

Blood Donor Deferral – Gay and Bisexual Men – Update

April 2017

This briefing provides an overview of the Australian Red Cross Blood Service's policy on blood donation by men who have sex with men (MSM), followed by an update on recent developments and next steps.

Background

The Australian Red Cross Blood Service (the Blood Service) requires that a man who has had sex with a man within the previous year be deferred from donating blood.¹⁻² This 12-month period is known as the *deferral period*. The current deferral period was put in place following the introduction of nucleic acid testing in 2000.

Following legal challenges in a number of Australian jurisdictions (generally brought under anti-discrimination laws), the Blood Service initiated an expert review of its donor deferral policies in 2012. After seeking broad stakeholder input, including from AFAO and its members, the expert panel recommended that the deferral period for sexual activity between men be reduced to six months.

The period recommended by the expert review – six months – is far in excess of the window period for HIV, and relates to the longer window period for hepatitis C, which is also more prevalent among MSM. The window period for hepatitis C is assessed as being up to ninety days, with the recommendation for six months being to provide for greater caution again on this window period.

While the Blood Service supported the recommendation to reduce the deferral period to six months, it is required to have changes to its donor policy approved by the Therapeutic Goods Administration. The Blood Service accordingly put this recommendation forward to the TGA for approval, but it was rejected by the TGA, leaving the 12-month deferral period in place.

AFAO's 2016 federal election survey of the three major parties outlined AFAO's claims across a range of issues, including blood donation policy. We asked parties to commit to implementing the recommendation of the Blood Service to reduce the deferral period from 12 to six months for MSM. The Greens committed to support the implementation of the recommendation, while Labor committed to tasking "the TGA with reviewing Australia's policy on blood donation by men who have had sex with men in light of international evidence". The Coalition made no public commitment.

AFAO's Position

AFAO believes that the 12-month deferral period for MSM is excessive and inconsistent with expert evidence, including that of the expert review panel. AFAO has supported the recommendation to reduce the deferral period to six months. In holding this position, AFAO believes that a six-month deferral period is cautious and conservative, but supports it as the conclusion of the most recent expert review on this policy.

¹ <http://www.donateblood.com.au/faq/sexual-activity>

² The Blood Service also excludes other donors from our communities other than men who have sex with men, including sex workers and people who inject drugs. These communities are not included in this paper as they are outside the scope of the current Blood Service review.

The Therapeutic Goods Administration's Position

The two reasons cited by the TGA in rejecting the expert panel recommendations were:

- a decrease in the deferral period was unlikely to significantly increase the blood supply
- a background of increasing HIV diagnoses, being “10% in Australia in 2012.... This is the largest annual increase in new cases in 20 years and can only partly be explained by increased HIV testing.”

Update

AFAO has been in regular discussion with the Blood Service regarding the deferral period. The Blood Service has confirmed that it will conduct an internal review of its deferral policy for MSM. It has also advised that it is conducting a simultaneous review of blood donations by trans and gender diverse people.

The deferral period for MSM received media attention on 7 October when the Council of Australian Governments Health Council, following advocacy from the Victorian Government, agreed:

“to request that the Australian Red Cross Blood Service bring forward their planned review of the blood donor deferral policy relating to sexual activity to ensure that the policy is aligned with contemporary evidence on risk. It is also noted that the TGA is required to approve any change on the deferral policy.”

AFAO has sought and received confirmation from the Blood Service that AFAO will be consulted in the development of terms of reference for the review and in the review itself. The Blood Service has also advised that they propose to convene an expert panel similar in composition to that of the 2012 review.

To inform their review, the Blood Service attended a conference of international blood services in Toronto, Canada in January 2017 on options for blood donation by MSM. The conference followed a commitment by the Canadian Prime Minister to review blood donation laws for gay and bisexual men. The conference was attended by blood service stakeholders from Canada, the US and other countries. As an outcome of the conference, participants agreed that a study should be conducted to address the following question: “is it possible to identify a low-risk cohort of men amongst MSM that ensures the risk of transmission is reduced”?

The Blood Service convened a forum on 7 March to explore issues relating to blood donations in Australia, including the deferral period for MSM. One option canvassed was reducing the deferral period to six months. Another option was to allow a cohort of lower-risk MSM to donate fractionated plasma products if they have had no new/sexual partner in the preceding four months. Plasma – a component of blood – is fractionated to obtain a number of proteins that have a therapeutic benefit. This process includes a ‘pathogen reduction’ step.

The June 2016 nightclub shooting in Orlando, New Orleans, triggered debate in the US about the exclusion of gay men from donating blood. In the wake of the shooting, the US Food and Drug Administration opened a consultation on its 12-month deferral period for MSM. The consultation closed 25 November 2016. While the outcomes of the review are not yet known, they will be of interest to those involved in the Australian review.

Next steps

The Blood Service has advised that it will commence the review of the deferral period in mid-2017. AFAO believes that any review should consider the latest evidence to ensure the safety and quality of the Australian blood supply, while avoiding the unnecessary exclusion of potential blood donors. AFAO is continuing to work closely with the Blood Service and through other means to ensure an evidence based approach to Australian blood donor policy.