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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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*).

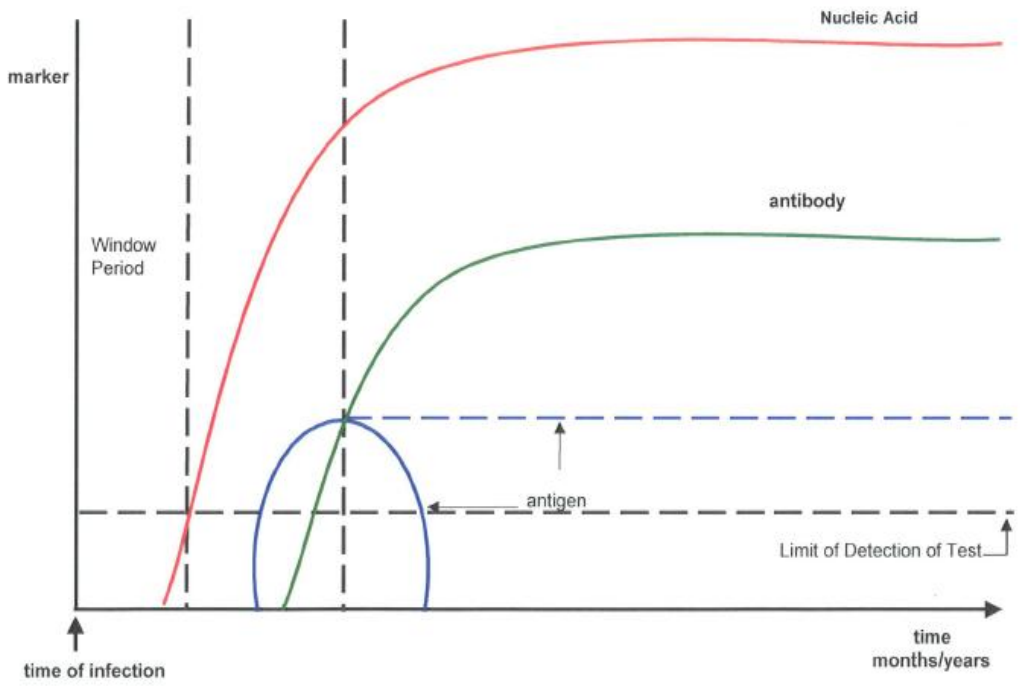
3.3.1 Window periods

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]

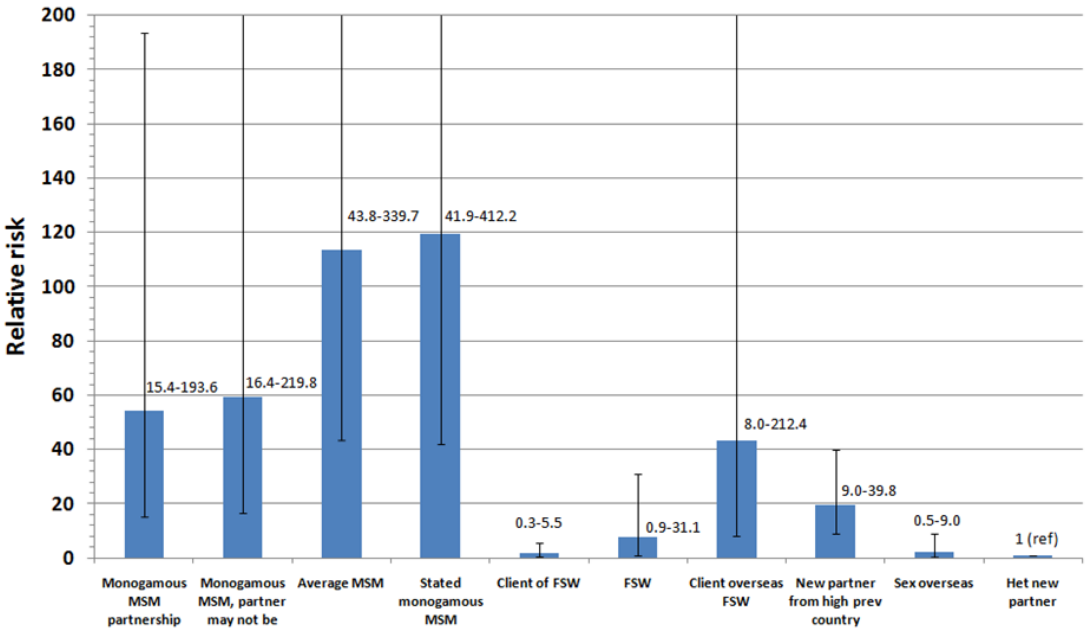
Variation in reported risk estimates across international studies is influenced by the variables included in different models and also reflects important differences in disease prevalence and incidence, screening tests used and process errors experienced across international blood services.

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
#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	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