

# **BLOOD DONATION IN AUSTRALIA**

# JOINT ISSUES BRIEF WITH THE AUSTRALIAN COLLEGE OF NURSING AND CRANAplus

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# **EXECUTIVE SUMMARY**

Blood and plasma donation in Australia are an essential health service that can help save the lives of others and can improve people's health. The World Health Organization (WHO) states that blood donation is needed by women with pregnancy complications, individuals with major trauma resulting from accidents or natural disasters, cancer patients, and patients requiring major surgery. There are also individuals in the community who require regular blood transfusions due to immune deficiencies or blood conditions such as thalassaemia, sickle cell disease and haemophilia<sup>1</sup>. More recently, the *Australian Red Cross Lifeblood* has been collecting convalescent plasma from individuals who have recovered from the COVID-19 infection. The convalescent plasma is a component of blood that contains antibodies developed against the virus. It is currently being trialled as a potential treatment by means of transferable passive immunity against COVID-19<sup>2</sup>.

A regular supply of blood through blood donation is needed because blood has a limited time for use and there is therefore a need to ensure blood is always available and on hand. Unfortunately, there is a shortage of blood donations in Australia. According to the Australian Red Cross Blood Service, only one in 30 Australians donate blood, but one in three Australians will require blood in their lifetime<sup>3</sup>. The shortage in blood donations has significantly worsened during the COVID-19 pandemic despite blood donation being considered essential and not constrained by any travel or venue restrictions<sup>4</sup>. At the end of March 2020, it was reported that roughly 900 blood donors were cancelling appointments on a daily basis, which had increased from 800 earlier in the same month<sup>5</sup>. This has been attributed to several reasons<sup>6</sup>:

A strong blood donation response was observed during the Australian bushfire season in early 2020. However, this has meant there are fewer people available to donate blood due to the required 12-week wait before individuals can give blood again;

Self-isolation measures excluding essential activities that are currently in place due to the COVID-19 pandemic. It is suspected that people will therefore be less inclined or worried about leaving their home to donate blood, due to the potential risk of becoming exposed to COVID-19; and

Previously eligible donors aged 70 and over are no longer able to donate blood as a result from Government advice to stay at home and self-isolate for their own protection.

In Australia, there are strict criteria around eligibility for blood donation intended to protect both the blood donor and the blood donation recipient from infectious blood borne diseases. Some of these criteria include to:

- i. "be healthy and not suffering from a cold, flu or other illness at the time of donation;
- ii. be aged between 18 and 70 years;
- iii. weigh at least 50 kg;
- iv. have normal temperature and blood pressure; and
- v. meet guidelines designed to protect both the donor and the people who will receive the blood"7.

<sup>7</sup> Better Health Channel 2020. Blood Donation. State of Victoria. Viewed 25 May 2020. https://www.betterhealth.vic.gov.au/health/ conditionsandtreatments/blood-donation



<sup>1</sup> WHO 2017. Why should I donate blood? Viewed 23 May 2020. https://www.who.int/news-room/q-a-detail/why-should-i-donate-blood

<sup>2</sup> Australian Red Cross Lifeblood – May 2020. Coronavirus update. Viewed 23 May 2020. https://www.donateblood.com.au/page/coronavirusupdate

<sup>3</sup> MyDr 2019. Blood Donations. Viewed 25 May 2020. https://www.mydr.com.au/heart-stroke/blood-donations

<sup>4</sup> Irving D - 31 March 2020. Coronavirus hasn't slowed our need for blood donations. Yours is more essential than ever (The Conversation). Viewed 23 May 2020. https://www.abc.net.au/news/2020-03-31/coronavirus-blood-donations-essential/12105326

<sup>5</sup> Ibid.

<sup>6</sup> Ibid.

Some of the guidelines designed to protect the donor and recipient include excluding or imposing a deferral period on certain groups of individuals as blood donors either permanently or temporarily. The ineligibility criteria is based on:

"age (the minimum age for donors is 16 years; people older than 80 cannot donate; and those over 70 cannot become new donors);

being pregnant, recently pregnant or breast feeding;

current or recent short-term illness;

recent dental work;

certain previous illnesses or treatments;

recently having a tattoo or body piercing;

recent travel to certain countries;

certain lifestyle issues (including 'at risk' sexual activity and intravenous drug use); and

having lived in the UK between 1980 and 1996 for a total (cumulative) time of 6 months or more"8.

Included in the group of individuals with certain lifestyles are men who have had sexual contact with other men in the past 12 months (MSM). The reason for this is that MSM individuals have shown to have a greater risk of infection by the Human Immunodeficiency Virus (HIV) compared to heterosexual Australians with a new sexual partner<sup>9</sup>. While the 12-month deferral period for MSM individuals has seen reduced blood transfusion-transmitted infection rates<sup>10</sup>; the contemporary and improved testing and screening of blood donations means that blood borne diseases are now detected earlier and more easily. For this reason, it is timely to reconsider the length of the deferral period for blood donation from MSM individuals.

This issues brief will focus on one of the exclusion criteria (ineligibility criteria) to blood donation: MSM individuals. The aim of this brief is to provide a potential solution to blood supply shortages; and to ensure that minority groups are not marginalised when it comes to blood donation based on their sexual orientation – particularly when safe screening measures are in place to protect blood donation recipients and international standards have shown no risk to the public.

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<sup>8</sup> MyDr 2019. Blood Donations. Viewed 25 May 2020. https://www.mydr.com.au/heart-stroke/blood-donations

<sup>9</sup> Australian Red Cross Blood Service. The blood service deferral for men who have sex with men. Viewed 25 May 2020. http://www. donateblood.com.au/sites/default/files/Male-to-male\_deferral\_factsheet\_0.pdf

<sup>10</sup> Ibid.

# DEFINITIONS

#### **BLOOD DONATION**

Blood donation is a *voluntary and safe procedure* that can help save the lives of others and improve people's health. Several types of blood donation exist to cater for different health needs e.g. whole blood donation (most common form), platelet donation, plasma donation and others<sup>11</sup>. Blood donation is considered a safe procedure due to the use of new, sterile disposable equipment with each donor, as well as the use of a blood donor questionnaire and screening of blood products to eliminate risk of contracting an infectious blood-borne disease<sup>12</sup>.

#### **BLOOD DONOR QUESTIONNAIRE**

In Australia, individuals who wish to donate blood must first complete a list of personal questions including information about their health, sexual activity and drug use. The eligibility questionnaire is intended to protect both the blood donor and recipient of the blood donation<sup>13</sup>.

#### 'MEN WHO HAVE SEX WITH MEN' (MSM) BLOOD DONATION

In Australia, the Blood Donor Questionnaire includes a question asking whether male donors have had sex (including oral or anal sex without a condom) with another man in the past 12 months<sup>14</sup>. The current eligibility criteria precludes MSM blood donations where sexual activity has occurred within the last 12 months, despite the Therapeutic Goods Administration (TGA) approving the Australian Red Cross Lifeblood's submission to reduce this postponement from 12 to three months since the last sexual contact. State and federal government approval is required before this can occur<sup>15</sup>.





<sup>11</sup> Mayo Clinic 2020. Blood Donation. Viewed 25 May 2020. https://www.mayoclinic.org/tests-procedures/blood-donation/about/pac-20385144

<sup>12</sup> Ibid.

<sup>13</sup> Australian Red Cross Lifeblood 2020. Eligibility. Viewed 25 May 2020. https://www.donateblood.com.au/eligibility

<sup>14</sup> Australian Red Cross Lifeblood. LGBQTI+ Donors. Viewed 25 May 2020. https://www.donateblood.com.au/lgbtqi-donors

<sup>15</sup> Ibid.

# INTRODUCTION

To donate blood in Australia, 'men who have sex with men' (MSM) must abide by a 12-month deferral period in order to be eligible. This deferral period is cautious and conservative with many other Organisation for Economic Co-operation and Development (OECD) nations either reviewing the 12-month guideline or reducing the deferral period to four-to-six months. Improvements in detection technology have driven this change. Current screening technology used in Australia can detect blood borne diseases and infections and have reduced the window period in which these infections can be detected. Considering changing international standards, CRANAplus and the Australian College of Nursing (ACN) call for a revision of the current guidelines governing MSM blood donations in Australia. We recommend a reduction in the deferral period for all MSM from 12 months to four-to-six months.

#### **KEY FACTS**

- Blood donation is vital in saving lives and improving health
- There are many individuals who would benefit from blood donation e.g. women with pregnancy complications, cancer patients, patients involved in major accidents, natural disasters, those who require major surgery.
- There is a shortage of blood donation.

#### CHALLENGES

- Blood can only be stored for a limited time, and therefore the need for regular and consistent blood donation is vital.
- The shortage of blood donation has become more pronounced during the COVID-19 pandemic and following the Australian bushfire season in early 2020.
- There are some limitations to blood donation due to strict eligibility criteria particularly for those who identify as MSM.

#### SOLUTIONS

 Reducing the deferral period for all MSM blood donations from 12 months to four-to-six months to boost blood bank supply.



#### **CASE FOR CHANGE**

There is an ever-present demand for blood donors in Australia and around the world. Health authorities and advocates are questioning whether legislation and guidelines regarding blood donations and MSM, adopted during the HIV scare of the 1980s and 1990s, remain useful and scientifically sound. As demand for blood remains high, increased donations from hitherto restricted groups such as MSM has been proposed to bridge donation deficits.

According to the Red Cross, a third of all Australians are not eligible to donate blood due to the safety and wellbeing of blood donors and the patients who receive donations<sup>16</sup>. The LGBTI community constitutes a large proportion of this ineligible group. While the current Australian policy does permit MSM to donate, there is a significant period known as a 'deferral period' in which MSM must refrain from all sexual activity including penetrative and non-penetrative sex, with and without the use of a condom for 12 months<sup>17</sup> (this deferral period also affects women who have or had intercourse with a bisexual man or MSM)<sup>18</sup>. The deferral period includes MSM in long-term monogamous relationships who have been screened and are free of blood borne viruses. This is a significant hurdle for MSM individuals wishing to donate blood regularly and address the need for blood donors in Australia.

Policy justifications for this prohibition in Australia are centered around risk mitigation and patient safety rather than any form of discrimination. In western and developed nations similar to Australia, risk mitigation and patient safety standards are also at the forefront of blood donation policies and many have adopted reduced deferral periods without compromising these standards.



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<sup>16</sup> Australian Red Cross Lifeblood. "FAQs - Deferrals." 2019. Accessed: https://www.donateblood.com.au/blood-service-deferrals

<sup>17</sup> Australian Red Cross Lifeblood. "Sexual Activity that will Affect my Ability to Donate Blood?" 2019. Accessed: https://www.donateblood. com.au/faq/sexual-activity

<sup>18</sup> Ibid.

### **SCREENING BLOOD DONATIONS**

All blood samples donated in Australia undergo rigorous testing to ensure they are free from disease and infection. There are, however, limitations on what medical technology can detect, particularly in the early stages of infection. This is known as the 'window period', i.e. the lag time between someone contracting a disease and it showing-up in a blood test.

In Australia, the Therapeutic Goods Administration (TGA) regulates and maintains standards for blood donations and blood products available for transfusion. Such standards regarding blood donations are set out under TGA Order Number 88 which outlines the importance of minimising the instances of infectious disease transmissions via blood products<sup>19</sup>. Under this order, the Australian Red Cross Blood Service derives its deferral periods as set out by their Technical Master File<sup>20</sup>, and more specifically, the 'Guidelines for Selection of Blood Donors.'<sup>21</sup>

The purpose of a deferral period for MSM is to keep the instances of Transfusion-Transmissible Infections (TTI) in Australia's blood supply as low as possible. TTI that have the greatest potential to cause significant risk and harm to blood donation recipients and blood supply include human immunodeficiency virus (HIV), hepatitis A virus (HAV), hepatitis B virus (HBV), hepatitis C virus (HCV), human T-lymphotropic virus (HTLV) as well as T. pallidum or syphilis<sup>22</sup>. These TTI are spread most commonly through sexual intercourse and have higher rates of prevalence within MSM in comparison to 'men who have sex with females' (MSF).

Broadly, there are two main forms of tests to screen for TTI within individual donations; Nucleic Acid Testing (NAT) and Serological Testing. NAT is a highly accurate and sensitive screening test for blood donations that involves using molecular techniques to detect blood borne TTI and is widely used in developed nations to ensure the integrity and safety of their blood supply<sup>23</sup>. This form of testing reduces the window period for TTI and provides a secondary 'check' to initial serology tests<sup>24</sup>. NAT is in current use by blood services including the Australian Red Cross Blood Service to screen and detect HIV, HBV and HCV in individual blood donations.

Similarly, serology tests are used to test donations for HIV, HBV, HCV, HTLV and syphilis. Serology tests detect antibodies that may reside in the blood and immune system<sup>25</sup>. With the use of both serology tests and NAT in our blood donation service, our blood supply is protected and shielded from the above diseases as well as a range of other blood borne infections to a highly accurate degree.



<sup>19</sup> Australian Government Department of Health and Ageing Therapeutic Goods Administration. "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." 2013.

<sup>20</sup> National Blood Authority Australia. "Blood Service Deed of Agreement." 2016. Accessed: https://www.blood.gov.au/system/files/Deed-of-Agreement.pdf

<sup>21</sup> Australian Red Cross Lifeblood. "Guidelines for the Selection of Blood Donors." Australia, 2014.

<sup>22</sup> Australian Red Cross Blood Service. "Review of Australian Blood Donor Deferrals Relating to Sexual Activity." 2012.

<sup>23</sup> Stolz, M., Gowland, P., Tinguely, C., & Niederhauser, C. "Safe-Testing Algorithm for Individual-Donation Nucleic Acid Testing: 10 Years of Experience in a Low-Prevalence Country." Transfusion Medicine and Hemotherapy. 2019. 104-110.

<sup>24</sup> Hans, Rekha, and Neelam Marwaha. "Nucleic acid testing-benefits and constraints." Asian journal of transfusion science vol. 8,1 (2014): 2-3.

<sup>25</sup> Hine, R. (Ed.). Serology. A Dictionary of Biology. Oxford University Press. 2019.

# **DECLINE IN WINDOW PERIODS**

With the development and improvement in testing technologies, the window period in which TTI can be detected has been significantly shortened. The window period is the lag time between someone contracting a disease and it showing-up in a blood test and yielding a positive or negative result<sup>26</sup>.

For HIV, it has an average window period of 22 days for serological testing and 5.6 days for NAT with a very maximum window period of 38 days to appear and be accurately tested and identified<sup>27</sup>. HBV has an average window period of 38 days for serological testing, 23.9 days for NAT testing and a maximum window period of 44 days<sup>28</sup>. HCV has an average window period of 66 days for serological testing and 3.1 days for NAT and a maximum window period of 94 days<sup>29</sup>. HTLV can only be detected by serological testing with an average window period of 51 days and an upper window period limit of 94 days<sup>30</sup>. Syphilis can also only be detected by serological testing and has an average window period of 28 days with a maximum window period of 38 days<sup>31</sup>.

The Australian Red Cross Blood Service has proposed in their 2012 submission to the TGA that a new set of deferral periods be adopted. These deferral periods consider not only the window periods of NAT and serological testing but also the uppermost incubation period of TTI to maximise the potential for all TTI being identified. The minimum deferral period suggested is 76 days for HIV, 88 days for HBV, 188 days for HCV, 144 days for HTLV and 56 days for syphilis<sup>32</sup>. From this information the Red Cross Blood Service supports and advocates a six-month deferral period that is a safe and cautious and has little chance of compromising the safety of blood and blood products in Australia<sup>33</sup>.

In 2017, a team of Australian researchers at the Kirby Institute concluded in a report published by scientific journal 'Transfusion' that a 12-month deferral "exceeds what is required to maintain blood safety .... While there is a moral imperative to maintain blood safety, there is also a moral imperative to ensure that differential treatment of population groups with regard to donation eligibility is scientifically justified (p816)."<sup>34</sup>

The Australian Federation of AIDS Organisations (AFAO) recommends a reduction to the deferral period of six months. AFAO supports a six-month deferral period which is cautious and conservative but still respects and maintains patient safety<sup>35</sup>.

- 31 Ibid.
- 32 Ibid.33 Ibid.

<sup>35</sup> https://www.afao.org.au/wp-content/uploads/2016/12/Blood-Donor-Deferral-AFAO-Update-April-2017.pdf





<sup>26</sup> Melbourne Sexual Health Centre. "Window Period." 2019. Accessed: https://www.mshc.org.au/WP/tabid/482/Default.aspx#.Xd8DzegzY2x

<sup>27</sup> Australian Red Cross Blood Service. "Review of Australian Blood Donor Deferrals Relating to Sexual Activity." 2012.

<sup>28</sup> Ibid.

<sup>29</sup> Ibid.

<sup>30</sup> Ibid.

<sup>34</sup> Haire, B., Whitfird, K., Kaldor, J. 'Blood Donor Deferral for Men Who Have Sex with Men: Still Room to Move' Transfusions, Vol 58 Is 3, 2017

### INTERNATIONAL POLICY DEVELOPMENTS REGARDING MSM BLOOD DONATIONS

Internationally, there have been notable policy changes regarding MSM and deferral periods to be eligible to donate blood. In Canada, deferral periods for all MSM donating blood was reduced from 12 months to three months in 2019 after Canada's two blood services Hema-Quebec and Canadian Blood Services presented a scientifically and medically endorsed application to Health Canada<sup>36</sup>. Similarly in the UK, all MSM can donate blood after a three-month deferral period due to a policy change recommended in 2017 by the Independent Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO)<sup>37</sup>.

The United States asks MSM to defer for 12-months, however, the American Red Cross Blood Services advocates and encourages the US Food and Drug Administration to instead endorse and adopt a three-month deferral period for MSM in line with the UK's and Canada's guidelines<sup>38</sup>.

In France, from February 1, 2020, MSM will be able to donate blood after a deferral period of four months and MSM who are in a relationship or have only one sexual partner within the four-month deferral period will also be eligible for blood donation<sup>39</sup>.

South Africa's National Blood Service<sup>40</sup> and Italy's Associazione Volontari Italiani Sangue (Association of Voluntary Italian Blood Donors)<sup>41</sup> do not enforce or have a deferral period for MSM and instead considers individual behavioural or lifestyle factors such as multiple sexual partners rather than a blanket rule on sexual orientation.



<sup>36</sup> Canadian Blood Services. "Blood Donation Waiting Period for Men Who Have Sex with Men Reduced to Three Months." 2019.

<sup>37</sup> National Health Service Blood and Transplant. "Men Who Have Sex with Men." 2019. Accessed: https://www.blood.co.uk/who-can-giveblood/men-who-have-sex-with-men/

<sup>38</sup> American Red Cross Blood Services. "LGBT+ Donors." 2019. Accessed: https://www.redcrossblood.org/donate-blood/how-to-donate/ eligibility-requirements/lgbtq-donors.html

<sup>39</sup> Etablissement Français Du San. "Agnès BUZYN, annonce l'évolution des conditions d'accès au don de sang." 2019. Accessed: https://www. efs.sante.fr/agnes-buzyn-annonce-levolution-des-conditions-dacces-au-don-de-sang

<sup>40</sup> South Africa National Blood Service. "Donors - Who Can Donate to this Cause?" 2019. Accessed: https://sanbs.org.za/donors/

<sup>41</sup> Associazione Volontari Italiani Sangue. "La Donazione - Chi puo donare." 2019. Accessed: https://www.avis.it/donazione/la-donazione/

# CONCLUSION

The current 12-month deferral period in Australia for all MSM wishing to donate blood is not only scientifically and medically excessive, it also perpetuates historical stigmas and stereotypes regarding queer, gay and bisexual men. A deferral period of 12-months is a blanket rule that disregards an individual's health, habits and relationships and instead makes broad negative behavioral assumptions for all MSM and especially disregards MSM who are in loving, monogamous and long-term relationships. A 12-month deferral for gay and bisexual men exceeds what is required to maintain blood safety. This disparity potentially causes social harm without any additional benefit to public health<sup>42</sup>. A reduced deferral period of four-to-six months will increase Australia's blood supply and will ensure Australia's blood supply continues to be one of the safest in the world.

Technological improvements have led to tremendous strides in reducing the 'window period' for disease detection, resulting in current deferral periods and other guidelines regarding MSM donations open to further discussion. Furthermore, many other nations have reduced deferral periods for MSM and the consensus among other OECD nations with similar deferral policies to Australia is for future adjustments to be made in accordance with evolving efficacy in screening technology.

# RECOMMENDATION

**CRANAplus and ACN recommend:** 

That the deferral period for all MSM individuals wishing to donate blood be reduced from 12 months to four-to-six months in line with international policy change and technological improvements in TTI detection.

Through this cautious and conservative policy evolution, Australia can continue to focus and maintain our reputation for patient safety and blood supply safety.

<sup>42</sup> Haire, B., Whitfird, K., Kaldor, 'J. 'Blood Donor Deferral for Men Who Have Sex with Men: Still Room to Move' Transfusions, Vol 58 Is 3, 2017





**ISSUES PAPER Blood donation in Australia** 

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