Terms of Reference for a follow-up review of donor deferral criteria relating to sexual activity with particular reference to a history of male-to-male sex

1. PART I: INTRODUCTION AND BACKGROUND

1.1. Internationally, blood services undertake a number of processes to minimise the risk of transfusion-transmissible viral infections. Because no single process can completely eliminate the risk, scientific evidence demonstrates that a combination approach is the more effective.

1.2. In accordance with this, in Australia, a four tier combination approach to safety currently applies:

a. Through pre-donation public education using the donateblood.com.au website, the media and the Blood Service National Contact centre as well as brochures and handouts in collection facilities, donors are informed of eligibility criteria for blood donation and the reasons for deferral from donation.

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

c. State-of-the-art tests are undertaken on donated blood to identify prospective donors with pre-existing infection and regular donors acquiring new infections.

d. Where available, physical and/or chemical measures are applied to inactivate viruses and other infectious agents (pathogen reduction technologies or PRT). Presently PRT are used for manufactured plasma products but are not routinely available in Australia for fresh blood components.

1.3. Sexual activity is a major route of transmission for a number of transfusion-transmissible infections including; human immunodeficiency virus (HIV) and hepatitis B virus (HBV). In 2010, the Blood Service convened an independently
chaired, expert committee (2012 review) to review all sexual activity-based eligibility policies. The review committee’s recommendation to reduce the deferral period for all sexual activity-based deferrals from 12 months to 6 months underpinned a proposal for formal approval by the regulator (TGA). In 2013, the TGA notified the Blood Service they did not support the proposal and the 12 month deferral periods remain in force.

Continued lobbying by affected communities and indications from Australian governments in support of increased participation by currently ineligible donors suggests the need for a second review.

2. **PART II: TERMS OF REFERENCE**

**The Review Committee**

2.1. To the extent possible, the original 2012 expert review committee is to be re-formed by invitation. The final makeup of the committee will be by agreement between the chair person and the Blood Service from willing, qualified and available candidates.

**Principal Task of Review Committee**

2.2. To review relevant local/international developments since the conclusion of the 2012 review in relation to the ongoing appropriateness of exclusion of donors on the basis of current and/or past sexual activity.

2.3. Considering 2.2, and in the context of ensuring the ongoing safety of blood and blood products provided in Australia, re-evaluate the recommendations of the 2012 review.

**Process**

2.4. The Blood Service does not seek to prescribe what mechanisms the Review Committee might consider of utility in achieving its task. However, the Blood Service does require that the Review Committee, at a minimum consider specified focus areas (refer 2.5) and data sources (refer 2.7). In addition, the
committee’s initial deliberations should prioritise reconsidering the appropriateness of the 2012 reviews recommendation for 6 month minimum period for MSM (refer 2.5 a(i) below). Apart from this, the review Committee shall decide for itself how it will discharge its Terms of Reference and provide to the Blood Service its report and recommendations.

2.5 Areas of emphasis

Particular emphasis should be placed in the following areas:

a. The appropriateness of the current policies for exclusion of men who have sex with men (MSM) and in particular:

   i. Whether the 2012 review’s recommended deferral period of 6 months for MSM remains appropriate, or whether a different minimum period of deferral is justified, based on current evidence.

   ii. 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.

   iii. Whether plasma for fractionation (which is subject to targeted pathogen inactivation during processing) provides an opportunity to expand donation by MSM without negatively impacting recipient safety. If so, given the risk mitigation measures in place for plasma for fractionation, consider whether it would be necessary to identify a lower risk cohort of MSM (e.g. those in sexually exclusive relationship for a defined period) and if so, how this cohort should be identified. In addition, consider whether a period of ‘quarantine’ (the process of physically holding donated plasma until the donor returns and tests negative for mandatory tests, including HIV) is required and if so of what duration.

b. The level of protection afforded by regular condom use and HIV pre-exposure prophylaxis (PrEP) and whether these alone, or in combination, are sufficient in the context of transfusion transmission to avoid exclusion,
or if not, whether the risk is changed such that the deferral period could be adjusted.

c. Considering developments since the 2012 review, the appropriateness of excluding current and former sex workers and the appropriate period of any exclusion.

2.6 Topics outside the scope of this review

2.6.1 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. For this reason, HHV-8 was not included in the evidence-based review of sexual activity-related deferral criteria

2.6.2 Deferral criteria not related to sexual activity

Several deferral policies that are not related to sexual activity, are therefore beyond the scope of the current review. These include:

- vCJD deferral – ‘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?’

- Illicit drug injection deferral – ‘Ever “used drugs” by injection or been injected, even once, with drugs not prescribed by a doctor or dentist?’

Sources to be consulted

2.7 In undertaking the review the following sources are required by the Blood Service to be considered by the Review Committee (in addition to any other
material that the Review Committee might consider relevant and helpful to these Terms of Reference):

a. The evidence presented to, findings and observations of the Tasmanian Anti-discrimination Tribunal in the matter of CAIN. Michael v the AUSTRALIAN RED CROSS SOCIETY (File No. 100-0607003) and the two previous anti-discrimination cases.

b. Relevant Blood Service research including past and current incidence, prevalence and risk trends for major blood-borne infections in the donor population as well as modelling of donor HIV risk behaviours and the retrospective analysis of the impact of implementing the current 12 month deferral for male-to-male sex.

c. Epidemiological and other survey data on the pattern and mechanisms of transmission of HIV infection and other blood borne infections in Australia and overseas.

d. Current international practice, past practice reviews and relevant research by major international Blood Services (e.g. the 2017 Canadian Blood Service/Hema-Quebec MSM 2017 Research meeting and 2017 UK SaBTO donor deferral working group report) as well as applicable international regulatory requirements.

e. Data in relation to transfusion transmission of blood borne viral infections in which sexual transmission is a major route of infection and mechanisms whereby this might be reduced.

f. Relevant studies/research concerning the level of compliance to current deferral policies and strategies to minimise non-compliance (i.e. failing to disclose information during the donor screening process which, if disclosed would lead to deferral).

g. Modelling to estimate the HIV-risk associated with changes to deferral periods and in particular the model developed by the International Society for Blood Transfusion (ISBT) Transfusion-Transmitted Infectious Diseases
working group.

Assistance and resources

2.8 The Blood Service is available to provide the Review Committee with assistance and resources in carrying out its functions. The Committee will be supported by a Research Officer with medical or scientific experience and background but otherwise it is not anticipated that the Review Committee will need to engage any contractors of its own to assist in carrying out its review.

2.9 The Blood Service will provide the Review Committee as a part of its process:

a. Access to legal opinion, should it be required by the committee.
b. Information about its own operations, including where relevant a demonstration of the blood donation process that is followed on a day to day basis by the Blood Service.

Expectations

2.10 In developing the recommendations the Review Committee is expected to address:

a. Compliance with current Australian (Commonwealth, State and Territory) legislation especially anti discriminatory legislation.
b. The over-riding obligation of the Blood Service to ensure that blood components provided for transfusion to patients are as safe as reasonably achievable.
c. The regulatory obligation of the Blood Service including conformance with mandatory and non mandatory recognised international standards.
d. Ethical issues in relation to both potential donors and recipients of blood and blood products.
e. The practicalities of implementing recommendations in the routine environment of the Blood Service activities.
Final Version (13 July 2017)
Endorsed by Blood Service and Committee Chair (Professor Steve Wesselingh)