

Terms of Reference for a 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 Australian Red Cross 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.

2. PART II: TERMS OF REFERENCE

The Review Committee

2.1. A review committee is to be formed comprised of a group of experts and a chair that will provide independent advice to the Blood Service. The Review Committee will be comprised of suitably qualified experts and will be selected by agreement between the chair person and the Blood Service from willing and available candidates.

Principal Task of Review Committee

- 2.2. To review the ongoing appropriateness of exclusion of donors on the basis of current and/or past sexual activity to ensure the ongoing safety of blood and blood products provided in Australia.
- 2.3. Where a form of screening dependent on sexual activity is considered appropriate, to recommend how exclusions from donation should be structured.

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 process follow a specified sequence, and that a public consultation exercise is undertaken. Apart from this constraint, 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.

Areas of Emphasis

- 2.5. Particular emphasis should be placed in the following areas:
 - a. The appropriateness of ongoing exclusion of men who have sex with men and in particular:
 - i. Whether it is possible to define sexual activities that should result in exclusion from donation.
 - ii. The level of protection afforded by regular condom use and whether this is sufficient in the context of transfusion transmission to avoid exclusion.
 - iii. Whether (in the context of routine blood donation operations) it is possible to consistently identify a set of criteria by which individuals might be identified as at greater risk of acquiring blood borne infections than that of the wider population.

- iv. The appropriate period (if any) of any exclusion.
- b. Consideration of possible additional approaches to protect the donated blood supply from the risks associated with HIV acquired through heterosexual activity, with a particular emphasis on risks associated with sexual activity with people living in or from geographic areas of high prevalence.
- c. The relative risk of male-to-female versus male-to-male sex.
- d. The appropriateness of excluding current and former sex workers and the appropriate period of any exclusion.
- e. Whether the potential for sexual transmission as a route of infection in an as yet identified (i.e. new or emerging) pathogen should impact the duration of current deferrals for sexual activity.
- f. Advise on the development of effective communication tools to improve overall compliance with the sexual activity-based donor criteria and to explain their ongoing use.

Sources to be Consulted

2.6. 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 this 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 (see 1.8 b and c)
- 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 2008 review of donor behavioural criteria conducted by the New Zealand Blood Service) 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.

Assistance and Resources

2.7. 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.

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

- a. A legal briefing at the outset so that the Human Rights issues can be properly appreciated and understood.
- 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

2.9. 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.

Approved by Review Committee Chair, September 2010