

Policy Document

Blood Donation Deferral

Background

The Australian Medical Students' Association (AMSA) is the peak representative body for medical students in Australia. Accordingly, AMSA advocates on issues that may impact health outcomes. AMSA believes that all patients should have the right to safe blood and blood products.

In Australia, the supply and transfusion of blood products is an important service provided by the Australian Red Cross Blood Service (ARCBS). Every week, over 25,000 Australians need blood donations, with the main supply of blood products coming from volunteers in the general public [1]. The ARCBS regularly calls for donors with specific blood groups to provide lifesaving donations due to blood shortages [2]. In light of regular shortfalls, AMSA encourages medical students nationally to donate blood and incentivises this practice through the "Vampire Cup", a competition between the university medical societies.

The safety of the blood products is paramount to the success of the service. As such, the ARCBS routinely tests each and every donation for blood borne infections (BBIs) including Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV), Hepatitis C Virus (HCV), human T-lymphotropic virus, and syphilis[3]. Donor health questionnaires (DHQs), first implemented in the 1980s, are used in conjunction with laboratory testing to reduce the likelihood of transfusion-transmitted infections (TTIs). The DHQ is designed to exclude individuals who pose a disproportionate risk to the safety of the blood supply or to their own safety, based upon their behaviour or health, from donating blood. If an individual is deemed a disproportionate risk for donation, then a deferral period is ordinarily imposed [4].

This policy focuses primarily on the current 12-month deferral period imposed on men who have sex with men (MSM). The relevant questions within the DHQ read:

In the last 12 months have you:

- ***Had sex (with or without a condom) with a man who you think may have had oral or anal sex with another man?***
- ***Had male to male sex (that is, oral or anal sex) with or without a condom?" [5]***

These questions screen for behaviours that are associated with contracting HIV in Australia. The Kirby Institute (2016) estimates approximately 25,313 individuals are living with HIV in Australia, and recorded 1,025 new HIV diagnoses in 2015. In

2015, 68 per cent of new HIV diagnoses were attributed to MSM and 20 per cent to heterosexual contact [6]. By contrast, other BBIs such as HBV and HCV are primarily transmitted through the use of intravenous drugs. Eleven per cent of all HBV transmissions between 2008 and 2012 were attributed to sexual contact; of these 75 per cent were attributed to heterosexual contact and 15 per cent to MSM. Of all HCV transmissions between 2008 and 2012, 3 per cent were attributed to sexual contact, however, data does not differentiate further based on sexual practice [7]. Thus the 12-month deferral period for MSM has been imposed, for the most part, to reduce the risk of transfusion-transmitted HIV. The risk of transmission of a BBI via sexual contact is calculated by multiplying the risk of transmission associated with a given sexual act (e.g. insertive anal intercourse, receptive vaginal intercourse, etc.) by the risk that the source carries the particular BBI [8]. Anal intercourse carries a higher risk of transmission of all BBIs due to the nature of the membrane within the anal canal, as compared to the vagina and the mouth, which have higher immunological defences [2].

While the practice of anal intercourse is not limited to MSM, the seroprevalence of HIV in the MSM population is significantly higher (~10 per cent) when compared to the total Australian population seroprevalence (0.1 per cent). This means that the overall risk of transmission of HIV from a single act of unprotected anal intercourse where the serostatus of the partner is unknown is 1 in 700 for the MSM population, compared to 1 in 70,000 for heterosexual anal sex [8].

Kesby (2014) states that DHQs allow population-level statistics to obscure within-group diversity [12]. As such, some have called for the DHQ to be altered to a behaviour-based questionnaire, which does not specify certain populations within the community but rather performs a risk assessment based on the risk behaviours of the individual applicant donor [13].

Specifically, those in favour of changing to a behaviour-based DHQ claim that certain subgroups of MSM (e.g. MSM in monogamous relationships or MSM that always practice safe sex) are at an equivalently low risk of HIV to their heterosexual peers and thus should not be subject to any deferral period. This policy was most recently examined and rejected by the US Food and Drug Administration, on the basis that:

“[T]he available epidemiologic data in the published literature do not support the concept that MSM who report mutual monogamy with a partner or who report routine use of safe sex practices are at low risk for HIV.” [14]

A similar conclusion was reached in an Australian context, as per the following figures from the 2012 ARCBS Review of Australian Blood Donor Deferrals Relating To Sexual Activity. The Relative Risk of not detecting HIV positive infection amongst MSM donations is significantly higher compared to

heterosexuals who have had a new sexual partner in the last 12 months [3]. For reference regarding the following graph, FSW refers to female sex workers.

Figure 2. Relative risk of not detecting positive infection by risk group compared to heterosexuals who have had a new sexual partner in the past 12 months

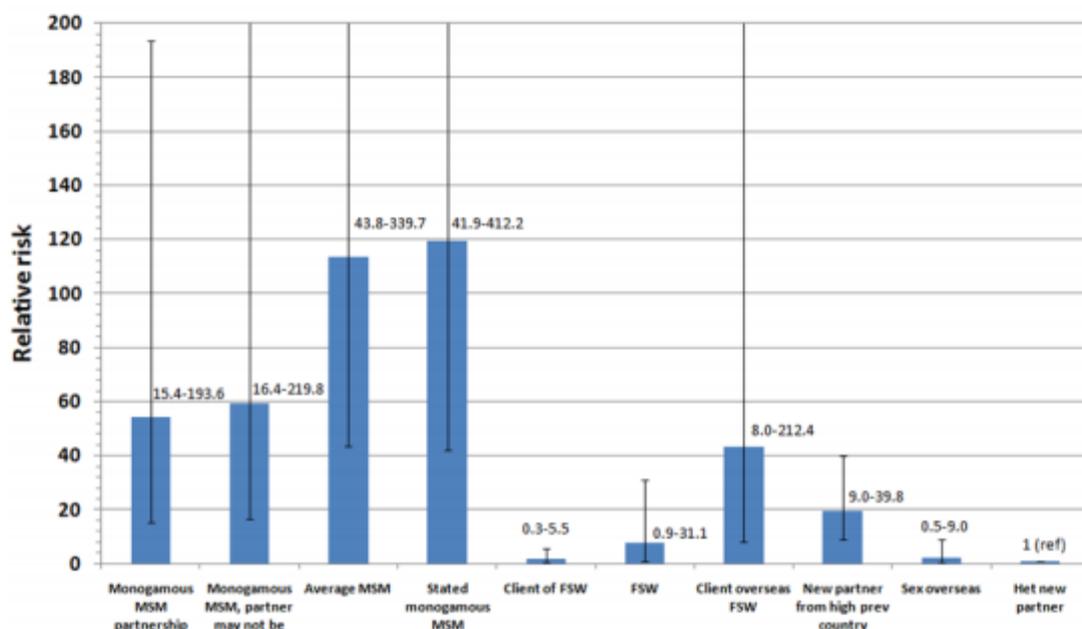


Table 9. Relative risk of failure to detect HIV infection in donations from MSM

Donor characteristics	Partner characteristics	Relative risk (95% UB)
MSM	-	113.5 (43.8-339.7)
MSM monogamous	monogamous	No risk based on sexual activity
MSM monogamous	unconfirmed HIV status	54.5 (15.4-193.6)
MSM monogamous	may not be monogamous HIV negative in previous 6-12 months	59.5 (16.4-219.8)
MSM monogamous	may not be monogamous unconfirmed HIV status	119.6 (41.9-412.2)

In recent years other proponents of policy change have argued that the 12 month deferral period is unnecessarily long and could safely be reduced [15]. In 2012, the ARCBS completed its own independent review regarding blood donor deferrals relating to sexual activity, and suggested that the deferral period should be lowered to 6 months. The serology test for HCV has the longest testing window period, and so the proposed six-month deferral is sufficiently long to safely incorporate this testing window period [(3)]. However, in late 2013 the Therapeutic Goods Administration (TGA) declined approval for this change. In making this decision, the TGA argued that their risk-benefit analysis had concluded that reducing the deferral period to six months for MSM would increase the risk of transfusion-transmitted infections without significantly

increasing donor numbers. They also cited an increasing incidence of new HIV infections, particularly among MSM [16].

Some have argued that the six-month deferral period for MSM constitutes discrimination, on the basis that such policies treat MSM differently to their heterosexual peers. In Australia, attempts to argue that deferral periods constitute illegal discrimination have been unsuccessful when heard before a number of anti-discrimination bodies, including: the Tasmanian Anti-Discrimination Tribunal, The Human Rights and Equal Opportunity Commission and the Victorian Civil and Administrative Tribunal [17].

Position Statement

AMSA believes that the safety of donated blood should be the consideration of highest priority. In instances where a prospective donor's desire to donate comes into conflict with the right of a blood product recipient to not be placed at increased risk of acquiring a TTI, AMSA believes that the right of the recipient takes precedence.

Correspondingly, AMSA believes that deferral periods should exist only to the extent to which the best available data suggests is required to maintain the safety and quality of donated blood products to recipients. Given that the data underlying the relevant risk assumptions are dynamic, AMSA also believes that deferral periods should be regularly reviewed so that they best reflect the most current BBI epidemiology.

Policy

AMSA calls upon:

1. The ARCBS to:
 - a. Continue to conduct research in order to ensure that donor screening adapts to any future changes in BBI epidemiology.
2. The Therapeutic Goods Administration to:
 - a. Impose restrictions on prospective donors only to the extent that best available evidence suggests is necessary to protect the safety of the blood supply.
3. The AMSA Vampire Cup Coordinator(s):
 - a. To explain the evidence-based rationale underlying deferral periods for MSM to medical students;
 - b. To investigate ways to engage students who are unable to donate blood for various reasons.
4. Commercial and Government research to:
 - a. Continue researching TTI screening tests in order to optimise the sensitivity and specificity of these tests and minimise their window period.

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Policy Details

Name: Blood Donation Deferral Policy

Category: F - Medicine in Australia

History: Adopted, Third Council, 2014
Reviewed, First Council, 2017