

Advisory Committee on Biologicals Meeting 3

Meeting date: 19th September 2013

Agenda Item: 4.2

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

BACKGROUND

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

Since 2000, the ARCBS has imposed a 12 month deferral¹ on blood donations from individuals who have participated in sexual behaviours including:

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

Current international donor deferral criteria

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

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

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

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

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

Risk of transfusion-transmitted HIV in Australia

Current estimates indicate that the residual risk of TTI with HIV or HCV in Australia are less than 1:1,000,000 per unit transfused; for HBV the residual risk is about 1:538,000 units transfused²

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

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

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

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

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

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

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

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

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

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

DISCUSSION

Summary of key and significant issues

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

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

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

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

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

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

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

CONCLUSION/CONSULTATION

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

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

Questions for ACB:

1. Does the Committee agree that there is sufficient evidence to support relaxing the blood donor deferral period in relation to sexual activity-based behaviours for currently identified ‘high risk’ groups?
2. If the Committee considers that there is insufficient evidence to support relaxing the deferral period for some or all high risk groups, what additional evidence should be sought?
3. Since compliance with providing correct answers to pre-donation questions is highlighted as critical to the mitigation of TTIs, does the Committee have sufficient confidence in the Blood Service's survey outcomes to demonstrate that Australia has a significantly lower level of non-compliance compared with overseas results? Does the Committee feel the Blood Service has properly accounted for the differences in survey results? If not, what further analysis would the Committee recommend the Blood Service undertake to address this matter?

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

ATTACHMENTS

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

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

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

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