Proposed changes to the Guidelines for the Selection of Blood Donors (GSBD) for sexual activity based risk factor deferral periods

1. Scope

Lifeblood proposes decreasing the twelve (12) month deferral period for donors with a sexual activity-based risk factor to three (3) months since last sexual contact.

Current guidelines

A 12-month deferral is applied to anyone reporting the following activities:

- for male donors: male-to-male sex
- for female donors: sex with a man who has ever had sex with a man
- for transgender donors: sexual contact with a male
- sex work
- sexual contact with a sex worker (male or female)
- overseas sexual contact with a resident of a HIV high prevalence country
- sexual contact with an injecting drug user (current or past)
- sexual contact with a partner known to be infected with a blood-borne virus (HIV, HBV, HCV or HTLV)

Proposed guidelines

Apply a 3-month deferral to anyone reporting the following activities:

- for male donors: male-to-male sex
- for female donors: sex with a man who has ever had sex with a man
- for transgender donors: sexual contact with a male
- sex work
- sexual contact with a sex worker (male or female)
- overseas sexual contact with a resident of a HIV high prevalence country
- sexual contact with an injecting drug user (current or past)
- sexual contact with a partner known to be infected with a blood-borne virus (HIV, HBV, HCV or HTLV)

This change will be implemented via changes to the *Guidelines for the Selection of Blood Donors* (GSBD) (SOP-00080), detailed in Appendix B.

Current standards

- Therapeutic Goods Order No. 88 (TGO 88) - Standards for donor selection, testing and minimising infectious disease transmission via therapeutic goods that are human blood and blood components, human tissues and human cellular therapy products - Part 3 section 9(4), table 1(k):
  - A donor whose sexual practices put them at increased risk of acquiring infectious diseases that can be transmitted by blood, cells or tissues - ineligible for 12 months from last contact.
- Therapeutic Goods Order No. 102 (TGO 102)/Council of Europe *Guide to the preparation, use and quality assurance of blood components*, 19th edition (CoE *Guide*) - Standards for selection of donors, Chapter 2, section 4, table 2.1:
  - Persons whose sexual behaviour puts them at a high risk of acquiring severe infectious diseases that can be transmitted by blood must be deferred permanently.
  - Current sexual partners of people with HIV must be deferred. Previous sexual partners of people with HIV are acceptable 12 months after the last sexual contact.

Submission structure

This submission is applicable to all blood components included in the Technical Master File, including clinical components and plasma for fractionation.

2. Establishing the context

Australian Red Cross Lifeblood has a responsibility to ensure that the risk to Australian blood recipients is as low as reasonably achievable. In this respect, Lifeblood has strict criteria on who is accepted to donate blood.

Currently a 12-month deferral period is applied from last contact for sexual activity-based risk factors including:

- for male donors: male-to-male sex
- for female donors: sex with a man who has ever had sex with a man
- for transgender donors: sexual contact with a male
- sex work
- sexual contact with a sex worker (male or female)
- overseas sexual contact with a resident of a HIV high prevalence country
- sexual contact with an injecting drug user (current or past)
- sexual contact with a partner known to be infected with a blood-borne virus (HIV, HBV, HCV or HTLV)

Other blood-borne viruses targeted by sexual activity-based deferrals include hepatitis B (HBV), hepatitis C (HCV) - including past or treated infection - and human T-lymphotropic virus (HTLV).

In 2012, an independently chaired review committee (*2012 Review*) on blood donor deferrals relating to sexual activity-based risk factors recommended a reduction in length for sexual activity-based deferrals from twelve to six months (https://www.donateblood.com.au/sites/default/files/blood_review_report_may_2012_electronic_version.pdf). Considering this recommendation and other supporting evidence for the policy change, Lifeblood (Australian Red Cross Blood Service at the time) submitted a proposal to the Therapeutic Goods Administration (TGA) in 2013. However, the proposal was not supported.

The TGA's response indicated a number of concerns, but particularly that HIV notifications among men having sex with men (MSM) - acknowledged by the *2012 Review* as representing the group with the highest transfusion-transmission risk - had been steadily increasing (although rates later reached a high point in 2014 before declining). Other concerns related to the lack of a significant increase in eligible donors and the accuracy of the Lifeblood estimate of "donor non-compliance" (i.e. failure to disclose information during assessment that would have resulted in deferral) among MSM, which at 0.23% [1] was substantially lower than other estimates that had been published at the time.

Excluding those countries with no specific deferral for male-to-male sex (e.g. Italy, Spain and Mexico), only three countries (Japan, Serbia and Lithuania - all 6 months) had a shorter deferral period than Australia at the time of the *2012 Review*, with the majority of countries having an indefinite deferral policy. Since then, a substantial number of countries have changed from indefinite deferral policies to finite deferral periods ranging from 3 to 12 months [2].

While the majority of those countries have moved to a 12-month deferral period, in November 2017 the UK became the first country to implement a 3-month deferral period for male-to-male sex following a comprehensive review conducted by a working group of their Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) [3]. This deferral period also applies to sex workers and their clients, sex with someone diagnosed with a confirmed HIV, HBV, HCV or HTLV infection, and sexual contact with a partner from a country with high HIV prevalence (defined as ≥1% of the adult population).

Subsequently Canada implemented a 3-month deferral period in June 2019, while the Netherlands, France and Denmark have all announced and/or implemented moves towards a 4-month deferral period. Most recently, in April 2020, the FDA has announced that US blood centres will be permitted to change the existing 12-month MSM deferral to 3 months

The progression of these international developments, together with continued improvements in screening for HIV and other relevant transfusion-transmissible infections (TTIs) and widespread public perception that the Lifeblood policy on MSM is discriminatory, prompted a direct request from the Council of Australian Governments (COAG) Health Council to review sexual activity-based deferral policies earlier than originally planned. As a result, the *2012 Review* committee (including 50% of its original membership) was re-convened in 2017 to re-examine all sexual activity-based deferrals with a primary focus on MSM.

The terms of reference (https://www.donateblood.com.au/sexual-activity-deferral-review/terms-reference) for the 2017 review committee (*2017 Review*) included a review of relevant local and international developments since the conclusion of the *2012 Review* in relation to the ongoing appropriateness of excluding donors on the basis of current and/or past sexual activity. Considering this, and in the context of ensuring the ongoing safety of blood and blood products provided in Australia, the committee was tasked with re-evaluating the recommendations of the *2012 Review*.

With respect to the current time-based donor deferral policies, the following evidence was considered by the committee:

- A literature review targeting new, relevant research published after the conclusion of the 2012 Review.
- Epidemiological data (both in the general Australian population and among blood donors) relating to the relevant sexually-transmissible TTIs.
- International policy developments, including relevant policy reviews (e.g. UK SaBTO review of donor deferrals [3]) and subsequent changes to MSM deferrals.
- Mathematical modelling conducted by Lifeblood to estimate the potential risk to Australia's blood supply associated with changing the Lifeblood deferral period for male-to-male sex from 12 months to 2, 3 or 6 months.

The *2017 Review* committee recommendations, along with the latest publications, relevant epidemiological data and international policy developments, were considered when formulating the Lifeblood recommendations.

Duration of deferral period

Lifeblood recommends a minimum time-based deferral period of three (3) months, based primarily on the following considerations:

- *The evolving impact of HIV PrEP (pre-exposure prophylaxis) amongst MSM.* The effectiveness of PrEP under trial conditions does not necessarily predict its real world impact following its PBS listing in Australia. It is reasonable to expect that medication compliance may vary from that observed under trial conditions. In addition, PrEP may affect the interpretation of HIV testing results. Using PrEP during early HIV infection can suppress viral load and delay the appearance of antibodies, thus potentially extending the window period for both nucleic acid testing (NAT) and serological testing [4]. PrEP has already been associated with an increase in other STIs - for example, syphilis - that are relevant to blood safety.
- *Hepatitis A virus (HAV) outbreaks have occurred in multiple states in which male-to-male sex was the predominant mode of transmission.* In the absence of HAV donation testing, a 3-month deferral period provides appropriate risk mitigation for hepatitis A among MSM.
- *Syphilis notifications are increasing in Australia, particularly in the MSM population.* The window period for the TPHA serological assay used by Lifeblood is not well defined, and its sensitivity is not as high as for other blood screening tests. The presence of syphilis spirochaetes in the bloodstream is greatest during primary and secondary syphilis, and there is evidence that the greatest risk of transmitting syphilis via blood transfusion is during the serological window period. A 3-month deferral period provides an appropriate safety margin considering the poorly defined TPHA window period and an incubation period that can be as long as 90 days.
- *Potential errors in memory recall.* A 3-month deferral period provides an appropriate safety margin considering that many donors will estimate the date of recent sexual contact events on a week-by-week or weekend-by-weekend basis.
- *Consistency with international practice and Australian public health guidelines for blood-borne virus exposure.* As noted above, the shortest blood donor deferral period applied for sexual activity risk factors is currently 3 months, implemented by the UK in November 2017 and Canada in June 2019. Three months is also the prescribed period for final testing of individuals with parenteral exposure to blood and body fluids (e.g. needlestick injuries) if the source is not cleared.
- *Consistency across all sexual activity-based deferral policies, including those for HTLV.* A 3-month deferral period will adequately cover the serological window period for HTLV testing.

Relevant sexual contact risks

Because the rationale for the required deferral period is the same for all relevant sexual activities - i.e. that the proposed deferral period is appropriate to cover the window period TTI risk - Lifeblood has included all

sexual activity risk factors in this submission. This will ensure that our deferral policies remain evidence-based and consistent across all types of sexual contact risk.

Lifeblood has considered the available evidence and proposes that the deferral period for donors with a sexual activity-based risk factor be decreased from twelve (12) months to three (3) months since the last sexual contact.

3. Epidemiology of increased transfusion-transmissible infection risk

Among pathogens that are both sexually transmissible and transfusion-transmissible, HIV is recognised as the highest concern for blood safety based on societal and political considerations as well as the clinical impact of HIV infection. Accordingly the blood safety "risk tolerability framework" assigns a tolerable risk threshold for HIV of 1 in 5 million per unit transfused, whereas a threshold of 1 in 1 million is tolerable for HCV, HBV, HTLV and syphilis.

The HIV epidemic in Australia is highly concentrated among MSM, who have by far the highest HIV prevalence of any group. The most recent annual surveillance report (published 2018, on 2017 data) from the Kirby Institute – Australia's pre-eminent research facility for HIV epidemiology – estimated that the prevalence of HIV infection in Australian MSM was 7.9%, while the prevalence of HIV among the general population was 0.14% [5]. Therefore the prevalence of HIV among MSM is 56 times higher than the general population rate.

That general population rate includes MSM, so in direct comparison the risk differential is larger. The 2018 Kirby report estimated HIV prevalence among Australian women and heterosexual men at 0.03%, which means that a person who has sex with a random Australian MSM is 263 times more likely to be exposed to HIV compared to having sex with a random Australian woman or heterosexual man.

Not only is the risk of HIV exposure substantially increased among MSM, but the risk of acquiring HIV is further increased because the "per contact" risk (i.e. risk of acquiring HIV for each sexual act) is greater for anal sex than for vaginal sex (see Table 3). Accordingly, the highest burden of transfusion-transmission risk associated with sexual activity in Australia is associated with male-to-male sex.

Nonetheless a deferral for sexual activity-based risk must consider all pathogens that have an increased prevalence in the group subject to deferral. In addition to HIV, HBV and syphilis are also recognised as transfusion-transmissible infections (TTIs) that have an increased prevalence among MSM and other sexual activity-defined risk groups in Australia. The following epidemiological data was derived primarily from the previously noted annual surveillance reports from the Kirby Institute, as well as blood donor-specific annual surveillance reports that are produced by the Kirby Institute in conjunction with Lifeblood [5, 6] (full reports available at https://transfusion.com.au/node/2433 https://kirby.unsw.edu.au/report/hiv-viral-hepatitis-and-sexually-transmissible-infections-australia-annual-surveillance), and supplemented by more recent data where relevant.

HIV

In 2017, 84% of newly-acquired HIV infections in Australia were attributed to male-to-male sex. The number of new diagnoses decreased after remaining relatively stable over the previous five years, and the annual total of 963 new diagnoses in 2017 was the lowest number since 2010. This represents a decrease of 4.9% on 2016 and 11.2% on the peak year of 2014. This decrease (despite increased testing) is thought to represent a downward trend in new HIV cases as a result of the increasing uptake of PrEP among MSM in Australia. Of the 963 new diagnoses in 2017, 898 were attributed to sexual contact, with 660 attributed to male-to-male sex (of these, 53 also had injecting drug use as a possible mode of transmission) and 238 attributed to heterosexual sex.

Among first-time blood donors, the prevalence of HIV from 2008 to 2017 was 0.002% - 59 times lower than the general population rate, reflecting the effectiveness of donor education and selection. As can be seen from Figure 1 below, HIV prevalence in first-time blood donors has remained relatively stable in the past decade without any significant trend [6].

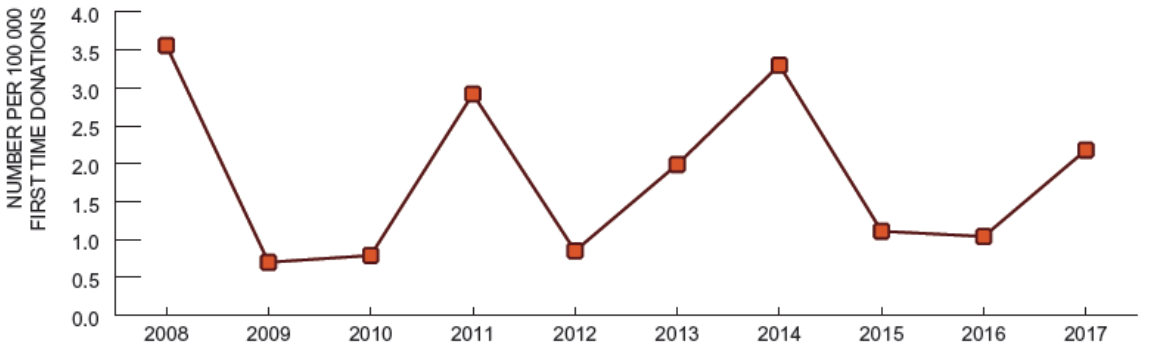

Figure 1: Prevalence of HIV infection in first-time blood donors in Australia, 2008–2017, by year of donation [6]

Similarly, HIV incidence among repeat donors (derived from the number of HIV positive donors with a previous HIV negative test within the last 12 months) is very low and was stable in the 2013–2017 period (Figure 2) with no significant trend. This is critical to our modelling because the estimated residual risk (RR) of HIV infection (1 in 31.7 million based on 2017–2018 data) is derived using a mathematical model (Weusten model [7]), with key input parameters based on the number of incident donors and the timing of their donation in relation to infection.

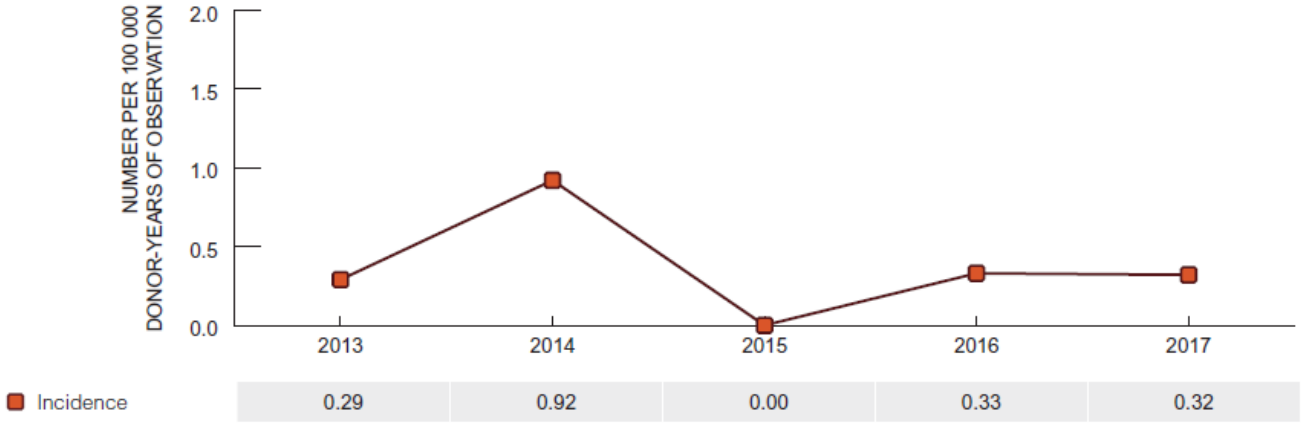

Figure 2: Incidence of HIV infection in repeat blood donors in Australia, 2013–2017, by year of donation [6]

The Kirby Institute has recently released its 2018/Q4 quarterly report on national HIV notifications (https://kirby.unsw.edu.au/sites/default/files/kirby/report/National-HIV-Quarterly-Report_2018-Q4.pdf). While the figures that will be reported in the upcoming 2019 annual surveillance report (due in November) may change pending further checking and data cleaning, the 2018/Q4 report shows a total of 835 new HIV diagnoses in 2018, which is 13% lower than in 2017 and represents a 23% decline over 5 years.

The Kirby noted that the 2018 figures confirm, at a national level, the previously state-based reductions attributed to PrEP uptake among MSM. Of the 835 new diagnoses, 759 were attributed to sexual contact, with 570 attributed to male-to-male sex (of these, 56 also had injecting drug use as a possible mode of transmission) and 189 attributed to heterosexual sex.

HBV

The prevalence of chronic HBV infection in Australia is approximately 0.9%, and is largely concentrated among indigenous Australians and people born in high-prevalence areas of the world, which include southern Europe, Asia and Africa. In 2017, first-time donor prevalence was 0.007%, which is 15 times lower

than the general population. HBV prevalence among first-time blood donors has been steadily declining since 2008 (Figure 3).

Since 2010 the Blood Service has tested all donations with single-donor NAT. Incident HBV donors continue to be rare, with only one recorded nationally in 2017, and incidence has been low and stable since 2008 (Figure 4) without any significant trend [6]. Consistent with the general population, the most common risk factors for HBV in donors were ethnicity and country of birth.

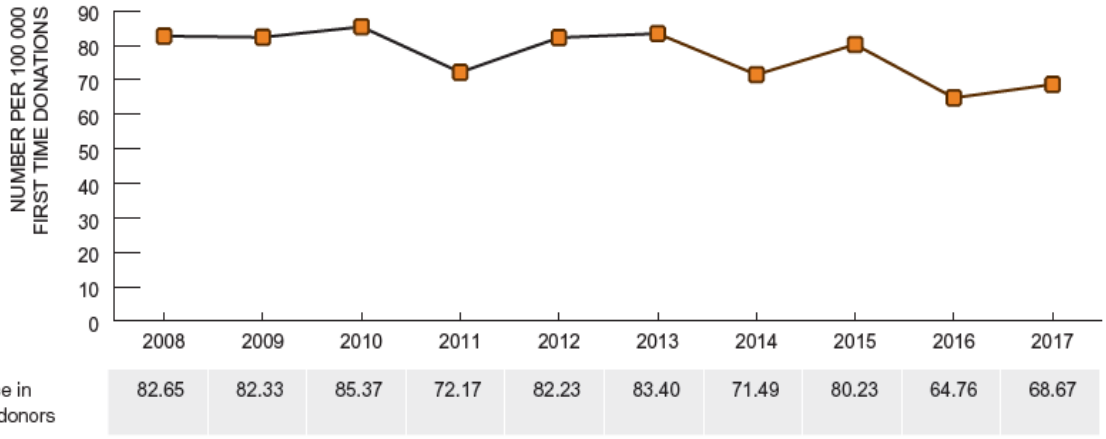

Figure 3: Prevalence of HBV infection in first-time blood donors in Australia, 2008–2017, by year of donation [6]

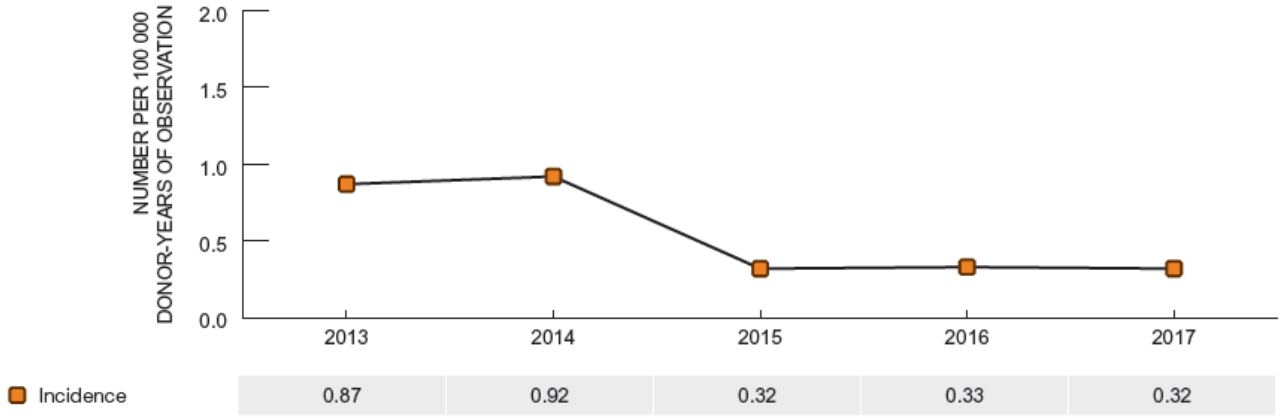

Figure 4: Incidence of HBV infection in repeat blood donors in Australia, 2013–2017, by year of donation [6]

Syphilis

High rates of syphilis are reported in both MSM and indigenous Australian populations. In the period 2008 to 2017, the notification rate of infectious (i.e. recently acquired) syphilis among men increased from 11.0 to 31.0 per 100,000 population. The majority (85%) of syphilis cases are reported in males, with an even higher male preponderance among non-indigenous people.

In the ten years from 2008 to 2017, the prevalence of active (i.e. potentially transfusion-transmissible) syphilis in first-time donors was very low at 3.4 per 100,000 donations. Overall, the prevalence of active syphilis in first-time donors showed no significant trend between 2008 and 2015 (Figure 5). However, the rate increased markedly in 2016, with a further increase in 2017 when 7.63 per 100,000 first-time donors tested positive for syphilis.

Despite this the residual risk of transfusion transmitted syphilis in Australia was recently estimated at 1 in 49.5 million, which is well below the tolerable threshold of 1 in 1 million [8]. A comparison between prevalence of active syphilis in blood donors and the general population could not be undertaken because the case definitions (i.e. “active” versus “infectious” syphilis) do not align.

Figure 5: Prevalence of active syphilis in first-time blood donors in Australia, 2008–2017, by year of donation [6]

Hepatitis C

Injecting drug use remains the predominant risk factor world-wide. There is evidence to support sexual transmission as a potential route of HCV infection, although in the absence of HIV co-infection the risk is low. Since 2012 there have been continued, rapid advances in the development of treatments for HCV infection. The development and roll out of direct-acting antiviral (DAA) medications has enabled sustained virological suppression of HCV, and cure rates approaching 100% [9].

During 2008–2017 there was a significant decrease in HCV prevalence in first-time donors in Australia: from 69.1 per 100,000 donations in 2008 to 41.40 per 100,000 donations in 2017 (Figure 6). This translates into a decrease from 0.07% of the total first-time donations in 2008 to 0.04% of the total first-time donations in 2017.

This trend is consistent with the rate of diagnosis of HCV infection reported through the Australian National Notifiable Disease Surveillance System, where the rate of diagnosis of HCV infection declined from 53 per 100,000 in 2008 to 43 per 100,000 in 2017 [10]. There has also been a decrease in prevalence of hepatitis C antibody among people seen at needle and syringe programs from 62% in 2008 to 49% in 2017.

Figure 6: Prevalence of HCV infection in first-time blood donors in Australia, 2008–2017, by year of donation [6]

HCV incidence among blood donors remains low and stable. Over the five-year period 2013-2017, a total of 12 incident HCV infections in donors were detected with no statistically significant trend observed for incidence rates (between 0.0 and 1.2 per 100,000 donor-years of observation - see Figure 7). Only one HCV incident donor was identified in 2017, equating to an incidence rate of 0.3 per 100,000 donor-years of observation (Figure 7).

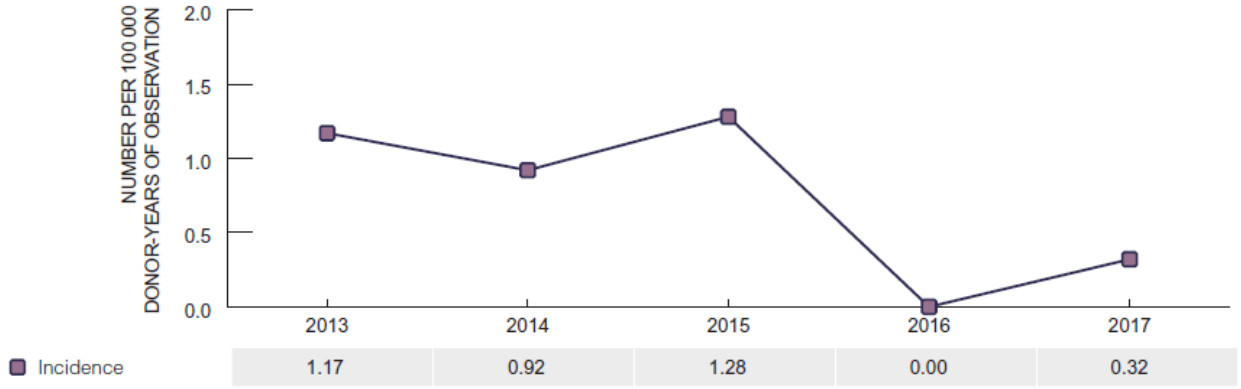

Figure 7: Incidence of HCV infection in repeat blood donors in Australia, 2013–2017, by year of donation

Data from the Australian Needle and Syringe Program Survey (ANSPS) shows a further decrease in the prevalence of hepatitis C antibody among people seen at needle and syringe programs. The 2018 figure of 45% is 8.2% lower than the 2017 figure and 27.4% lower than the 2008 figure.

HTLV

HTLV is not a notifiable infection in Australia except in the Northern Territory (NT), and very few studies have examined the epidemiology in Australia. The HTLV−1 prevalence in Australia reported in published studies varies considerably, from 1.7% among Aboriginal and Torres Strait Islander adults in the entire NT to 51.7% among adults in the Anangu Pitjantjatjara lands of South Australia. A recent HTLV-1 seroprevalence study conducted in a remote indigenous community of the NT reported 31 of 97 (32.0%) participants being anti-HTLV-1 positive, including 30 of 74 (40.5%) adults and 1 of 23 (4.3%) children <15 years [5].

In blood donors, detection is overwhelmingly in the first-time donor population. In the past ten years, 2008–2017, a total of 43 HTLV positive donors have been detected (42 first-time donors & only one repeat donor). The prevalence has varied from 0.79 to 8.94 per 100,000 first time donors (Figure 8)

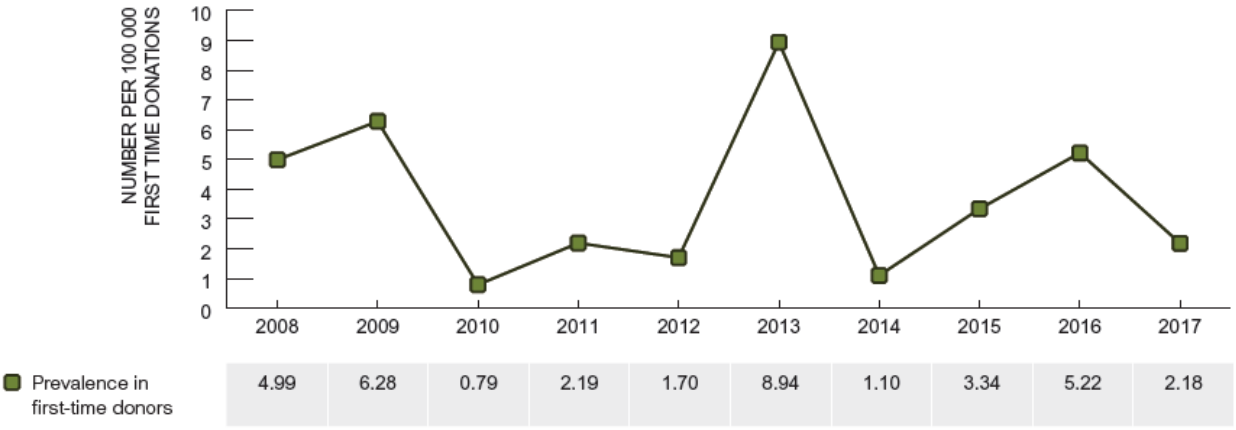

Figure 8: Prevalence of HLTV infection per 100,000 in first-time blood donors in Australia, 2008–2017, by year of donation

4. Risk analysis

As indicated by the donor-specific epidemiological data described above, the risk of transmitting HIV and other infectious diseases through blood transfusion is now extremely remote. However, the risk cannot be completely eliminated. The Lifeblood Risk Tolerability Framework provides a strategy whereby the transfusion-transmission risk of infectious agents can be categorised as acceptable, tolerable or intolerable based on a numerical estimation of the risk level which also takes into account the disease severity in

recipients. As noted previously, HIV transmission is deemed "tolerable" at a frequency less than 1 in 5 million per unit transfused, while HBV, HCV, HTLV and syphilis transmission are deemed "tolerable" at a frequency of less than 1 in 1 million per unit transfused.

TTI-infected donors attending during the testing window period constitute the majority of the residual risk and therefore the duration of deferral must adequately cover this window [11]. Accordingly, the key issue in determining an appropriate deferral period is the duration of the testing window period for the relevant TTI risks.

Of the TTIs that are considered relevant to MSM and sexual activity-based deferrals (i.e. HIV, HBV and syphilis), the longest testing window period is for *Treponema pallidum* – the causative agent of syphilis – which is approximately 30 days.

Agent and testing method	Window period in days (95% confidence interval)	2017–18 estimate of residual risk per fresh component unit transfused**
HIV NAT (HIV-1 RNA)	5.9 (5.3–6.8)	Less than 1 in 31.7 million*
HIV serology (anti-HIV-1/2 + p24 Ag)	15 (13.3–16.7)	Less than 1 in 4.1 million
HCV NAT (HCV RNA)	2.6 (2.4–2.9)	Less than 1 in 96 million
HCV serology (anti-HCV)	66 (38–94)	Less than 1 in 0.9 million
HBV NAT (HBV DNA)	15.1 (13.2–17.5)	Less than 1 in 2.6 million
HBV serology (HBsAg)	38.3 (33–43.7)	Less than 1 in 0.7 million
HTLV serology (anti-HTLV-1/2)	51 (36–72)	Less than 1 in 85 million
Syphilis serology (antibody to *Treponema pallidum*)	Approximately 30	Approximately 1 in 49 million

Table 1: The testing window period and estimated risks of transfusion for relevant TTI agents

**Estimate used for HIV risk modelling described in Appendix A.*

***Most recent estimates available at time of writing.*

Risk modelling

Because HIV among MSM constitutes the largest transfusion-transmission risk for any TTI in any group subject to sexual activity-based deferral (including sexual contact with a known HIV-positive partner - see analysis on next page), the risk modelling focused on HIV among MSM. In light of ongoing HAV outbreaks in NSW and Victoria at the time, in which MSM was the predominant route of transmission, HAV risk modelling was also performed (see Appendix A). It should be noted that these MSM-related HAV outbreaks have since ceased, but the modelling has been included to provide risk context should future outbreaks occur.

HIV among MSM

As noted, the testing window period is the "at risk" period for transmission. In the modelling it is assumed that a three-month deferral period prevents donation in the HIV window period by a presenting donor who accurately discloses their risk activity within the last three months. Failure to disclose risk activity (i.e. "donor non-compliance") leading to the collection of a "window period donation" (i.e. a donation from a donor infected with HIV but testing negative) therefore represents the predominant residual risk.

The following scenarios are graded from the most conservative assumptions (Scenario 1) to the least conservative (Scenario 4), with each scenario assuming the same donation frequency among newly-eligible MSM donors as among existing male donors (i.e. 2.4%):

- **Scenario 1** assumes a baseline residual risk of HIV among existing donors that is four times the current rate, a donor non-compliance rate among MSM donors that is ten times the rate reported in the 2013 Australian compliance study [9], and an HIV incidence among MSM donors that is equal to the general incidence of HIV among Australian MSM (0.89 per 100 person-years as per ACCESS database). Even with these extremely pessimistic assumptions, a reduction in deferral period from 12 months to 3 months (or any deferral period that adequately covers the HIV window period) results in an estimated residual risk of *1 in 5.03 million* - still below the tolerable risk threshold of 1 in 5 million.
- **Scenario 2** uses the same extremely pessimistic assumptions for donor non-compliance and HIV incidence among MSM donors as Scenario 1; the only difference being that the residual risk of HIV among the existing donor population remains unchanged at 1 in 31.7 million. With this more realistic assumption on the risk of the existing donor population, the resulting estimate for HIV residual risk would be *1 in 9.6 million*.
- In **Scenario 3**, both donor non-compliance and the incidence of HIV among new MSM donors are halved compared to Scenario 2, so that non-compliance is only five times the rate reported in the 2013 Australian compliance study and the incidence of HIV in new MSM donors is half the rate reported in the ACCESS database rate for MSM. While both these assumptions remain highly pessimistic, the predicted HIV residual risk would be *1 in 20.1 million*.
- **Scenario 4** uses the same highly pessimistic assumptions for baseline HIV residual risk and HIV incidence among MSM donors as Scenario 3, but with a donor non-compliance rate of 0.115% (i.e. half the rate reported by the 2013 Australian compliance study). This scenario predicts a reduction in HIV residual risk from the current 1 in 31.7 million to *1 in 44.8 million*. A trend towards lower non-compliance with shorter MSM deferral periods has been observed internationally (Table 2), so this is in fact the most realistic of the four scenarios. The decreased non-compliance rate of 0.115% reflects both the direction and magnitude of change reported by the UK, Canada and France after changing from an indefinite deferral period to a 12-month deferral (see Table 4).

Modelling scenarios	Baseline HIV residual risk (RR) among existing donors	Non-compliance among new MSM donors	HIV incidence among new MSM donors	Predicted HIV RR among overall donor cohort	Effect of CSL Behring pathogen reduction steps*
Scenario 1	1 in 7.93 million (= 4x increase)	2.3% (= 10x rate in 2013 compliance study)	0.89 per 100 person-years ("high-point" estimate = same as ACCESS rate for MSM)	1 in 5.03 million	1 in 5,030,000 million
Scenario 2	1 in 31.7 million (= current RR)	2.3% (= 10x rate in 2013 compliance study)	0.89 per 100 person-years ("high-point" estimate = same as ACCESS rate for MSM)	1 in 9.59 million	1 in 9,590,000 million
Scenario 3	1 in 31.7million (= current RR)	1.15% (= 5x rate in 2013 compliance study)	0.445 per 100 person-years ("mid-point" estimate = half the ACCESS rate for MSM)	1 in 20.12 million	1 in 20,120,000 million
Scenario 4	1 in 31.7 million (= current RR)	0.115% (= 0.5x rate in 2013 compliance study)	0.445 per 100 person-years ("mid-point" estimate = half the ACCESS rate for MSM)	1 in 44.83 million	1 in 44,830,000 million

Table 2: Modelled HIV residual risk for a 3-month deferral period (see Appendix A for details)

** For FFP that is sent for plasma fractionation: if the risk reduction attributed to CSLB pathogen reduction steps is rounded down to 10^6 (a highly conservative estimate used in historical risk modelling), then the HIV*

RR for fractionated plasma is reduced by a factor of 10^6 or 1 million. As of March 2017, the lowest validated virus reduction (VVR) claim for any CSLB plasma product was >=$10^{6.3}$ for PROTHROMBINEX-VF: a figure that has since improved to >=$10^{12.6}$ according to CSLB internal data.

Donors with a partner known to have HIV

A donor whose partner has known HIV infection would appear to carry higher risk of HIV exposure than a donor whose partner has unknown HIV status but known risk activity. In the context of blood safety, however, a person with known HIV is likely to be on anti-retroviral treatment and have an undetectable viral load. Therefore their partner's risk of sexual exposure to HIV is likely to be zero because "undetectable = untransmittable" (U = U) [12].

Type of exposure with known HIV-positive source who is NOT on antiretroviral treatment	Estimated risk of HIV transmission/exposure*
Receptive anal intercourse (RAI) – ejaculation – withdrawal	 1/70 1/155
Shared needles and other injecting equipment	1/125
Insertive anal intercourse (IAI) uncircumcised	1/160
Insertive anal intercourse (IAI) circumcised	1/900
Receptive vaginal intercourse (RVI)	1/1250
Insertive vaginal intercourse (IVI)	1/2500
Receptive or insertive oral intercourse	Unable to estimate risk – extremely low
Needlestick injury (NSI) or other sharps exposure	1/440
Mucous membrane and non-intact skin exposure †	< 1/1000

* These estimates are based on prospective studies, not cross-sectional data or figures derived from modelling. These estimates do not take into account source viral load, which if undetectable markedly reduces risk estimates.

† Human bites are extremely low risk.

Table 3: Exposure and transmission risk/exposure with a known HIV-positive source who is NOT on antiretroviral treatment [13]

In any case, no appreciable blood safety risk would remain after the proposed deferral period of 3 months from last sexual contact because this more than adequately covers the window period for HIV. This is consistent with the outcome of the UK SaBTO donor deferral review, which recommended that sexual contact with an HIV-positive partner be subject to a 3-month deferral.

HAV sexual exposure

For hepatitis A, the unmitigated transmission risk (i.e. with no deferral period for MSM) during the 2017 outbreak in NSW (predominantly associated with MSM) was approximately 1 in 1.8 million per unit transfused, which is lower than the acceptable risk threshold of 1 in 1 million for HAV. With a 3-month deferral period for MSM this is further reduced to a miniscule risk, given that all documented transfusion-transmission events of HAV described in the literature have occurred during the incubation period (15–50 days) of infection prior to symptom onset.

It should be noted that the HAV outbreak in NSW is not currently ongoing, and hence the unmitigated residual risk is now considerably less than 1 in 1.8 million per unit transfused. Whilst there is uncertainty around the duration of infectious viraemia and the potential for asymptomatic infection to result in transfusion transmission, a 3-month MSM deferral is expected to cover the vast majority - if not all - of this theoretical risk.

HBV sexual exposure

There are two main sexual activity-based deferrals relevant to hepatitis B; firstly, male-to-male sex (ACCESS data indicates that MSM have a rate of HBV infection approximately three times that of the general Australian population) and secondly, sexual contact with an HBV-positive partner.

Lifeblood already accepts donors with ongoing exposure to an HBV-positive partner if they have confirmed immunity to HBV, which is defined as a level of antibodies to hepatitis B surface antigen (anti-HBs) of 10 IU/litre or higher. Hepatitis B vaccination for close contacts of confirmed cases is funded in all states and territories, and HBV transmission from immune individuals is not considered a risk [14].

Vaccinated individuals with anti-HBs below 10 IU/litre may still be protected against HBV infection by an anamnestic immune response, so even without a deferral period this "non-immune" group poses minimal risk of transmitting HBV.

It should also be noted that occult hepatitis B infection (OBI) is the predominant transmission risk for HBV with Lifeblood testing methods [15]. The residual risk of HBV excluding OBI is currently 1 in 43 million, while the total HBV residual risk including OBI is 1 in 2.6 million. Because OBI is a chronic condition, however, the risk of OBI cannot be mitigated by a finite deferral period. Hence the value of a sexual activity-based deferral period for HBV is specific to acute HBV.

In this context, the 15.1 day HBV NAT testing window period (range: 13.2–17.5 days) for acute HBV is well-covered by a 3-month deferral period for sexual activity-based risk exposure to hepatitis B, and therefore HBV transmission risk would not be affected by the proposed change.

HCV sexual exposure

The risk of transmitting HCV through sexual contact is extremely low. The HCV Partners Study [16] studied monogamous, heterosexual couples in long-term relationships (≥36 months), without confounding exposures such as viral coinfection (HIV or HBV) or both partners having a history of injecting drug use. This study found the maximal risk of transmission per sexual contact was 1 in 380,000 (95% CI: 1/600,000–1/280,000).

The current deferral policy makes no distinction between sexual partners with ongoing HCV infection and sexual partners with treated and/or resolved HCV infection. Considering the widespread roll-out of DAA treatment for chronic HCV infection in Australia, many donors who are excluded by this policy therefore have no actual risk of acquiring HCV.

The window period for HCV NAT testing is very short at 2.6 days, and therefore a 3-month deferral period is more than adequate to cover potential sexual exposure to HCV - whether that exposure results from contact with a person known to have HCV infection or a person at risk of HCV, such as an injecting drug user.

HTLV sexual exposure

Risk modelling has demonstrated that the blood safety risk posed by HTLV in Australia is negligible because the incidence in repeat donors is extremely low and because leucodepletion of all cellular products is an effective risk mitigation strategy [17]. Lifeblood has reviewed its internal data and no cases of HTLV infection have been identified in repeat donors subsequent to sexual or household contact with a known positive case.

The UK has decreased its deferral period for sexual contact for HTLV to three months in line with its deferral period for male-to-male sex. The window period for serological HTLV screening in Australia is 51 days (36–72 days), which means that the proposed 3-month deferral period provides a safety margin of 18–54 days.

It is noted that the Lifeblood screening protocol for HTLV will be changing following TGA approval of a "first-attendance only" screening strategy. When this change occurs, any donor who is deferred for sexual contact with a HTLV-positive partner will be subject to additional HTLV screening if they later return and the deferral is no longer applicable. System controls will require "re-entry" testing for antibodies to HTLV (anti-HTLV), and full product issue will only be permitted if anti-HTLV screening is negative and no current HTLV deferrals remain active.

Syphilis sexual exposure

No cases of transfusion-transmitted syphilis have been reported in developed countries for almost 40 years. The conservative assumption that syphilis infection is capable of being transmitted through blood transfusion with modern blood storage techniques remains unproven. It is known, however, that the presence of syphilis spirochaetes in the blood is greatest during primary and secondary syphilis. Therefore the risk of

transfusion-transmitted syphilis, if it exists, is greatest during early infection - which coincides with the testing window period.

On this basis, any deferral for sexual contact with a partner known to have syphilis must cover the syphilis testing window period. While this window period is not well-defined, it is estimated to be around 30 days (see Table 1). Therefore a 3-month deferral period for sexual contact with known syphilis will provide a safety margin of approximately 60 days.

The prevalence of infectious syphilis in MSM is estimated to be 18 times higher than the general population (ref ACCESS database). Lifeblood recently published a risk model which demonstrates the negligible risk of transmitting syphilis via blood transfusion [8]. Assuming that modern storage methods still allow such transmission, the risk model conservatively estimated the current risk of syphilis exposure at 1 in 49.5 million.

There would need to be over 245 cases of infectious syphilis in blood donors every year (compared to 10–15 currently) for the modelled residual risk to approach the tolerable threshold of 1 in 1 million. Providing that the deferral period exceeds the testing window period, reducing the deferral period for sexual contact with known syphilis will not affect this risk.

Summary of risk modelling

Using conservative model input parameter values, the modelled residual risk estimates for relevant TTIs will not exceed the defined tolerable risk thresholds if sexual activity-based deferral periods were decreased from 12 months to 3 months. Given the highly conservative assumptions made in the risk modelling, this conclusion is robust even if key input parameters have been substantially underestimated or overestimated.

Risk modelling shows that changing the duration of sexual activity-based deferrals from 12 months to 3 months would not result in an HIV risk increase above the tolerable level, and could potentially lead to a reduction in risk if donor non-compliance were to decrease. A trend towards reduced donor non-compliance with decreasing deferral periods is consistent with international experience.

For HAV, conservative risk modelling indicates that the risk of transfusion transmission associated with previous MSM-associated outbreaks in NSW would have remained below the tolerable level even without any MSM deferral in place.

For HBV, HCV, HTLV and syphilis, sexual activity-based deferrals are comparatively less important and therefore the impact of a decreased deferral period can be assessed as negligible.

Supporting data from other countries

Information on international practice is provided in Section 5 below. As noted, the change in the United Kingdom and Canada from a 12-month to a 3-month sexual activity risk deferral is of particular interest. The rates of TTI-positive blood donations following implementation in England, Wales and Scotland have not yet been fully published, but have been provided to Lifeblood under a confidentiality agreement.

While it is too early to draw definitive conclusions, there is no indication from the first twelve months of data that the UK policy change has resulted in a substantial rise in HIV or recently acquired syphilis infections among blood donors. In fact, they have observed a lower rate of HIV and a similar rate of syphilis so far, and importantly a lower rate of donor non-compliance:

- In 2017 (prior to the change from 12-month deferral to 3-month deferral) there were 6 HIV-positive donors detected (2 female and 4 male), among whom 2 were non-compliant MSM. In 2018 (after the deferral change) there were 3 HIV-positive donors (1 female and 2 male), among whom none were non-compliant and none were MSM.
- 19 recently-acquired syphilis infections were observed in 2017 (3 female and 16 male), among whom 4 were non-compliant and 3 were MSM. Following the change in deferral period in 2018, there were again 19 donors with recently-acquired syphilis but a smaller proportion were male, MSM or non-compliant (7 female and 12 male, among whom 2 were MSM and 1 was non-compliant).
- Additional data presented at the International Society for Blood Transfusion [ISBT] Regional conference in Basel (Davison et al - *Monitoring the impact of three-month deferral of sexual behaviours and scoping evidence for the assessment of an individualised risk* (FAIR) – abstract supplied) augments and confirms the preliminary observations above. The ISBT abstract concludes 'HIV prevalence and incidence have continued to decline. HBV incidence in repeat donors increased in 2018 although initial analysis suggests this is not associated with the policy change. Monitoring continues, and residual risks will be re-

estimated as data post-change accumulate. These data are reassuring, and therefore it is appropriate to scope the evidence for, and feasibility of, a more individualised approach to selection policy.'

Donor non-compliance [2] is the major contributor to HIV residual risk, through the donation of infected blood during the HIV testing window period [18, 19]. Therefore reduced non-compliance results in lower residual risk, as was seen in Table 2.

The accumulating evidence strongly indicates that shorter deferral periods for male-to-male sex result in lower rates of donor non-compliance [20, 21]. Countries that have adopted a deferral period of 12 months or less have consistently reported lowered non-compliance rates of less than 1% for both first-time and repeat donors, as shown in Table 4.

Country	Indefinite deferral	12-month deferral
France	2.1%	0.73%
Hong Kong	3.2%	-
USA	2.6%	0.4%
Canada	1.4% FTD, 1.0% RD	0.5% FTD, 0.1% RD
Australia	-	0.23%
UK	1.4%	0.4%

Table 4: Non-compliance rates for reporting male-to-male sex

France, where a 12-month MSM deferral currently applies, has recently completed MSM research including a large donor compliance study (Complidon et al; n = 108,000 donors) which identified a non-compliance rate to the current 12-month MSM deferral of 0.73%. Consistent with the experience of other countries in Table 4, this rate was substantially lower than the 2.1% that had been estimated under an indefinite deferral [21].

To inform a potential change in French policy (see below), modelling was conducted for two scenarios using the 0.73% non-compliance rate [22]. Scenario 1 constituted deferral of MSM for 4 months from last sexual contact and Scenario 2 deferral of MSM who have had more than 1 sexual partner in the 4 months preceding donation (which already applies to all other potential donors in France). Baseline (12-month deferral) HIV residual risk [RR] (using the incidence-WP model) was estimated as 1 in 6.4 million donations.

For Scenario 1, the number of additional MSM donors was estimated as 733, with 0.09 additional HIV positive donors resulting in an HIV residual risk of 1 in 6.3 million donations. For Scenario 2 the number of additional MSM donors was estimated as 3,103 and the number of additional HIV positive donations as 4.92 resulting in a residual risk of 1 in 4.3 million donations. Sensitivity analysis showed that the number of MSM and the HIV incidence were multiplied by 1.5, the risk would be 1 in 6,225,000 donations for Scenario 1 and 1 in 3,000,000 for Scenario 2.

The authors concluded that 'For both scenarios, the HIV residual risk remains very low. For Scenario 1 (4-month deferral) the risk is identical to the baseline RR and is very robust to variations in model parameters. For Scenario 2 (no more than 1 sexual partner, 4 months) the risk is 1.5 times higher than the point estimate of the baseline RR and sensitivity analysis shows that this estimate is less robust than for Scenario 1, since the risk could be 2x higher than the baseline RR. For both scenarios there was a modest increase in eligible MSM donating'.

The model assumes that the residual risk is non-compliant donors donating in the test window period. Consequently the HIV residual risk for any selected deferral period that exceeds the HIV window period is equivalent. Thus, had the French chosen a 3-month period it would have the equivalent (i.e. 1 in 6.3 million donations) residual risk to the 4-month period modelled in Scenario 1. We believe that 4 months was selected to be consistent with the existing deferral for sexual contact with more than one partner in the past 4 months.

5. International practice

Since 2012 an increasing number of countries have reduced their MSM deferral period (see Table 5 below), and a number have progressed to a deferral period less than 12 months.

Canada (Canadian Blood Services and Hema-Quebec) moved from a 12-month deferral period to a 3-month deferral period in June 2019, while Denmark and France are planning to implement a 4-month deferral. The French Health Ministry announced that they intend to implement the new deferral on 1 February 2020, stating that 'the decision to relax the abstinence period was based on the latest scientific evidence and medical advances.' (https://www.france24.com/en/20190717-france-12-month-deferral-blood-donations-homosexual-gay-men-four-months). In Denmark, while the Health Minister announced that Denmark would implement a 4-month MSM deferral in 2019, implementation has been delayed because of a recent increase in syphilis notifications and the absence of syphilis donor testing in Denmark. We believe that the implementation of the 4-month deferral is dependent on re-introduction of syphilis testing for MSM-eligible donors only.

Iceland is undertaking a review of their current indefinite deferral period for MSM, and indications from the Minister of Health are that they will change to an "abstinence period of some months". (http://www.starobserver.com.au/news/international-news-news/iceland-considers-ending-ban-on-gay-and-bisexual-men-donating-blood/174848)

Sanquin (the national blood service of the Netherlands), which has had a 12-month deferral in place since 2015, has implemented a 4-month deferral for MSM (https://www.sanquin.nl/artikelen/nieuwsberichten/2019/02/verkorting-uitsteltermijn-voor-gedrag-met-verhoogd-risico-op-bloedoverdraagbare-infectie). According to the ABC Newsletter (22 March 2019): "To arrive at this new policy, Sanquin has studied extensive scientific research and available practical information from home and abroad in the previous years, conducted its own research and consulted with the Ministry of Health, Welfare and Sport, patient organizations and the COC. Just as before, Sanquin will continuously evaluate its own policy and, if possible, adjust it based on further research."

Most recently, in April 2020, the US FDA announced that as one component of a response to donor shortages resulting from the COVID-19 pandemic, it would permit US blood centres to change the existing 12-month MSM deferral to 3 months, a policy change that will remain effective after the pandemic subsides (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/revised-recommendations-reducing-risk-human-immunodeficiency-virus-transmission-blood-and-blood).

Countries with 12 month deferral	Countries with indefinite deferral	Countries with individualised assessment	Other
Argentina	Lebanon	Chile	Japan (6 months)
Australia	Belgium	Italy	Serbia (6 months)
Brazil	Croatia	Mexico	Lithuania (6 months)
Czech Republic	China	Poland	Netherlands (4 months)
Finland	*Denmark (intend to implement 4-month deferral)*	Portugal	England, Wales, Scotland (3 months)
Sweden	*Iceland*	Russia	Canada (3 months)
Northern Ireland (change to 3-month deferral not yet implemented)	Israel (plus quarantined plasma)	Spain	
France (plus quarantined plasma)- intend to implement 4-month deferral Feb 1, 2020	Norway	Thailand	
New Zealand	Slovenia	South Korea	
Republic of Ireland	Austria	South Africa	
USA (FDA have approved 3 months)	Taiwan		
Hungary			
Macau			
Hong Kong			
Switzerland			
Germany			
Turkey			

Table 5: Summary of international deferral policies for male-to-male sex

Many international blood services have reduced their MSM deferral period to 12 months or less. Canada and the UK (except Northern Ireland) have implemented a 3-month deferral for all sexual activity-based deferrals covered in this submission. The FDA has approved a 3-month MSM deferral, and the Netherlands has moved to 4 months with France and Denmark intending to do the same. Preliminary post-implementation TTI data from the UK supports the safety of a 3-month deferral in England, Wales and Scotland.

6. Predicted Impact on Donor Base

Reducing the length of a sexual activity-related deferral increases the number of eligible donors. Estimating this increase, however, is problematic due to difficulties in estimating the size of affected populations. Of those people who would be newly eligible under the proposed policy changes, MSM represent a substantial majority based on deferral figures and population statistics, and therefore will be the focus of this analysis.

Data published in 2008 on the size of the homosexual and bisexual male population reported an estimate of 182,624 and an average across all states and territories of 2.03% of the adult Australian male population [23]. More recent data was used to estimate the numbers of MSM who would be eligible for prescription of PrEP. These estimates were based on MSM numbers at the end of 2014 (2.3% of the male Australian population) and the proportion who were sexually active (81·9% within the previous 12 months), minus the number known to be HIV positive [24]. The estimated number of sexually active MSM at risk for HIV infection was 108,850 nationally.

Estimates and assumptions for MSM

Adult MSM population:

- Australia-wide there are 108,850 sexually active MSM who are HIV negative.
- While the proportion of MSM who have not engaged in male-to-male sex for 12 months or more (i.e. currently eligible to donate blood) is known to be 18.1%, it is not known how many of these MSM are actually donating blood.

- The proportion of MSM who have not had sex within the past 3 months (and who would therefore become eligible after the proposed change to a 3-month deferral) is also unknown. Unfortunately there is a paucity of data on this as most of the relevant Australian behavioural data is based on sexual contact in the past 6 months.
- Considering these limitations, expert opinion (Dr Garrett Prestage, Kirby Institute) is that around 10% of MSM would become newly eligible under the proposed 3-month policy.
- Based on 2018 data, about 2.4% of age eligible (18+) Australian males currently donate blood. If these newly eligible MSM were to donate at the same rate as other 18+ males, there would be 261 (i.e. 0.1 x 108,850 x 0.024) extra donors Australia-wide. If these donors donated at the average donation frequency, based on 2018 data, of three donations (across all types of blood collection) then this would yield an additional 784 donations annually.
- This is a conservative estimate of the sufficiency yield because for newly-eligible MSM, the assumed donation rate of 2.4% may be an underestimate given that:
  - The MSM community has long expressed a strong level of interest in blood donation, and also considers the ability to donate blood to be an important indicator of equality and community acceptance. This indicates that the MSM donation rate could exceed the average male participation rate of 2.4%.
  - Lifeblood market research to assess donor intentions (including MSM and non-MSM, donors and non-donors) in the event of a change in sexual activity-based deferral policies. The key findings of this research indicate a very high level of trust in Lifeblood and in Australia's blood supply among existing donors as well as a strong willingness to donate among those participants who identified as MSM. Existing donors were generally less likely than non-donors to currently be worried about risks associated with donations, and more likely to say that a change in deferrals, including MSM wouldn't change their level of trust in the blood supply. Regarding MSM, a significant proportion (31%) of the 138 MSM participants have tried to donate in the past or have donated before (42%). In response to whether a change in the deferral period from 12 to 3 months would make them more likely to donate, 11% indicated it would.
  - Unpublished findings from the Kirby Institute's ongoing Flux (Following Lives Under Change) study on drug use in a national sample of Australian gay and bisexual men (which has recently added questions about attitudes to blood donation) supports this strong intention to donate. Of 1,702 men who answered the blood donation questions, over one-quarter (28.7%) of men had a prior history (ever) of blood donation. The remaining 71.3% who had never donated included 46.0% who said they would be interested in donating blood.
  - Feedback from community members to Lifeblood indicates that many already-eligible MSM and non-MSM (including friends and family of MSM) choose not to donate blood in "conscientious objection" to Lifeblood policy. Should the deferral period be reduced leading to a change in attitude, this represents an additional group of potentially eligible donors.
  - Some demographic factors that are known to favour blood donor participation, such as urban residence and higher levels of education and income, may be more applicable to MSM as a group.

7. Conclusion

There is strong supportive evidence for a change from the existing 12 months to a 3-month deferral period for all the proposed sexual activity-based deferrals. The evidence base includes a robust body of local and international epidemiological data and improved testing technology, and is consistent with the recommendations of the *2017 Review* committee and a number of overseas blood establishments.

Most importantly, predictive risk modelling indicates that a 3-month deferral period for male-to-male sex would keep the risk of transfusion-transmitted HIV well below the tolerable threshold. Because no other sexual activity-based risk group carries a higher burden of any TTI than HIV among MSM, this modelling also establishes the safety of applying the same 3-month deferral period to all sexual activity-based exposure risks.

Lifeblood anticipates that adopting this proposal would yield a modest sufficiency gain without affecting patient safety.

Appendix A: Modelling the risk of transfusion transmission of HIV and hepatitis A virus associated with male-to-male sex

Background

Since the male-to-male sex deferral was introduced in the early 1980s, donation testing and management systems have considerably improved such that the risk of a potentially infectious HIV donation not being detected on testing, or a positive donation being released in error (process failure), has significantly decreased. Importantly, the period before HIV is detectable in the bloodstream (termed the 'window period' or WP) has been substantially reduced by incremental technological advances [25].

Given these improvements and in the context of continuing criticism of the rationale for indefinite deferral, blood services commenced reviewing the potential to implement time-limited male-to-male sex deferral, with some applying mathematical modelling techniques to assess the impact of the proposed policy on HIV risk [26] [26-31]. In all cases, it was predicted that a reduced deferral period would increase HIV risk, albeit by varying magnitude. In contrast, review of post-implementation HIV surveillance data from several countries (including Australia [18]) showed stable HIV prevalence rates, suggesting the models used were overly pessimistic [20, 32, 33].

The basis of the models developed by the different countries were similar: each estimated HIV risk under an alternative time-based (e.g. 5 years or 1 year) deferral by predicting the additional number of donations made by the newly eligible population and the number of HIV positive donations among them, although the details and assumptions varied between them. As model output is directly dependent on the accuracy of input parameters, it appears that the inaccuracy of existing models is in part due to inaccuracy of some or all input parameters. Improving estimates for these – for example the HIV incidence in newly eligible donors – is pivotal to improving model accuracy.

One important factor is the level of 'compliance' to the deferral policy [18, 34]. The factors determining non-compliance (i.e. not disclosing a deferrable risk at the time of donation) are complex, but the accumulating evidence indicates that compliance under time-limited (e.g. 12 months since last contact) MSM deferrals appears to improve, or at least does not worsen, with the paradoxical potential to cause a lowering of HIV risk [20]. Only one of the current models (UK model) incorporates compliance as a central parameter [28, 29, 34]. Notably, the latest iteration of this model provided the best prediction (albeit still an overestimate by 73%) of the number of HIV positive donors after changing from indefinite to time-limited deferral in Australia, UK and Canada [33].

While HIV transmission risk is the predominant risk associated with male-to-male sex, hepatitis A virus (HAV) can also be transmitted by male-to-male sex and currently there are ongoing outbreaks among MSM in Europe, North America and, to a lesser extent, Australia. Blood donations are not tested for HAV and the current HAV risk mitigation is reliant on deferral of symptomatic donors, or those with known contact with an infected person within the past 2 months. The risk of HAV transfusion transmission is proportional to the number of community cases of HAV (non-MSM and MSM combined) and the recent increase in the number of cases among MSM suggests the need to consider the HAV risk impact associated with changing the current 12-month male-to-male sex deferral.

Here we model the impact on the risk of HIV transmission associated with reducing the current 12 month deferral to 3 months. Our approach to model the HIV risk is similar to the UK model, being based on estimating the additional risk imposed by newly eligible MSM donors under varying compliance levels.

For HAV, we adapt a published simulation model (European Upfront Risk Assessment Tool - EUFRAT [35]) to estimate the transfusion transmission risk based on an outbreak of HAV in NSW and then assess how this risk changes with the change in the duration of infectious viraemia. This is done by two methods, incorporating the MSM risk to the total risk and presenting the risk that an individual MSM will be infectious.

Method

HIV modelling

Estimation of the current HIV residual risk is based on the Weusten model [7] plus a worst-case scenario increasing the number of incident donors by four-fold (covering the widest variation from observed Lifeblood surveillance data). The Weusten model is designed to estimate the risk of infection in a recipient of a tested blood component based on the lower limit of detection of the applied NAT test and the probability of transmission based on a number of factors, including the volume of transfused plasma and the presumed 'infectious dose' of HIV.

The Weusten model assumes a concentration-dependent probability that the virus is not detected in the log-linear ramp-up phase of plasma viraemia in acute infection, and a dose-dependent probability that an infection develops in the recipient of the contaminated blood product. Both these probabilities contribute to the overall residual risk.

As the non-compliance rate and the mean HIV incidence rate of "newly eligible" donors are both major risk determinants, we vary these two parameters to provide a "most likely" estimate with plausible limits. The "most likely" estimate assumes that MSM donate at the same frequency as existing blood donors, have an HIV incidence midway between blood donors (low) and MSM attending STD clinics (high) and have a non-compliance rate 5x that measured in existing blood donors to account for any underestimation resulting from methodological limitations.

The predicted risk is considered against the Lifeblood "tolerable risk" level. As defined in the Lifeblood EREEID risk tolerability framework developed in consultation with the TGA, the risk of HIV transmission per unit transfused must be maintained below 1 in 5 million.

Model

Total new risk (with various rates of non-compliance) = (Current residual risk* [1-proportion attributable to new non-compliant donors from new MSM deferral]) + (additional risk from newly non-compliant donors from new MSM deferral* proportion of total donations provided from this group).

Assumptions

1. Donation is independent of infection – i.e. infected donors do not donate earlier or later than the average inter-donation interval for all blood donors.
2. The chosen deferral period – e.g. 3 months or any deferral period longer than the testing window period – will adequately protect against window period donations if there is 100% compliance, and therefore any change to the risk is dependent on changes in compliance that result from the deferral change.
3. Any donation in the window period is infectious; i.e. for this model a transmissibility function is not included for the MSM proportion.
4. The current residual risk already includes a proportion of non-compliant MSM, but this is not removed in the model.

Note - the assumptions result in a conservative estimate.

Proportion additional risk from newly non-compliant MSM donors resulting from the new deferral = a*b*c*d*e

a) The proportion of MSM in Australia from total adult population. Classify MSM who have engaged in sexual activity in last 12 months.
b) Yearly incidence of HIV in MSM.

Probability of donating in the window period =

c) Window period.
d) Average number of donations in a year.
e) Proportion of those non-compliant. Model various scenarios.

Scenario 1 assumes that MSM donate at the same average frequency as those in the general population; i.e. this directly relates to the proportion of MSM in the population. However, the existing donor base is assumed to have 4 times the current risk of HIV – i.e. 1 in 7.93 million.

Scenario 2 assumes that MSM donate at the same average frequency as those in the general population; i.e. this directly relates to the proportion of MSM in the population. The existing donor base is assumed to have the current risk of HIV – i.e. 1 in 31.7 million.

Scenario 3 represents the "most likely" conservative estimate with parameters selected based on the assumption that the entire MSM population does not have the HIV incidence of that found from the ACCESS database and the fact that non-compliance is already occurring in the current residual risk, which is added to this scenario as a proportion and therefore additionally included.

Scenario 4 models an alternative paradigm where the decreased deferral results in a decrease in non-compliance, and therefore non-compliance in MSM is halved to 0.115% and MSM are assumed to contribute 35% of the total residual risk. This scenario demonstrates that the risk could potentially decrease with a shorter deferral period.

Results

Data/assumptions	Risk estimate and comments
Current HIV risk 2017–2018 data (Lifeblood)	1 in 31.7 million or 0.031514 per million donations Note this includes the assumed 0.23% baseline MSM non-compliance rate. This is not removed in the model and the non-MSM donors are assumed to have this risk despite it being lower. Data from 2011–2015 indicates that approximately 35% of the current HIV risk is from MSM.
Worst case residual risk*4 i.e. increase above RR by four fold	1 in 7.93 million or 0.12606 per million donations
a) Proportion of MSM in population	2.7% of males report MSM in the last 12 months [36], so 1.35% of total population
b) Yearly incidence of HIV in MSM	1.3 per 100 person years. Based on high risk sexual health clinic cohort with approximately 30% attending with symptoms [37] – not used. 0.89 per 100 person years from ACCESS data for high risk MSM attending sexual health clinic. Average and 2015 incidence [38] – used. Average risk MSM. There is no data on average risk cohorts. Therefore the mid-point between the donor incidence and the high risk MSM incidence is used, which is 0.445 per 100 person years.
c) Window period	5.9 days (individual donation NAT – Grifols TMA)
d) Donations per year using 2015 data	= donations/donors = 1,271,324/464,137 = 2.73 for 2015 This includes plasma for fractionation donations Proportion of donations that are plasma for fractionation donations are 265,947/655,328 based on Jan–Jun 2017 data therefore 40.58%. Fresh components estimate therefore = = (271,324*0.594)/464,137 = 1.63 fresh component donations a year.
e) Proportion of those non-compliant various scenarios	Current estimated median donor non-compliance for MSM is 0.23% [1]. The change in risk estimate is modelled to increase 10-fold to 2.3% as a worst case to determine if this would approach the intolerable level >1 in 5,000,000.

Data/assumptions	Risk estimate and comments
Results: **2.3% (10x increase) in non-compliance** **Scenario 1. Four-fold increase in current residual risk among existing donors** **Scenario 2. Current residual risk among existing donors**	 **1 in 5.03 million** **1 in 9.58 million**
Scenario 3 **Assumes – Current residual risk among existing donors** **Newly eligible MSM:** **donate at the population frequency** **have an HIV incidence midway between high risk (from ACCESS data) and low risk (current blood donors)** **have a non-compliance rate 5x the measured rate (i.e. 5 x 0.23% or 1.15%) to allow for underestimation inherent in the study design.**	The total risk is modelled to be **1 in 20.1 million**.
Results: Scenario 4 **Assumes – Current residual risk and MSM contributes 35%.** **Newly eligible MSM:** **donate at the population frequency** **have an HIV incidence midway between high risk (from ACCESS data) and low risk (current blood donors)** **have a noncompliance rate of 0.115%** **For this scenario the 35% of the current RR is removed and replaced with the calculated MSM risk.**	The total risk is modelled to be **1 in 44.8 million**. If compliance improves because of the reduced deferral, this could result in a decreased risk for HIV.

HAV modelling

HAV is a known transfusion-transmissible agent. The risk of TT-HAV is in the pre-symptomatic viraemic period (as when a donor becomes unwell they will be deferred) and the theoretical risk of the total period of infectious viraemia in an asymptomatic infection. Case reports of TT-HAV are rare; however, all case reports have occurred in the pre-symptomatic period from donations given 6–28 days prior to clinical onset in the donor [39-42]. Combined data from 8 studies, including 163 patients, document that 80–85% of viraemia has resolved by 4 months from infection [43-50].

However, it should be noted that these are unwell people and therefore not directly applicable to the risk from a donor. In addition, resolving viraemia after seroconversion has not been confirmed to be infectious and this is unlikely the case. There are no prospective HAV RNA screening studies with adequate follow-up of people with asymptomatic infection and therefore the duration of infectious viraemia in donors with asymptomatic infection is unknown. However, in the absence of reported cases of TT-HAV from asymptomatic infection and the absence of infectivity data in prolonged viraemia with neutralising antibodies, this is assumed to be brief as estimated below.

The following input parameters were used to calculate a risk of a HAV transfusion-transmission. The risk modelled is based on the HAV MSM outbreak in NSW and models the risk in NSW over 105 days. The modelling is done assuming a total population risk and assuming an MSM-only risk. As defined in the Lifeblood EREEID risk tolerability framework agreed with the TGA, the risk of HAV transmission per unit transfused must be maintained below 1 in 1,000,000 to be an acceptable risk.

Cumulative infections reported	30 (total population risk) 28 (assuming all infected males are MSM) Source: NSW Communicable Diseases Weekly Report (CDWR) – Week 45, 2017
Duration of epidemic	105 days
Population size Sydney	5,029,788 Source: http://www.abs.gov.au/ausstats/abs@.nsf/mf/3218.0 MSM population in Sydney = 0.0135*2 = 0.027 assuming Sydney has twice the general population rate (1.35%) of MSM
Proportion of undetected cases:	30% from EUFRAT model (likely underestimate)
Duration of infectivity for acute infection	= 14 days (EUFRAT model). Assumes the infectivity is for the pre-symptomatic viraemic period only for symptomatic infections and asymptomatic infection (the duration of which is unknown). Sensitivity analysis increase to 28 days.
Donors and donations	74,204 donors with 107,529 components in 105 days in NSW. For MSM only risk 0.027 of donors i.e. 2 times the general population estimate Source: Internal data.
Risk of transmission and donor relative risk	100%
Number of infected products released	**Total population** 0.12. Risk of viraemia = 0.12/107,530 1 in 0.88 million for total population **Sensitivity analysis with 28 day duration of viraemia** 0.24 1 in 440,000 **Risk in MSM population** 0.11. Risk of viraemia = 0.11/2903 1 in 25,500 for MSM donors with no deferral **Sensitivity analysis with 28 day duration of viraemia** 0.23 1 in 12,700 for MSM with no deferral
Recipient immunity	51% [51]
Risk of transmission to recipient during HAV outbreak in Sydney	**Total population risk:** 1 in 1.80 million **MSM risk of TT** 1 in 52,000 **Sensitivity analysis with 28 day duration of viraemia** Total population risk 1 in 0.90 million MSM risk of TT 1 in 26,000

Discussion

HIV modelling

The modelling indicates that the impact of changing from the current 12-month deferral for MSM to 3 months would not result in a risk level above the 1 in 5 million per unit transfused 'tolerable risk' threshold Lifeblood applies for HIV. Based on the 'most likely' conservative estimate (Scenario 3), the risk of HIV transmission after implementing a 3-month deferral is predicted to increase marginally, from the currently estimated 1 in 31.7 million to approximately 1 in 20.1 million per unit transfused. Should the non-compliance rate improve, as modelled in Scenario 4, then a decreased deferral can decrease the risk, with a modelled risk of 1 in 44.8 million. Improved compliance has been the case in the UK, France and Canada after implementing 12-month deferrals.

As noted, the modelled estimates are subject to substantial uncertainty and are impacted most by two key parameters: the HIV incidence (in newly eligible donors and in all donors) and the level of non-compliance [34]. Accordingly, we designed three scenarios which vary these key parameters to determine the impact on the estimates. In Scenario 1, we model a 4-fold increase in HIV incidence (to take account of the maximum observed year to year variation in HIV incidence). In recognition that the 0.23% non-compliance estimate for MSM from our donor survey likely underestimates the true rate of non-compliance, we model a 10-fold increase, which is arbitrarily selected to represent a 'worst case' scenario. Combined, these two changes result in a predicted risk level of 1 in 5.03 million per unit transfused, importantly still below the tolerable risk level and given the conservative input parameter values used in the model, this is likely a significant overestimate.

Scenario 3 is designed to represent the 'most likely' conservative estimate. It assumes that newly eligible MSM donate at the population frequency, have an HIV incidence midway between high risk MSM (from ACCESS data) and low risk (current blood donors), and have a non-compliance rate 5 times the measured rate to allow for underestimation inherent in the blood donor compliance study design. The predicted HIV risk under these conditions is approximately 1 in 20.1 million per unit transfused – comfortably below the tolerable threshold.

HAV modelling

The modelled unmitigated (i.e. with no deferral for male-to-male sex) estimate of HAV transmission risk associated with the NSW MSM outbreak is approximately 1 in 1.8 million per unit transfused, which is below the acceptable risk threshold of 1 in 1 million. It should also be noted that if this risk was an annualised risk or was expanded to include donations on a national level it would be considerably lower than the presented risk. Notably, the modelled transmission risk within the MSM population (approximately 1 in 52,000) is substantially higher than the population risk, but not high enough in itself to increase the average transmission risk to recipients above the acceptable threshold. Any duration of deferral longer than 2 months would be expected to cover the vast majority of the risk and reduce it substantially lower than the acceptable level (1 in 1,000,000).

The major limitation to the modelling is the uncertainty over the period of infectious viraemia in donors who do not develop symptoms (i.e. the period of asymptomatic viraemia). To account for this uncertainty and considering a recent literature search conducted by Lifeblood, we have modelled the risk using periods of 14 days (best estimate) and 28 days (upper estimate). Applying the 28 day upper estimate increases the population risk from approximately 1 in 1.8 million to approximately 1 in 0.9 million (unmitigated risk) per component transfused.

Lifeblood already has a deferral period for contacts of known hepatitis A cases. An *additional* 3-month deferral period to cover sexual contact with MSM at potential risk of hepatitis A because of a sexual risk exposure would adequately cover the period of infectious viraemia.

Conclusion

Using conservative model input parameter values, the modelled estimates for HIV and HAV transfusion transmission under a 3-month deferral period would not increase above the Lifeblood defined 'tolerable' or 'acceptable' risk thresholds. This conclusion is robust even if key input parameters have been substantially underestimated or overestimated given the conservative nature of the modelling.

Appendix B: Proposed changes to the Guidelines for Selection of Blood Donors (SOP-00080 v15)

					Recall Requirements		
Donor Event	**Category**	**Explanation**	**Action**	**Use NBMS deferral Code**	**Recall Fresh Components?**	**Notify Clinician?**	**Recall Plasma for Fractionation? (CSLB)**
Sexual contact							
Sexual contact	Bisexual male contact	**This entry relates to Donor Declaration question 7.** If a woman had sex with a man who had sex with a man, an allogeneic donation is not possible until a deferral period expires, regardless of when the male-to-male sex took place. **Exception:** If the woman's partner is a current Lifeblood donor, the deferral may not apply. See 'Managing exceptions to Donor Declaration questions C5, C6 and C7' on page 56-7.	Allogeneic: • Defer for ~~12~~ 3 months from the date of last sexual contact with a bisexual male unless the exception listed applies. • **For this question, if a donor contradicts a 'Yes' answer from any previous attendance (i.e. a related active deferral is in place), contact an MO.** • If a recall is required, collect UR samples for testing. Autologous: Accept. Therapeutic: Accept and discard until allogeneic conditions are met.	T340	Yes, and collect UR samples.	Yes. MO to assess UR test results and manage accordingly.	Yes
Sexual contact (continued)	HIV risk contact, while **overseas**	If a donor had sex while overseas in an HIV risk area with a current resident of that area (including a regular partner who lives overseas), an allogeneic donation is not possible until a deferral period expires. Couples emigrating together from HIV geographical risk areas require deferral for 12 months from the date of arrival in Australia. See 'Geographical considerations' on page 386 for a list of countries/places that are HIV risk areas. See also 'HIV/AIDS' on page 198 for general information.	Allogeneic: • Defer for ~~12~~ 3 months from the date of last sexual contact. • If a recall is required, collect UR samples for testing. Autologous: Accept. Therapeutic: Accept and discard until allogeneic conditions are met.	T344	Yes, and collect UR samples.	Yes. MO to assess UR test results and manage accordingly.	Yes

Donor Event	Category	Explanation	Action	Use NBMS deferral Code	Recall Requirements		
					Recall Fresh Components?	Notify Clinician?	Recall Plasma for Fractionation? (CSLB)
Sexual contact							
	Injecting drug user contact, current or past	**This entry relates to Donor Declaration question 5.** If a donor had sex with a person who ever injected drugs not prescribed by a registered doctor or dentist, an allogeneic donation is not possible until a deferral period expires, regardless of when the drug use took place. **Exception:** If the person's partner is a current Lifeblood donor, the deferral may not apply. See 'Managing exceptions to Donor Declaration questions C5, C6 and C7' on page 56-7.	Allogeneic: • Defer for ~~12~~ 3 months from the date of last sexual contact with an injecting drug user. • **For this question, if a donor contradicts a 'Yes' answer from any previous attendance (i.e. a related active deferral is in place), contact an MO.** • If a recall is required, collect UR samples for testing. Autologous: Accept. Therapeutic: Accept and discard until allogeneic conditions are met.	T190	Yes, and collect UR samples.	Yes. MO to assess UR test results and manage accordingly.	Yes
Sexual contact (continued)	Male to male contact	**This entry relates to Donor Declaration question 8.** If a man had oral or anal sex with a man, including safe sex with a condom, an allogeneic donation is not possible until a deferral period expires.	Allogeneic: • Defer for ~~12~~ 3 months from the date of last sexual contact with a male. • **For this question, if a donor contradicts a 'Yes' answer from any previous attendance (i.e. a related active deferral is in place), contact an MO.** • If a recall is required, collect UR samples for testing. Autologous: Accept. Therapeutic: Accept and discard until allogeneic conditions are met.	T339	Yes, and collect UR samples.	Yes. MO to assess UR test results and manage accordingly.	Yes

Donor Event	Category	Explanation	Action	Use NBMS deferral Code	Recall Requirements		
					Recall Fresh Components?	Notify Clinician?	Recall Plasma for Fractionation? (CSLB)
Sexual contact							
	Sex worker	**This entry relates to Donor Declaration question 9.** If a donor has worked as a sex worker, an allogeneic donation is not possible until a deferral period expires. See also 'Sexual contact, Sex worker contact' on this page.	Allogeneic: • Defer for ~~12~~ 3 months from the date of ceasing sex work. • **For this question, if a donor contradicts a 'Yes' answer from any previous attendance (i.e. a related active deferral is in place), contact an MO.** • If a recall is required, collect UR samples for testing. Autologous: Accept. Therapeutic: Accept and discard until allogeneic conditions are met.	T342	Yes, and collect UR samples.	Yes. MO to assess UR test results and manage accordingly.	Yes
Sexual contact (continued)	Sex worker contact	**This entry relates to Donor Declaration question 10.** If a donor had sex with a sex worker, an allogeneic donation is not possible until the deferral period expires. A sex worker is someone who has received payment (e.g. money, gifts or drugs) in exchange for sex within the previous 12 months.	Allogeneic: • Defer for ~~12~~ 3 months from the date of last sexual contact with a sex worker. • **For this question, if a donor contradicts a 'Yes' answer from any previous attendance (i.e. a related active deferral is in place), contact an MO.** • If a recall is required, collect UR samples for testing. Autologous: Accept. Therapeutic: Accept and discard until allogeneic conditions are met.	T345	Yes, and collect UR samples.	Yes. MO to assess UR test results and manage accordingly.	Yes
	Transgender donor contact with a male or transgender partner	If a transgender donor has sexual contact with a male or transgender partner, an allogeneic donation is not possible until a deferral period expires. **This applies regardless of the donor's original biological sex or their current sex.** See also Assessing Transgender and Gender Diverse Donors (SOP-00094).	Allogeneic: • Defer for ~~12~~ 3 months from the date of last sexual contact with a male or transgender partner. • If a recall is required, collect UR samples for testing. Autologous: Accept. Therapeutic: Accept and discard until allogeneic conditions are met.	T343	Yes, and collect UR samples.	Yes. MO to assess UR test results and manage accordingly.	Yes

Donor Event	Category	Explanation	Action	Use NBMS deferral Code	Recall Requirements		
					Recall Fresh Components?	Notify Clinician?	Recall Plasma for Fractionation? (CSLB)
Sexual contact							
Sexual contact (continued)	Viral agent, possible past contact	**This entry relates to Donor Declaration question 5.** If a donor answers 'Yes' to question 5 in the Donor Declaration but cannot provide information about the virus that may be implicated, an allogeneic donation is not possible until a deferral period expires. Use this entry when the specific virus is not known. See also sexual contact entries for 'Hepatitis B', 'Hepatitis C' and 'HIV/AIDS' on pages 190-1, 193-4, and 199-200.	Allogeneic: • Defer for ~~12~~ 3 months from the date of last sexual contact with the person who is the subject of question 5 in the Donor Declaration. • **For this question, if a donor contradicts a 'Yes' answer from any previous attendance (i.e. a related active deferral is in place), contact an MO** • If a recall is required, collect UR samples for testing. Autologous: Accept. Therapeutic: Accept and discard until allogeneic conditions are met.	T483	Yes, and collect UR samples	Yes. MO to assess UR test results and manage accordingly.	Yes

Donor Event	Category	Explanation	Action	Use NBMS deferral Code	Recall Requirements		
					Recall Fresh Components?	Notify Clinician?	Recall Plasma for Fractionation? (CSL)
Hepatitis							
Hepatitis B	Past contact – sexual, mucosal and close household	If a donor has had past close household contact (e.g. they have shared personal items like razors or toothbrushes) or sexual/mucosal contact with someone who has hepatitis B, they must be deferred for ~~12~~ 3 months from the date of last exposure unless testing confirms that they are immune as per History of Hepatitis and Immunity Testing (WI-00851). To confirm immunity, the donor will need to undergo HBV immunity testing (refer to 3. Collect – Managing Sample Test Code Requests (PPM-00003)). An MO will evaluate the test results (including checking that the anti-HBs level is greater than or equal to 100 IU/L) to assess if an allogeneic donation is possible.	Allogeneic/Therapeutic: Accept if it is ~~12~~ 3 **months or more from the date of last exposure**. If it is **less than** ~~12~~ 3 **months** from the date of last exposure, defer unless the donor is believed to be immune (i.e. they have been vaccinated). If the donor is believed to be immune, collect HBV samples for testing **but do not collect a donation.** Accept if previously tested at Lifeblood and proven immune. **If a recall is required,** take UR and HBV immunity samples for testing. Autologous: Perform HBV immunity testing. Accept if well and cleared by HBV immunity testing.	T332	Yes, if exposed within the ~~12~~ 3 months prior to donation and not immune.	Yes. MO to assess UR test results and manage accordingly.	Yes
Hepatitis C	Past contact – sexual, mucosal and close household	If a donor had past close household contact (e.g. they have shared personal items like razors or toothbrushes) or sexual/mucosal contact with someone who has a history of hepatitis C, they must be deferred for ~~12~~ 3 months from the date of last exposure. **Even if the person with a history of hepatitis C has had successful antiviral treatment,** an allogeneic donation is **only possible** after the ~~12~~ 3 month deferral period has expired.	Allogeneic: Defer for ~~12~~ 3 months from the date of last exposure. Autologous: Accept. Therapeutic: Accept and discard until allogeneic conditions are met.	T333	Yes, for collections taken after the date of exposure.	Yes. MO to assess UR test results and manage accordingly.	Yes

Donor Event	Category	Explanation	Action	Use NBMS deferral Code	Recall Requirements		
					Recall Fresh Components?	Notify Clinician?	Recall Plasma for Fractionation? (CSL)
HIV/AIDS							
HIV/AIDS	Contact, past – sexual, mucosal and close household	**This entry relates to Donor Declaration question 5**. If a donor had past close household contact (e.g. they shared personal items like razors or toothbrushes) or sexual/mucosal contact with someone who had AIDS or was known to be HIV positive (e.g. a past partner with HIV), an allogeneic donation is not possible until a deferral period expires. Sexual/mucosal contact, in this context includes oral sex, penetrative vaginal sex and anal sex, with or without condoms. Kissing and mutual masturbation are not classified as sexual/ mucosal contact.	Allogeneic: • Defer for ~~12~~ 3 months from the date of last exposure • **For this question, if a donor contradicts a 'Yes' answer from any previous attendance (i.e. a related active deferral is in place), contact an MO** • If a recall is required, collect UR samples for testing. Autologous: Accept. Therapeutic: Allow for therapeutic discard for ~~12~~ 3 months from date of last exposure as long as donor remains HIV negative.	T341	Yes, and collect UR samples.	Yes. MO to assess UR test results and manage accordingly.	Yes

Donor Event	Category	Explanation	Action	Use NBMS deferral Code	Recall Requirements		
					Recall Fresh Components?	Notify Clinician?	Recall Plasma for Fractionation? (CSL)
HTLV*	Contact, past – sexual, mucosal and close household	**This entry relates to Donor Declaration question 5**. If a donor had past close household contact (e.g. they shared personal items like razors or toothbrushes) or sexual/mucosal contact with someone who had HTLV or was known to be HTLV positive (e.g. a past partner with HTLV), an allogeneic donation is not possible until a deferral period expires. Sexual/mucosal contact, in this context includes oral sex, penetrative vaginal sex and anal sex, with or without condoms. Kissing and mutual masturbation are not classified as sexual/ mucosal contact.	Allogeneic: • Defer for ~~12~~ 3 months from the date of last exposure • For this question, if a donor contradicts a 'Yes' answer from any previous attendance (i.e. a related active deferral is in place), contact an MO • If a recall is required, collect UR samples for testing. Autologous: Accept. Therapeutic: Allow for therapeutic discard for ~~12~~ 3 months from date of last exposure as long as donor remains HTLV negative.	T347	Yes, and collect UR samples.	Yes. MO to assess UR test results and manage accordingly.	No

**Note that after cessation of universal testing of repeat donors, HTLV testing will become a re-entry requirement for donors who become eligible after a HTLV contact deferral expires in the absence of ongoing contact*

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