



## Special article

# Blood donation deferral policies among men who have sex with men in Brazil



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## ABSTRACT

Reevaluation of the deferral from voluntary blood donation by men who have sex with men (MSM) is being discussed in several countries, motivated by the need to ensure a blood supply free from transfusion-transmissible infections (e.g., HIV, syphilis). Policies being considered include: permanent exclusion for any male-male sexual encounter, temporary deferral (3 months, 12 months, 5 years) from the last encounter, or specifying behaviors that differentiate MSM at high risk from those at low risk. Current Brazilian regulations defer MSM from blood donation for 12-months after the last male-male sexual encounter. Broad epidemiological evidence indicates that many MSM are at increased risk for HIV in the present era, and few data exist to distinguish which men are likely to be in the immunological window for detection of these infections. A multicenter study developed in Brazil demonstrated that the history of male-male sex was the most strongly associated with being an HIV-positive blood donor. Meanwhile, the blanket deferral of MSM from blood donation has generated considerable controversy. Rejection of the deferral policies stems in part from perspectives defending human rights, promoting equality and citizenship, and alleging bias and discrimination. The objective of this report is to discuss the current situation of blood donation among MSM in Brazil. We highlight the lack of evidence for a true risk profile for male-male sex in the context of blood donation upon which to base sound policy. We recommend research to establish effective and acceptable criteria for blood donation by MSM and other blood donors.

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## Introduction

A safe and stable supply of blood for transfusion is necessary in all societies to prevent morbidity and save lives. A safe supply of blood is maintained by recruiting altruistic volunteers, screening them for certain health conditions, and testing their blood for markers of transfusion-transmissible infections. In Brazil, these infections include HIV, syphilis, hepatitis B, hepatitis C, HTLV I/II, Chagas disease, and malaria in endemic regions. While the serological tests for these infections are highly accurate, and nucleic acid testing in combination with serological tests are used for HIV, hepatitis B and hepatitis C, some infections may escape detection due to the limits of the sensitivity of each test, human error, and the possibility that the donor may be in the “window period” at the time of donation – that is, the period following infection but before a test will be reactive.

Policies regulating the recruitment and selection of blood donors have been put in place to minimize the risk of transfusion-transmissible infections. The Brazilian Ministry of Health ordinance number 5 of September 28, 2017 (annex IV), requires trained health professionals to evaluate specific criteria that may pose a risk to blood donors and transfusion recipients. These criteria exclude or temporarily defer potential donors with a wide range of conditions, including diabetes, tattoos or piercings, history of rape, sex work or partners of sex workers, persons with multiple casual partners, and men who have sex with men (MSM).

This last criterion, the deferral of MSM from blood donation, has been controversial. In 2004, Brazil changed the policy of permanent deferral for any male-male sexual behavior to the temporary deferral of 12 months from the last encounter. This policy has been adopted and implemented by all Brazilian hemotherapy services since then.<sup>1–3</sup> In effect, the Brazilian regulation requires a 12-month celibacy period for MSM to donate blood.

The policy of permanent or temporary deferral of MSM from blood donation is under discussion in many countries.<sup>3–15</sup> There are three approaches that countries have adopted regarding MSM deferral: (1) permanent deferral for any male-male sexual encounter, (2) temporary deferral (e.g., between three months and five years) from the last male-male sexual encounter, and (3) diverse criteria based on specific behaviors deemed as high-risk (e.g., type of sexual practice, number of partners). Many countries have adopted a 12-month temporary deferral policy similar to Brazil's, including Australia, Canada, Finland, France, the Netherlands, New Zealand, and the United States.<sup>4,13,16–18</sup> The United States changed its permanent deferral of MSM only in 2015 and the current 12-month deferral remains a topic of vigorous debate.<sup>5,16,19</sup> Canada changed from permanent deferral to a 5-year deferral in 2013 to later reduce the period to 12-months in 2016.<sup>12,18,20</sup> In some European countries, such as Denmark, Austria, and Croatia, standards are more restrictive than in Brazil, recommending that MSM be definitively unable to donate blood for any male-male sexual contact since 1977.<sup>4,18,21,22</sup> Other countries, such as Argentina, Chile, Peru, Uruguay, Portugal, Spain and Italy, define their regulations

based on sexual behavior without distinction of male-male specific practices.<sup>23–25</sup>

## The issue of increased risk for HIV among MSM

In 2015, the World Health Organization (WHO) defined five categories of risk for HIV infection, regardless of local context, among which is the sexual practice of men with other men.<sup>22</sup> The WHO reports that the global odds of HIV infection for MSM is 19.3 times that of the general population, and although the incidence of HIV is declining in some countries it is increasing in others in several regions of the world.<sup>22,26–29</sup>

Although the rate of AIDS detection has been declining in recent years, Brazil has annually registered an average of 40,000 new cases of AIDS in the last five years. The proportional distribution of cases, identified from 1980 to June 2017, shows a concentration in the Southeast and South regions, each accounting for 52.3% and 20.1% of all cases, respectively.<sup>30</sup> According to data from the National Survey on Biological and Behavioral Surveillance,<sup>31</sup> conducted in 12 municipalities in the five major regions of Brazil in 2009 and 2016, HIV prevalence among MSM increased to 18.4% in 2016 – beyond expectations from the 12.1% prevalence in 2009. In other words, nearly one in five MSM is living with HIV. In addition, it is estimated that about 150,000 people, out of 700,000 people living with HIV in Brazil, do not know that they are infected by the virus.<sup>32</sup> Studies regarding the prevalence of HIV have also been indicative of a possible under-reporting of HIV on the Brazilian cases database (SINAN, from the Brazilian Ministry of Health) in some states of the country, which may bias the prevalence mainly in the north and northeast regions.<sup>30,33</sup>

Thus, recommendations for the deferral of MSM from blood donation are based on the broad epidemiology of HIV, as reported by the WHO, the Pan American Health Organization (PAHO), and the Brazilian Ministry of Health. According to these organizations, the regulations aim at a collective interest in the maximum guarantee of transfusional quality and safety. A temporary deferral of MSM, as well as other groups at increased risk for HIV and other transfusion-transmissible infectious diseases, is held to be a strategy that contributes to the protection of blood recipients.<sup>22,34,35</sup> Despite the dramatic reduction of transfusion risk for infectious diseases with the introduction of laboratory screening tests since 1988, especially with the more recent nucleic acid tests for HIV and HCV,<sup>36,37</sup> and now including HBV, the risk of viral transmission through blood donations persists due to the window period. Hence, the duration of deferral is therefore recommended to be long enough to ensure a potential donor is not in the window period for a given infection.

A case-control study investigating epidemiological profiles for blood donors testing positive for transfusion-transmissible infections was conducted at four large Brazilian blood banks in 2013.<sup>38</sup> The study included more than 340 HIV-positive donor cases and nearly 800 HIV-negative donor controls in São Paulo, Belo Horizonte, Rio de Janeiro, and Recife. History of male-male sex was the factor most strongly associated with being an HIV-positive blood donor, followed by having had an

HIV-positive sexual partner. The study highlighted the need to improve awareness of the reasons for risk screening prior to blood donation since many cases, and some controls, revealed their risk behaviors at the time of the research study rather than at donation.<sup>38</sup> Another identified challenge is that blood centers are often sought out for the purpose of HIV testing by people at increased risk,<sup>39-41</sup> a behavior that may circumvent screening questions and increase infectious donations if the infection is recent.

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### The controversy over the 12-month deferral policy for MSM in blood donation

Despite broad epidemiological and some blood donation contextual evidence that male-male sexual practices can be associated with an increased risk of infection for HIV, the temporary deferral of MSM for blood donation has generated heated discussion elsewhere.<sup>5,7</sup> Objections mainly arise from social groups promoting human rights, equality, and citizenship who consider the deferral as a biased and discriminatory.<sup>2,3,12,13,15</sup> According to Zhou and Berkman (2018), there is a peculiar contradiction in the fact that the inclusion of MSM who practice safe sex in consensual and monogamous relationships, messages promoted by HIV prevention policies, is considered high-risk for HIV transmission. Compounding this double standard is the policy that heterosexual donors who have unprotected sex, including with multiple partners, are not deferred from blood donation and not required to be celibate for long periods of time. These authors believe that the deferral is a bias based on the ideology that all male-male sex is risky, rather than focusing on the true risk factors for transmission.

In fact, there is a scarcity of studies investigating the impact of MSM exclusion and deferral policies on blood safety, including the recruitment and retention of low-risk volunteers and the effectiveness of screening questions and criteria.<sup>14,15,19,42</sup> According to the WHO and the Brazilian Health Regulatory Agency (ANVISA), the temporary deferral is based on the most recent studies in scientific literature, and affirm that the criterion will be maintained until good studies are conducted in this context.<sup>22,43</sup> On the other hand, other researchers and policy analysts assert that the criteria are not based on sound data or a complete picture. For example, according to Haire et al.,<sup>13</sup> the 12-month ban on MSM exceeds the current window periods of tests used in blood banking and is therefore unnecessary to maintain blood safety, causing social harm without any additional public health benefit. Accordingly, reducing the deferral period to 3 months would not increase the risk to recipient health and may have the social benefit of increasing inclusion.

Needed studies at the intersection of blood donation and risk among MSM can follow two paths. The first focuses on blood donors, making an assessment of potential deferral criteria and the impact of asking specific questions on sexual practices to persons presenting to donate. The second focuses on MSM in the community, to evaluate attitudes, perceptions, opinions, and intentions to donate, given the current or new policies on blood donation.<sup>19</sup> Some studies have been conducted in the first approach.<sup>9,44,45</sup> However,

to our knowledge, no Brazilian study has been performed under the second approach, investigating the population of MSM outside blood banks. There is therefore a lack of evidence on the epidemiological profile of MSM who may or may not seek to donate blood, including their intentions toward donation and their attitudes and understanding of the 12-month deferral period adopted in Brazil.

Recently, the discussion on blood donation by MSM has been brought to Brazilian courts. According to the Attorney General's Office and lesbian, gay, bisexual and transgender advocacy groups, the deferral policy is unconstitutional and raises questions on fundamental rights of these marginalized populations. In addition, they emphasize that the restrictions are based on the immutable gender and sexual orientation of the individuals and not on risk behavior. According to a press release in October 2017 by the Federal Supreme Court Ministry rapporteur, Edson Fachin, the policy violates the rights of MSM and the foundation of respect for diversity and human dignity of those who wish to donate blood.<sup>46</sup>

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### Way forward

The deferral period for blood donation among MSM and the controversy of the legality of the regulations remain under discussion in the Brazilian Federal Supreme Court (STF). According to the Brazilian Ministry of Health, the current 12-month MSM celibacy deferral policies for blood donation should be considered as a technical issue and therefore should not be treated as a matter of constitutionality. In a letter, signed by 26 blood centers directors to the STF at the end of 2017, the precautionary principle should continue to be valid while further studies are carried out in Brazil.

We argue that further studies are necessary to provide scientific evidence regarding blood donation by MSM. These studies should focus on the adequacy of the deferral period versus the impact on blood safety and stability of supply in Brazil. Approaches for improved donor selection are important and urgently necessary, as well as studies regarding non-compliance with the deferral period, epidemiological and risk profile of MSM and studies regarding the impact of MSM exclusion and deferral policies on blood safety. In summary, studies to understand the impact of blood donation by MSM in Brazil must be conducted in the country with the engagement of MSM communities, taking into consideration the cultural diversity in our nation.

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### Conflicts of interest

The authors declare no conflicts of interest.

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