, Sweden) or sex with multiple partners (i.e. Italy, Spain, Switzerland).

The following tables (Table 4-Table 7) provide an overview of sexual activity-related donor deferral policies for OECD member countries.

Table 4. Sexual activity-based donor deferral policies in New Zealand

Country	Sexual behaviour	Deferral policy
New Zealand	MSM oral or anal sex with or without a condom	5 years
	Sex for payment	5 years
	Sex with IDU, MSM, someone who has received payment for sex, someone from a country at high risk of HIV, or someone who carries HBV, HCV	1 year

Table 5. Sexual activity-based donor deferral policies in Europe

Country	Sexual behaviour	Deferral policy
England and North Wales[a]	MSM	12 months[b]
	Sex for money or drugs	Permanent
	Sex with MSM, IDU, someone who has received sex for money or drugs, someone who is HIV, HCV, or HBV positive, or someone from a country with high HIV/AIDS prevalence	12 months
France[a]	MSM	Permanent
	Unprotected intercourse with a new sexual partner within the past three months	4 months
Hungary[a]	MSM	12 months

Country	Sexual behaviour	Deferral policy
Iceland	MSM	Permanent
	Engaged in prostitution	Permanent
	Had sex with MSM, anyone who has engaged in prostitution, or IDU	Permanent
Italy[a,c]	MSM	No national policy
	Sex for money or drugs	Permanent
	Sex with someone at risk of transmission of infectious diseases	4 months or indefinite
	Occasional sexual relationships at risk of transmission of infectious diseases	4 months or indefinite
Norway	MSM	Permanent
	Sex with heterosexual sex worker	6 months
Spain[a,c]	MSM	No national policy
	Had sexual relations with more than one partner without a condom	12 months
	Slept with many partners or slept with someone who they know has had multiple partners	12 months
Sweden[a]	Sexually risky behaviour	Permanent
	Sex with new or multiple heterosexual partners	3 months
Switzerland	MSM since 1977	Permanent
	Sex for money since 1977	Permanent
	Sex with multiple partners (protected or unprotected sex)	12 months
	Sex with anyone considered at risk (sex worker, MSM, IDU, people from countries of high HIV prevalence)	12 months
	Change of sexual partner (protected or unprotected sex)	6 months

[a]Member states of the European Union. [b]UK implemented 12 month deferral for MSM in 2011. [c]Policies may vary between regions.

Table 6. Sexual activity-based donor deferral policies in the Americas

Country	Sexual behaviour	Deferral policy
Pan American Health Organisation (PAHO)	Behaviours that pose a risk for HIV infection	12 months
	Females with male sexual partners who have had insertive or receptive anal sex with another male during the previous 12 months	12 months
	Individuals who have had sex with a new partner	6 months
US	MSM since 1977	Permanent
	Sex for money or drugs	Permanent
	Sex with MSM or someone who has sex for money or drugs	12 months
Canada	MSM since 1977	Permanent
	Sex for money or drugs	Permanent
	Sex with anyone who was born in or lived in Africa since 1977	Permanent
	Sex with MSM, IDU, someone who has sex for money or drugs	12 months
	Sex with someone whose sexual background you don't know	6 months

Table 7. Sexual activity-based donor deferral policies in Asian and Middle-Eastern countries

Country	Sexual behaviour	Deferral policy
Israel	MSM since 1977	Permanent
	Sex for payment	Permanent
	Sex with MSM or someone who has received payment for sex	12 months
Japan	MSM	6 months
Korea	MSM	Permanent
Turkey	MSM	Permanent
	Sex for money	Permanent
	Sex with someone at high risk (MSM, sex worker, IDU)	Permanent

5.3 Previous and ongoing reviews to inform international policies

There were no systematic reviews of blood donor deferral policies identified in our search however we identified several international reviews of sexual activity-related deferral policies that have been prepared for blood services, government departments and regulatory bodies in UK, Canada, and New Zealand (Table 8).

International blood services are required to make decisions regarding donor screening and selection based on the most up to date evidence of disease patterns in their populations. Clearly, this will vary from country to country and it is important to acknowledge that evidence-informed policies developed for one country may not be applicable to other countries due to differences in disease prevalence and donation screening methods.

Using risk management principles, a report to Canadian Blood Services in 2007 argued that changing permanent deferral of MSM to one year would introduce an unacceptable risk, however it was less clear whether there would be any incremental increase in risk if a five or 10 year deferral period were introduced.[39] A decision to change deferral of MSM to between five and 10 years is currently pending (see text below regarding international reviews in process).

New Zealand reduced the deferral of MSM from 10 years to five years following an evidence-based review in 2008.[20] The report recommended one year deferral of sex workers in New Zealand, however sex workers from outside New Zealand are deferred five years to be consistent with five year deferral of heterosexuals from countries with high HIV prevalence.

The UK reviewed its donor deferral policies in 2009 [40] and again more recently in 2011.[41] The most recent evidence-based review of deferrals conducted by the Advisory Committee for the Safety of Blood, Tissue and Organs (SaBTO) resulted in a change to 12 month deferral for MSM in 2011.

In 2010, the Council of Europe (CoE) established a working group on 'Risk Behaviours having impact on Blood Donor Management and Transfusion Safety' that comprised regulatory bodies, scientific agencies, and relevant organisations in Europe and other countries with comparable epidemiology. The working group aimed to provide a harmonised interpretation of what constitutes temporary versus permanent deferral and an evidence-based evaluation for possible differentiation of high risk behaviours. The outcomes of the review were reported in December 2011 with majority of the working group favouring no change to permanent deferral of MSM, commercial sex workers (CSW) and other persons with high-risk sexual behaviour until new evidence is available.[42]

Table 8. International reports on blood donor deferral policies

Title	Summary of Findings
Canadian Blood Services[a]: MSM donor deferral risk assessment (2007) [39]	Change from exclusion to one year deferral period for MSM would result in an unacceptable increase in risk. Implications for a five or 10 year deferral is less clear, but a small increase in risk could not be ruled out. A 10 year deferral policy for MSM would provide an additional margin of safety. Changing to five or 10 years would allow collecting actual evidence regarding residual risk (rather than estimates).

Title	Summary of Findings
New Zealand Blood Service: Behavioural donor deferral criteria review (2008) [20]	Change from current 10 year deferral of MSM to five years will not increase risk to the blood supply. The term 'sex' should be defined as 'you have had oral or anal sex with or without a condom'. It is not practicable at present to further define specific MSM activities for exclusion. Heterosexuals who have lived in or come from countries with higher prevalence of HIV should be deferred for five years. Sex workers in NZD should be deferred one year, those from outside NZD should be deferred five years. The report recommended an ongoing systematic program of public education to enable informed self-deferral. The effectiveness, reliability and validity of the current donor questionnaire should be evaluated as well as the reliability and validity of the donor interview.
UK Advisory Committee on the Safety of Blood, Tissue & Organs (SaBTO): Donor selection criteria review (2011) [41]	The review focused on permanent deferral of MSM and CSW. The findings noted that process improvements and automation have reduced the risk of chance errors and changing the deferral to 12 months would not ultimately affect the risk of undetected HIV infection entering the blood supply if compliance remained the same.
Council of Europe: Risk behaviours having an impact on blood donor management (2011) [42]	The Working Group found the superiority of permanent or temporary deferral or individual risk assessment with respect to sexual risk behavior was unclear. However, based on modeling studies there was an increased risk of undetected infections if the ban on MSM were lifted. They ruled in favour of no change to permanent deferral of MSM, CSW or individuals with high risk behavior in the interest of patient safety until new evidence is available.

[a]CBS currently reviewing deferral policies for new recommendations in 2012

Evaluations of international donor deferral policies for risk behavior are ongoing. In particular, updated reports and reviews of MSM policy are presently being undertaken in Canada and US.

In 2011, Canadian Blood Services (CBS) was involved in a court case regarding its policy for permanent deferral of MSM. The court ruled in favour of CBS but recommended a review of deferral policies. Subsequently, the Board of CBS recommended to its regulator, Health Canada, that MSM deferral should be changed to between five and 10 years. CBS are currently in consultation with key stakeholders and will make a formal request to Health Canada by March 2012 to have the permanent deferral of MSM changed http://www.blood.ca/CentreApps/Internet/UW_V502_MainEngine.nsf/page/CanadianBloodServicesPolicyOnExcludingMSMFromDonatingBlood?OpenDocument&CloseMenu).

Major blood suppliers in the US (AABB, America's Blood Centers and the American Red Cross) have publicly advocated that permanent deferral of MSM is not supported by scientific evidence, however there has been no change in policy despite several reviews by the FDA. In its review of the policy in 2010, the Health and Human Services (HHS) Advisory Committee on Blood Safety and Availability (ACBSA) acknowledged the policy was suboptimal but felt that scientific evidence available at the time was inadequate to support changing the deferral. Following these recommendations, a Blood, Organ, and Tissue Safety Working Group (BOTS WG) was organised to develop a plan of action, including conducting the necessary studies to allow a further review of the existing policy.

Information regarding risk factors in blood donors, causes of quarantine release errors, comprehension and compliance of donors for the donor history questionnaire, as well as consideration of alternative screening strategies (e.g. donor testing for infectious diseases) is currently being sought. The BOTS WG estimated 18-36 months to conduct such studies (pending available funding) before re-evaluation of the US MSM deferral policy (http://www.hhs.gov/ash/bloodsafety/advisorycommittee/recommendations/resolutions.html).

There has been limited information about the impact of policy changes in countries that have implemented shorter deferral periods for MSM. To date, Australia has been the only country to report assessment of the impact of changing from permanent deferral to 12 month deferral for MSM using empirical data collected before and after the change in policy.[35] Seed et al compared donor data from the five years prior and five years after the change in policy and showed there was no change in the number of HIV cases detected in blood donations, therefore validating the safety of a 12 month deferral policy in Australia.[35]

The impact of the removal of MSM deferral in Italy and Spain is regarded with particular interest worldwide. In Spain, epidemiological data has shown a significant increase in HIV positive donations in recent years compared to other European countries and the majority of these cases (74%) have reported a history of MSM.[37, 43] Spanish authorities are currently drafting new regulatory policies in response to the evidence and the new blood donor deferral criteria will exclude MSM for up to 12 months.[37] The situation in Italy is less clear and evaluation has proved challenging especially due to regional variation in policies. Detailed data from the Lombardy region of Italy did not demonstrate a clear trend in HIV infections in donors.[44] There has been an overall increased prevalence of HIV in Italian blood donations [37, 43] that is consistent with overall observed increases in HIV incidence in donors across Europe.[45] An increase in the percentage of MSM among repeat donors after the change in deferral policy in Italy has been noted, however there are likely to be other reasons for these observed increases.[42]

Evaluation of the impact of recent changes to deferral policies in countries such as UK and Japan will be an important source of evidence to inform future policy decisions worldwide.

5.4 Evidence-based risk analysis for scenarios with changes to deferral criteria

Several international studies have reported the use of mathematical models to estimate the impact of changes to deferral policy. These studies have typically focused on deferral of MSM.

In 2003, a model constructed by Soldan et al considered the incidence of HIV for MSM, the testing window period, and the interval between donations. It also incorporated the risk of testing errors (i.e. false negatives) and process errors (i.e. erroneous release of infectious units). Based on their model, they estimated a 60% increase in risk if lifetime deferral of MSM in the UK was changed to 12 months.[29] With the introduction of NAT, re-analysis by Davison et al indicated the change in risk for five year deferral of MSM was within the range of -4% to 15%, depending on the level of compliance with the deferral.[32]

In another study, Germain et al estimated an 8% increase in HIV risk if lifetime deferral of MSM in Canada was changed to 12 months.[30] Their model considered the potential increase in eligible donors and the proportion of HIV infected units for which screening would fail (based on HIV incidence and donor adherence as well as failure of screening tests and technical release errors). US modeling estimates that focus on test errors and handling errors only, have indicated HIV risk would increase by 3% if lifetime deferral of MSM were changed to 12 months or 0.5% if deferral was five years.[46]

In France, mathematical modeling was used to estimate the impact of changing the permanent deferral of MSM to deferral only if MSM had more than one sexual partner in the previous 12 months. This model takes into account data from epidemiological and behavioural surveys and estimated that HIV risk would be up to 3.7 times higher than the current risk.[47]

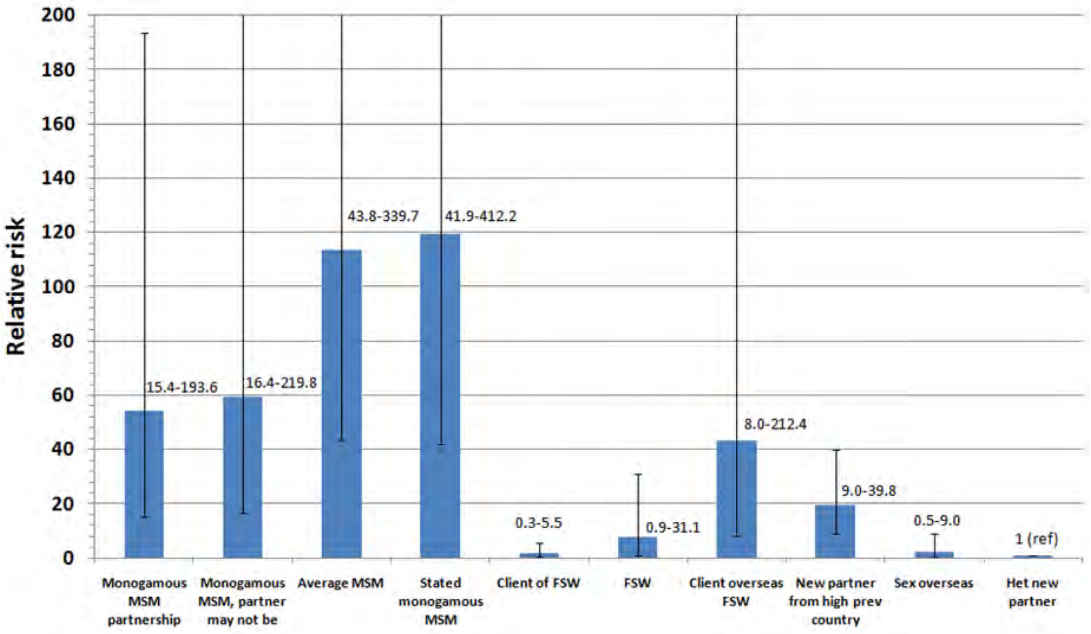
Variation in reported risk estimates across international studies is influenced by the variables included in different models and also reflects important differences in disease prevalence and incidence, screening tests used and process errors experienced across international blood services.

By 2000, Australia had already implemented 12 month deferral of MSM. As a separate approach to other international models, Musto et al developed a mathematical model focusing on risk of HIV for specific behaviours rather than HIV risk associated with length of deferral periods. The model was used to estimate the probability that a donor with high risk behaviour had newly acquired HIV infection that was undetectable by screening. The model assumes a donor gives blood twice in a 12 month period and estimates the risk of donors acquiring HIV based on prevalence in the contact population, frequency of contact, and transmission risk per contact. This approach can be used to assess the appropriateness of deferral based on sexual activity. Results of this study indicated MSM were at highest risk of becoming infected and donating in the window period compared to other groups, which was at least 10-fold greater than men who have sex with women in Australia.[31]

For the current review, a mathematical model was constructed based on HIV prevalence in partner populations, frequency of sexual contact, risk of transmission per contact, condom use and efficacy, and the length of testing window periods.[33, 34]

A summary histogram of the relative risk of failing to detect a TTI, by scenario, is shown in Figure 2. The estimated risk of failing to detect an incident HIV infection for scenarios of potential change to deferral criteria was compared with the risk of failure to detect an incident infection among a reference case of an average heterosexual person who had a new sexual partner (in the past 12 months; where the partner is not from a high HIV prevalence country). The columns in the figure represent the expected relative risk for each scenario compared with the reference case and the error bars represent the lower and upper 95% uncertainty bounds (UB).

Figure 2. Relative risk of not detecting positive infection by risk group compared to heterosexuals who have had a new sexual partner in the past 12 months



5.4.1 Evidence-based assumptions when estimating risk

A number of limitations exist when using mathematical modeling to estimate the risk of window period infections in specific donor groups. Results can vary because incidence of infection in narrowly defined sub-groups is not available and therefore has to be estimated. Risk estimates usually have wide uncertainty bounds because of the very low number of events and the need to estimate some of the variables. Assumptions often rely on survey data from sample populations that may not be truly representative of the sub-group of interest. This is particularly true for studies with small sample sizes or those limited by the age or location of participants. Estimates for risk behavior and transmission of HIV in the MSM population in Australia are often criticised as they are based on sample populations in Sydney or Melbourne and it has been argued this is not representative of the broader population of MSM.[8] Estimates for the transmission of HIV per sex act have also been criticised.[48] Options for evidence-based data will always be limited by the studies that have been performed to date. Estimates for variables in the scenario analyses in this review were based on published data where it was available or were otherwise based on expert opinion as described below.

5.4.1.1 HIV window period

The window period for HIV NAT is thought to be 5.6 days (5-6.4),[21] and the antibody HIV test to be 22 days (6-38) [22]; the more conservative range of 22 days (6-38 days) was used in the calculations.

5.4.1.2 HIV infection

Primary HIV infection refers to the very early stages of HIV infection. During this stage of HIV infection, infected people may have symptoms of acute HIV seroconversion illness, and will typically

have very high HIV RNA levels which are associated with substantially higher (5-10-fold) transmission risks compared to subsequent latent periods of untreated infection. The duration of primary HIV infection was assumed to be 90 days (60-180 days) [49] and the multiplicative increase in transmission during this period was taken to be 6 (ranging 3.42-10.63).[50]

5.4.1.3 HIV transmission per sex act

Probabilities of transmission were based on international best estimates for different biological routes.[36] Specifically, the probability of transmission per discordant act of unprotected anal intercourse was taken to be 1% (best estimate, uncertainty bounds of 0.24-3%); male-to-female penile-vaginal intercourse risk was taken to be 0.8% (best estimate, uncertainty bounds of 0.04-2%); female-to-male penile-vaginal intercourse risk was taken to be 0.4% (best estimate, uncertainty bounds of 0.02-1.5%).

5.4.1.4 Frequency of sexual contact

It was assumed that regular sexual partners involve an average of 100 acts per year (range 50-150), commercial clients of sex workers have 20 (10-50) acts per year with sex workers, and the number of casual sexual encounters (such as when travelling overseas) for people who engage in this behavior was an average of 2 (1-10) acts. The average number of clients per sex worker per year was taken to be 1040 (52-2640) based on the LASH study, which indicated a median of 15 (2-75) per week,[51] and Estcourt et al that reported a median 20 (1-120) per week.[52]

5.4.1.5 HIV incidence and prevalence

The Health In Men (HIM) study involved a cohort of initially HIV-negative gay men from Sydney followed up over time. From this cohort there was an average annual incidence of approximately 1%, which varied by risk behavior reported by men and duration of follow up.[53] In this cohort 35.6% of men who reported monogamy also had casual partners [54] and 70.1% had no unprotected anal intercourse with casual partners.[55] Given these factors, a best estimate of 0.55% as a mid-range was used with plausible limits of 0.11-1% for scenarios involving 'monogamous' MSM, and incidence of 1% (0.7-1.4%, based on limits from the HIM study) was used for average MSM.

The prevalence of HIV among MSM in Australia is estimated to be 8-12% and the extent of undiagnosed infections is believed to be 10-20% [13]; assuming disclosure of known serostatus occurs in the vast majority of regular partnerships, the probability of unknown discordant partnership was taken to be 1.5% (0.8-2.4%).

The incidence and prevalence of STIs in sex workers in Australia is very low. There are no documented cases of HIV among Australian sex workers in recent history.[52] We assume HIV prevalence among sex workers may be approximately 0.01% (similar to the prevalence in the general female population in Australia) with an uncertainty range of 0-0.4%. The prevalence of HIV among casual non-commercial sexual partners of sex workers was taken to be 0.0324% (0.0229-0.0688%); this is based on the following equation:

> Estimated number of HIV cases in Australia ((diagnosed + estimated undiagnosed) - MSM) = 22,000 x (1 - (60-80% MSM)) / (0.8-0.9 diagnosed) / 16,000,000 Australian adults

The prevalence of HIV among sex workers overseas varies vastly between regions; a review by Talbott suggests that prevalence among sex workers is approximately 42% in sub-Saharan Africa, 5% in Asia and 18% in the Caribbean and Central America.[56] A mid estimate of 10% is used in our analysis with a range of 5-40%.

The prevalence of HIV among male clients of female sex workers was assumed to be higher than the prevalence among the general male population because of increased number of lifetime sexual partners and history of STIs. It was assumed that clients of sex workers had a prevalence of HIV of 0.05% (0.03-0.1%).[13]

Prevalence of HIV among the general heterosexual population in Australia was estimated by adjusting overall estimated numbers of people living with HIV to remove high-risk population groups, leading to 0.0324% (0.0229-0.0688%).[13] The prevalence of HIV among people in Australia who are originally from a high HIV prevalence country is greater than the prevalence among the general Australian population. Using the Australian Bureau of Statistics Census data (http://www.abs.gov.au/census) for the numbers of people living in Australia whose region of birth is sub-Saharan Africa, Southeast Asia, South/Central America or the Caribbean, multiplied by the estimated HIV prevalence in these populations (relative levels estimated from ratios of HIV diagnoses in Australia's National HIV Registry), a weighted average HIV prevalence among people from a high HIV prevalence country was obtained: 0.79% (0.65-0.95%) [13].

5.4.1.6 Condom use

Based on the LASH study and a study by Estcourt et al, it is assumed that condom use among sex workers in Australia is almost universal with commercial partners (99% (89-100%)) and is estimated to be slightly lower for condom use with sex workers overseas (90% (80-99%)).[51, 52] Based on the Sex in Australia study, it was assumed that average condom use with casual non-commercial partners of sex workers was 40% (20-80%) [57]; the same level of condom use was assumed for casual (or new) sexual partners in the general population. The efficacy of condom use was taken to be 95% (80-99%).[58]

It was assumed that condom use among new heterosexual partners is 30% (5-40%) based on the Sex in Australia Survey and that condom efficacy is not as high among the general population to account for inexperience, slippage, and breakage: 80% (75-95%).[57] Average condom use among people who have had sex overseas (not with a sex worker) was assumed to be 60% (40-100%).

5.4.2 Scenarios

5.4.2.1 MSM

Based on epidemiological evidence, the risk of failure to detect an HIV infection among MSM is substantially greater than the risk associated with heterosexual people who have recently obtained a new regular sexual partner (Figure 2). Although the risk for MSM is relatively high, there will be some individuals who are at lower risk such as those in monogamous partnerships. A major limitation when determining the risk of unknown HIV infection in a potential blood donor is the difficulty in making definitive statements about a partner's sexual behavior and the information provided may not always be accurate. It is therefore important to consider the impact of partners engaging in sex outside monogamous relationships and the associated risk of HIV.

The estimated risks of failing to detect a positive HIV infection for different scenarios for MSM partnerships are presented in Table 9. There is no risk for MSM who are in truly monogamous sexual partnerships and both partners have evidence of negative HIV tests in the interval 6-12 months prior to donation. However, without evidence of the previous negative HIV tests of both partners there is the possibility of an unknown discordant partnership, which has an average relative risk of 54.5 (95% UB: 15.4-193.6). If a potential donor in an MSM relationship is monogamous, it is possible that his partner may not be. Data from the Health In Men study found that 35.6% of men who reported monogamy also had casual partners (personal communication with study authors). Accordingly, the relative risk of a man, who himself is monogamous, donating with an infection that would be undetected is 59.5 (16.4-219.8). The relative risk associated with MSM in Australia is 113.5 (43.8-339.7) and the relative risk of a man who states he and his partner are monogamous but they may not be and his partner's status is unknown is 119.6 (41.9-412.2). Therefore, the risk to the blood supply of an undetected TTI would be increased according to each of these scenarios.

Table 9. Relative risk of failure to detect HIV infection in donations from MSM

Donor characteristics	Partner characteristics	Relative risk (95% UB)
MSM	-	113.5 (43.8-339.7)
MSM monogamous	monogamous	No risk based on sexual activity
MSM monogamous	unconfirmed HIV status	54.5 (15.4-193.6)
MSM monogamous	may not be monogamous HIV negative in previous 6-12 months	59.5 (16.4-219.8)
MSM monogamous	may not be monogamous unconfirmed HIV status	119.6 (41.9-412.2)

5.4.2.2 Sex workers

The risk of failure to detect an incident HIV infection among female sex workers in Australia was estimated to be 7.7 (0.9-31.1). As such, the risk is of a similar but still elevated magnitude compared with the risk associated with a heterosexual person who has recently obtained a new regular sexual partner. The difference in risk is not significant (as the lower 95% uncertainty bound is less than 1). Similarly, the relative risk of failure to detect a TTI from a donation from a client of a sex worker in Australia (1.7 (0.3-5.5)) is not significantly different to the reference case but incorporates a small elevated risk within the uncertainty bounds. However, if the potential donor had sex with a sex worker overseas then the relative risk would be substantially elevated, to an estimated level of 43.2 (8.0-212.4).

A separate scenario specifically for male sex workers was not included. Studies indicate a high proportion of male sex workers are MSM [52] therefore the deferral policy for MSM will apply to those individuals.

5.4.2.3 Heterosexual

The general heterosexual population has relatively little risk of donating with an undetectable TTI. However, if someone has a new regular sexual partner and the partner comes from a high HIV prevalence country then the risk of failure to detect an incident HIV infection is significantly increased, to an estimated level of 19.5 (9.0-39.8). If a potential donor has casual sex encounters with someone from a high HIV prevalence country while traveling overseas then the risk is comparable to someone in Australia who has a new regular sexual partner, albeit slightly elevated (2.3, (0.5-9.0)).

6 COMMITTEE REPORT TO THE AUSTRALIAN RED CROSS BLOOD SERVICE

6.1 Appropriateness of current sexual activity-based donor deferral criteria

6.1.1 Sexual activity

Sexual activities considered in this review included vaginal, anal, and oral sex. Although the risk of transmission of blood-borne viruses via oral sex is considered very low there is a lack of data available to support exclusion of this sexual activity and the committee could not rule out the possibility of transmission via oral sex (particularly HIV transmission).

The use of condoms can minimise but not eliminate the risk of sexually transmitted disease. Quantitative estimates of their efficacy vary between 35 and 95%.[58] An Australian study involving a survey of almost 20,000 Australians found that condom slippage or breakage had been experienced by 38.7% of male respondents in the year prior to interview and that condom failure is related to certain characteristics of individuals (e.g. younger age) and is not randomly distributed across all condom users.[59] Based on these findings, the committee found that recommendations for the current deferral policies should be made irrespective of condom use due to the variation in risk for individuals as well as variation in risk at the population level.

The current questionnaire and interview schedule employed by the Blood Service does not enable risk assessment based on individual sexual activities. The committee discussed at length various approaches to enable detailed risk assessment based on an individual's sexual history, however they were unable to determine any practical alternatives to current donor screening practices carried out by the Blood Service. The committee was also unclear about the potential impact an extensive donor assessment would have on the overall number of donors (i.e. recruitment of new donors or loss of existing donors), donor compliance with the questionnaire, or indeed the overall safety and sufficiency of the blood supply. In the absence of this information, the committee proceeded to discuss the appropriateness for ongoing deferral based on groups identified in the current donor questionnaire.

Given that most of the epidemiological and behavioural data available for TTIs is based on HIV, our analyses mainly focused on HIV risk within groups and other TTIs such as HAV, HBV, HCV, HTLV and syphilis were considered based on available evidence related to each group.

6.1.1.1 MSM

- MSM is associated with a significantly higher risk of failing to detect HIV infection in donors within the testing window period compared to heterosexuals with a new partner.
- MSM with lower risk of HIV infection (e.g. monogamous) remain at high risk for undetected infections in the testing window period due to the risk of acquiring infection from their partner. The risk of partners becoming infected from sexual encounters outside regular HIV

sero-concordant relationships is significantly greater for MSM partners compared to partners in a heterosexual relationship.

- Evidence supports ongoing deferral of MSM due to the increased risk of undetectable HIV infection during the testing window period.

6.1.1.2 Sex workers

- Evidence supports that Australian sex workers are at lower risk of acquiring or transmitting STIs compared to other casual heterosexual partnerships. However, the available evidence only applies to a subgroup of the sex worker population that is brothel-based female sex workers.
- There is a lack of information available for STIs in people who have received payment for sex (e.g. money, gifts or drugs) such as self-employed or street-based sex workers in Australia. The increased number of sexual partners in these sub-populations compared to the average heterosexual population places them at greater risk of exposure to TTIs and the committee was unable to rule out the possibility they posed a greater risk for failing to detect an infected donation during the window period.
- Evidence indicates there is significant overlap between male sex workers and MSM.[52] As a result, there is a much greater risk of failing to detect unknown positive HIV infections in male sex workers and their clients compared to female sex workers, their clients, or any heterosexual with a new partner.
- The committee found that removing deferral of all sex workers is not currently supported by the available evidence and would introduce an unacceptable risk to the blood supply.

6.1.1.3 Sex with someone from countries with high HIV prevalence

- There is an increased risk of failing to detect HIV infection in donors within the testing window period for heterosexuals with partners from countries with high HIV prevalence compared to heterosexuals with new partners from Australia.
- Individuals from countries with high HIV prevalence also have increased risk of HBV and HTLV.
- It is appropriate that deferral of individuals from countries with high HIV prevalence and their sexual partners is ongoing due to the increased risk of undetectable HIV and HBV in the testing window periods.

6.1.1.4 Sex with someone who has received clotting factors

- The committee considered the current risk of HIV transmission to people who have had sex in the past 12 months with someone who has ever received Factor VIII or Factor IX concentrates. Given the risk of HIV transmission through plasma-derived products has been significantly reduced compared to the 1980s and 1990s (last case of transmission in Australia was 1993), as well as the introduction of recombinant products to the Australian market in 1994, it seems feasible that people treated with plasma-derived products in Australia for the first time in the current era should have a much decreased HIV incidence compared to the

past and should share similar levels of HIV prevalence with the general population. If this is the case, it would follow that sexual partners of people receiving these products will no longer be at increased risk of acquiring HIV (compared to the average population risk).

- The committee suggests the Blood Service, in collaboration with CSL Biotherapies, explore whether a time threshold can be identified for individuals receiving clotting factors in Australia that would indicate the risk of being infected with blood-borne viruses is comparable to the average population. Where the evidence supports such a time threshold, the Blood Service should reconsider deferral of sexual partners of individuals treated with products since this time.
- The committee did not consider it appropriate to defer individuals who have had sex with someone in the past 12 months who have had treatment with clotting factors but have only ever received recombinant (not human-derived) Factor VIII or Factor IX. Acknowledging that some individuals may not have accurate information regarding the treatment they have received, the Blood Service may need to request a letter from the relevant treating practitioner to confirm that recombinant products have only ever been used by the individual.
- The committee found that deferral based on a partner's use of Factor VIII or Factor IX could be restructured to specify only those cases where individuals had received treatment with clotting factors prior to an agreed time threshold.

6.1.1.5 Sex with someone who has ever used drugs

- Given the epidemiological evidence reviewed by the committee for this report, a lifetime deferral of injecting drug users appears incompatible with available evidence. The committee suggests the Blood Service should undertake a separate review to determine the appropriateness of lifelong deferral of individuals who have ever injected drugs not prescribed by a doctor or dentist.
- Evidence supports the current deferral of individuals who have had sex with someone who injects drugs due to the increased risk of undetectable HIV, HBV or HCV in infected donors who donate within the window period.

6.1.2 Length of deferral periods

Table 10 provides data available for the testing window periods or incubation period of sexually transmissible TTIs and the minimum deferral periods used by the Blood Service.

Table 10. Minimal deferral periods for TTIs

Agent	Testing window period (WP)		Incubation period	Upper WP/Incubation period estimate (days)	Minimum deferral period with required safety margin (days)[a]
	NAT Mean days (range)	Serology Mean days (range)	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
***T. Pallidum* (syphilis)**		28[b][26]		28	56

[a]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. [b]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 NAT 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 estimate 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 current TGA-approved guidelines. It is suggested 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 months to six months will not impact the current safety of the blood supply as any unknown incident infections acquired through sexual risk 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, the committee found the duration of deferral could be

further reduced to 100 days based on 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 it being an unknown event with unknown variables 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.

6.2 Effective communication tools to improve compliance with behavioural donor criteria

6.2.1 Donor compliance

Donor compliance with deferral periods is an important factor impacting any change in risk to the blood supply. Blood donation data for 2005-2010 indicate almost a quarter of the donors who tested positive for TTIs were 'non-compliant' and would have been deferred from donating if they had provided full disclosure of risk factors at the pre-donation interview.[2]

No studies to date have assessed overall donor compliance with deferral criteria in Australia (i.e. level of compliance among all donors not just those who have subsequently tested positive for TTI). This lack of information made it difficult for the committee to determine any potential effects of donor compliance on the safety of the blood supply if the deferral criteria were changed.

Surveys of donor populations that have been conducted internationally have indicated up to 4% of donors surveyed are non-compliant with deferral criteria in their respective countries. A US study previously showed 1.2% of surveyed donors reported MSM since 1977.[61] Recent estimates from continental Europe suggest between 0.7-2.2% of male donors are MSM irrespective of permanent deferral policies in these countries [42] and in the UK, a recent survey estimated 4% of MSM had donated blood in the 12 months prior to the survey.[32] Potential reasons for non-compliance in these studies have included 'test-seeking' behavior. The term 'test-seeking' is used to describe individuals who are aware they are at risk of infection and rely on the Blood Service's routine screening of blood donations to confirm their status. In their study of US donors, Sanchez et al revealed 7-13% of individuals reporting MSM behavior since 1977 had sought testing for HIV or other infectious diseases through blood donation.[61]

Test-seeking behavior was identified as a potential compliance issue for the Blood Service. The occurrence of test-seeking behavior in Australian donors was suggested in the public submissions

however the committee was unable to determine whether this is actually occurring in practice. The Blood Service should be aware of test-seeking behavior as a potential compliance issue that could be addressed through education and communication strategies targeted to those at risk of acquiring TTIs in the wider community. Based on the best available information and expert advice, the committee formed the view that test-seeking behavior was less likely to be an issue in the Australian context compared to other countries due to the availability of low-cost tests for STIs outside the Blood Service.

6.2.2 Interventions to improve donor compliance

Recent studies in Europe and the US have aimed to improve donor compliance through evaluation and re-design of donor questionnaires. Based on input from experts in survey design, behavioural science, infectious diseases, and blood collection, studies have shown that direct questions about sexual activities that are worded in simple terms leads to improved understanding of donor questionnaires and greater self-deferral.[42, 62, 63] Protecting individuals' privacy through confidential self-administered computer-based questionnaires has also been shown to promote self-deferral and improve compliance with deferral criteria.[64, 65]

6.2.3 Education and communication about blood donation

The review of submissions received from the public highlighted to the committee the need for greater education in the community regarding screening tests used by the Blood Service to detect TTIs. Content from public submissions and qualitative data from non-compliant Australian blood donors [2, 27] indicates that some degree of non-compliance in the community is due to an incorrect belief that testing undertaken by the Blood Service is 100% effective and therefore deferral or disclosure of risk behavior is unnecessary. The committee identified it is particularly important that the public understand that screening tests are not infallible and there is a testing window period where recent infections will not be detected. This is consistent with data suggesting lack of understanding about window periods in other donor populations.[42] It should be made clear to the public that deferral periods aim to reduce the risk of failing to detect unknown recent infections in blood donors. The Blood Service also needs to ensure the public understand the duration of deferral periods is based on antibody/antigen testing window periods and NOT the shorter window periods associated with NAT testing. Community awareness regarding the increased sensitivity of NAT testing with reduced window periods has possibly led to some misunderstanding regarding the contribution of NAT testing to the broader context of risk management undertaken to protect the blood supply.

A number of the public submissions contained comments regarding the lack of blood donors in Australia and that changes to the deferral criteria could aid the shortage of donors and ensure a sufficient blood supply. Advertising campaigns conducted periodically by the Blood Service to request blood donations were identified as a possible reason for this perception within the community. Whilst current forecasts indicate a steady but small increase in the requirement of fresh blood components within the next few years, the Blood Service has a strong track record of consistently maintaining sufficient inventory of fresh blood components to meet patient needs. The committee was informed that the current donor pool is sufficient to meet current demand.

Occasional requests for donations by the Blood Service typically reflect a temporary shortage in a specific product (mainly platelets due to a short shelf life of approximately 5 days and occasionally O negative blood cells because it is the universal blood type) and are usually intended to prompt return donors as only about 3% of the eligible donor pool is donating at any given time. The current forecasts indicate a greater increase in the requirement for plasma donations for fractionation into plasma-derived products, such as intravenous immunoglobulin. Demand for intravenous immunoglobulin in Australia is currently met by both domestic production and importation. It is worth noting that ongoing importation of intravenous immunoglobulin is considered an important risk mitigation strategy to assure security of supply. It is suggested that any communication strategy involving requests for donations should carefully consider any potential misunderstanding that there is a permanent shortage of donors and reinforce to the public that safety will always underpin any changes to deferral criteria (i.e. sufficiency alone is not a driver for changes to deferral criteria). The Blood Service should clearly communicate to the community that sufficiency and safety of the blood supply relies on the ongoing support of donors who are compliant with the current deferral criteria.

Further to the above, the committee suggests the Blood Service engage with advocates who can provide evidence-based information targeted specifically to communities affected by the deferral criteria regarding blood donation testing window periods and the epidemiological risk of incident infections within these communities.

The committee regards the Blood Service as responsible for developing a communication strategy that effectively conveys their evidence-based approach to risk management and that public confidence in the safety of the blood supply is maintained in the event of any evidence-based changes to the current deferral criteria.

7 RECOMMENDATIONS TO THE BLOOD SERVICE

The committee conducted a careful and considered review of current scientific evidence relevant to the terms of reference outlined in section 2 of this report. Based on the findings, the committee has the following recommendations for sexual activity-related donor deferral policies as well as important research that could contribute to an evidence-based review of these deferral policies in the future.

7.1 Sexual activity-related donor deferral

The committee recommends the following for sexual activity-related donor deferral policies:

- The period for sexual activity-related deferrals could be reduced to six months based on the current sensitivity of tests used by the Blood Service to detect TTIs and an adequate safety margin that is compliant with TGA-approved guidelines. The committee recommends that the Blood Service considers the results of a compliance study (currently in progress) before implementing the recommendation to reduce the deferral period. The study should inform whether reducing the deferral period is likely to have any positive or negative impacts on compliance.
- Ongoing deferral of individuals based on the current sexual activity-related deferral policies of the Blood Service is appropriate. This recommendation is supported by findings in this review that indicate there would be an increased risk of failing to detect TTIs in blood donations if any of the current deferrals were removed. This would result in an unacceptable risk to donor recipients.
- Deferral of MSM, including those in monogamous relationships, should be ongoing. The main point of concern from the evidence-based risk assessment is the risk of acquiring HIV from a non-monogamous partner in an MSM relationship is significantly greater than the risk of acquiring HIV from a non-monogamous partner in a heterosexual relationship because the risk of transmission of HIV is greater in the MSM community. The significant difference in risk means that removing the deferral for MSM in monogamous relationships would introduce an unacceptable risk to the ongoing safety of the blood supply. However, the committee agreed the deferral period for MSM, including those in monogamous relationships, could safely be reduced to six months.
- Deferral of sex workers should be ongoing. Despite research indicating sex workers are at lower risk of acquiring STIs compared to other heterosexuals, there is still a paucity of evidence regarding the risk of infection in individuals that receive payment for sex who are not brothel-based sex workers. The committee found that removing deferral of all sex workers is not currently supported by the available evidence and would introduce an unacceptable risk to the blood supply. However, the committee agreed the deferral period for sex workers could safely be reduced to six months.
- Sexual partners of individuals who have only ever received recombinant clotting factors do not pose a risk to the blood supply. The Blood service should explore the feasibility of identifying this group as potential donors.

- The Blood service, in collaboration with CSL Biotherapies, should explore whether a reliable time threshold can be identified where the risk of being infected with blood-borne viruses via plasma-derived products in Australia has been comparable to the average population risk for TTIs. Where the evidence supports such a time threshold, the Blood Service should reconsider deferral of sexual partners of individuals treated with products since this time.
- The Blood Service should consider establishing an advisory panel 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 reasons for deferral and the importance of compliance.
- The Blood Service should provide evidence-based information that is specifically targeted at communities affected by deferral criteria. Tailored information regarding blood donation, the risk of TTIs related to sexual activity, and the relationship between testing window periods and donor deferral should be provided to each of these groups.
- A systematic review of interventions used to increase donor compliance is required in order to provide an evidence-based approach for implementing strategies to improve compliance with deferral criteria.
- Evidence-based review of deferral policies should be ongoing as more evidence becomes available. Changes to deferral policies should be made where it is supported by current scientific evidence.

7.2 Future research

Compliance with deferral criteria

To date, there have been no studies that assess overall donor compliance with sexual activity-based deferral criteria in Australia. The committee regards this as an important gap in the available evidence that should be highlighted to the Blood Service as an area of further research needed to inform any future review of deferral criteria. It is important to understand the degree of non-compliance in Australian donors (e.g. through anonymous donor surveys) and the reasons for non-compliance (e.g. through qualitative interviews). This information could be used to tailor future intervention strategies to improve compliance with deferral criteria and minimise the risk of collecting blood from donors with infections that may not be detected by testing.

The committee identified several primary studies describing interventions to improve donor compliance such as detailed individual donor assessment and computer-based questionnaires (see section 6.2.2). These studies provide examples of interventions rather than an exhaustive list of interventions that have been described and evaluated in the international literature. The committee suggests the Blood Service undertake a systematic review of the evidence for interventions to improve donor compliance to inform future decisions about interventions that could be used to improve compliance in Australian donors.

Safety margin for deferral periods

TGA-approved guidance adhered to by the Blood Service currently require that deferral periods include a safety margin that is based on doubling the length of the window period or incubation period. The current deferral period of 12 months for sexual activity-related deferrals seems arbitrary and is not consistent with current evidence regarding the length of window periods for TTIs. Even after applying a safety margin that doubles the length of window periods, this results in minimum deferral periods that are all less than 12 months (see Table 10 in section 6.1.2). The committee was unable to find evidence to support or refute the doubling of window periods to provide an adequate safety margin when deciding the length of deferral periods and suggest the Blood Service conduct further research to determine an appropriate length of time for a safety margin that is supported by evidence.

Sexual transmission of HCV

The committee discussed the uncertainty regarding whether HCV is sexually transmitted. A recent study of HCV incidence in a Melbourne cohort of HIV infected MSM identified a significant proportion of MSM who were not injecting drug users that contracted HCV, possibly via sexual transmission.[19] Based on available evidence and expert opinion, the committee could not rule out the possibility of sexually-transmitted HCV infection, particularly for MSM. This may change as more evidence becomes available in future. The recommended deferral period could be further reduced to 100 days (based on the symptomatic window period of HAV being 50 days) if sexual activity is ruled out as a risk factor for HCV transmission. This is an area requiring further research. A comprehensive systematic review of the evidence for HCV transmission is recommended to inform whether HCV should be considered for sexual activity-based donor deferral. If the review findings are inconclusive, the Blood Service should endeavour to support primary research that will determine whether HCV is sexually transmissible.

HIV transmission and condom use

A number of large international prospective cohort studies investigating HIV transmission are currently in process. The PARTNER study aims to prospectively follow up thousands of sero-discordant couples in order to quantify risks between different transmission routes and different patterns of condom use. Results of this study are expected in 2014 (http://partnerstudy.eu/). The RV217 study aims to prospectively study acute HIV infection in high risk populations. The study will focus on acute infection acquisition in a cohort of 2000 individuals at high risk of HIV infection in Uganda, Tanzania, Kenya, and Thailand (http://www.mmrp.org/index.php/projects/cohort-studies/rv217.html). It is anticipated these studies will make important contributions to understanding HIV transmission and risk behavior and will further inform future evaluations of donor deferral policies.

Pathogen reduction technologies

Pathogen reduction technologies (PRT) used by CSL Biotherapies are currently limited to the treatment of plasma products. Pathogen reduction for fresh components such as plasma and platelets is available internationally and a cost/benefit evaluation of this technology has recently been undertaken by the Health Policy Advisory Committee on Technology (HealthPACT).

Development of PRT for the treatment of red blood cells is an ongoing area of research that is being closely monitored by the Blood Service. Evaluations of these new technologies will need to be undertaken to assess the potential benefits for TTI risk reduction as well as the potential costs of implementing these systems.

Plasma supply

Plasma requirements over the next few years are anticipated to increase more rapidly (largely driven by increasing use of intravenous immunoglobulin). Whilst the promotion of national self sufficiency is a secondary policy aim for Australian States and Territories, a primary policy for the Australian blood sector is to provide an adequate, safe, secure and affordable supply of blood products (National Blood Agreement; http://www.nba.gov.au/policy/agreement.html). Some plasma products are imported to supplement locally produced products as part of a risk minimisation strategy to assure security of supply.

The committee considered the possibility of allowing individuals that are currently deferred based on sexual activity to provide plasma donations only. In the event there is increased demand for plasma-derived products, the Blood Service may wish to consider the opportunity to increase the donor pool by allowing individuals that are currently deferred to donate plasma only. This would require further investigation in collaboration with CSL Biotherapies and would need to consider the potential risk of TTIs in donated plasma and the risk of transmitting infection to recipients based on their use of different plasma-derived products.

7.3 Ethical implications

The Blood Service currently defers groups at higher risk of acquiring TTIs through sexual activity. It is accepted that within the diversity of these populations there are individuals whose risk of exposure to TTIs are comparable to those who are not deferred from donating. In terms of practical equality, all donors are required to be treated the same unless there is a relevant material difference which can be reliably and practically determined. This review supports that groups of individuals that share similar risks of exposure and greater risk of infection pose a relevant material risk and are relevantly different in scientifically defensible terms.

The risk of infected donations largely depends on the timing of donations following risk exposure and this is the same for all groups regardless of different sexual activities. The current review indicates the risk of failing to detect an infection in the window period is equivalent for all groups after six months deferral compared to longer deferral periods as the timeframe is dependent on the sensitivity of available tests to detect TTIs in those at risk. Any differences in length of deferral periods for different groups is not supported by the evidence and a morally acceptable approach is to apply the same length of deferral for all groups identified as being at risk of infection.

Blood donation is not considered a human right and the deferral of groups on the basis of infectious risk does not represent any direct threat to an individual's privacy or freedom of sexual choice. In the context of blood donation, deferral policies represent the execution of a duty of care on the part of a blood service. For these reasons, a policy of deferral based on infectious risk is not considered to constitute discrimination if the reasons for deferral are scientifically defensible.

7.4 Legal implications

The evidence underpinning the deferral policies was carefully considered by the committee in order to ensure the Blood Service achieves a safe blood supply without inappropriate deferral of groups in the community. It has been argued the Blood Service policy of deferring groups such as MSM or sex workers acts to marginalise these groups and adds to the history of stigmatisation experienced by these groups in the community. Whilst the impact of deferral may be significant for those affected, it remains that blood donation is not a right and deferral from donation does not deprive any individual of any right that is essential to their identity. The Blood Service has a legal obligation to protect the safety of recipients. The review findings confirm that deferral of groups is supported by evidence of risk of exposure to TTIs and that removing the current deferrals would introduce an unacceptable risk to donor recipients.

8 CONCLUDING COMMENTS

Protecting the blood supply from both proven and potentially transfusion-transmissible infectious agents is a complex process which must balance the community's expectation of 'zero risk' against finite and competing financial resources.

The feedback provided in this report is based on evidence available in 2011 and will need to be reconsidered as further evidence becomes available in the future.

Since the 1980s there have been incremental improvements in the sensitivity of tests to detect TTIs in blood donations. Although these advances have greatly reduced the risk of not detecting a recently infected donor, they are still not 100% effective due to the existence of testing 'window periods' when infections in early stages are undetectable by the tests.

While there is a need to increase blood donations to meet an expanding demand and the decision to defer donors is not taken lightly, the safety of the blood supply is paramount. The Australian community demands, and is entitled to, the safest possible blood supply

Whilst considering the impact of deferral on the affected communities and anti-discrimination laws, the committee sought to systematically assess the available evidence and consult with experts to determine the appropriate duration of ongoing deferrals. The committee's findings indicate that a deferral period of six months could be applied to the current sexual activity-related criteria without introducing an unacceptable risk to the blood supply.

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APPENDIX A: Organisations approached for public submissions

Liberty Australia

Liberty Victoria

Office of the Public Guardian (TAS)

Public Trustee (ACT)

NSW Trustee & Guardian (NSW)

Office of the Public Advocate (VIC)

The Public Trustee (QLD)

Office of the Public Advocate (WA)

Office of the Public Advocate (SA)

Public Health Laboratory Network

DonateLife Network

Royal College of Pathologists of Australasia

Australasian Society for Infectious Diseases

HSANZ (Haematology Society of Australia and New Zealand)

Thalassaemia society

Hepatitis Australia

Australian and New Zealand Society of Blood Transfusion (ANZSBT)

Sexual Health and Family Planning Australia

The National Association of People Living with AIDS

The National Alliance on Gay and Lesbian Health

Gay and Lesbian Health Victoria

Australian Coalition for Equality

Australian Research Centre in Sex, Health & Society

Australian Haemophilia Centre Directors' Organisation

APPENDIX B: Countries reviewed for blood donor policies related to sexual activity

Australia

Iceland

Israel

Japan

Korea

New Zealand

Norway

Switzerland

Turkey

Member states of the European Union

Austria

Belgium

Czech Republic

Denmark

Finland

France

Germany

Greece

Hungary

Ireland

Italy

Netherlands

Poland

Portugal

Slovak Republic

Slovenia

Spain

Sweden

United Kingdom

Member states of the Pan American Health Organisation

Canada

Chile

Mexico

United States

APPENDIX C: Search strategies

MEDLINE (OvidSP) Search date: 27/09/10

#1	exp Sexuality/	123511
#2	(sex$ adj3 (behav$ or activit$ or intercours$ or safe$ or unsafe or contact$ or orientation$ or partner$ or promiscu$)).mp.	101913
#3	((oral or anal or anus) adj3 (sex$ or intercours$)).mp.	3638
#4	('men who have sex with men' or 'male to male sex' or MSM).mp.	3642
#5	sexual$.mp.	216935
#6	(multiple adj3 partner$).mp.	2335
#7	(monogam$ or polygam$).mp.	2014
#8	exp Condoms/	11786
#9	condom$.mp.	14785
#10	((sex adj5 work$) or prostitut$).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer]	8561
#11	(homosexual$ or heterosexual$ or bisexual$ or gay$ or lesbian$ or transgender$ or GLBT or LGBT).mp.	33076
#12	1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11	267360
#13	exp Sexually Transmitted Disease/	61625
#14	exp sexual transmission/	4488
#15	exp bloodborne bacterium/	1256
#16	exp human immunodeficiency virus infection/	246951
#17	exp human immunodeficiency virus prevalence/	4748
#18	exp virus hepatitis/	112719
#19	exp Human T cell leukemia virus/	9740
#20	exp Syphilis/	19244
#21	(sexual$ adj3 (infecti$ or disease$ or transmi$)).mp.	54038
#22	(STD$ or STI$ or HIV or AIDS or venereal).mp.	1895339
#23	'human immunodeficiency virus'.mp.	247271
#24	(HCV or HBV or hepatitis).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer]	209767
#25	((htlv or lymphotropic) adj3 infectio$).mp.	3162
#26	syphili$.mp.	26056
#27	13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26	2197501
#28	exp Blood Transfusion/	94235
#29	exp Blood Donor/	20066

#30	exp Blood Bank/	6726
#31	Donor Selection/	1576
#32	((blood or platelet$ or plasma) adj3 (bank$ or service$ or suppl$ or provi$ or transfus$ or don$ or safe$)).mp.	163180
#33	28 or 29 or 30 or 31 or 32	176897
#34	12 and 27 and 33	3024
#35	limit 34 to (human and english language and yr="1980 -Current")	2323

EMBASE (OvidSP) Search date: 27/09/10

#1	exp Sexuality/	123511
#2	(sex$ adj3 (behav$ or activit$ or intercours$ or safe$ or unsafe or contact$ or orientation$ or partner$ or promiscu$)).mp.	101913
#3	((oral or anal or anus) adj3 (sex$ or intercours$)).mp.	3638
#4	('men who have sex with men' or 'male to male sex' or MSM).mp.	3642
#5	sexual$.mp.	216935
#6	(multiple adj3 partner$).mp.	2335
#7	(monogam$ or polygam$).mp.	2014
#8	exp Condoms/	11786
#9	condom$.mp.	14785
#10	((sex adj5 work$) or prostitut$).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer]	8561
#11	(homosexual$ or heterosexual$ or bisexual$ or gay$ or lesbian$ or transgender$ or GLBT or LGBT).mp.	33076
#12	1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11	267360
#13	exp Sexually Transmitted Disease/	61625
#14	exp sexual transmission/	4488
#15	exp bloodborne bacterium/	1256
#16	exp human immunodeficiency virus infection/	246951
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#18	exp virus hepatitis/	112719
#19	exp Human T cell leukemia virus/	9740
#20	exp Syphilis/	19244
#21	(sexual$ adj3 (infecti$ or disease$ or transmi$)).mp.	54038
#22	(STD$ or STI$ or HIV or AIDS or venereal).mp.	1895339
#23	'human immunodeficiency virus'.mp.	247271
#24	(HCV or HBV or hepatitis).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer]	209767
#25	((htlv or lymphotropic) adj3 infectio$).mp.	3162
#26	syphili$.mp.	26056
#27	13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26	2197501
#28	exp Blood Transfusion/	94235
#29	exp Blood Donor/	20066
#30	exp Blood Bank/	6726
#31	Donor Selection/	1576
#32	((blood or platelet$ or plasma) adj3 (bank$ or service$ or suppl$ or provi$ or transfus$ or	163180

	don$ or safe$)).mp.	
#33	28 or 29 or 30 or 31 or 32	176897
#34	12 and 27 and 33	3024
#35	limit 34 to (human and english language and yr="1980 -Current")	2323

The Cochrane Library **(Wiley) Search date: 27/09/10**

#1	MeSH descriptor Sexual Partners explode all trees	231
#2	MeSH descriptor Sexual Behavior explode all trees	1737
#3	MeSH descriptor Reproductive Behavior explode all trees	98
#4	(sex* NEAR/3 (behav* or activ* or intercours* or contact* or safe* or unsafe or orientation* or partner* or promiscu*)):ti,ab,kw	2686
#5	((oral* or anal* or anus) NEAR/3 (sex* or intercours*)):ti,ab,kw	838
#6	"men who have sex with men" or "male to male sex" or MSM:ti,ab,kw	137
#7	sexual*:ti,ab,kw	5020
#8	multiple NEAR/3 partner*:ti,ab,kw	55
#9	monogam* or polygam*:ti,ab,kw	40
#10	MeSH descriptor Condoms explode all trees	349
#11	condom*:ti,ab,kw	781
#12	sex* NEAR/5 work*:ti,ab,kw	204
#13	prostitut*:ab,ti,kw	99
#14	homosexual* or heterosexual* or bisexual* or gay* or lesbian* or transgender* or GLBT or LGBT:ti,ab,kw	1492
#15	(#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14)	7356
#16	MeSH descriptor Sexually Transmitted Diseases explode all trees	7309
#17	MeSH descriptor Blood-Borne Pathogens explode all trees	35
#18	MeSH descriptor HIV Infections explode all trees	6194
#19	MeSH descriptor Hepatitis, Viral, Human explode all trees	3422
#20	MeSH descriptor HTLV-I Infections explode all trees	16
#21	MeSH descriptor HTLV-II Infections explode all trees	2
#22	MeSH descriptor Syphilis explode all trees	95
#23	(sexual* NEAR/5 (infect* or disease*)):ti,ab,kw	1022
#24	(STD* or STI* or HIV or AIDS or venereal):ti,ab,kw	60614
#25	"human immunodeficiency virus":ti,ab,kw	2350
#26	(HCV or HBV or hepatitis):ti,ab,kw	8782
#27	((htlv or lymphotropic) NEAR/3 infect*):ti,ab,kw	12
#28	syphili$:ti,ab,kw	0
#29	(#16 OR #17 OR #18 OR #19 OR #20 OR #21 OR #22 OR #23 OR #24 OR #25 OR #26 OR #27 OR #28)	70099
#30	MeSH descriptor Blood Transfusion explode all trees	2867
#31	MeSH descriptor Blood Donors explode all trees	271
#32	MeSH descriptor Blood Banks explode all trees	61

#33	MeSH descriptor Donor Selection explode all trees	8
#34	((blood or platelet* or plasma) NEAR/3 (bank* or service* or suppl* or provi* or transfus* or don* or safe*)):ti,ab,kw	13402
#35	(#30 OR #31 OR #32 OR #33 OR #34)	13704
#36	(#15 AND #29 AND #35)	56

Transfusion-transmissible infections in Australia

2012
Surveillance Report

Australian Red Cross BLOOD SERVICE

Kirby Institute

UNSW AUSTRALIA

This publication is available online at: http://www.kirby.unsw.edu.au
and http://www.transfusion.com.au

Recommended citation:
Transfusion-transmissible infections in Australia: 2012 Surveillance Report. The Kirby Institute, The University of New South Wales and Australian Red Cross Blood Service

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Published 2012

ISBN 978-0-7334-3188-3

Transfusion-transmissible infections in Australia

2012 Surveillance Report

edited by

Tarana Lucky and Clive Seed

The Kirby Institute

in collaboration with

Australian Red Cross Blood Service

Acknowledgements

The report was prepared by the following investigators of the University of New South Wales[1] and the Australian Red Cross Blood Service[2].

Edited by	Tarana Lucky[1], Clive Seed[2]
Chief investigators	David Wilson[1], Sue Ismay[2]
Associate investigators	Ann McDonald[1], June Lee[2], Anthony Keller[2], Claire Styles[2], Handan Wand[1], Hung-Sing Yang[2] and Joanne Pink[2]

The following Australian Red Cross Blood Service staff are acknowledged for their contribution to this report and ongoing surveillance activities:

- Donor Services and Manufacturing staff involved in donor assessment or blood donation testing for transfusion-transmissible infections
- Medical Services staff medical officers undertaking donor counselling and risk factor assessment
- Anthea Cheng, Susan Parker and the Blood Service Infectious Disease and Nucleic Acid Testing (NAT) functional teams
- Medical Services Lookback committee
- Performance and Analysis team
- Members of the Donor and Product Safety Policy Unit

Australian governments fully fund the Australian Red Cross Blood Service for the provision of blood products and services to the Australian community.

Foreword

This report is produced jointly by the Australian Red Cross Blood Service and the Surveillance and Evaluation Program for Public Health at the Kirby Institute. This is the second report that summarises available surveillance data and trends for transfusion-transmissible infections among Australian blood donors. While the report focuses on data collected during the 2011 calendar year, it also assesses for trends against the previously published data for 2005-2010 contained in the inaugural transfusion-transmissible infections surveillance report '*Safe blood – a focus on education, epidemiology and testing*.' Data on malaria testing and surveillance activity for emerging infections are also included in the 2012 report.

Consistent with previous years, the overall number of infections remained low in 2011 with the vast majority (90%) identified in first time donors. Reassuringly, the overall rate of infections has decreased gradually over the past five years. Infected first time donors in 2011 mostly had undiagnosed prevalent infections but we continued to identify a small number of recently acquired (incident) infections among repeat donors. Notably, in 2011 there was an increase in the number of incident HBV infections. While the increase was specific to Queensland and Western Australia and no obvious epidemiological link was established, four of the five infected donors were HBsAg negative/HBV DNA positive highlighting the blood safety contribution of HBV DNA testing implemented by the Blood Service in July 2010. Incident infections are the most concerning from a blood safety perspective as, in contrast to prevalent infections they are more likely to be in the so called testing 'window period' making them undetectable by donation testing. For this reason the pre-donation questionnaire remains a critical safety procedure and its effectiveness is directly dependent on the accuracy (termed 'compliance') of the donor's answers.

Optimal compliance is therefore a blood safety imperative and it is encouraging that the non-compliance rate among TTI positive donors has been gradually declining since 2008 (24.4%), and the rate of 12.9% recorded in 2011 is the lowest recorded to date. The importance of monitoring and understanding non-compliance was highlighted in May 2012 when the Blood Service was presented with the final report from the '*Review of Australian Blood Donor Deferrals relating to sexual activity*'. This comprehensive report recommended that the Blood Service consider reducing the length of the period since last contact for sexual activity-based deferrals from 12 to 6 months. Importantly, this recommendation was dependent on supporting evidence that non-compliance would not increase as a result of the policy change. Accordingly, the Blood Service has commenced targeted research with the aim of estimating the current rate of non-compliance among donors testing negative for transfusion-transmissible infections and gauging opinion among donors and prospective donors on future policy change with respect to donor deferral.

Contents

Summary of the main findings

General characteristics of blood donors in Australia

1. Over the period 2005-2011, there were more than 8.6 million blood donations in Australia with an average of 1.2 million donations per year. The numbers of blood donations have been increasing since 2005.
2. About 3.4% of the Australian population aged between 16-80 years donated blood during 2011.
3. First time and repeat donors comprised 17% and 83% of all blood donors in Australia over the period 2005-2011, respectively. As in previous years, this ratio remained relatively stable nationally and across all states and territories. Male donors constitute approximately 49% of all donors.

Trends in transfusion-transmissible infections in Australian blood donors

1. A total of 217 blood donors were detected as having at least one transfusion-transmissible infection (HBV, HCV, HIV, HTLV or syphilis) in 2011; more than 91% of these donors were infected with either HBV or HCV. This gives a total count of 1 700 TTI-positive donors in 2005-2011. In 2011, no donors had more than one transfusion-transmissible infection.
2. HTLV was the least common infection among both first time and repeat donors in 2011. Overall in 2005-2011, HIV and HTLV were the least common infections among first time and repeat donors, respectively.
3. Although only representing 17% of the donor population, first time blood donors contributed 90% of all donors with transfusion-transmissible infections in Australia during 2005-2011, highlighting the importance of promoting education of potential new donors.
4. No transfusion-transmitted HIV, HCV, HTLV or syphilis infections were reported during 2008-2011. Three probable cases of transfusion-transmitted HBV infection were reported in the 2008-2011 period, two in 2009 associated with the same donor and one further case in 2011.

HBV infection among Australian blood donors

1. The prevalence of HBV among first time donors decreased by 15.5% from 85.4 per 100 000 donations in 2010 to 72.2 per 100 000 donations in 2011. However, of all transfusion-transmissible infections, HBV continued to have the highest prevalence among first time donors since 2007.
2. HBV incidence increased during 2010-2011 and this directly correlated with the implementation of HBV NAT in July 2010. Highlighting this, four of the seven seroconverters in the 2010-2011 period were HBsAg negative but had detectable HBV DNA and thus would not have been identified by HBsAg screening alone.
3. The most common infective risk factor for donors with HBV infection during 2008-2011 was ethnicity/country of birth (82%) which is consistent with the findings of a previous Blood Service study for the period 2000-2006.
4. In 2011, HBV positive donors were slightly younger (mean age 38 years versus 40 years for all donors), more likely to be male (67% versus 49% male donor proportion) and only 13% were born in Australia. These characteristics remain fairly similar compared with previous years.

HCV infection among Australian blood donors

1. The prevalence of HCV infection among first time donors has been gradually declining over the past seven years.
2. After HBV, HCV was the most common infection found in first time blood donors.
3. HCV had the highest incidence rate among previously negative repeat donors during 2006 to 2011.
4. The most common infective risk factor for donors with HCV infection during 2008-2011 was intravenous drug use (25%) which was also the predominant route (60%) of exposure in cases of newly acquired HCV infection in the general population in 2011.
5. In 2011, the mean age of donors with HCV infection was 42 years. Like HBV, male donors were over-represented (68% versus 49% male donors overall) but in contrast to HBV, the majority (63%) were born in Australia. The key attributes of HCV-positive donors in 2011 remained similar to HCV-positive donors in the previous three years.

HIV infection among Australian blood donors

1. The prevalence of HIV infection among first time donors during 2005-2011 remained very low (2 per 100 000 donations) in comparison to HBV (83.9 per 100 000 donations) and HCV (73.9 per 100 000 donations).
2. After HCV, HIV had the highest incidence rate among previously negative repeat donors during 2006-2010. However, in 2011, HBV incidence exceeded HIV incidence among previously negative blood donors. Although remaining very low compared to the general population, the incidence rate of HIV in donors steadily, but not significantly increased between 2005-2009 then subsequently declined in 2010-2011. Overall, the donor HIV incidence rate was relatively stable in 2005-2011. Diagnoses of newly acquired HIV infection in Australia were also relatively stable in 2005-2010 but increased by more than 20% in 2011.
3. The two most common routes of exposure for donors with HIV infection during 2008-2011 were partners with known risk or known to be positive (37%) followed by male-to-male sexual contact (30%)[1]. This is consistent with the general population where men who have sex with men accounted for 67%, and men and women with a history of heterosexual contact, either in Australia or overseas, accounted for 25% of new HIV diagnoses in Australia in 2008-2011.
4. As in 2008-2010, HIV positive donors in 2011 were generally younger (36 years versus 40 years for all donors) and male (71% versus 49% male donors overall). However, unlike previous years, most donors (71%) were born in a country other than Australia.

HTLV infection among Australian blood donors

1. The prevalence of HTLV among first time donors has remained very low over the past seven years.
2. No donor seroconverted for HTLV in 2011. There was only one incident case of HTLV among previously negative repeat donors during 2005-2011.
3. The most common infective risk factor for donors with HTLV infection during 2008-2011 was ethnicity or country of birth (65%).
4. In 2011, the mean age of donors with HTLV infection was 38 years. Among the HTLV positive donors in 2011, 33% were male and all of them were born overseas.

Active syphilis infection among Australian blood donors

1. The prevalence of active syphilis among blood donors has remained low (overall prevalence of 0.37 per 100 000 donations) in 2005-2011.
2. However, the rate among first time donors has gradually increased over the past five years, paralleling the trend for increased diagnoses in the general population.

Malaria testing

1. In 2011, 116 610 donations were tested for malaria antibody of which 2 411 (2.1%) were found to be repeat reactive. None of these antibody repeat reactive donors had evidence of current infection since all were negative for both plasmodial antigen and DNA by supplementary testing. This is consistent with past infection.
2. There were no reported cases of transfusion transmitted malaria during 2011, with the last Australian case occurring in 1991.

1 Includes declaration form compliant and non-compliant donors (see section *Non-compliance among positive donors*, page 22).

Emerging infections

1. During the period January – March 2011, four dengue fever outbreaks totalling 55 reported cases were declared in Queensland: one outbreak each in Townsville and Cairns, and two in Innisfail. To mitigate the transmission risk, donors visiting or residing in these areas were restricted to donating plasma for fractionation only. Restrictions were lifted 28 days after the last case onset date.
2. In 2011 the Blood Service monitored the risk associated with West Nile virus (WNV) outbreaks in the European Union (EU) and surrounding countries during the European transmission season (July to November 2011). The risk of a donor returning and donating while viraemic was monitored on a weekly basis but unlike in 2010 did not exceed the threshold requiring additional donor selection measures.
3. A variant WNV strain ($WNV_{NSW2011}$) closely related to the prototype Australian WNV strain (Kunjin virus or WNV_{KUN}) caused a large equine outbreak. While there were no associated human cases reported, the proximity to major urban centres and increased virulence compared to the prototype WNV_{KUN} strain warranted a close watching brief.
4. In 2011 the first presumed case of locally acquired human babesiosis in Australia was reported. There are potential blood safety implications as transfusion transmitted babesiosis is well documented in North America and Europe. The Blood Service has already initiated targeted research to assess the threat level.

Key messages

1. Supporting the effectiveness of donor education and selection, the prevalence of transfusion-transmissible infections is substantially lower among both first time blood donors (12 to 39 times) and all donors (99 to 225 times) than in the general population in 2011 and shows a stable or declining trend since 2005.
2. The prevalence of transfusion-transmissible infections among first time donors was much higher than their prevalence among all donors, highlighting the importance of promoting donor education of potential new donors and ensuring first-time donors read the pre-donation information and understand the importance of self deferral.
3. The incidence of newly acquired infection measured by the rate of seroconversion in repeat blood donors is also much lower than in the general population. This supports the general effectiveness of the donor questionnaire and specifically that repeat donors understand what constitutes 'risk behaviour' for acquiring infection.
4. Infective risk factors identified in blood donors with transfusion-transmissible infections closely parallel those for the general population with no 'unique' risk factors identified to date among blood donors.
5. Almost one-fifth of the positive donors in 2008-2011 were 'non-compliant' in that they had risk factors identified during their post-donation interview that would have deferred them from donating had they disclosed them at the pre-donation interview. Reassuringly, the rate of non-compliance among TTI positive donors has been gradually declining since 2008 and notably in 2011 was the lowest recorded to date (12.9%). Understanding the reasons for, and minimising the rate of non-compliance is important because it reduces the risk of collecting blood from a potentially infected donor whose infection may not be detected by testing.
6. The estimated residual risk of transmission for HIV, HCV, HBV HTLV and syphilis in Australia is very low, less than one in one million per unit transfused for all. The residual risk of transmission of HBV is higher (approx 1 in 764 000). This supports the claim that Australia's blood supply is among the safest worldwide in respect of transfusion-transmissible infections for which testing is conducted. Despite this, there remains a minimal but real risk of transfusion-transmissible infections which must be carefully considered before any transfusion.
7. In addition to established transfusion-transmissible infections, emerging infectious diseases continue to demand vigilant surveillance. Mosquito-borne agents such as dengue virus and West Nile virus are currently the principal threats but many other novel or emerging infectious diseases are constantly monitored by the Blood Service to assess their threat to the safety of the blood supply.

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Glossary

Active syphilis

Defined by reactivity on treponemal and non-treponemal syphilis testing and/or clinically apparent infection (i.e. excluding past treated infections).

First time donor

A donor who has not previously donated in Australia.

Intravenous drug user

Defined as ever "used drugs" by injection or been injected, even once, with drugs not prescribed by a doctor or a dentist.

Incidence

The rate of newly acquired infection among repeat donors.

Infective risk factor

A potential route of infection in positive donors reported at the post-donation interview.

Non-compliance

Disclosure of information post donation that would have led to deferral from donation had it been disclosed at the pre-donation interview.

Prevalence

The frequency of infection in the first time donor population.

Positive donor

A donor confirmed (by additional testing) to have the relevant transfusion-transmissible infection.

Repeat donor

A donor who has donated in Australia on at least one occasion prior to the current donation.

Seroconverter

A positive repeat donor whose last donation tested negative for the same transfusion-transmissible infection.

Transfusion-transmissible infection

A virus, parasite, or other bloodborne infectious agent in donated blood that can be transmitted by transfusion to a recipient.

Transfusion-transmitted infection

Any infection that has been transmitted to a recipient through a transfusion.

Window period

The duration of the period from infection to the point of first detection in the bloodstream.
The window period differs dependent on the infection and the test used.

Abbreviations

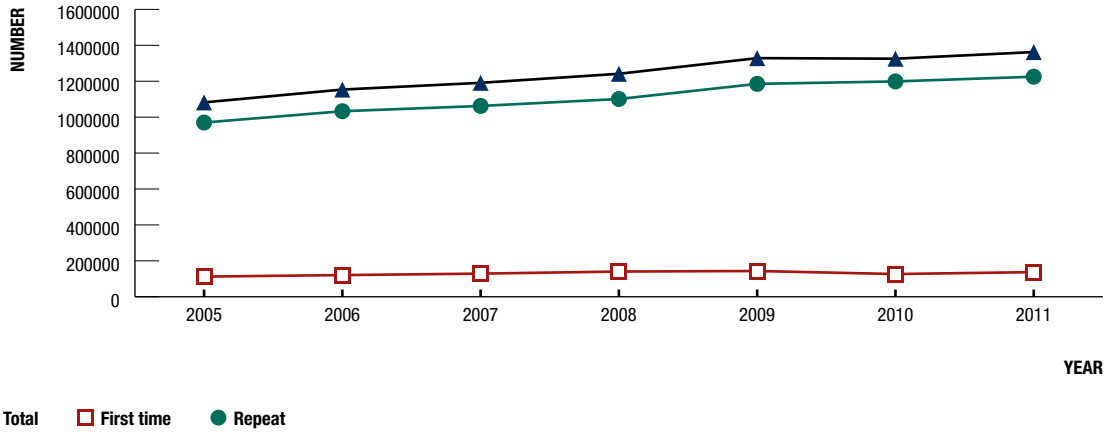
anti-HBc	antibody to hepatitis B core antigen
anti-HBe	antibody to hepatitis B e antigen
anti-HBs	antibody to hepatitis B surface antigen
anti-HeV	antibody to Hendra virus
HBsAg	hepatitis B surface antigen
Blood Service	Australian Red Cross Blood Service
CFS	chronic fatigue syndrome
HBeAg	hepatitis B e antigen
HBsAg	hepatitis B surface antigen
HBV	hepatitis B virus
HCV	hepatitis C virus
HeV	Hendra virus
HIV	human immunodeficiency virus
HTLV	human T-cell lymphotropic virus
IDU	intravenous drug user
NAT	nucleic acid testing
STIs	sexually transmissible infections
TTVI	transfusion-transmissible viral infections
TTIs	transfusion-transmissible infections
WNV	West Nile virus
WP	window period
XMRV	xenotropic murine leukaemia virus-related virus

Main findings

Blood donors in Australia

More than 8.6 million donations were tested for transfusion-transmissible infections in Australia during 2005-2011 with an average of about 1.2 million donations per year. Overall, the number of blood donations increased by more than 25% over the past seven years (Figure 1). During 2005-2010, about 3.6% of the general population who were aged between 16-80 years donated blood in Australia. This ratio remained fairly similar in 2011 (3.4%). As in previous years, more than 85% of all donations in 2011 were from repeat donors and 90% of all positive donations were made by first time donors.

Figure 1 **Number of blood donations in Australia by year of donation, 2005-2011**

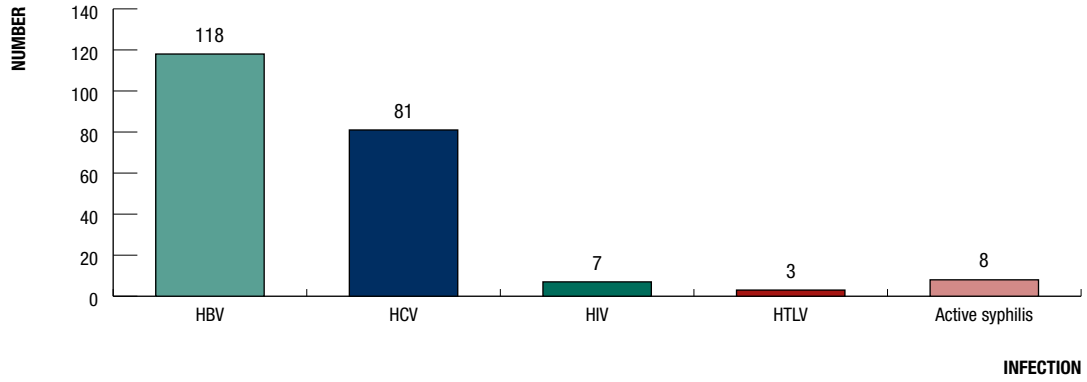


Among all blood donors who donated in 2011, 51% were female, 30% were younger than 30 years and 32% were from New South Wales. Median ages of both male and female donors in 2011 ranged between 40 and 49 years. Together New South Wales, Queensland and Victoria accounted for more than 75% of all blood donations in Australia in 2011.

Trends in incidence and prevalence of transfusion-transmissible infections

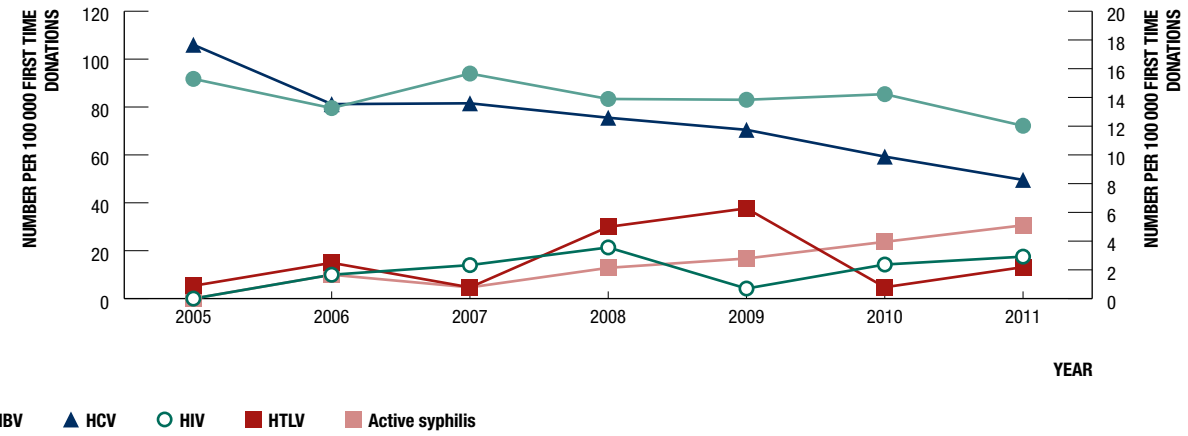
In 2011, a total of 217 (15.8 per 100 000 donations) were found positive for at least one of the transfusion-transmissible infections – HBV, HCV, HIV, HTLV and active syphilis. In 2011, no donors had more than one transfusion-transmissible infection. Overall, HCV and HBV were the two most common infections identified in Australian blood donors in 2011, together contributing more than 91% of all infections (Figure 2). HBV and HCV were the most common infections in first time and repeat donors, respectively. In general, the presence of any transfusion-transmissible infection among Australian blood donations has remained low during 2005-2011 and has decreased gradually over the past four years, from 22.3 per 100 000 donations in 2008 to 15.8 per 100 000 donations in 2011.

Figure 2 **Number of blood donors with transfusion-transmissible infections in Australia, 2011, by infection**



Among all donors during 2005-2011, the prevalence of HCV infection has been declining significantly[2] with an overall 50% reduction from 2005 to 2011; however, prevalence of active syphilis infection increased significantly. Both HIV and HTLV prevalence showed a slight, non-significant overall increase and HBV prevalence remained relatively stable.

Figure 3 **Prevalence of transfusion-transmissible infections in first time blood donors in Australia, 2005- 2011, by infection[1] and year of donation**



1 Prevalence of HIV, HTLV and active syphilis are provided according to the scale on the secondary axis on the right hand side.

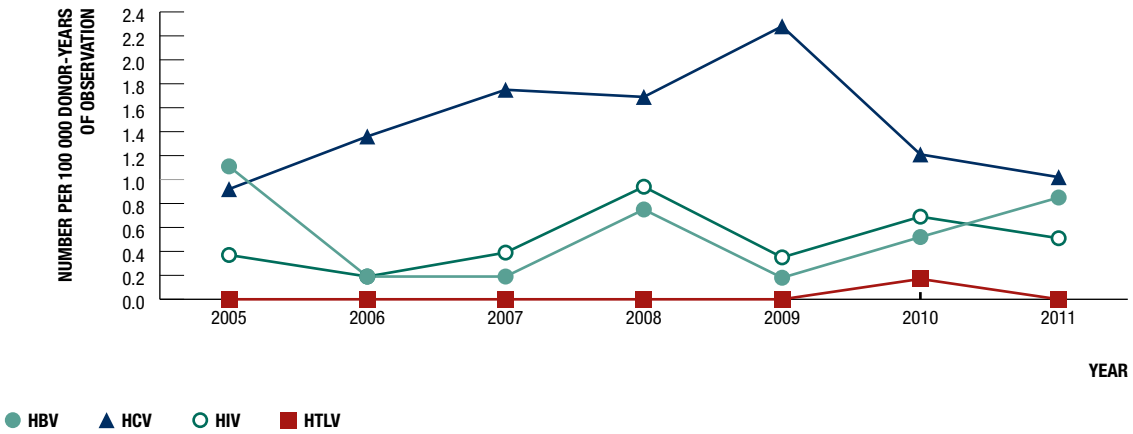
The prevalence of HBV in first time donors has substantially declined from 85.4 per 100 000 donations in 2010 to 72.2 per 100 000 donations in 2011 after remaining steady at around 80 per 100 000 donations since 2008 (Figure 3). During 2005-2011, there has been a significant decrease in HCV prevalence in first time donors in Australia. This trend is also apparent in the per capita rate of diagnosis of HCV infection reported through the National Notifiable Disease Surveillance System[3] which declined in the period 2006-2011.

In contrast with HBV and HCV, the prevalence of HIV, HTLV and active syphilis in first time donors remained very low over the last seven years. Apart from an increase in 2008, HIV prevalence has been stable over the 2005-2011 period. During 2005-2011, HTLV prevalence demonstrated a slight, non-significant increased trend in first time donors in Australia. The prevalence of active syphilis in first time donors significantly increased during 2005-2011 (Figure 3). The annual number of diagnoses of infectious syphilis reported through the National Notifiable Diseases Surveillance System peaked at 1 418 in 2007 and has remained above 1 000 in 2008–2011.

2 Throughout the document the term 'significant' is used only where a statistical test has a p value <0.05

3 The Kirby Institute. *HIV, viral hepatitis and sexually transmissible infections in Australia Annual Surveillance Report 2012*. The Kirby Institute, the University of New South Wales, 2012.

Figure 4 **Incidence of transfusion-transmissible infection in repeat blood donors in Australia, 2005-2011, by infection and year of donation**



HBV was the most frequent infection in repeat donors in Australia in 2011(Table 1). The incidence of HCV among repeat donors continued to reduce further after it sharply declined from 2.3 per 100 000 donor-years of observation in 2009 to 1.2 per 100 000 donor-years of observation in 2010 (Figure 4). However, although not significant, there was an overall increase in both HCV (by 10%) and HIV (by 38%) incidence in repeat blood donors over the past seven years. There has been a substantial increase in diagnoses of newly acquired HIV infection in the general population in 2011. Nonetheless, diagnoses of newly acquired HCV infection in the general population remained fairly stable or declined over the past decade[4]. The HTLV incidence among repeat Australian donors in 2011 was zero. During 2005-2011, HTLV incidence remained very low with only one incident case identified in 2010.

Trends in HBV infection by state/territory

In 2011, the prevalence of HBV among first time donors differed markedly across Australia. While the national prevalence was 72.2 per 100 000 donations this ranged from 27.88 to 388.6 per 100 000 donations (Table 1). From 2010 to 2011, the prevalence of HBV has reduced in all states/territories except Northern Territory and Western Australia. In New South Wales/Australian Capital Territory, HBV prevalence among first time donors gradually declined during the past four years from 92.6 per 100 000 donations in 2008 to 75.7 per 100 000 donations in 2011. In Victoria, the prevalence of HBV in first time donors varied during 2005-2011. Overall, Queensland had a lower HBV prevalence than both New South Wales/Australian Capital Territory and Victoria and the rate remained relatively stable across the study period. In Western Australia, HBV prevalence in first time donors has been decreasing steadily since 2009.

There was no obvious trend in blood donor HBV incidence in any state/territory except in Queensland and Western Australia, both jurisdictions showing a recent increasing trend. An investigation of the five seroconverterting donors identified in 2011 failed to find any obvious epidemiological link. Notably, the index donations from four of the five donors were HBV DNA positive but HBsAg negative, highlighting the value of implementing HBV NAT during 2010. Among donors in New South Wales/Australian Capital Territory, HBV incidence remained zero since 2008 following a steady decline from 2005 to 2007.

Trends in HCV infection by state/territory

In New South Wales/Australian Capital Territory, the prevalence of HCV in first time donors has steadily decreased from 102.9 per 100 000 donations in 2008 to 58.2 per 100 000 donations in 2011. In both Victoria and Queensland, HCV prevalence in first time donors remained fairly stable over the last three years following a gradual decline over the period of 2005-2009. From 2010 to 2011, the rates have decreased in all jurisdictions except in Queensland and Western Australia.

In contrast to the declining prevalence across most jurisdictions HCV incidence in repeat donors varied during the past seven years. There was a gradual decline in New South Wales/Australian Capital Territory from 1.8 per 100 000 donor-years of observation in 2008 to 1 per 100 000 donor-years of observation in 2011. In contrast to the previous years, the rate in Queensland was lower and reduced gradually from 4.6 per 100 000 donor-years of observation in

4 The Kirby Institute. *op.cit.*

2008 to 0.9 per 100 000 donor-years of observation in 2011. The rate in Victoria continued to decline since 2009 and the rate in South Australia, Tasmania and Western Australia remained unchanged during the past two years.

Trends in HIV infection by state/territory

The prevalence of HIV infection in first time donors remained very low in comparison with HBV and HCV in 2005-2011, with the national average prevalence being 2 per 100 000 donations. In 2011, the prevalence of HIV in first time donors remained zero in all jurisdictions except in New South Wales/Australian Capital Territory, Queensland and Western Australia. In 2010-2011, HIV prevalence was stable around 2 and 7 per 100 000 first time donations in New South Wales/Australian Capital Territory and Queensland, respectively. There was a gradual decline in HIV prevalence in first time donors in Victoria since 2007 but no obvious trends in other jurisdictions.

Nationally there was a 38% increase in HIV incidence since 2005 but no clear jurisdictional trends were observed over the period of 2005-2011. The rate in Queensland declined gradually by 50% from 1.8 per 100 000 donor-years of observation in 2009 to 0.9 per 100 000 donor-years of observation in 2011 following an increase during 2006-2010. The rate in Victoria stayed relatively unchanged in the past two years at around 0.7 per 100 000 donor-years of observation.

Trends in HTLV infection by state/territory

In 2011, only three donors were found to be HTLV-positive and all were first time donors. HTLV prevalence remained zero in all jurisdictions in 2011 except in New South Wales/Australian Capital Territory, South Australia and Western Australia. HTLV incidence remained very low with only one incident case reported during 2005-2011.

Trends in active syphilis infection by state/territory

The rate of active syphilis infection remained very low in blood donors across Australia over the seven year period. In both Queensland and Victoria, the prevalence of active syphilis infection in first time blood donors decreased in 2011 following a substantial increase from 2008-2010. Overall, the prevalence of active syphilis infection has increased progressively in the past five years with a national prevalence of 5.1 per 100 000 donations in 2011. This trend may be in part explained by an increase in diagnoses of infectious syphilis in the general population from 2004[5,6].

5 The Kirby Institute. *op.cit.*

6 National Centre in HIV Epidemiology and Clinical Research. *HIV, viral hepatitis and sexually transmissible infections in Australia Annual Surveillance Report 2010*. National Centre in HIV Epidemiology and Clinical Research, The University of New South Wales, Sydney, NSW, 2010.

Table 1 The number and rate of transfusion-transmissible infections in Australia by type of donation and state/territory, 2011

	All accepted donations			HBV			HCV			HIV			HTLV			Syphilis			Total positive donations		
State/Territory of donation	First time	Repeat	All	First time	Repeat	All	First time	Repeat	All	First time	Repeat	All	First time	Repeat	All	First time	Repeat	All	First time	Repeat	All
NSW/ACT	**51 528**	**390 455**	**441 983**	**42**	**5**	**47**	**30**	**3**	**33**	**1**	**0**	**1**	**1**	**0**	**1**	**0**	**1**	**1**	**74**	**9**	**83**
Number (Number per 100 000 donations)				*81.51*	*1.28*	*10.63*	*58.22*	*0.77*	*7.47*	*1.94*	*0.00*	*0.23*	*1.94*	*0.00*	*0.23*	*0.00*	*1.94*	*0.23*	*143.61*	*2.31*	*18.78*
NT	**772**	**10 782**	**11 554**	**3**	**0**	**3**	**0**	**1**	**1**	**0**	**1**	**1**	**0**	**0**	**0**	**2**	**0**	**2**	**5**	**2**	**7**
Number (Number per 100 000 donations)				*388.60*	*0.00*	*25.97*	*0.00*	*9.27*	*8.66*	*0.00*	*9.27*	*8.66*	*0.00*	*0.00*	*0.00*	*259.07*	*0.00*	*17.31*	*647.67*	*18.55*	*60.59*
QLD	**28 839**	**245 975**	**274 814**	**13**	**3**	**16**	**13**	**3**	**16**	**2**	**1**	**3**	**0**	**0**	**0**	**1**	**0**	**1**	**29**	**7**	**36**
Number (Number per 100 000 donations)				*45.08*	*1.22*	*5.82*	*45.08*	*1.22*	*5.82*	*6.94*	*0.41*	*1.09*	*0.00*	*0.00*	*0.00*	*3.47*	*0.00*	*0.36*	*100.56*	*2.85*	*13.10*
SA	**10 164**	**124 199**	**134 363**	**3**	**2**	**5**	**4**	**1**	**5**	**0**	**0**	**0**	**1**	**0**	**1**	**1**	**0**	**1**	**9**	**3**	**12**
Number (Number per 100 000 donations)				*29.52*	*1.61*	*3.72*	*39.35*	*0.81*	*3.72*	*0.00*	*0.00*	*0.00*	*9.84*	*0.00*	*0.74*	*9.84*	*0.00*	*0.74*	*88.55*	*2.42*	*8.93*
TAS	**3 587**	**44 661**	**48 248**	**1**	**0**	**1**	**1**	**0**	**1**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**2**	**0**	**2**
Number (Number per 100 000 donations)				*27.88*	*0.00*	*2.07*	*27.88*	*0.00*	*2.07*	*0.00*	*0.00*	*0.00*	*0.00*	*0.00*	*0.00*	*0.00*	*0.00*	*0.00*	*55.76*	*0.00*	*4.15*
VIC	**31 286**	**288 085**	**319 371**	**27**	**4**	**31**	**12**	**2**	**14**	**0**	**1**	**1**	**0**	**0**	**0**	**1**	**0**	**1**	**40**	**7**	**47**
Number (Number per 100 000 donations)				*86.30*	*1.39*	*9.71*	*38.36*	*0.69*	*4.38*	*0.00*	*0.35*	*0.31*	*0.00*	*0.00*	*0.00*	*3.20*	*0.00*	*0.31*	*127.85*	*2.43*	*14.72*
WA	**10 992**	**121 057**	**132 049**	**10**	**5**	**15**	**8**	**3**	**11**	**1**	**0**	**1**	**1**	**0**	**1**	**2**	**0**	**2**	**22**	**8**	**30**
Number (Number per 100 000 donations)				*90.98*	*4.13*	*11.36*	*72.78*	*2.48*	*8.33*	*9.10*	*0.00*	*0.76*	*9.10*	*0.00*	*0.76*	*18.20*	*0.00*	*1.51*	*200.15*	*6.61*	*22.72*
National	**137 168**	**1 225 214**	**1 362 382**	**99**	**19**	**118**	**68**	**13**	**81**	**4**	**3**	**7**	**3**	**0**	**3**	**7**	**1**	**8**	**181**	**36**	**217**
Number (Number per 100 000 donations)				*72.17*	*1.55*	*8.66*	*49.57*	*1.06*	*5.95*	*2.92*	*0.24*	*0.51*	*2.19*	*0.00*	*0.22*	*5.10*	*0.73*	*0.59*	*131.95*	*2.94*	*15.93*

Comparison of prevalence of transfusion-transmissible infections among blood donors and the general population

Consistent with a previous Blood Service study for the period 2000-2006[7], a marked reduction is evident in the prevalence of HBV, HCV and HIV in blood donors compared with the general population (Table 2). Prevalence of these infections are substantially lower in blood donors than in the general population, with a 12 to 39-fold reduction in first time donors and 99 to 225-fold reduction among all donors in 2011. As in 2005-2010, the greatest comparative reduction among first time donors (39-fold lower) was observed for HIV infection. Given blood donors are drawn from the general population the prevalence reduction observed in first time donors is interpreted to reflect the combined effectiveness of donor education and donor selection policies.

Table 2 Comparison of prevalence of transfusion-transmissible infections in blood donors with population prevalence by infection, 2005-2011

Infection	Population prevalence (per 100 000 people)		Prevalence in all blood donors (per 100 000 donations)		Prevalence in first time blood donors (per 100 000 donations)		Overall prevalence reduction in all blood donors		Prevalence reduction in first time blood donors	
	2005-2010	2011	2005-2010	2011	2005-2010	2011	2005-2010	2011	2005-2010	2011
HBV	500-800	856-1 121	9.66	8.66	86.02	72.17	52-83 times	99-129 times	6-10 times	12-16 times
HCV	1 400	1 074-1 748	9.53	5.95	78.24	49.57	147 times	181-294 times	18 times	22-35 times
HIV	96	115	0.41	0.51	1.81	2.92	240 times	225 times	53 times	39 times
HTLV[1]	–	–	0.31	0.22	2.85	2.19	–	–	–	–

1 Population prevalence for HTLV is unknown.

Demographic factors associated with transfusion-transmissible infections in blood donors

Contrasting the prevalence/incidence data which covers 2006-2011, the risk factor analysis is restricted to 2008 to 2011 where standardised national risk factor data is available. Data on the demographic characteristics (sex, age group, state/territory and year of donation) for all blood donors in 2011 was analysed[8] to determine the association between demographic factors and presence of transfusion-transmissible infections among Australian blood donors (Table 3). Male donors, donors aged less than 20 years and donors from New South Wales were used as reference groups for comparison of positivity rate by sex, age group and state/territory of donation, respectively.

HBV positivity and associated demographic risk factors

Overall, there were no significant trends in 2008-2011 for HBV positivity among Australian donors by different age group, sex or state/territory of the donor. However, as in 2008-2010, female donors were approximately half as likely to have acquired HBV infection and donors from Queensland and South Australia were significantly less likely to be HBV positive compared with those from New South Wales. There was no significant association with age group and HBV infection among Australian blood donors in 2011.

HCV positivity and associated demographic risk factors

Overall, there were no significant trends in 2008-2011 for HCV positivity among Australian donors by different age group, sex or state/territory of the donor. However, like HBV, female donors were significantly less likely to be HCV positive. Donors aged between 40-49 years were about 4 times more likely to be HCV positive compared with those younger than 20 years. There was no association with state/territory of the donor and HCV infection among Australian blood donors in 2011.

HIV and HTLV positivity and associated demographic risk factors

Given the small number of donors with HIV and HTLV infection no meaningful analysis was possible.

7 Polizzotto MN, Wood EM, Ingham H, Keller AJ. Reducing the risk of transfusion-transmissible viral infection through blood donor selection: the Australian experience 2000 through 2006. *Transfusion*. 2008;48(1):55-63. Epub 2007/09/27.

8 See methodological notes for details

Table 3 Association of demographic characteristics with presence of transfusion-transmissible infection among blood donors in Australia by infection, 2011

		HBV		HCV		HIV		HTLV	
	Number of donors	Number of positive donors (Number per 100 000 donors)	IRR[1] and their 95% CI[2] (Multivariate adjusted)	Number of positive donors (Number per 100 000 donors)	IRR and their 95% CI (Multivariate adjusted)	Number of positive donors (Number per 100 000 donors)	IRR and their 95% CI (Multivariate adjusted)	Number of positive donors (Number per 100 000 donors)	IRR and their 95% CI (Multivariate adjusted)
Sex									
Male	*288 683*	*79 (27.37)*	*1 (ref)*	*55 (19.05)*	*1 (ref)*	*5 (1.73)*	*1 (ref)*	*1 (0.35)*	*1 (ref)*
Female	*304 368*	*39 (12.81)*	*0.53 (0.36-0.77)*	*26 (8.54)*	*0.48 (0.30-0.77)*	*2 (0.66)*	*0.46 (0.09-2.39)*	*2 (0.66)*	*2.22 (0.20-24.67)*
Age group (years)									
Less than 20	*54 814*	*13 (23.72)*	*1 (ref)*	*3 (5.47)*	*1 (ref)*	*0 (0)*	*1 (ref)*	*0 (0)*	
20-29	*125 666*	*29 (23.08)*	*0.98 (0.51-1.88)*	*15 (11.94)*	*2.21 (0.64-7.64)*	*4 (3.18)*	–	*1 (0.8)*	–
30-39	*92 303*	*25 (27.08)*	*1.21 (0.62-2.36)*	*13 (14.08)*	*2.75 (0.78-9.68)*	*0 (0)*	–	*0 (0)*	–
40-49	*106 214*	*22 (20.71)*	*0.94 (0.47-1.86)*	*23 (21.65)*	*4.25 (1.27-14.19)*	*2 (1.88)*	–	*2 (1.88)*	–
50 and above	*214 054*	*29 (13.55)*	*0.62 (0.32-1.20)*	*27 (12.61)*	*2.51 (0.76-8.30)*	*1 (0.47)*	–	*0 (0)*	–
State/Territory									
NSW	*188 495*	*47 (24.93)*	*1 (ref)*	*30 (15.92)*	*1 (ref)*	*1 (0.53)*	*1 (ref)*	*1 (0.53)*	
ACT	*15 175*	*0 (0)*	–	*1 (6.59)*	*0.4 (0.05-2.91)*	*0 (0)*	–	*0 (0)*	–
NT	*4 621*	*3 (64.92)*	*2.58 (0.80-8.30)*	*1 (21.64)*	*1.26 (0.17-9.27)*	*1 (21.644)*	*37.09 (2.32-593.21)*	*0 (0)*	–
QLD	*119 967*	*16 (13.34)*	*0.54 (0.31-0.96)*	*16 (13.34)*	*0.81 (0.44-1.49)*	*3 (2.5)*	*4.6 (0.48-44.19)*	*0 (0)*	–
SA	*56 105*	*5 (8.91)*	*0.37 (0.15-0.93)*	*5 (8.91)*	*0.53 (0.21-1.37)*	*0 (0)*	–	*1 (1.78)*	*3.44 (0.21-55.19)*
TAS	*17 692*	*1 (5.65)*	*0.23 (0.03-1.67)*	*1 (5.65)*	*0.33 (0.05-2.45)*	*0 (0)*	–	*0 (0)*	–
VIC	*139 051*	*31 (22.29)*	*0.91 (0.57-1.42)*	*16 (11.51)*	*0.7 (0.38-1.28)*	*1 (0.72)*	*1.27 (0.08-20.24)*	*0 (0)*	–
WA	*51 945*	*15 (28.88)*	*1.19 (0.66-2.13)*	*11 (21.181)*	*1.29 (0.64-2.57)*	*1 (1.93)*	*3.46 (0.22-55.40)*	*1 (1.93)*	*3.43 (0.21-54.86)*
Total	**593 051**	**118 (19.9)**		**81 (13.7)**		**7 (1.2)**		**3 (0.5)**	

1 IRR = Incident Rate Ratio

2 CI = Confidence Intervals

Risk factors associated with infected donors

In 2011, 217 donors were confirmed positive for at least one of the transfusion-transmissible infections with a total of 992 confirmed positive donors over the period of 2008-2011. Among them, 29 donors were positive for active syphilis. As risk factor data was not available for donors with active syphilis, the data on the remaining 963 donors who were positive for any of the other transfusion-transmissible infections (HBV, HCV, HIV and HTLV) were analysed to determine the key attributes of blood donors with transfusion-transmissible infections, stratified by year of donation (Table 4-7).

Donors with HBV infection, 2008-2011

Of 493 HBV positive donors during 2008-2011, 89% were first time donors, 65% were male, with a mean age of 35 years (Table 4). Most of the HBV positive donors were born overseas which reflects the epidemiology of HBV in the general population. There were only eleven blood donors who seroconverted for HBV during the last four years, consistent with a low incidence rate. Ethnicity or country of birth (82%) was the most frequent risk factor for HBV positivity, followed by having a sexual partner with known risk or known to be positive for any transfusion-transmissible infection (3%).

Table 4 Attributes of donors positive for HBV infection by year of donation, 2008-2011

Characteristics	2008	2009	2010	2011	2008-2011
Number of positive donors	124	124	127	118	493
Number of positive first time donors (%)	116 (93%)	118 (95%)	108 (84%)	99 (83%)	441 (89%)
% male	78 (63%)	79 (63%)	84 (66%)	79 (67%)	320 (65%)
Mean age (range) in years	32 (16 to 63)	34 (16 to 69)	37 (16 to 71)	38 (16 to 77)	35 (16 to 77)
Number of seroconverters	2	1	2	5	11
% born in Australia	18 (15%)	16 (13%)	17 (13%)	15 (13%)	66 (13%)
Main reported risk factor	Ethnicity/COB[1]	Ethnicity/COB	Ethnicity/COB	Ethnicity/COB	Ethnicity/COB
	87%	77%	83%	85%	82%
Second reported risk factor	Partner with known risk or known to be positive	Household contact	Partner with known risk or known to be positive	TBP[2],PRP[3] each	Partner with known risk or known to be positive
	2%	6%	4%	3%	3%

1 COB=Country of birth

2 TBP= Tattoo/ Body piercing

3 PRP= Partner with known risk/known to be positive

Donors with HCV infection, 2008-2011

Of 423 donors positive for HCV in 2008-2011, 73% were first time donors (Table 5). The mean age of HCV positive donors was 43 years which remained fairly steady over the last four years. Male donors represented more than 60% of all donors with HCV infection but unlike HBV where birth overseas predominated, the majority (68%) of HCV positive donors were born in Australia. The number of HCV seroconverters (31 donors) was the highest among all transfusion-transmissible infections. Overall, the most important risk factor for HCV positivity was intravenous drug use (25%) followed by tattoo or body piercing (20%).

Table 5 Attributes of donors positive for HCV infection by year of donation, 2008-2011

Characteristics	2008	2009	2010	2011	2008-2011
Number of positive donors	134	122	86	81	423
Number of positive first time donors (%)	98 (73%)	83 (68%)	67 (79%)	59 (73%)	306 (73%)
% male	80 (59%)	72 (59%)	53 (62%)	55 (68%)	260 (61%)
Mean age (range) in years	42 (17 to 65)	44 (17 to 71)	42 (16 to 63)	42 (16 to 78)	43 (16 to 78)
Number of seroconverters	4	11	10	6	31
% born in Australia	85 (63%)	90 (74%)	61 (71%)	51 (63%)	287 (68%)
Main reported risk factor	Intravenous drug use	Intravenous drug use	Tattoo/Body piercing	Intravenous drug use	Intravenous drug use
	25%	35%	21%	21%	25%
Second reported risk factor	Tattoo/Body piercing	Tattoo/Body piercing	Intravenous drug use	Tattoo/Body piercing	Tattoo/Body piercing
	22%	18%	19%	20%	20%

Donors with HIV infection, 2008-2011

In contrast to the donors with HBV or HCV infection, the majority of donors with HIV infection during 2008-2011 were repeat donors (59%) (Table 6). Most were male (74%) of younger age (mean age 36 years) and Australian born (63%). In respect of country of birth, 2011 was notable as the proportion born in Australia (29%) was markedly lower that the average for 2008-2011 (63%). Overall though, the pattern in donors is very similar to new HIV diagnoses in the general population. According to the recent population data, people born in Australia accounted for 58% of cases of HIV infection newly diagnosed in 2006-2011, most of the newly diagnosed HIV cases were male (86.2%) in 2008-2011 with a mean age of 37 years[9]. Of 16 HIV positive repeat donors, 12 donors seroconverted for HIV during the last four years. Having a sexual partner with known risk or known to be positive for any transfusion-transmissible infection (37%) and male-to-male sexual contact (30%) were the two most important risk factors for HIV positivity in blood donors during 2008-2011.

Table 6 Attributes of donors positive for HIV infection by year of donation, 2008-2011

Characteristics	2008	2009	2010	2011	2008-2011
Number of positive donors	10	3	7	7	27
Number of positive first time donors (%)	5 (50%)	1 (33%)	1 (14%)	4 (57%)	11 (41%)
% male	8 (80%)	2 (67%)	5 (71%)	5 (71%)	20 (74%)
Mean age (range) in years	35 (19 to 53)	38 (26 to 50)	37 (23 to 57)	36 (22 to 62)	36 (18 to 57)
Number of seroconverters	3	2	4	3	12
% born in Australia	7 (70%)	2 (67%)	6 (86%)	2 (29%)	17 (63%)
Main reported risk factor	Male-to-male sexual contact	Male-to-male sexual contact	Partner with known risk or known to be positive	Partner with known risk or known to be positive	Partner with known risk or known to be positive
	60%	33%	57%	57%	37%
Second reported risk factor	Partner with known risk or known to be positive	Partner with known risk or known to be positive	Male-to-male sexual contact	Male-to-male sexual contact	Male-to-male sexual contact
	33%	33%	14%	14%	30%

9 The Kirby Institute. *op. cit.*

Donors with HTLV infection, 2008-2011

Only 21 donors were positive for HTLV infection during the 2008-2011 period, 95% were first time donors and 62% were male, with a mean age of 38 years (Table 10). Most of the HTLV positive donors (86%) were born overseas. There was only one donor who seroconverted for HTLV in 2010. Ethnicity or country of birth (65%) was the most important risk factor for HTLV infection in accepted blood donors in Australia.

Table 7 Attributes of donors positive for HTLV infection by year of donation, 2008-2011

Characteristics	2008	2009	2010	2011	2008-2011
Number of positive donors	7	9	2	3	21
Number of positive first time donors (%)	7 (100%)	8 (89%)	1 (50%)	3 (100%)	19 (95%)
% male	4 (57%)	6 (67%)	1 (50%)	1 (33%)	12 (62%)
Mean age (range) in years	35 (27 to 49)	38 (18 to 65)	70 (70)	38 (23 to 46)	38 (18 to 70)
Number of seroconverters	0	0	1	0	1
% born in Australia	0 (0%)	3 (33%)	0 (0%)	0 (0%)	3 (14%)
Main reported risk factor	Ethnicity/COB	Ethnicity/COB	Ethnicity/COB	Ethnicity/COB	Ethnicity/COB
	86%	44%	50%	66%	65%
Second reported risk factor	Partner with known risk or known to be positive	BTR[1],HHC[2],HCE[3] each	–	Tattoo/Body piercing	BTR,HHC,HCE,PRP[4] each
	10%	11%		33%	5%

1 BTR= Blood/tissue recipient

2 HHC=Household contact

3 HCE=Exposure in healthcare setting

4 PRP= Partner with known risk/known to be positive

Comparison of major exposure categories between blood donor and the general population

A comparison of major exposure categories between blood donors and the general population was conducted to determine if any unique source of infection exists for Australian donors (Table 8).

Consistent with previous years, the most frequent risk factor for HBV positive donors was ethnicity or country of birth which accounted for 85% of the HBV positive donors in 2011. This finding also parallels the population data that shows that country of birth is the strongest risk factor for chronic HBV infection in Australia[10,11,12]. However, intravenous drug use (31%) was reported to be the most common route of infection for newly acquired HBV infection in the general population in 2011.

The most frequent risk factor for HCV infection in blood donors in 2011 was intravenous drug use followed by tattoo or body piercing. These were also the two most important risk factors for HCV in general population in 2011, both for new HCV diagnoses and for newly acquired HCV infection. Nonetheless, the proportion of individuals reporting intravenous drug use among newly acquired HCV infections in the general population[13] (60%) was comparatively higher than in the donor population (21%) reflecting the impact of the Blood Services' permanent deferral for intravenous drug use.

10 Nguyen VTT, Razali K, Amin J, Law MG, Dore GJ. Estimates and projections of hepatitis B-related hepatocellular carcinoma in Australia among people born in Asia-Pacific countries. *Journal of Gastroenterology and Hepatology*. 2008;23(6):922-9.

11 O'Sullivan BG, Gidding HF, Law M, Kaldor JM, Gilbert GL, Dore GJ. Estimates of chronic hepatitis B virus infection in Australia, 2000. *Australian and New Zealand Journal of Public Health*. 2004;28(3):212-6.

12 Williams S, Vally H, Fielding J, Cowie B. Hepatitis B prevention in Victoria, Australia – the potential to protect. *Euro Surveillance*. 2011;16(22):pii: 19 879.

13 The Kirby Institute. *op. cit.*

Sexual contact that included male-to-male sexual contact, partners with known risk and engagement in sex work, together contributed 71.4% of the risk for HIV positive donors and 79% of newly diagnosed HIV infection in Australia. In 2011, approximately 73.7% of all newly diagnosed HIV infections in the general population were attributed to male-to-male sexual contact compared with 30% of HIV-positive donors, demonstrating the effectiveness of the current donor deferral criteria. Having a sexual partner with known risk or known to be positive for any transfusion-transmissible infection accounted for 57% of all HIV positive donors in 2011.

Table 8 Comparison between positive blood donors and general population in Australia by infection and major risk categories, 2011

	HBV[1]		HCV[1]		HIV[2]		HTLV	
Major risk category	**General population (%)**	**Blood donors (%)**	**General population (%)**	**Blood donors (%)**	**General population (%)**	**Blood donors (%)**	**General population (%)**	**Blood donors (%)**
Intravenous drug use	31.0	0.0	60.0	21.0	1.9	0.0	–	0.0
Country of birth/Ethnicity	–	84.8	–	13.6	8.9	0.0	–	66.7
Sexual contact[3]	19.0	2.5	3.5	2.5	88.1	71.4	–	0.0
Blood or tissue recipient	0.8	0.0	0.0	11.1	0.2	0.0	–	0.0
Tattoo or body piercing	11.1	2.5	3.5	19.8	0	0.0	–	33.3
Exposure in health care setting	4.0	0.9	1.0	4.9	0	0.0	–	0.0
Household contact	2.4	0.0	0.5	8.6	0	0.0	–	0.0
Other blood to blood contact	–	0.0	–	6.2	0	14.3	–	0.0
Other/undetermined	31.7	8.5	31.5	9.9	0.9	14.3	–	0.0
No risk factors identified	**–**	**0.9**	**–**	**2.5**	**–**	**0**	**–**	**0.0**
Not reported	**–**	**0.0**	**–**	**0.0**	**–**	**0**	**–**	**0.0**

1 Includes exposure categories for newly acquired HBV and newly acquired HCV infections only

2 Includes exposure categories for new HIV diagnoses

3 Includes three sub-groups: Male-to-male sexual contact, Partner with known risk or known to be positive and Engaged in sex work

Due to the scarcity of reliable data on prevalence of key risk factors for HTLV in the Australian population, no meaningful comparison was possible. However, HTLV is highly endemic in certain geographic regions including Japan, the Caribbean and central Africa and to a lesser extent in Iran, Iraq, southern India and China[14]. This is consistent with our finding that ethnicity or country of birth was the infective risk in the majority (66.7%) of HTLV positive donors in 2011.

Non-compliance among positive donors

About one-fifth of the positive donors in 2008-2011 had risk factors identified during their post-donation interview that would have deferred them from donating had they disclosed their risk behaviour at the pre-donation interview (Table 9). This is termed 'non-compliance' with donor selection guidelines and the Blood Service remains highly committed to minimise it by developing improved methods of ascertaining donor risk behaviour. A donor who does not appropriately report risk behaviour for a transfusion-transmissible infection poses a potential risk to the safety of the blood supply for two reasons. Firstly, if a donor with a history of risk behaviour for a transfusion-transmissible infection donates blood within the window period, there is a very small but real possibility that infection is not detected by testing and the blood is included in the blood supply. Secondly, even where successfully detected there is an extremely remote risk of erroneously issuing this positive unit (i.e. a process failure). The Blood Service takes measures including the use of computerised release systems to minimise this risk. These are both avoidable risks if a positive donor appropriately discloses their risk (i.e. complies - leading to deferral) since no donation will not be collected.

14 Verdonck K, González E, Van Dooren S, Vandamme A-M, Vanham G, Gotuzzo E. Human T-lymphotropic virus 1: recent knowledge about an ancient infection. *The Lancet Infectious Diseases*. 2007;7(4):266-81

Table 9 **Non-compliance rate among donors who were positive for HBV, HCV, HIV and HTLV, and reason for non-compliance, 2008–2011**

Non-compliance by year and reason for deferral	2008	2009	2010	2011	2008-2011
Number (%) of non-compliant donors by reasons for deferral					
Intravenous drug user	37 (55.2)	47 (77)	30 (66.7)	15 (55.6)	129 (64.5)
Known status : previous positive	18 (26.9)	10 (16.4)	8 (17.8)	8 (29.6)	44 (22)
Male-to-male-sexual contact	6 (9)	1 (1.6)	2 (4.4)	0 (0)	9 (4.5)
Partner with known risk or known to be positive	4 (6)	3 (4.9)	1 (2.2)	3 (11.1)	11 (5.5)
Others	2 (3)	0 (0)	4 (8.9)	1 (3.7)	7 (3.5)
Total number (per 100 positive donors) of non-compliant donors by year	**67 (24.4)**	**61 (23.6)**	**45 (20.4)**	**27 (12.9)**	**200**

The rate of non-compliance in positive donors appears to have been stable for the past decade but there is some evidence of a declining trend since 2008. The rate observed in the previous Blood Service study[15] for 2000-2006 was 22%. The number of donors and rates for 2008, 2009, 2010 and 2011 are 67 (24.4%), 61 (23.6%), 45 (20.4%) and 27 (12.9%) respectively, indicating a gradual decline in recent years. Particularly pleasing is the rate in 2011, which is the lowest recorded. However, future annual data will be required to confirm this as a trend. The majority of non-compliant positive donors in 2011 had a history of intravenous drug use (55.5%), which is a permanent donor deferral criterion in Australia irrespective of time since last episode of intravenous drug use. Overall, during the period of 2008-2011, 64.5% of non-compliance was attributed to intravenous drug use followed by known status of previously being positive for a virus (22%), having a sexual partner with known risk or known to be positive for any transfusion-transmissible infection (5.5%) and male-to-male sexual contact within the last 12 months (4.5%).

While the rate of non-compliance among donors with transfusion-transmissible infections is known, the rate in non-positive donors has yet to be measured in the Australian donor population. This rate is arguably even more important as recently infected, window period donors (who would test negative) pose the greatest risk if they fail to self-defer. Based on anonymous surveys of donors in the UK and North America,[16,17] the non-compliance rate among test negative donors ranged from 0.2-11% dependent on the deferral risk question. Perhaps not surprisingly the highest rates of non-compliance were for permanent deferrals, for example intravenous drug use. This reflects the previous observation that non-compliant donors have a high propensity to dismiss remote risk behaviour[18]. The Blood Service is currently undertaking an anonymous Australian donor survey to determine the rate of non-compliance to high risk behaviour-related questions on the pre-donation questionnaire.

Seroconverters

The Blood Service uses the rate of seroconversion as a measure of the incidence rate of newly acquired infection in donors which correlates directly with the risk of transmission. During 2005-2011, a total of ninety seven donors whose previous donation tested negative were positive for that transfusion-transmissible infection, designating them as 'seroconverters'. Consistent with 2008-2010, the highest number of rate of seroconversion in 2011 occurred for HCV, accounting for 42.9% of all seroconverters. This was followed by HBV and HIV, accounting for 35.7% and 21.4%, respectively. No donors seroconverted for HTLV or active syphilis in 2011.

Similar to the findings from previous years, seroconverters in 2011 were disproportionately male (78.6%). However, unlike 2008-2010, the majority of them were born overseas (64.3%). The mean age of seroconverters in 2011 was 41.6 years (40.8 years for HBV, 41.2 years for HCV and 43.7 years for HIV).

15 Polizzotto. *op. cit.*

16 Grenfell P, Nutland W, McManus S, Datta J, Soldan K, Wellings K. Views and experiences of men who have sex with men on the ban on blood donation: a cross sectional survey with qualitative interviews. *BMJ*. 2011;343.

17 Goldman M, Yi Q-L, Ye X, Tessier L, O'Brien SF. Donor understanding and attitudes about current and potential deferral criteria for high-risk sexual behavior. *Transfusion*. 2011;51(8):1829-34.

18 Polizzotto. *op. cit.*

Residual risk estimates/estimated risk of window period donation

The rate of seroconversion can be used to estimate the risk of collecting a unit of blood from a donor with very early infection (window period) which might test negative. Individuals donating in the window period (incident infections) pose the majority of the risk in terms of transmission because they may be missed by testing whereas long standing (prevalent) infections are readily detected by modern screening tests.

Using the number of seroconversions reported for the 2010 and 2011 calendar year periods and applying these to three published risk models, residual risk estimates[19] (per unit transfused) were derived for the four transfusion-transmissible viral infections subject to mandatory testing (Table 10). The risk estimate for active syphilis is not derived by the same method but rather assumed from the lack of reported cases of transfusion-transmission for several decades. The estimates for all except for HBV fall below the 'negligible' risk threshold of 1 in 1 million used by the Blood Service to contextualise the risks for transfusion recipients. The HBV residual risk estimate of 1 in 764 000 is lower than internationally comparable data and considered 'minimal' on the risk scale, roughly equating with the risk of death from a train accident. Further information can be obtained from the following website http://www.transfusion.com.au/adverse_events/risks/estimates.

Based on the estimates and assuming approximately 1.3 million donations collected per annum (2010-2011) one to two transfusion-transmissions (most likely HBV) would be predicted per annum. The reported frequency of cases of transfusion-transmission supports that the modelled estimates are conservative with no cases of transfusion-transmitted HCV reported in Australia since 1991, none for HTLV since testing commenced in 1993, none for HIV since 1998 and three probable cases of HBV in the 2005-2011 period.

Table 10 Estimated risk of window period donation/risk of not detecting true infection for HBV, HCV, HIV, HTLV and syphilis in Australian blood donations (2010-2011)

	HBV	HCV	HIV	HTLV	Active syphilis
Estimated rate of collecting infectious unit (per million donations)	1-2	<1	<1	<1	<1
Residual Risk to recipient - per unit transfused	Approximately 1 in 764 000	Less than 1 in 1 million	Less than 1 in 1 million	Less than 1 in 1 million	Less than 1 in 1 million

Testing for malaria

In Australia, testing for malaria infection is limited to 'at risk' donors. This includes donors who report at the pre-donation interview travel to or residence in malaria endemic countries, as well as those with a previous history of infection[20]. The availability of malaria antibody testing results in significant recovery of valuable fresh blood components (red blood cells and platelets) as prior to the commencement of testing such donors were restricted to donating plasma for fractionation only for 1-3 years. Annually an estimated 65 000 red cells and 7 000 platelets are recovered as a result of non reactive malaria antibody test results. Since malaria antibodies can indicate both recent and past infection all antibody repeat reactive donors are also tested for malaria antigen and malaria DNA to exclude current infection. Donors positive for one or both supplementary tests are immediately referred for clinical assessment.

In 2011, a total 116 610 donations were tested for malaria antibody of which 2 411 (2.1%) were found to be repeat reactive for malaria antibodies. None of these 2 411 donations were positive for either malaria antigen or malaria DNA indicating all were from donors with past infection and thus posed negligible transmission risk.

19 Seed CR, Kiely P, Keller AJ. Residual risk of transfusion transmitted human immunodeficiency virus, hepatitis B virus, hepatitis C virus and human T lymphotrophic virus. *Internal Medicine Journal*. 2005;35(10):592-8.

20 Seed CR, Kee G, Wong T, Law M, Ismay S. Assessing the safety and efficacy of a test-based, targeted donor screening strategy to minimize transfusion transmitted malaria. *Vox Sanguinis*. 2010;98(3p1):e182-e92.

Surveillance for emerging infections

The Blood Service maintains surveillance for emerging infections through close liaison with Government communicable disease control units, CSL Biotherapies, membership of international medical/infectious disease groups and active horizon scanning. Potential threats are regularly reviewed by the Blood Service Donor and Product Safety Advisory Committee (DAPS Advisory Committee) and risk assessment performed in the event that a threat is identified as a clear and present threat to the safety of the blood supply. Where appropriate this will be performed in collaboration with CSL Biotherapies (in their capacity as national plasma fractionator) and the Therapeutic Goods Administration (TGA).

2011 summary

Dengue outbreaks in Queensland

Dengue virus transmission by fresh blood components has been demonstrated and thus poses a risk to transfusion safety[21]. During the period January – March 2011, four dengue fever outbreaks were declared in Queensland: one outbreak each in Townsville and Cairns, and two in Innisfail. For this period there were 55 reported cases of locally transmitted dengue in Innisfail, 9 cases in Townsville and 5 in Cairns. Blood Service risk modelling[22] indicated that the average probability of collecting blood from a viraemic donor during this period was approximately 1 in 820 in Innisfail, 1 in 77 000 in Townsville and 1 in 153 000 in Cairns. To mitigate this risk, supplementary donor selection measures and product restrictions were implemented for travel to/residence in affected regions i.e. Innisfail, Cranbrook in Townsville and the Cairns suburbs of Mooroobool and Manunda. Donations from these areas were restricted to CSL fractionation/processing which has been shown to effectively eliminate dengue virus. All restrictions were lifted by 2 May 2011.

West Nile virus (WNV)

Outbreaks in Europe and Blood Service risk assessment

Transmission of West Nile virus by blood, tissue and organ transplantation has been documented[23]. A virulent strain of WNV is endemic in North America and therefore donors visiting USA (including Hawaii) and Canada are restricted to donating plasma for fractionation for 28 days after their return. In 2010 large WNV outbreaks occurred in Greece and the Russian Federation resulting in an extension of the WNV restrictions to these countries which were lifted at the conclusion of these outbreaks. In 2011 the Blood Service monitored WNV outbreaks in the European Union (EU) and surrounding countries during the European transmission season (July to November 2011). Monitoring was based on regular updates of WNV cases provided by the European Centre for Disease Prevention and Control (ECDC), and the Hellenic Centre for Disease Control and Prevention (HCDCP-KEELPNO). During the 2011 transmission season the highest number of cases within the EU were reported in Greece (69 cases) and in the neighbouring countries the highest number of cases were reported in the Russian Federation (136 cases). For both these countries the Blood Service performed weekly risk modelling to estimate the risk of a donor returning from these countries and donating while infectious (i.e. viraemic). This modelling indicated that the additional level of risk to the Australian blood supply associated with donors returning from Greece and the Russian Federation during the 2011 WNV transmission season did not exceed the threshold (established for local dengue outbreaks) that requires cessation of fresh blood component manufacture.

Novel virulent WNV strain in NSW horses

In 2011 there was an outbreak of encephalitis in horses in NSW with cases close to Newcastle and Sydney. Subsequent genomic analysis of the viruses isolated from the affected horses showed that most of the cases were due to a variant WNV strain ($WNV_{NSW2011}$) closely related to the prototype Australian WNV strain (Kunjin virus or WNV_{KUN})[24]. The $WNV_{NSW2011}$ strain was found to be substantially more neuroinvasive than the prototype WNV_{KUN} strain. While there were no associated human cases reported, the proximity to major urban centres and increased virulence compared to the prototype WNV_{KUN} warranted a close watching brief.

21 Teo D, Ng LC, Lam S. Is dengue a threat to the blood supply? *Transfusion Medicine*. 2009;19(2):66-77.

22 Seed CR, Kiely P, Hyland CA, Keller AJ. The risk of dengue transmission by blood during a 2004 outbreak in Cairns, Australia. *Transfusion*. 2009;49(7):1 482-7.

23 Petersen LR, Busch MP. Transfusion-transmitted arboviruses. *Vox Sanguinis.* 2010;98(4):495-503.

24 Frost MJ, Zhang J, Edmonds JH, et al. "Characterization of virulent West Nile virus Kunjin strain, Australia, 2011," *Emerging Infectious Diseases.* 2012; 18(5).

Xenotropic murine leukaemia virus-related virus

Xenotropic murine leukaemia virus-related virus (XMRV) was initially identified in patients with prostate cancer and this finding was supported by some initial studies reporting the detection of XMRV genomic sequences in prostate cancer patients. However, subsequent studies have either failed to detect XMRV sequences in prostate cancer patients or have found them at the same prevalence as that for non-cancerous prostates. Thus the association between XMRV and prostate cancer remains to be clarified. Subsequently, in 2009 a report was published indicating that XMRV was associated with chronic fatigue syndrome (CFS). At this time the Blood Service already deferred donors with current symptoms of CFS. As a precautionary measure against the possibility XMRV being established as the causative agent CFS and that it might be transfusion transmissible, the Blood Service extended the deferral to blood donors with a history of CFS. Subsequently a number of studies failed to detect XMRV sequences in CFS patients (including patients who were initially found to be infected with XMRV) and the current scientific consensus is that the association, if any, between XMRV and CFS has not been established and the initial findings of XMRV genomic sequences may have been due to laboratory contamination. The original article reporting an association between CFS and XMRV, published in the journal Science, was fully retracted by the editor-in-chief in December 2011 who cited a lack of confidence in the report and the validity of its conclusions[25,26]

First reported case of human babesiosis in Australia

Human babesiosis is an emerging tick-borne parasitic disease and transfusion transmission has been documented in over 170 cases in North America[27] . While animal babesiosis is well recognised in Australian cattle and dogs, no locally acquired human cases had previously been documented. Notably, a transfusion recipient was diagnosed with babesiosis unrelated to known strains in Australian animals in April 2011[28]. Subsequent follow up indicated that the recipient was infected with the parasite prior to entering hospital and the infection was therefore not transfusion related. Subsequent sequencing indicated that the recipient was infected with *B. microti* the organism associated with the vast majority of transfusion associated cases. This is the first human case of babesiosis identified in Australia and is thought to have been locally acquired. The Blood Service has responded by initiating targeted research to identify the extent of any potential threat to the Australian blood supply.

Hendra virus

Human Hendra virus (HeV) infection is an emerging zoonotic disease associated with high mortality (4/7 infections fatal)[29]. To date all seven recorded cases of HeV transmission to humans have occurred from Pteropus bats (flying foxes) via horses. While no cases of human disease were recorded, in 2011 Australia experienced its largest reported outbreak of equine HeV. Beginning in June, infected horses were reported from a number of properties in NSW and Queensland. More than 20 infected horses were identified along with the first report of a naturally infected dog. The primary mode of human exposure to HeV is thought to be from the respiratory secretions and/or blood of infected horses. HeV has been isolated from the nasopharyngeal secretions, saliva, urine, foetal material and organs of horses[30]. Transfusion transmission has not been reported but is theoretically possible and as a precautionary measure the Blood Service permanently excludes donors with HeV infection. In addition contacts of infected horses are notified they should not donate blood for a period of at least 6 weeks and thereafter are required to provide documented evidence of lack of anti-HeV seroconversion before being accepted to donate.

25 Dodd RY, Hackett Jr J, Linnen JM, Dorsey K, Wu Y, Zou S, et al. Xenotropic murine leukaemia virus–related virus does not pose a risk to blood recipient safety. *Transfusion*. 2012;52(2):298-306.

26 Alberts B. Retraction. *Science*. 2011;334(6063):1636.

27 Leiby DA. Transfusion-associated babesiosis: shouldn't we be ticked off? *Ann Intern Med*. 2011;155(8):556-7.

28 Senanayake SN, Paparini A, Latimer M, Andriolo K, Dasilva AJ, Wilson H, et al. First Report of Human Babesiosis in Australia. *MJA* 196, 350-353 (2012).

29 Young JR, Selvey CE, Symons R. Hendra virus. *MJA*. 2011;195(5):250-1.

30 Tulsiani SM, Graham GC, Moore PR, Jansen CC, Van Den Hurk AF, Moore FAJ, et al. Emerging tropical diseases in Australia. Part 5. *Annals of Tropical Medicine and Parasitology*, 2011. 105(1): p. 1-11.

Conclusions

1. Supporting the effectiveness of donor education and selection, the prevalence of transfusion-transmissible infections is substantially lower among both first time blood donors (12 to 39 times) and all donors (99 to 225 times) than in the general population and shows a stable or declining trend since 2005.
2. The prevalence of transfusion-transmissible infections among first time donors was much higher than the rates among all donors, highlighting the importance of promoting donor education of potential new donors and ensuring first-time donors read the pre-donation information and understand the importance of self deferral.
3. The incidence of newly acquired infection measured by the rate of seroconversion in repeat blood donors is also much lower than in the general population. This supports the general effectiveness of the donor questionnaire and specifically, that repeat donors understand what constitutes 'risk behaviour' for acquiring infection.
4. Infective risk factors identified in transfusion-transmissible infection positive blood donors closely parallel those for the general population with no 'unique' risk factors identified to date among blood donors.
5. Almost one-fifth of the positive donors in 2008-2011 were 'non-compliant' in that they had risk factors identified during their post-donation interview that would have deferred them from donating had they disclosed them at the pre-donation interview. Reassuringly, the rate of non-compliance among positive donors has been gradually declining since 2008 and notably in 2011 was the lowest recorded to date (12.9%). Understanding the reasons for, and minimising the rate of non-compliance is important because it reduces the risk of collecting blood from a potentially infected donor that may not be detected by testing.
6. The estimated residual risk of transmission for HIV, HCV, HBV, HTLV and active syphilis in Australia is very low, less than one in one million per unit transfused for all except HBV (approx 1 in 764 000). This supports the claim that Australia's blood supply is among the safest worldwide in respect of transfusion-transmissible infections for which testing is conducted. Despite this, there remains a real risk to patients which must be carefully considered before any transfusion.
7. In addition to established transfusion-transmissible infections, emerging infectious diseases continue to demand vigilant surveillance. Mosquito-borne agents such as dengue virus and West Nile virus are currently the principal threats but many other novel or emerging infectious diseases are constantly monitored by the Blood Service to assess their threat to the safety of the blood supply.

Supporting figures

Figure 1 **Percentage of age-eligible general population who donated blood in 2011, by state/territory**

Figure 2 **Number of blood donors with transfusion-transmissible infections in Australia, by infection and year of donation, 2005-2011**

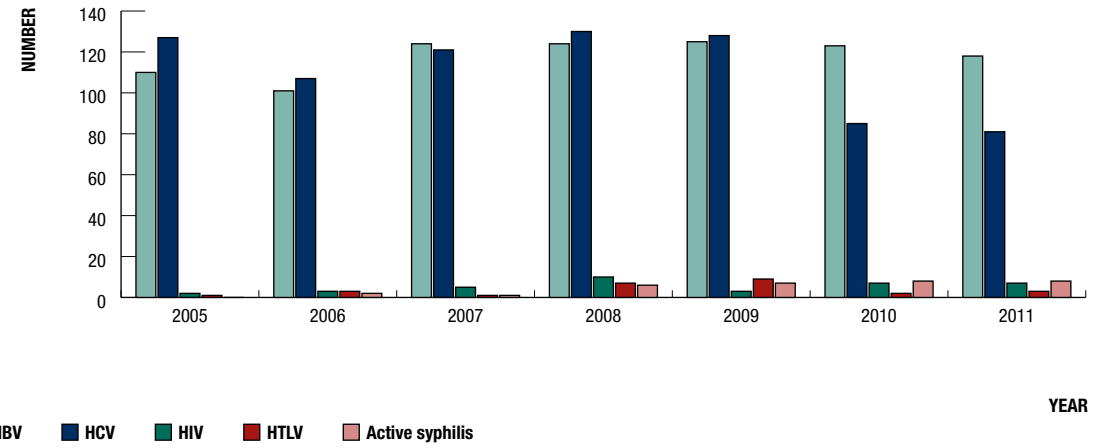


Figure 3 **Percentage of donations made by first time and repeat donors among all blood donations in Australia, 2005-2011**

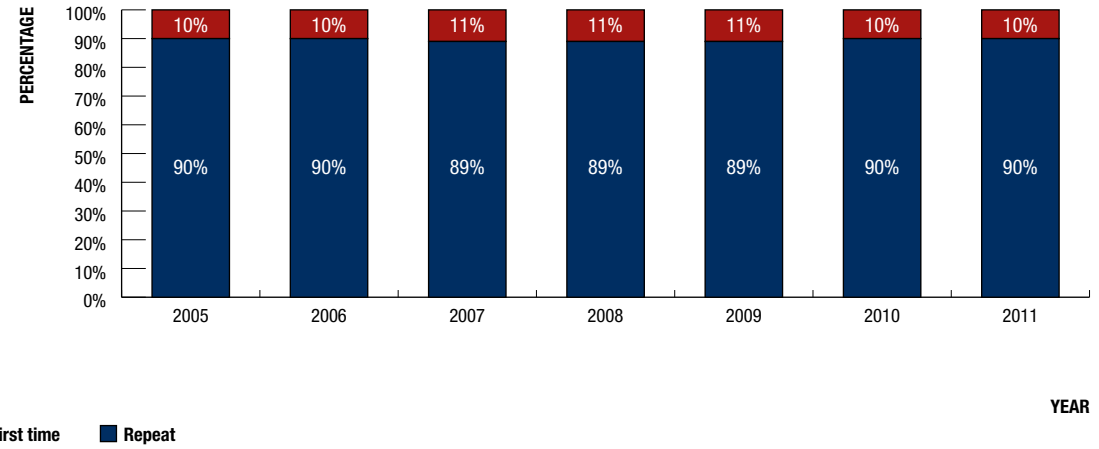


Figure 4 **Distribution of blood donors in Australia by age group and sex, 2011**

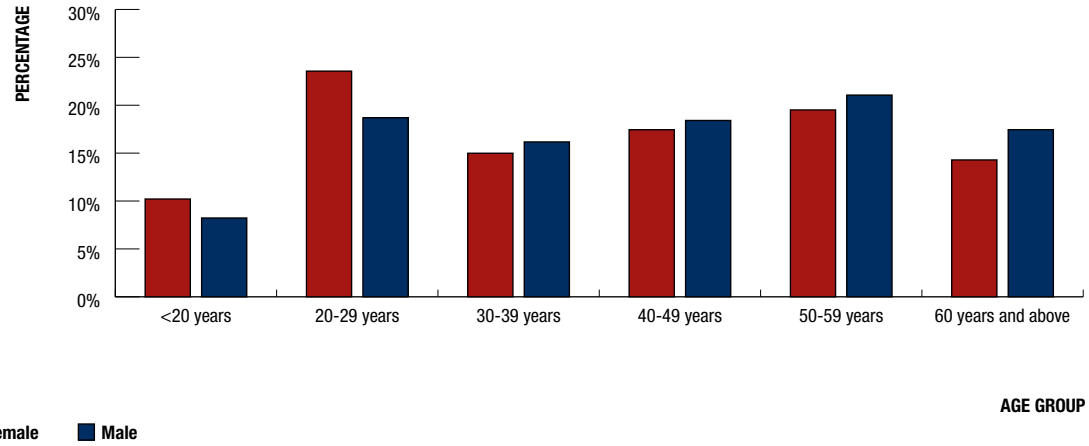


Figure 5 **Prevalence of any transfusion-transmissible infection among all accepted donations, 2005-2011**

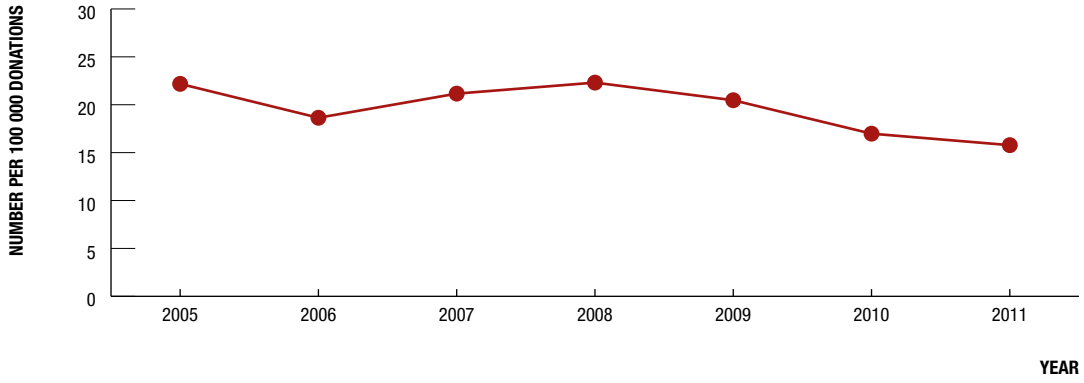


Figure 6 **Percentage of first time and repeat donations among all positive blood donations in Australia, 2005-2011**

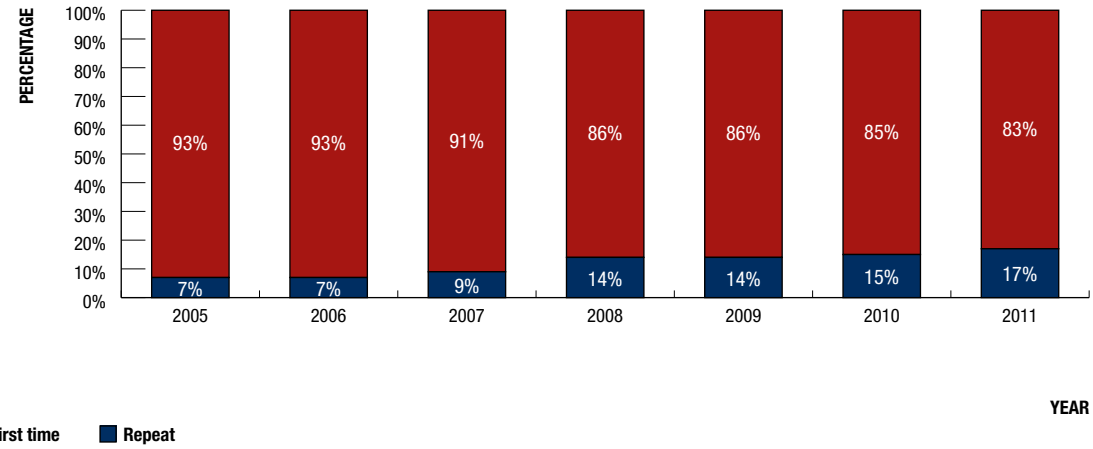


Figure 7 **Prevalence of HBV among first time donors by state/territory and year of donation, 2005-2011**

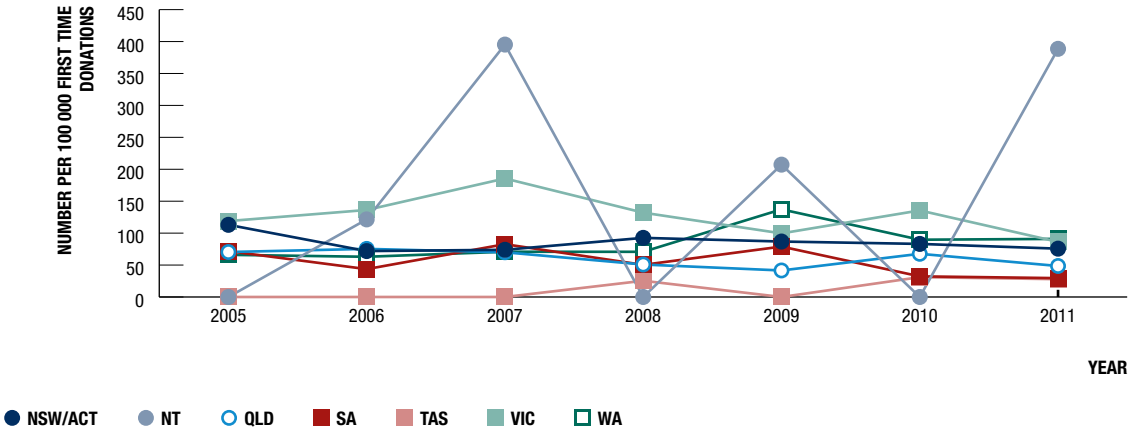


Figure 8 **Incidence of HBV among repeat donors by state/territory and year of donation, 2005-2011**

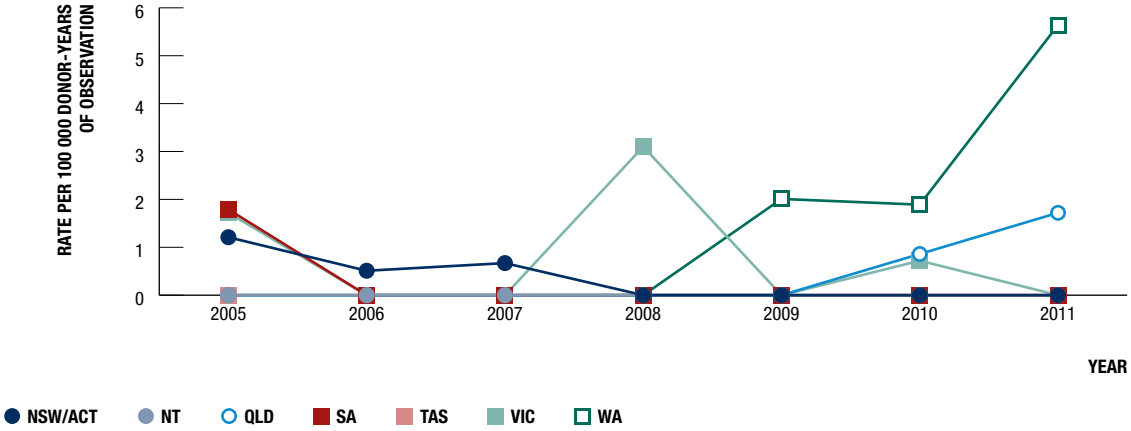


Figure 9 **Prevalence of HCV among first time donors by state/territory and year of donation, 2005-2011**

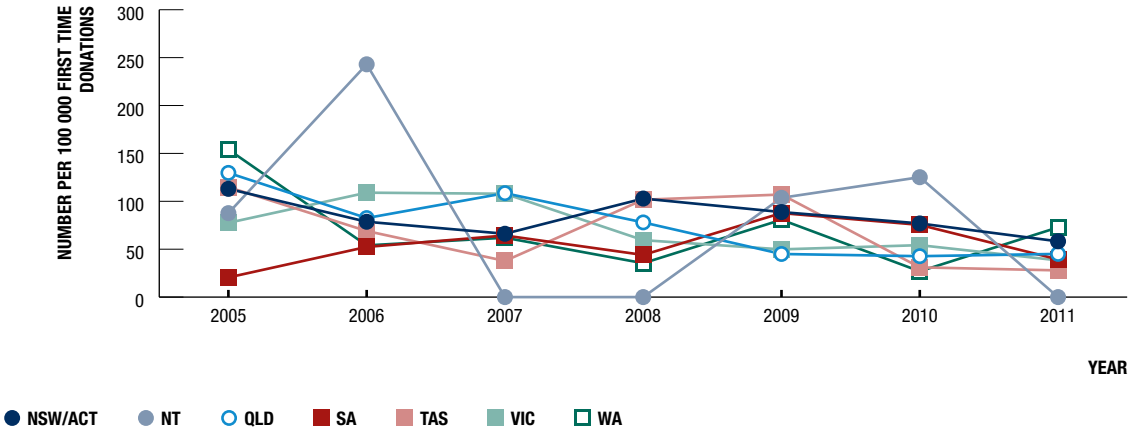


Figure 10 Incidence of HCV among repeat donors by state/territory and year of donation, 2005-2011

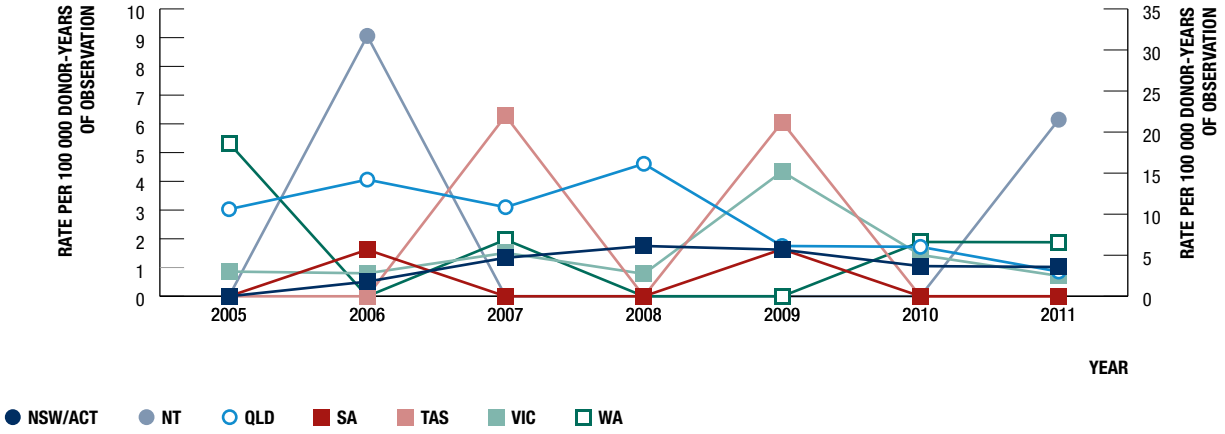
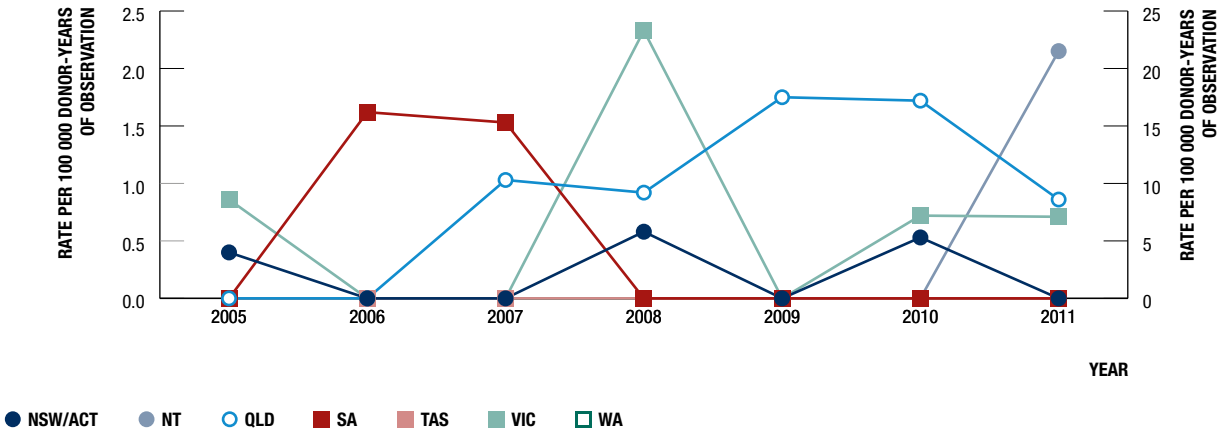


Figure 11 Prevalence of HIV among first time donors by state/territory and year of donation, 2005-2011

Figure 12 Incidence of HIV among repeat donors by state/territory[1] and year of donation, 2005-2011



1 Incidence in NT provided according to the scale on the secondary axis on the right hand side.

Figure 13 Prevalence of HTLV among first time donors by state/territory and year of donation, 2005-2011

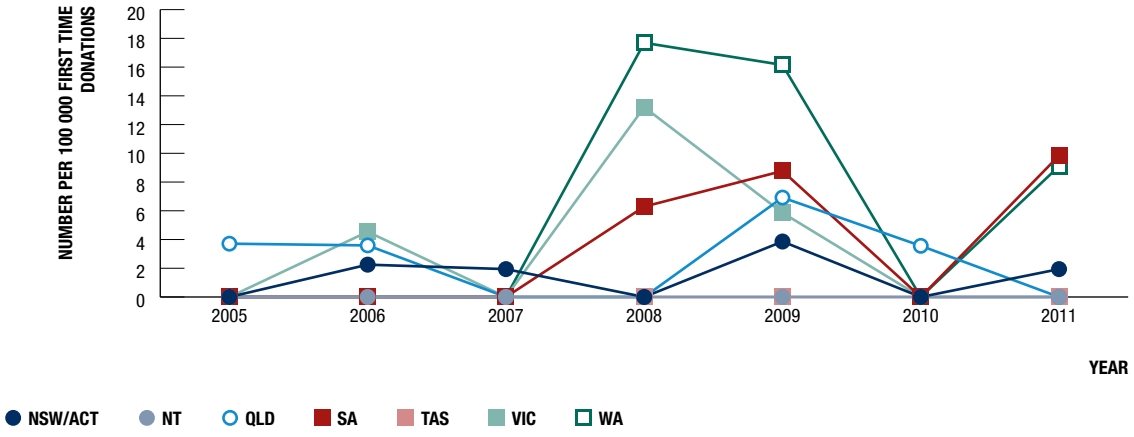


Figure 14 Prevalence of active syphilis among first time donors by state/territory[1] and year of donation, 2005-2011

1 Prevalence in QLD and VIC are provided according to the scale on the secondary axis on the right hand side.

Figure 15 Donors with HBV infection by sex and donor status, 2008-2011

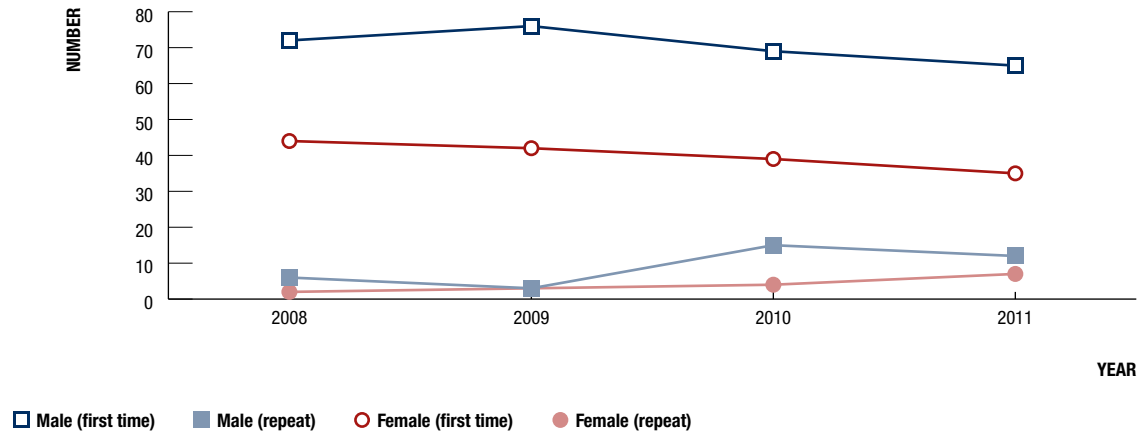


Figure 16 Rate of HBV infection among blood donors by age group and year of donation, 2008-2011

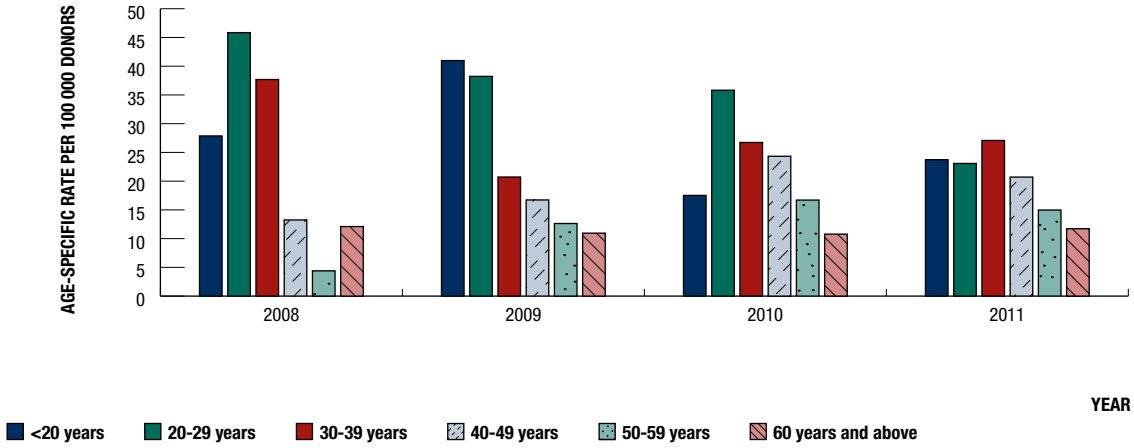


Figure 17 Donors with HBV infection by region of birth, 2011

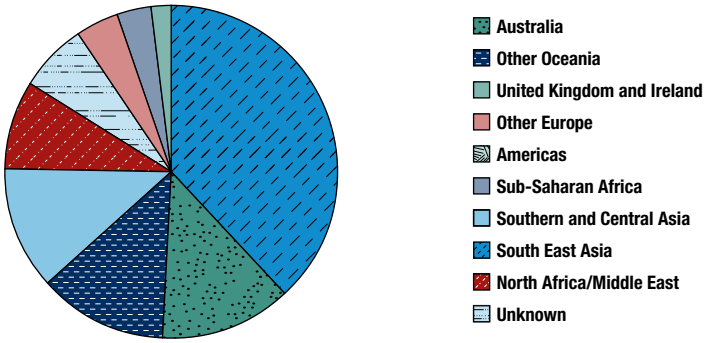


Figure 18 Donors with HCV infection by sex and donor status, 2008-2011

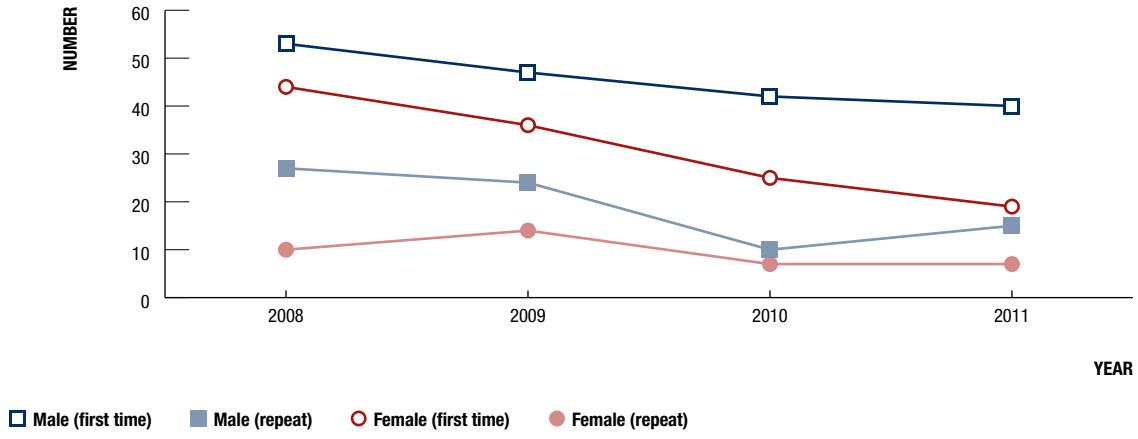


Figure 19 Rate of HCV infection among blood donors by age group and year of donation, 2008-2011

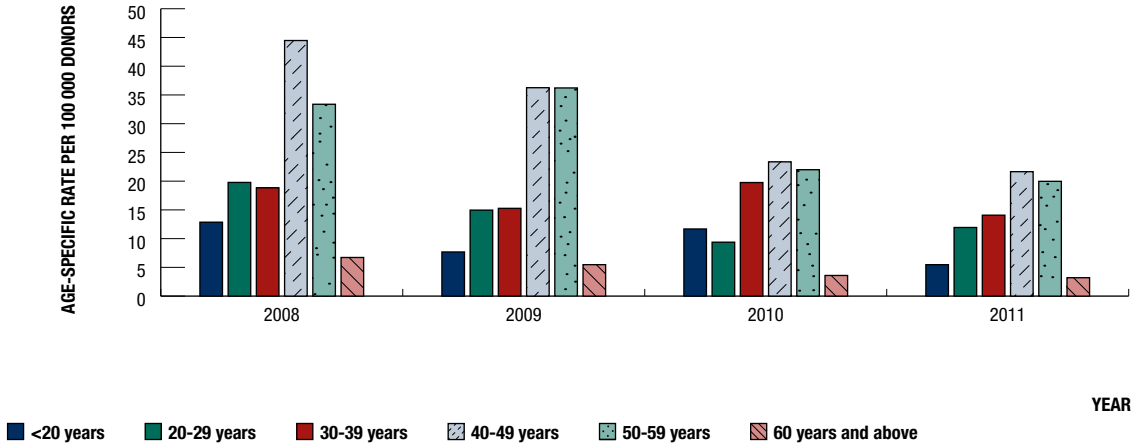


Figure 20 Donors with HCV infection by region of birth, 2011

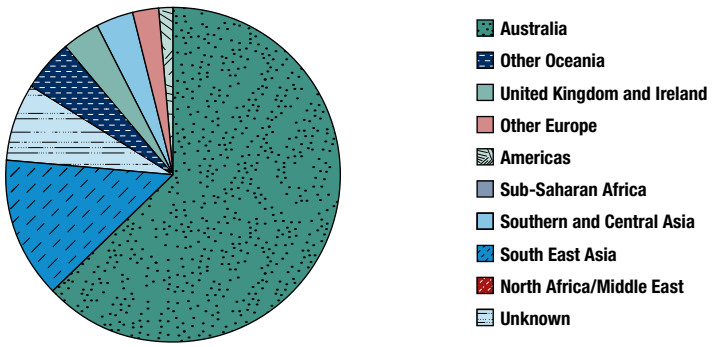


Figure 21 Donors with HIV infection by sex and donor status, 2008-2011

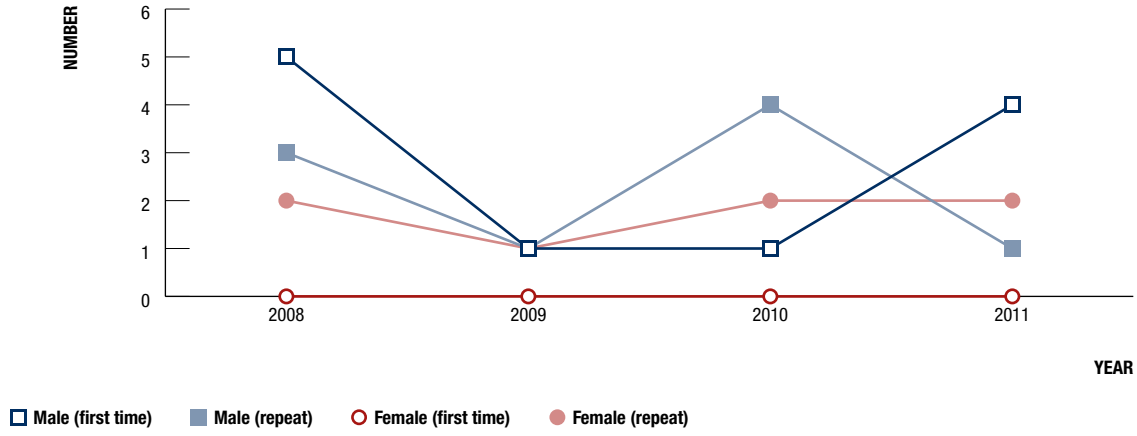


Figure 22 Rate of HIV infection among blood donors by age group and year of donation, 2008-2011

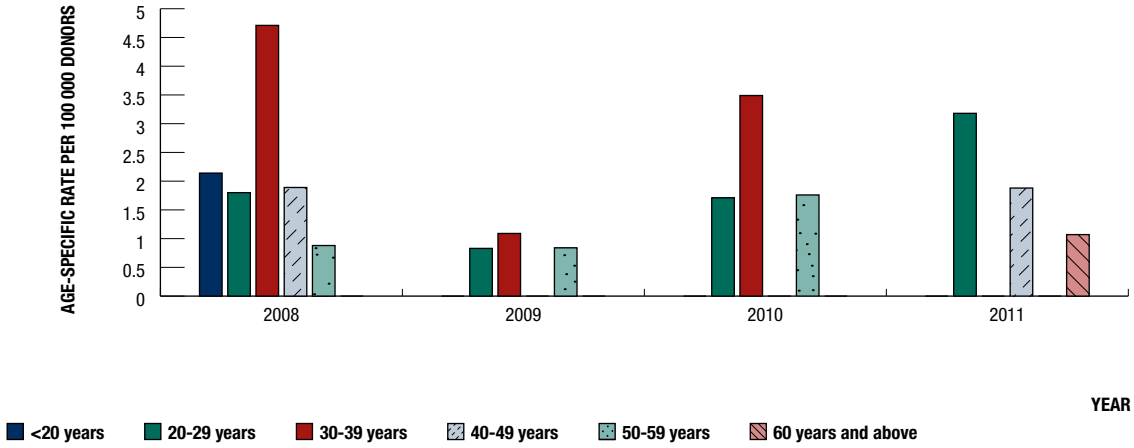


Figure 23 Donors with HIV infection by region of birth, 2011

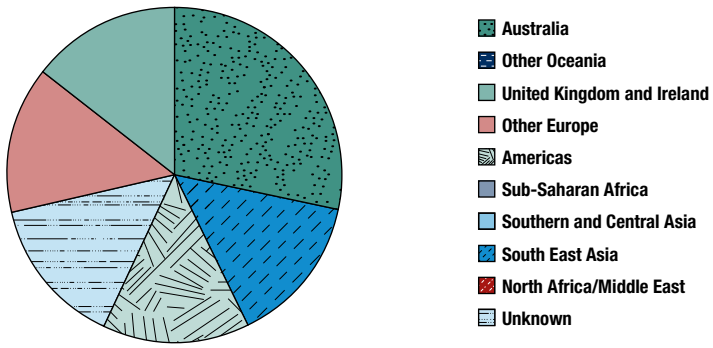


Figure 24 Donors with HTLV infection by sex and donor status, 2008-2011

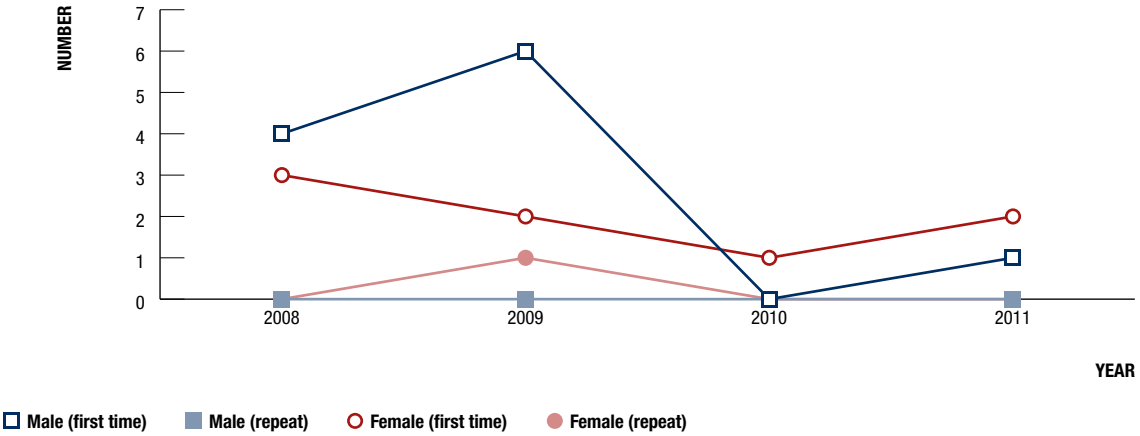


Figure 25 Rate of HTLV infection among blood donors by age group and year of donation, 2008-2011

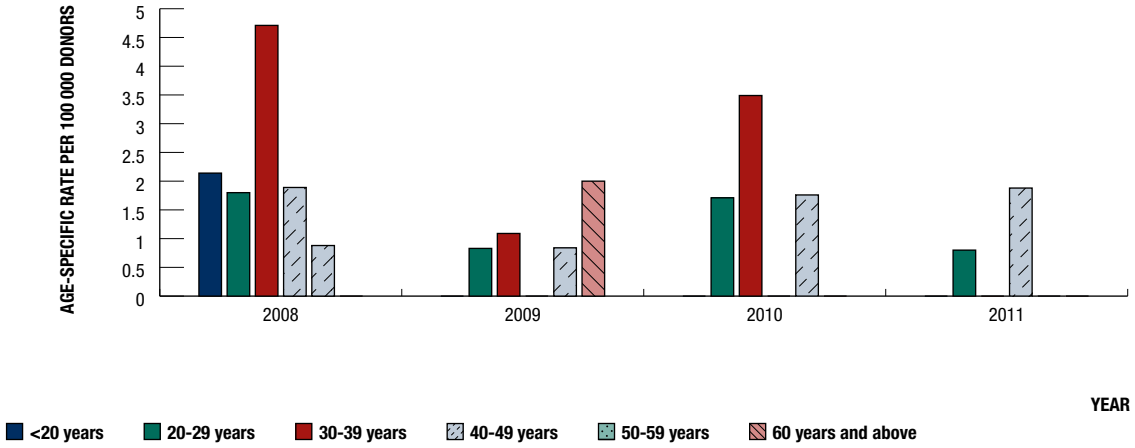
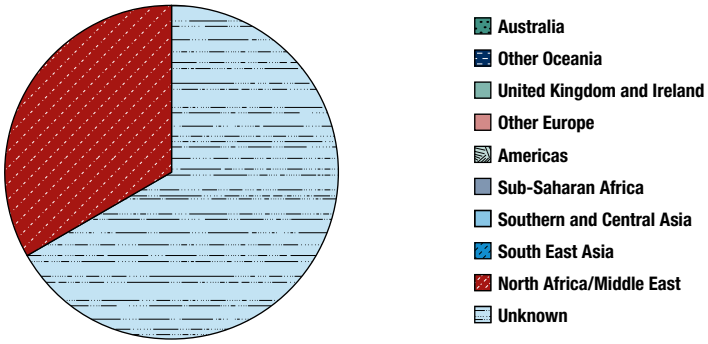


Figure 26 Donors with HTLV infection by region of birth, 2011



Supporting tables

Table 1 Screening tests for transfusion-transmissible infections

Transfusion-Transmissible infection	Mandatory screening tests	Test Target	Year of introduction	Median window period estimate	Estimated risk of window period donation (per million transfusion)
Syphilis	*Treponema pallidum* Haemagglutination Assay (TPHA)	Antibodies to *Treponema pallidum*	~1949	45 days	<1 in 1 million
HBV	HBsAg[1]	Hepatitis B surface antigen (HBsAg)	1970	38 days	–
	Nucleic Acid Test for HBV	HBV DNA	2010	23.9 days	Approx 1 in 764 000
HIV	anti-HIV-1[1] anti-HIV-2[1]	Antibody to both HIV-1 and HIV-2 (anti-HIV-1/2)	1985 (HIV-1) 1993 (HIV-1/HIV-2)	22 days	–
	Nucleic Acid Test for HIV-1[2]	HIV-1 RNA	2000	5.6 days	<1 in 1 million
HCV	anti-HCV[1]	Antibody to HCV	1990	66 days	–
	Nucleic Acid Test for HCV[2]	hepatitis C RNA	2000	3.1 days	<1 in 1 million
HTLV	anti-HTLV-1[1] anti-HTLV-2[1]	Antibody to both HTLV-1 and HTLV-2	1993	51 days	<1 in 1 million

1 Currently Abbott PRISM (Abbott Diagnostics, Wiesbaden-Delkenheim, Germany) Chemiluminescent Immunoassay system.

2 Chiron Procleix HIV-1/HCV (Multiplex) Assay, and the HIV-1 and HCV Discriminatory Assays (Chiron Blood Testing, Emeryville, California) form June 2000 until July 2010. Subsequently replaced by Novartis HIV-1/HCV/HBV Procleix Ultrio assay using a fully automated testing system (Procleix Tigris).

Table 2 The number and rate of transfusion-transmissible infections in Australia by type of donations and state/territory, 2005-2011

	All accepted donations			HBV			HCV			HIV			HTLV			Syphilis			Total positive donations		
State/Territory of donation	First time	Repeat	All	First time	Repeat	All	First time	Repeat	All	First time	Repeat	All	First time	Repeat	All	First time	Repeat	All	First time	Repeat	All
NSW/ACT	**338 491**	**2 465 273**	**2 803 764**	**290**	**23**	**313**	**280**	**32**	**312**	**5**	**3**	**8**	**5**	**1**	**6**	**0**	**3**	**3**	**580**	**62**	**642**
Number (Number per 100 000 donations)				*85.67*	*0.93*	*11.16*	*82.72*	*1.30*	*11.13*	*1.48*	*0.12*	*0.29*	*1.48*	*0.04*	*0.21*	*0.00*	*0.89*	*0.11*	*171.35*	*2.51*	*22.90*
NT	**6 074**	**71 148**	**77 222**	**9**	**1**	**10**	**5**	**2**	**7**	**0**	**1**	**1**	**0**	**0**	**0**	**4**	**2**	**6**	**18**	**6**	**24**
Number (Number per 100 000 donations)				*148.17*	*1.41*	*12.95*	*82.32*	*2.81*	*9.06*	*0.00*	*1.41*	*1.29*	*0.00*	*0.00*	*0.00*	*65.85*	*32.93*	*7.77*	*296.35*	*8.43*	*31.08*
QLD	**198 759**	**1 589 989**	**1 788 748**	**119**	**8**	**127**	**150**	**33**	**183**	**8**	**7**	**15**	**5**	**0**	**5**	**6**	**2**	**8**	**288**	**50**	**338**
Number (Number per 100 000 donations)				*59.87*	*0.50*	*7.10*	*75.47*	*2.08*	*10.23*	*4.02*	*0.44*	*0.84*	*2.52*	*0.00*	*0.28*	*3.02*	*1.01*	*0.45*	*144.90*	*3.14*	*18.90*
SA	**78 851**	**808 841**	**887 692**	**44**	**7**	**51**	**43**	**11**	**54**	**0**	**2**	**2**	**3**	**0**	**3**	**4**	**0**	**4**	**94**	**20**	**114**
Number (Number per 100 000 donations)				*55.80*	*0.87*	*5.75*	*54.53*	*1.36*	*6.08*	*0.00*	*0.25*	*0.23*	*3.80*	*0.00*	*0.34*	*5.07*	*0.00*	*0.45*	*119.21*	*2.47*	*12.84*
TAS	**23 514**	**238 062**	**261 576**	**3**	**0**	**3**	**17**	**2**	**19**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**1**	**1**	**20**	**3**	**23**
Number (Number per 100 000 donations)				*12.76*	*0.00*	*1.15*	*72.30*	*0.84*	*7.26*	*0.00*	*0.00*	*0.00*	*0.00*	*0.00*	*0.00*	*0.00*	*4.25*	*0.38*	*85.06*	*1.26*	*8.79*
VIC	**186 059**	**1 819 225**	**2 005 284**	**232**	**14**	**246**	**125**	**18**	**143**	**3**	**6**	**9**	**7**	**0**	**7**	**3**	**1**	**4**	**370**	**39**	**409**
Number (Number per 100 000 donations)				*124.69*	*0.77*	*12.27*	*67.18*	*0.99*	*7.13*	*1.61*	*0.33*	*0.45*	*3.76*	*0.00*	*0.35*	*1.61*	*0.54*	*0.20*	*198.86*	*2.14*	*20.40*
WA	**77 330**	**783 168**	**860 498**	**66**	**9**	**75**	**52**	**9**	**61**	**2**	**0**	**2**	**5**	**0**	**5**	**5**	**2**	**7**	**130**	**20**	**150**
Number (Number per 100 000 donations)				*85.35*	*1.15*	*8.72*	*67.24*	*1.15*	*7.09*	*2.59*	*0.00*	*0.23*	*6.47*	*0.00*	*0.58*	*6.47*	*2.59*	*0.81*	*168.11*	*2.55*	*17.43*
National	**909 078**	**7 775 706**	**8 684 784**	**763**	**62**	**825**	**672**	**107**	**779**	**18**	**19**	**37**	**25**	**1**	**26**	**22**	**11**	**33**	**1 500**	**200**	**1 700**
Number (Number per 100 000 donations)				*83.93*	*0.80*	*9.50*	*73.92*	*1.38*	*8.97*	*1.98*	*0.24*	*0.43*	*2.75*	*0.01*	*0.30*	*2.42*	*1.21*	*0.38*	*165.00*	*2.57*	*19.57*

Table 3 Number and prevalence[1] of HBV infection among first time donors, 2005-2011, by state/territory and year of donation

	2005			2006			2007			2008		
State/ Territory	**Donations**	**Positive**	**Prevalence**	**Donations**	**Positive**	**Prevalence**	**Donations**	**Positive**	**Prevalence**	**Donations**	**Positive**	**Prevalence**
NSW/ACT	42 479	48	113.00	44 499	32	71.91	51 427	38	73.89	48 607	45	92.58
NT	1 141	0	0.00	823	1	121.51	759	3	395.26	815	0	0.00
QLD	26 988	19	70.40	27 873	21	75.34	28 575	20	69.99	29 498	15	50.85
SA	9 752	7	71.78	11 457	5	43.64	10 886	9	82.67	15 908	8	50.29
TAS	3 484	0	0.00	2 899	0	0.00	2 650	0	0.00	3 936	1	25.41
VIC	19 346	23	118.89	22 016	30	136.26	23 172	43	185.57	30 286	40	132.07
WA	9 087	6	66.03	11 116	7	62.97	11 292	8	70.85	11 307	8	70.75
Total	**112 277**	**103**	**91.74**	**120 683**	**96**	**79.55**	**128 761**	**121**	**93.97**	**140 357**	**117**	**83.36**

	2009			2010			2011			Total 2005-2011		
State/ Territory	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Prevalence**	**Donations**	**Positive**	**Prevalence**
NSW/ACT	51 821	45	86.84	48 130	40	83.11	51 528	42	81.51	338 491	290	85.67
NT	965	2	207.25	799	0	0.00	772	3	388.60	6 074	9	148.17
QLD	28 889	12	41.54	28 097	19	67.62	28 839	13	45.08	198 759	119	59.87
SA	11 400	9	78.95	9 284	3	32.31	10 164	3	29.52	78 851	44	55.80
TAS	3 736	0	0.00	3 222	1	31.04	3 587	1	27.88	23 514	3	12.76
VIC	34 133	34	99.61	25 820	35	135.55	31 286	27	86.30	186 059	232	124.69
WA	12 387	17	137.24	11 149	10	89.69	10 992	10	90.98	77 330	66	85.35
Total	**143 331**	**119**	**83.02**	**126 501**	**108**	**85.37**	**137 168**	**99**	**72.17**	**909 078**	**763**	**83.93**

1 Rate per 100 000 first time donations

Table 4 Number and rate[1] of HBV infection among repeat donors, 2005-2011, by state/territory and year of donation

	2005			2006			2007			2008		
State/ Territory	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**
NSW/ACT	311 513	4	1.28	333 250	5	1.50	338 173	3	0.89	339 062	1	0.29
NT	8 862	0	0.00	8 496	0	0.00	10 214	0	0.00	11 166	0	0.00
QLD	205 398	0	0.00	216 496	0	0.00	209 556	0	0.00	226 726	1	0.44
SA	93 172	1	1.07	107 934	0	0.00	114 618	0	0.00	118 476	1	0.84
TAS	24 577	0	0.00	28 726	0	0.00	28 019	0	0.00	33 321	0	0.00
VIC	225 332	2	0.89	238 684	0	0.00	252 340	0	0.00	259 052	4	1.54
WA	101 063	0	0.00	99 376	0	0.00	109 425	0	0.00	113 274	0	0.00
Total	**969 917**	**7**	**0.72**	**1 032 962**	**5**	**0.48**	**1 062 345**	**3**	**0.28**	**1 101 077**	**7**	**0.64**

	2009			2010			2011			Total 2005-2011		
State/ Territory	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**
NSW/ACT	372 806	1	0.27	380 014	4	1.05	390 455	4	1.02	2 132 055	22	1.03
NT	11 158	0	0.00	10 470	1	9.55	10 782	0	0.00	62 653	1	1.60
QLD	242 001	1	0.41	243 837	3	1.23	245 975	3	1.22	1 373 514	8	0.58
SA	126 855	0	0.00	123 587	3	2.43	124 199	3	2.42	700 912	8	1.14
TAS	37 274	0	0.00	41 484	0	0.00	44 661	0	0.00	209 336	0	0.00
VIC	276 835	1	0.36	278 897	3	1.08	288 085	4	1.39	1 580 571	14	0.89
WA	118 327	3	2.54	120 646	1	0.83	121 057	5	4.13	683 799	9	1.32
Total	**1 185 256**	**6**	**0.51**	**1 198 935**	**15[2]**	**1.25**	**1 225 214**	**19[2]**	**1.55**	**6 742 840**	**62**	**0.92**

1 Rate per 100 000 first time donations

2 The increase is attributed to the introduction of HBV NAT which identified additional acute HBsAg negative and chronic occult HBV cases

Table 5 Number and percentage of donors with HBV infection, 2008-2011, by year of donation, sex and age group

	Year of donation											
	2008		2009		2010		2011		2008-2011			
Donor status	**M**	**F**	**M**	**F**	**M**	**F**	**M**	**F**	**M**	**F**	**Total**	**%**
First time donors												
<20 years	7	6	10	6	5	4	6	7	28	23	51	10.3
20-29 years	32	18	29	16	23	17	17	12	101	63	164	33.3
30-39 years	23	8	12	6	16	6	17	5	68	25	93	18.9
40-49 years	7	4	10	7	15	4	16	4	48	19	67	13.6
50-59 years	1	4	10	3	7	5	5	5	23	17	40	8.1
60 years and above	2	4	5	4	3	3	4	1	14	12	26	5.3
Repeat donors												
<20 years	0	0	0	0	0	0	0	0	0	0	0	0.0
20-29 years	1	0	0	1	0	2	0	0	1	3	4	0.8
30-39 years	1	0	1	0	1	0	3	0	6	0	6	1.2
40-49 years	1	2	1	0	6	0	2	0	10	2	12	2.4
50-59 years	0	0	0	2	6	1	6	2	12	5	17	3.4
60 years and above	3	0	1	0	2	1	3	3	9	4	13	2.6
Total	**78**	**46**	**79**	**45**	**84**	**43**	**79**	**39**	**320**	**173**	**493**	**100**

Table 6 Number and percentage of donors with HBV infection, 2008-2011, by year of donation and region of birth[1]

	2008		2009		2010		2011		2008-2011	
Region of birth	**Number**	**%**	**Number**	**%**	**Number**	**%**	**Number**	**%**	**Number**	**%**
Australia	18	15	16	13	17	13	15	13	66	13
Overseas born										
Other Oceania	*11*	*9*	*9*	*7*	*14*	*11*	*15*	*13*	*49*	*10*
United Kingdom and Ireland	*1*	*1*	*1*	*1*	*0*	*0*	*2*	*2*	*4*	*1*
Other Europe	*7*	*6*	*12*	*10*	*8*	*6*	*5*	*4*	*32*	*6*
Middle East/North Africa	*7*	*6*	*6*	*5*	*3*	*2*	*10*	*8*	*26*	*5*
Sub-Saharan Africa	*3*	*2*	*6*	*5*	*4*	*3*	*4*	*3*	*17*	*3*
South East Asia	*55*	*44*	*54*	*44*	*67*	*53*	*45*	*38*	*221*	*45*
Southern and Central Asia	*13*	*10*	*16*	*13*	*9*	*7*	*14*	*12*	*52*	*11*
North America	*1*	*1*	*0*	*0*	*0*	*0*	*0*	*0*	*1*	*0*
South/Central America and the Caribbean	*0*	*0*	*1*	*1*	*0*	*0*	*0*	*0*	*1*	*0*
Total with a reported country of birth	**116**	**94**	**121**	**98**	**122**	**96**	**110**	**93**	**469**	**95**
Not reported	**8**	**6**	**3**	**2**	**5**	**4**	**8**	**7**	**24**	**5**
Total	**124**	**100**	**124**	**100**	**127**	**100**	**118**	**100**	**493**	**100**

1 Region of birth from the Australian Bureau of Statistics.

Table 7 Number and percentage of HBV infection among first time donors, 2008-2011, by exposure category and sex

	2008		2009		2010		2011		Total (2008-2011)			
Exposure categories	**Male**	**Female**	**Male**	**Female**	**Male**	**Female**	**Male**	**Female**	**Male**	**Female**	**Total**	**%**
Ethnicity/Country of birth	66	39	63	32	62	34	56	32	247	137	384	87.1
Intravenous drug user	0	0	1	0	0	0	0	0	1	0	1	0.2
Tattoo/Piercing	1	0	1	1	0	0	1	1	3	2	5	1.1
Partners with any risks or known to be positive	1	0	2	2	1	0	1	0	5	2	7	1.6
Male-to-male sexual contact	0	0	0	0	0	0	0	0	0	0	0	0.0
Exposure in health care setting	0	0	1	2	0	0	0	0	1	2	3	0.7
Engaged in sex work	0	0	0	0	0	0	0	0	0	0	0	0.0
Blood or tissue recipient	0	2	1	1	2	1	0	0	3	4	7	1.6
Household contact	0	0	3	4	0	0	0	0	3	4	7	1.6
Other blood to blood contact	0	0	1	0	0	1	0	0	1	1	2	0.5
Other	1	0	1	0	0	0	1	0	3	0	3	0.7
No risk factors identified	0	0	1	0	1	1	0	0	2	1	3	0.7
Not reported	3	3	1	0	3	2	6	1	13	6	19	4.3
Total	**72**	**44**	**76**	**42**	**69**	**39**	**65**	**34**	**282**	**159**	**441**	**100**

Table 8 Number and percentage of HBV infection among repeat donors, 2008-2011, by exposure category and sex

	2008		2009		2010		2011		Total (2008-2011)			
Exposure categories	**Male**	**Female**	**Male**	**Female**	**Male**	**Female**	**Male**	**Female**	**Male**	**Female**	**Total**	**%**
Ethnicity/Country of birth	1	2	0	1	9[1]	1	10[1]	2	20	6	26	50.0
Intravenous drug user	0	0	1	1	1	0	0	0	2	1	3	5.8
Tattoo/Piercing	0	0	0	0	1	0	0	1	1	1	2	3.8
Partners with any risks or known to be positive	2	0	2	0	3	1	1	1	8	2	10	19.2
Male-to-male sexual contact	0	0	0	0	0	0	0	0	0	0	0	0.0
Exposure in health care setting	2	0	0	0	1	1	1	0	4	1	5	9.6
Engaged in sex work	0	0	0	0	0	0	0	0	0	0	0	0.0
Blood or tissue recipient	0	0	0	0	0	0	0	0	0	0	0	0.0
Household contact	0	0	0	1	0	0	0	0	0	1	1	1.9
Other blood to blood contact	0	0	0	0	0	1	0	0	0	1	1	1.9
Other	0	0	0	0	0	0	2	0	2	0	2	3.8
No risk factors identified	1	0	0	0	0	0	0	1	1	1	2	3.8
Not reported	0	0	0	0	0	0	0	0	0	0	0	0.0
Total	**6**	**2**	**3**	**3**	**15**	**4**	**14**	**5**	**38**	**14**	**52**	**100**

1 The increase is attributed to the introduction of HBV NAT which identified chronic occult HBV cases among repeat donors

Table 9 Number and rate[1] of HCV infection among first time donors, 2005-2011, by state/territory and year of donation

	2005			2006			2007			2008		
State/ Territory	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**
NSW/ACT	42 479	48	113.00	44 499	35	78.65	51 427	34	66.11	48 607	50	102.87
NT	1 141	1	87.64	823	2	243.01	759	0	0.00	815	0	0.00
QLD	26 988	35	129.69	27 873	23	82.52	28 575	31	108.49	29 498	23	77.97
SA	9 752	2	20.51	11 457	6	52.37	10 886	7	64.30	15 908	7	44.00
TAS	3 484	4	114.81	2 899	2	68.99	2 650	1	37.74	3 936	4	101.63
VIC	19 346	15	77.54	22 016	24	109.01	23 172	25	107.89	30 286	18	59.43
WA	9 087	14	154.07	11 116	6	53.98	11 292	7	61.99	11 307	4	35.38
Total	**112 277**	**119**	**105.99**	**120 683**	**98**	**81.20**	**128 761**	**105**	**81.55**	**140 357**	**106**	**75.52**

	2009			2010			2011			Total 2005-2011		
State/ Territory	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Prevalence**	**Donations**	**Positive**	**Prevalence**
NSW/ACT	51 821	46	88.77	48 130	37	76.88	51 528	30	58.22	338 491	280	82.72
NT	965	1	103.63	799	1	125.16	772	0	0.00	6 074	5	82.32
QLD	28 889	13	45.00	28 097	12	42.71	28 839	13	45.08	198 759	150	75.47
SA	11 400	10	87.72	9 284	7	75.40	10 164	4	39.35	78 851	43	54.53
TAS	3 736	4	107.07	3 222	1	31.04	3 587	1	27.88	23 514	17	72.30
VIC	34 133	17	49.81	25 820	14	54.22	31 286	12	38.36	186 059	125	67.18
WA	12 387	10	80.73	11 149	3	26.91	10 992	8	72.78	77 330	52	67.24
Total	**143 331**	**101**	**70.47**	**126 501**	**75**	**59.29**	**137 168**	**68**	**49.57**	**909 078**	**672**	**73.92**

1 Rate per 100 000 first time donations

Table 10 Number and rate[1] of HCV infection among repeat donors, 2005-2011, by state/territory and year of donation

	2005			2006			2007			2008		
State/ Territory	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**
NSW/ACT	311 513	1	0.32	333 250	1	0.30	338 173	7	2.07	339 062	11	3.24
NT	8 862	0	0.00	8 496	1	11.77	10 214	0	0.00	11 166	0	0.00
QLD	205 398	2	0.97	216 496	4	1.85	209 556	3	1.43	226 726	8	3.53
SA	93 172	2	2.15	107 934	2	1.85	114 618	0	0.00	118 476	2	1.69
TAS	24 577	0	0.00	28 726	0	0.00	28 019	1	3.57	33 321	0	0.00
VIC	225 332	1	0.44	238 684	1	0.42	252 340	3	1.19	259 052	2	0.77
WA	101 063	2	1.98	99 376	0	0.00	109 425	2	1.83	113 274	1	0.88
Total	**969 917**	**8**	**0.82**	**1 032 962**	**9**	**0.87**	**1 062 345**	**16**	**1.51**	**1 101 077**	**24**	**2.18**

	2009			2010			2011			Total 2005-2011		
State/Territory	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**
NSW/ACT	372 806	6	1.61	380 014	3	0.79	390 455	3	0.77	2 132 058	32	1.50
NT	11 158	0	0.00	10 470	0	0.00	10 782	1	9.27	62 654	2	3.19
QLD	242 001	9	3.72	243 837	4	1.64	245 975	3	1.22	1 373 516	33	2.40
SA	126 855	4	3.15	123 587	0	0.00	124 199	1	0.81	700 913	11	1.57
TAS	37 274	1	2.68	41 484	0	0.00	44 661	0	0.00	209 338	2	0.96
VIC	276 835	7	2.53	278 897	2	0.72	288 085	2	0.69	1 580 565	18	1.14
WA	118 327	0	0.00	120 646	1	0.83	121 057	3	2.48	683 798	9	1.32
Total	**1 185 256**	**27**	**2.28**	**1 198 935**	**10**	**0.83**	**1 225 214**	**13**	**1.06**	**6 742 842**	**107**	**1.59**

1 Rate per 100 000 repeat donations

Table 11 Number and percentage of donors with HCV infection, 2008-2011, by year of donation, sex and age group

	Year of donation											
	2008		2009		2010		2011		2008-2011			
Donor status	**M**	**F**	**M**	**F**	**M**	**F**	**M**	**F**	**M**	**F**	**Total**	**%**
First time donors												
<20 years	3	2	0	3	6	0	2	1	11	6	17	4.0
20-29 years	14	6	10	4	6	3	8	6	38	19	57	13.5
30-39 years	7	4	9	2	9	5	11	2	36	13	49	11.6
40-49 years	17	14	12	13	12	7	12	4	53	38	91	21.5
50-59 years	10	16	14	12	9	8	6	5	39	41	80	18.9
60 years and above	2	2	2	2	0	2	1	1	5	7	12	2.8
Repeat donors												
<20 years	1	0	0	0	1	0	0	0	2	0	2	0.5
20-29 years	1	1	1	3	1	1	1	0	4	5	9	2.1
30-39 years	3	2	3	0	1	2	0	0	7	4	11	2.6
40-49 years	13	3	11	3	3	1	5	2	32	9	41	9.7
50-59 years	9	3	9	7	5	2	8	5	31	17	48	11.3
60 years and above	0	1	1	1	1	1	1	0	3	3	6	1.4
Total	**80**	**54**	**72**	**50**	**54**	**32**	**55**	**26**	**261**	**162**	**423**	**100**

Table 12 Number and percentage of donors with HCV infection, 2008-2011, by year of donation and region of birth[1]

	2008		2009		2010		2011		2008-2011	
Region of birth	**Number**	**%**	**Number**	**%**	**Number**	**%**	**Number**	**%**	**Number**	**%**
Australia	85	63	90	74	61	71	51	63	287	68
Overseas born										
Other Oceania	*3*	*2*	*4*	*3*	*2*	*2*	*4*	*5*	*13*	*3*
United Kingdom and Ireland	*10*	*7*	*5*	*4*	*2*	*2*	*3*	*4*	*20*	*5*
Other Europe	*8*	*6*	*6*	*5*	*5*	*6*	*2*	*2*	*21*	*5*
Middle East/North Africa	*3*	*2*	*3*	*2*	*1*	*1*	*0*	*0*	*7*	*2*
Sub-Saharan Africa	*1*	*1*	*1*	*1*	*1*	*1*	*0*	*0*	*3*	*1*
South East Asia	*6*	*4*	*7*	*6*	*2*	*2*	*11*	*14*	*26*	*6*
Southern and Central Asia	*7*	*5*	*4*	*3*	*4*	*5*	*3*	*4*	*18*	*4*
North America	*1*	*1*	*0*	*0*	*1*	*1*	*1*	*1*	*3*	*1*
South/Central America and the Caribbean	*0*	*0*	*1*	*1*	*2*	*2*	*0*	*0*	*3*	*1*
Total with a reported country of birth	**124**	**93**	**121**	**99**	**81**	**94**	**75**	**93**	**401**	**95**
Not reported	**10**	**7**	**1**	**1**	**5**	**6**	**6**	**7**	**22**	**5**
Total	**134**	**100**	**122**	**100**	**86**	**100**	**81**	**100**	**423**	**100**

1 Region of birth from the Australian Bureau of Statistics.

Table 13 Number and percentage of HCV infection among first time donors, 2008-2011, by exposure category and sex

	2008		2009		2010		2011		Total (2008-2011)			
Exposure categories	**Male**	**Female**	**Male**	**Female**	**Male**	**Female**	**Male**	**Female**	**Male**	**Female**	**Total**	**%**
Ethnicity/Country of birth	9	8	7	2	8	2	10	1	34	13	47	15.4
Intravenous drug user	6	13	19	10	10	4	7	2	42	29	71	23.2
Tattoo/Piercing	15	10	5	9	8	7	8	3	36	29	65	21.2
Partners with any risks or known to be positive	4	2	1	4	1	2	1	1	7	9	16	5.2
Male-to-male sexual contact	0	0	0	0	0	0	0	0	0	0	0	0.0
Exposure in health care setting	2	1	5	1	1	1	0	2	8	5	13	4.2
Engaged in sex work	0	0	0	1	0	0	0	0	0	1	1	0.3
Blood or tissue recipient	5	4	7	6	2	5	5	2	19	17	36	11.8
Household contact	3	4	2	2	5	2	1	4	11	12	23	7.5
Other blood to blood contact	3	0	0	0	2	0	3	2	8	2	10	3.3
Other	2	0	1	0	2	0			5	0	5	1.6
No risk factors identified	1	0	0	1	1	0	2	0	4	1	5	1.6
Not reported	3	2	0	0	2	2	3	2	8	6	14	4.6
Total	**53**	**44**	**47**	**36**	**42**	**25**	**40**	**19**	**182**	**124**	**306**	**100**

Table 14 Number and percentage of HCV infection among repeat donors, 2008-2011, by exposure category and sex

	2008		2009		2010		2011		Total (2008-2011)			
Exposure categories	**Male**	**Female**	**Male**	**Female**	**Male**	**Female**	**Male**	**Female**	**Male**	**Female**	**Total**	**%**
Ethnicity/Country of birth	0	0	0	0	0	0	0	0	0	0	0	0.0
Intravenous drug user	12	3	9	4	1	1	7	1	29	9	38	32.5
Tattoo/Piercing	2	3	4	4	2	1	3	2	11	10	21	17.9
Partners with any risks or known to be positive	1	2	1	2	1	2	0	0	3	6	9	7.7
Male-to-male sexual contact	0	0	0	0	0	0	0	0	0	0	0	0.0
Exposure in health care setting	1	0	1	1	1	1	0	2	3	4	7	6.0
Engaged in sex work	0	0	0	0	0	0	0	0	0	0	0	0.0
Blood or tissue recipient	0	1	5	1	2	1	0	2	7	5	12	10.3
Household contact	3	1	0	0	1	0	2	0	6	1	7	6.0
Other blood to blood contact	2	0	2	0	0	0	0	0	4	0	4	3.4
Other	2	0	0	0	1	0	0	0	3	0	3	2.6
No risk factors identified	1	1	2	2	1	1	0	0	4	4	8	6.8
Not reported	4	0	0	0	0	1	3	0	7	1	8	6.8
Total	**28**	**11**	**24**	**14**	**10**	**8**	**15**	**7**	**77**	**40**	**117**	**100**

Table 15 Number and rate[1] of HIV infection among first time donors, 2005-2011, by state/territory and year of donation

	2005			2006			2007			2008		
State/ Territory	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**
NSW/ACT	42 479	0	0.00	44 499	1	2.25	51 427	1	1.94	48 607	1	2.06
NT	1 141	0	0.00	823	0	0.00	759	0	0.00	815	0	0.00
QLD	26 988	0	0.00	27 873	1	3.59	28 575	0	0.00	29 498	3	10.17
SA	9 752	0	0.00	11 457	0	0.00	10 886	0	0.00	15 908	0	0.00
TAS	3 484	0	0.00	2 899	0	0.00	2 650	0	0.00	3 936	0	0.00
VIC	19 346	0	0.00	22 016	0	0.00	23 172	1	4.32	30 286	1	3.30
WA	9 087	0	0.00	11 116	0	0.00	11 292	1	8.86	11 307	0	0.00
Total	**112 277**	**0**	**0.00**	**120 683**	**2**	**1.66**	**128 761**	**3**	**2.33**	**140 357**	**5**	**3.56**

	2009			2010			2011			Total 2005-2011		
State/ Territory	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Prevalence**	**Donations**	**Positive**	**Prevalence**
NSW/ACT	51 821	0	0.00	48 130	1	2.08	51 528	1	1.94	338 491	5	1.48
NT	965	0	0.00	799	0	0.00	772	0	0.00	6 074	0	0.00
QLD	28 889	0	0.00	28 097	2	7.12	28 839	2	6.94	198 759	8	4.02
SA	11 400	0	0.00	9 284	0	0.00	10 164	0	0.00	78 851	0	0.00
TAS	3 736	0	0.00	3 222	0	0.00	3 587	0	0.00	23 514	0	0.00
VIC	34 133	1	2.93	25 820	0	0.00	31 286	0	0.00	186 059	3	1.61
WA	12 387	0	0.00	11 149	0	0.00	10 992	1	9.10	77 330	2	2.59
Total	**143 331**	**1**	**0.70**	**126 501**	**3**	**2.37**	**137 168**	**4**	**2.92**	**909 078**	**18**	**1.98**

1 Rate per 100 000 first time donations

Table 16 Number and rate[1] of HIV infection among repeat donors, 2005-2011, by state/territory and year of donation

	2005			2006			2007			2008		
State/ Territory	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**
NSW/ACT	311 513	1	0.32	333 250	0	0.00	338 173	0	0.00	339 062	1	0.29
NT	8 862	0	0.00	8 496	0	0.00	10 214	0	0.00	11 166	0	0.00
QLD	205 398	0	0.00	216 496	0	0.00	209 556	1	0.48	226 726	1	0.44
SA	93 172	0	0.00	107 934	1	0.93	114 618	1	0.87	118 476	0	0.00
TAS	24 577	0	0.00	28 726	0	0.00	28 019	0	0.00	33 321	0	0.00
VIC	225 332	1	0.44	238 684	0	0.00	252 340	0	0.00	259 052	3	1.16
WA	101 063	0	0.00	99 376	0	0.00	109 425	0	0.00	113 274	0	0.00
Total	**969 917**	**2**	**0.21**	**1 032 962**	**1**	**0.10**	**1 062 345**	**2**	**0.19**	**1 101 077**	**5**	**0.45**

	2009			2010			2011			Total 2005-2011		
State/ Territory	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**
NSW/ACT	372 806	0	0.00	380 014	1	0.26	390 455	0	0.00	2 132 024	3	0.14
NT	11 158	0	0.00	10 470	0	0.00	10 782	1	9.27	62 652	1	1.60
QLD	242 001	2	0.83	243 837	2	0.82	245 975	1	0.41	1 373 494	7	0.51
SA	126 855	0	0.00	123 587	0	0.00	124 199	0	0.00	700 907	2	0.29
TAS	37 274	0	0.00	41 484	0	0.00	44 661	0	0.00	209 336	0	0.00
VIC	276 835	0	0.00	278 897	1	0.36	288 085	1	0.35	1 580 541	6	0.38
WA	118 327	0	0.00	120 646	0	0.00	121 057	0	0.00	683 792	0	0.00
Total	**1 185 256**	**2**	**0.17**	**1 198 935**	**4**	**0.33**	**1 225 214**	**3**	**0.24**	**6 742 746**	**19**	**0.28**

1 Rate per 100 000 repeat donations

Table 17 Number and percentage of donors with HIV infection, 2008-2011, by year of donation, sex and age group

	Year of donation											
	2008		2009		2010		2011		2008-2011			
Donor status	**M**	**F**	**M**	**F**	**M**	**F**	**M**	**F**	**M**	**F**	**Total**	**%**
First time donors												
<20 years	1	0	0	0	0	0	0	0	1	0	1	3.7
20-29 years	0	0	1	0	0	0	3	0	4	0	4	14.8
30-39 years	3	0	0	0	1	0	0	0	4	0	4	14.8
40-49 years	0	0	0	0	0	0	1	0	1	0	1	3.7
50-59 years	1	0	0	0	0	0	0	0	1	0	1	3.7
60 years and above	0	0	0	0	0	0	0	0	0	0	0	0.0
Repeat donors												
<20 years	0	0	0	0	0	0	0	0	0	0	0	0.0
20-29 years	2	0	0	0	1	1	0	1	3	2	5	18.5
30-39 years	0	1	0	1	2	0	0	0	2	2	4	14.8
40-49 years	1	1	0	0	0	0	0	1	1	2	3	11.1
50-59 years	0	0	1	0	1	1	0	0	2	1	3	11.1
60 years and above	0	0	0	0	0	0	1	0	1	0	1	3.7
Total	**8**	**2**	**2**	**1**	**5**	**2**	**5**	**2**	**20**	**7**	**27**	**100**

Table 18 Number and percentage of donors with HIV infection, 2008-2011, by year of donation and region of birth[1]

	2008		2009		2010		2011		2008-2011	
Region of birth	**Number**	**%**	**Number**	**%**	**Number**	**%**	**Number**	**%**	**Number**	**%**
Australia	7	70	2	67	6	86	2	29	17	63
Overseas born										
Other Oceania	*0*	*0*	*0*	*0*	*1*	*14*	*0*	*0*	*1*	*4*
United Kingdom and Ireland	*1*	*10*	*0*	*0*	*0*	*0*	*1*	*14*	*2*	*7*
Other Europe	*0*	*0*	*0*	*0*	*0*	*0*	*1*	*14*	*1*	*4*
Middle East/North Africa	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*
Sub-Saharan Africa	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*
South East Asia	*1*	*10*	*1*	*33*	*0*	*0*	*1*	*14*	*3*	*11*
Southern and Central Asia	*1*	*10*	*0*	*0*	*0*	*0*	*0*	*0*	*1*	*4*
North America	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*
South/Central America and the Caribbean	*0*	*0*	*0*	*0*	*0*	*0*	*1*	*14*	*1*	*4*
Total with a reported country of birth	**10**	**100**	**3**	**100**	**7**	**100**	**6**	**86**	**26**	**96**
Not reported	**0**	**0**	**0**	**0**	**0**	**0**	**1**	**14**	**1**	**4**
Total	**10**	**100**	**3**	**100**	**7**	**100**	**7**	**100**	**27**	**100**

1 Region of birth from the Australian Bureau of Statistics

Table 19 Number and percentage of HIV infection among first time donors, 2008-2011, by exposure category and sex

	2008		2009		2010		2011		Total (2008-2011)			
Exposure categories	**Male**	**Female**	**Male**	**Female**	**Male**	**Female**	**Male**	**Female**	**Male**	**Female**	**Total**	**%**
Ethnicity/Country of birth	0	0	0	0	0	0	0	0	0	0	0	0.0
Intravenous drug user	0	0	0	0	0	0	0	0	0	0	0	0.0
Tattoo/Piercing	1	0	0	0	0	0	0	0	1	0	1	9.1
Partners with any risks or known to be positive	1	0	0	0	1	0	3	0	5	0	5	45.5
Male-to-male sexual contact	3	0	1	0	0	0	1	0	5	0	5	45.5
Exposure in health care setting	0	0	0	0	0	0	0	0	0	0	0	0.0
Engaged in sex work	0	0	0	0	0	0	0	0	0	0	0	0.0
Blood or tissue recipient	0	0	0	0	0	0	0	0	0	0	0	0.0
Household contact	0	0	0	0	0	0	0	0	0	0	0	0.0
Other blood to blood contact	0	0	0	0	0	0	0	0	0	0	0	0.0
Other	0	0	0	0	0	0	0	0	0	0	0	0.0
No risk factors identified	0	0	0	0	0	0	0	0	0	0	0	0.0
Not reported	0	0	0	0	0	0	0	0	0	0	0	0.0
Total	**5**	**0**	**1**	**0**	**1**	**0**	**4**	**0**	**11**	**0**	**11**	**100**

Table 20 Number and percentage of HIV infection among repeat donors, 2008-2011, by exposure category and sex

	2008		2009		2010		2011		Total (2008-2011)			
Exposure categories	**Male**	**Female**	**Male**	**Female**	**Male**	**Female**	**Male**	**Female**	**Male**	**Female**	**Total**	**%**
Ethnicity/Country of birth	0	0	0	0	0	0	0	0	0	0	0	0.0
Intravenous drug user	0	0	0	0	0	0	0	0	0	0	0	0.0
Tattoo/Piercing	0	0	0	0	0	0	0	0	0	0	0	0.0
Partners with any risks or known to be positive	0	2	0	1	2	2	0	1	2	6	8	50.0
Male-to-male sexual contact	3	0	0	0	1	0	0	0	4	0	4	25.0
Exposure in health care setting	0	0	0	0	0	0	0	0	0	0	0	0.0
Engaged in sex work	0	0	0	0	0	0	0	0	0	0	0	0.0
Blood or tissue recipient	0	0	0	0	0	0	0	0	0	0	0	0.0
Household contact	0	0	0	0	0	0	0	0	0	0	0	0.0
Other blood to blood contact	0	0	0	0	1	0	1	0	2	0	2	12.5
Other	0	0	0	0	0	0	0	0	0	0	0	0.0
No risk factors identified	0	0	1	0	0	0	0	0	1	0	1	6.3
Not reported	0	0	0	0	0	0	0	1	0	1	1	6.3
Total	**3**	**2**	**1**	**1**	**4**	**2**	**1**	**2**	**9**	**7**	**16**	**100**

Table 21 Number and rate[1] of HTLV infection among first time donors, 2005-2011, by state/territory and year of donation

	2005			2006			2007			2008		
State/ Territory	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**
NSW/ACT	42 479	0	0.00	44 499	1	2.25	51 427	1	1.94	48 607	0	0.00
NT	1 141	0	0.00	823	0	0.00	759	0	0.00	815	0	0.00
QLD	26 988	1	3.71	27 873	1	3.59	28 575	0	0.00	29 498	0	0.00
SA	9 752	0	0.00	11 457	0	0.00	10 886	0	0.00	15 908	1	6.29
TAS	3 484	0	0.00	2 899	0	0.00	2 650	0	0.00	3 936	0	0.00
VIC	19 346	0	0.00	22 016	1	4.54	23 172	0	0.00	30 286	4	13.21
WA	9 087	0	0.00	11 116	0	0.00	11 292	0	0.00	11 307	2	17.69
Total	**112 277**	**1**	**0.89**	**120 683**	**3**	**2.49**	**128 761**	**1**	**0.78**	**140 357**	**7**	**4.99**

	2009			2010			2011			Total 2005-2011		
State/ Territory	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Prevalence**	**Donations**	**Positive**	**Prevalence**
NSW/ACT	51 821	2	3.86	48 130	0	0.00	51 528	1	1.94	338 491	5	1.48
NT	965	0	0.00	799	0	0.00	772	0	0.00	6 074	0	0.00
QLD	28 889	2	6.92	28 097	1	3.56	28 839	0	0.00	198 759	5	2.52
SA	11 400	1	8.77	9 284	0	0.00	10 164	1	9.84	78 851	3	3.80
TAS	3 736	0	0.00	3 222	0	0.00	3 587	0	0.00	23 514	0	0.00
VIC	34 133	2	5.86	25 820	0	0.00	31 286	0	0.00	186 059	7	3.76
WA	12 387	2	16.15	11 149	0	0.00	10 992	1	9.10	77 330	5	6.47
Total	**143 331**	**9**	**6.28**	**126 501**	**1**	**0.79**	**137 168**	**3**	**2.19**	**909 078**	**25**	**2.75**

1 Rate per 100 000 first time donations

Table 22 Number and percentage of donors with HTLV infection, 2008-2011, by year of donation, sex and age group

	Year of donation											
	2008		2009		2010[1]		2011		2008-2011			
Donor status	**M**	**F**	**M**	**F**	**M**	**F**	**M**	**F**	**M**	**F**	**Total**	**%**
First time donors												
<20 years	0	0	1	0	0	0	0	0	1	0	1	5.0
20-29 years	0	1	1	1	0	0	0	1	1	3	4	20.0
30-39 years	3	0	3	0	0	0	0	0	6	0	6	30.0
40-49 years	1	2	0	0	0	0	1	1	2	3	5	25.0
50-59 years	0	0	1	1	0	0	0	0	1	1	2	10.0
60 years and above	0	0	0	0	0	1	0	0	0	1	1	5.0
Repeat donors												
<20 years	0	0	0	0	0	0	0	0	0	0	0	0.0
20-29 years	0	0	0	0	0	0	0	0	0	0	0	0.0
30-39 years	0	0	0	0	0	0	0	0	0	0	0	0.0
40-49 years	0	0	0	0	0	0	0	0	0	0	0	0.0
50-59 years	0	0	0	1	0	0	0	0	0	1	1	5.0
60 years and above	0	0	0	0	0	0	0	0	0	0	0	0.0
Total	**4**	**3**	**6**	**3**	**0**	**1**	**1**	**2**	**11**	**9**	**20**	**100**

1 Age of one HTLV positive repeat male donor in 2010 was unknown

Table 23 Number and percentage of donors with HTLV infection, 2008-2011, by year of donation and region of birth[1]

	2008		2009		2010		2011		2008-2011	
Region of birth	**Number**	**%**	**Number**	**%**	**Number**	**%**	**Number**	**%**	**Number**	**%**
Australia	0	0	3	33	0	0	0	0	3	14
Overseas born										
Other Oceania	*1*	*14*	*0*	*0*	*0*	*0*	*0*	*0*	*1*	*5*
United Kingdom and Ireland	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*
Other Europe	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*
Middle East/North Africa	*1*	*14*	*0*	*0*	*0*	*0*	*1*	*33*	*2*	*10*
Sub-Saharan Africa	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*
South East Asia	*0*	*0*	*1*	*11*	*0*	*0*	*0*	*0*	*1*	*5*
Southern and Central Asia	*5*	*71*	*2*	*22*	*0*	*0*	*0*	*0*	*7*	*33*
North America	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*0*
South/Central America and the Caribbean	*0*	*0*	*0*	*0*	*1*	*50*	*0*	*0*	*1*	*5*
Total with a reported country of birth	**7**	**100**	**6**	**67**	**1**	**50**	**1**	**33**	**15**	**71**
Not reported	**0**	**0**	**3**	**33**	**1**	**50**	**2**	**67**	**6**	**29**
Total	**7**	**100**	**9**	**100**	**2**	**100**	**3**	**100**	**21**	**100**

1 Region of birth from the Australian Bureau of Statistics

Table 24 Number and percentage of HTLV infection among first time donors, 2008-2011, by exposure category and sex

	2008		2009		2010		2011		Total (2008-2011)			
Exposure categories	**Male**	**Female**	**Male**	**Female**	**Male**	**Female**	**Male**	**Female**	**Male**	**Female**	**Total**	**%**
Ethnicity/Country of birth	4	2	3	1	0	1	1	1	8	5	13	81.3
Intravenous drug user	0	0	0	0	0	0	0	0	0	0	0	0.0
Tattoo/Piercing	0	0	0	0	0	0	0	1	0	1	1	6.3
Partners with any risks or known to be positive	0	1	0	0	0	0	0	0	0	1	1	6.3
Male-to-male sexual contact	0	0	0	0	0	0	0	0	0	0	0	0.0
Exposure in health care setting	0	0	0	0	0	0	0	0	0	0	0	0.0
Engaged in sex work	0	0	0	0	0	0	0	0	0	0	0	0.0
Blood or tissue recipient	0	0	0	1	0	0	0	0	0	1	1	6.3
Household contact	0	0	1	0	0	0	0	0	1	0	1	6.3
Other blood to blood contact	0	0	0	0	0	0	0	0	0	0	0	0.0
Other	0	0	0	0	0	0	0	0	0	0	0	0.0
No risk factors identified	0	0	0	0	0	0	0	0	0	0	0	0.0
Not reported	0	0	2	0	0	0	0	0	2	0	2	12.5
Total	**4**	**3**	**6**	**2**	**0**	**1**	**1**	**2**	**11**	**8**	**19**	**119**

Table 25 Number and rate[1] of active syphilis among first time donors, 2005-2011, by state/territory and year of donation

	2005			2006			2007			2008		
State/ Territory	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**
NSW/ACT	42 479	0	0.00	44 499	0	0.00	51 427	0	0.00	48 607	0	0.00
NT	1 141	0	0.00	823	0	0.00	759	0	0.00	815	1	122.70
QLD	26 988	0	0.00	27 873	1	3.59	28 575	1	3.50	29 498	0	0.00
SA	9 752	0	0.00	11 457	1	8.73	10 886	0	0.00	15 908	0	0.00
TAS	3 484	0	0.00	2 899	0	0.00	2 650	0	0.00	3 936	0	0.00
VIC	19 346	0	0.00	22 016	0	0.00	23 172	0	0.00	30 286	0	0.00
WA	9 087	0	0.00	11 116	0	0.00	11 292	0	0.00	11 307	2	17.69
Total	**112 277**	**0**	**0.00**	**120 683**	**2**	**1.66**	**128 761**	**1**	**0.78**	**140 357**	**3**	**2.14**

	2009			2010			2011			Total 2005-2011		
State/ Territory	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Prevalence**	**Donations**	**Positive**	**Prevalence**
NSW/ACT	51 821	0	0.00	48 130	0	0.00	51 528	0	0.00	338 491	0	0.00
NT	965	1	103.63	799	0	0.00	772	2	259.07	6 074	4	65.85
QLD	28 889	1	3.46	28 097	2	7.12	28 839	1	3.47	198 759	6	3.02
SA	11 400	0	0.00	9 284	2	21.54	10 164	1	9.84	78 851	4	5.07
TAS	3 736	0	0.00	3 222	0	0.00	3 587	0	0.00	23 514	0	0.00
VIC	34 133	1	2.93	25 820	1	3.87	31 286	1	3.20	186 059	3	1.61
WA	12 387	1	8.07	11 149	0	0.00	10 992	2	18.20	77 330	5	6.47
Total	**143 331**	**4**	**2.79**	**126 501**	**5**	**3.95**	**137 168**	**7**	**5.10**	**909 078**	**22**	**2.42**

1 Rate per 100 000 first time donations

Table 26 Number and rate[1] of active syphilis among repeat donors, 2005-2011, by state/territory and year of donation

	2005			2006			2007			2008		
State/ Territory	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**
NSW/ACT	311 513	0	0.00	333 250	0	0.00	338 173	0	0.00	339 062	1	0.29
NT	8 862	0	0.00	8 496	0	0.00	10 214	0	0.00	11 166	0	0.00
QLD	205 398	0	0.00	216 496	0	0.00	209 556	0	0.00	226 726	0	0.00
SA	93 172	0	0.00	107 934	0	0.00	114 618	0	0.00	118 476	0	0.00
TAS	24 577	0	0.00	28 726	0	0.00	28 019	0	0.00	33 321	1	3.00
VIC	225 332	0	0.00	238 684	0	0.00	252 340	1	0.40	259 052	0	0.00
WA	101 063	0	0.00	99 376	0	0.00	109 425	0	0.00	113 274	1	0.88
Total	**969 917**	**0**	**0.00**	**1 032 962**	**0**	**0.00**	**1 062 345**	**1**	**0.09**	**1 101 077**	**3**	**0.27**

	2009			2010			2011			Total 2005-2011		
State/ Territory	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**	**Donations**	**Positive**	**Rate**
NSW/ACT	372 806	0	0.00	380 014	1	0.26	390 455	1	0.26	2 132 023	3	0.14
NT	11 158	1	8.96	10 470	1	9.55	10 782	0	0.00	62 652	2	3.19
QLD	242 001	1	0.41	243 837	1	0.41	245 975	0	0.00	1 373 494	2	0.15
SA	126 855	0	0.00	123 587	0	0.00	124 199	0	0.00	700 908	0	0.00
TAS	37 274	0	0.00	41 484	0	0.00	44 661	0	0.00	209 336	1	0.48
VIC	276 835	0	0.00	278 897	0	0.00	288 085	0	0.00	1 580 541	1	0.06
WA	118 327	1	0.85	120 646	0	0.00	121 057	0	0.00	683 792	2	0.29
Total	**1 185 256**	**3**	**0.25**	**1 198 935**	**3**	**0.25**	**1 225 214**	**1**	**0.08**	**6 742 746**	**11**	**0.16**

1 Rate per 100 000 repeat donations

Methodological notes

Age-specific rate

Age-specific rate is defined as the proportion of blood donors in a particular age group who have the infection, usually expressed per 100 000 donors in the specified age group. Age-specific rate was calculated as follows:

$$\text{Age-specific rate of HBV infection among donors aged 20-29 years} = \left(\frac{\text{Number of donors with HBV infection aged 20-29 years}}{\text{Total number of donors aged 20-29 years}} \right) \times 100\,000$$

Donor-years of observation

Data on interval between each donation by all donors who donated at least twice in 2008-2010 were available from the Blood Service database. For all donors with negative tests for transfusion-transmissible viral infections, donor-years of observation were calculated as the sum of all inter-donation intervals. For positive donors, donor-years of observation were calculated as the sum of all inter-donation intervals between the first negative and the positive donation.

Exposure categories

A single most important risk factor for each positive donor was identified using the primary risk factor data from the Blood Service risk factor database. The key exposure categories for positive donors were classified as follows:

1. Intravenous drug use (IDU)
2. Country of birth (COB)/Ethnicity
3. Partners with any risks or known to be positive
4. Engaged in sex work within the previous 12 months
5. Male-to-male sexual contact within the previous 12 months
6. Blood or tissue recipient
7. Tattoo or body piercing
8. Exposure in health care setting (both occupational and non-occupational)
9. Household contact
10. Other blood to blood contact
11. Others
12. No risk factors identified
13. Not reported

For a consistent comparison of the prevalence of major exposure categories between blood donors and the general population, *Partners with any risks or known to be positive*, *Engaged in sex work within the previous 12 months* and *Male-to-male sexual contact within the previous 12 months* were combined to create a broader risk category named *Sexual contact*. Thus, from the above thirteen key categories, the following exposure groups were established to match the main exposure groups in general population for each of the transfusion-transmissible infections.

The key exposure categories modified for comparison with general population were as follows:

1. Intravenous drug use (IDU)
2. Country of birth (COB)/Ethnicity
3. Sexual contact
    a. Partners with any risks or known to be positive
    b. Engaged in sex work within the previous 12 months
    c. Male-to-male sexual contact within the previous 12 months
4. Blood or tissue recipient
5. Tattoo or body piercing
6. Exposure in health care setting
7. Household contact
8. Other blood to blood contact
9. Others
10. No risk factors identified
11. Not reported

Please note that unlike general population the risk categories namely *Engaged in sex work and Male-to-male sexual contact* are time restricted for blood donors in Australia. Any history of engagement in sex work within the past 12 months and history of male-to-male sexual contact within the past 12 months are defined as the risk factors for transfusion-transmissible infections in blood donors.

Incidence

Incidence of transfusion-transmissible infection is defined as a rate per 100 000 donor-years of observation. It was calculated as follows:

$$\text{Incidence per 100 000 donor-years of observation} = \left(\frac{\text{Number of seroconverters}}{\text{Total donor-years of observation}} \right) \times 100\,000$$

Newly acquired infection

Newly acquired infection was defined as newly diagnosed infection with evidence of a previous negative or indeterminate test result.

Newly diagnosed infection

Newly diagnosed infection was defined as the first occasion of diagnosis in Australia.

Prevalence

Prevalence is defined as the number of positive donations per 100 000 donations. It was calculated as follows:

$$\text{Prevalence in first time donors} = \left(\frac{\text{Number of positive first time donations}}{\text{Total number of first time donations}} \right) \times 100\,000$$

$$\text{Prevalence in all donors} = \left(\frac{\text{Number of donations (both first time and repeat) positive for a TTI marker}}{\text{Total number of accepted donations (both first time and repeat)}} \right) \times 100\,000$$

Residual risk estimates

Estimates were derived based on minor refinement to the method described in earlier studies[31,32]. Briefly, viral point estimates are derived by determining the probability of an undetected 'window period' donation in a given time period. Three models are applied providing a median and upper and lower plausible estimate. The models essentially assess the rate of seroconversion (i.e. positive donors who have previously tested negative for the same marker) in the repeat donor (RD) population as a measure of viral incidence (i.e. early or acute infection). In order to incorporate the incidence in first time donors (FTD) (who have no previous testing at the Blood Service), one model uses a separate calculation whereas the other two use a correction factor for the RD incidence based on the proportion of NAT positive/antibody negative (i.e. NAT yield) donors in the FTD and RD populations respectively. Two models also incorporate the average inter-donation interval for all seroconverters (in days) between the positive result and previous negative result. The longer this interval for an individual donor, the less risk the donor was in the WP at the time of donation i.e. the inter-donation interval is inversely proportional to the risk.

The models assume that the risk of collecting blood from an infectious donor predominantly relates to them being in the WP (i.e. incident infection) and the best estimate of incidence is the rate of seroconversion in the RD population. While the assumption that WP donors account for the majority of risk seems to hold true for HIV, HCV and HTLV, HBV is problematic because of 'chronic' infection (i.e. HBsAg negative/anti-HBc positive). Whereas one model includes a correction factor for the incidence to compensate for chronic infection the other two do not. This is a potential confounder for HBV RR estimation with the relative impact dependent on the proportion of acute versus chronic HBV infection in the donor population.

The number of seroconverters for the 2009-2011 period used in the models is as shown in tables 4-7 for the appropriate virus. Further information is available at http://www.transfusion.com.au/adverse_events/risks/estimates

Statistical tests to analyse trends in transfusion-transmissible infections

Trends in prevalence and incidence of transfusion-transmissible infections were examined for the year 2011. Poisson regression analysis was used to calculate incidence rate ratios (IRRs) and their 95% confidence intervals. A p-value of less than 0.05 was considered as statistically significant.

Tabulated count data on the demographic characteristics (sex, age group, state/territory and year of donation) for all blood donors (both positive and negative donors) were retrieved for the year 2011. The association between demographic factors and presence of any transfusion-transmissible viral infections (HBV, HCV, HIV and HTLV) among Australian blood donors were assessed using multivariate Poisson regression model for each infection separately.

31 Seed CR, Kiely P, Keller AJ. *op. cit.* 2005

32 Seed Clive R, Cheng A, Ismay Susan L, Bolton Wayne V, Kiely P, Cobain Trevor J, et al. Assessing the accuracy of three viral risk models in predicting the outcome of implementing HIV and HCV NAT donor screening in Australia and the implications for future HBV NAT. *Transfusion*. 2002;42(10):1 365-72.

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