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See table of contents

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Article abstract

In 2022, the Colombian Constitutional Court mandated the removal of the 12-month deferral for blood donation for potential male donors who reported having had sexual relations with other men in the past year in the national guidelines for blood donor selection, aiming to combat stigma and discrimination against diverse sex-gender identities. This article explores the complex dynamics of this mandate, and examines the tension between private moral values, like self-determination and freedom of expression, with public values, such as non-maleficence, equality and vulnerability approach. The analysis delves into the challenges of Colombia's hemovigilance system, the epidemiological patterns of HIV, and the lack of supporting studies for these guideline changes. Structural and logistical constraints in minimizing transfusion risks are highlighted, emphasizing the need for improved safety measures. The implications of reduced deferral times for high-risk groups without adequate testing protocols are also addressed. The necessity for national studies to determine the actual risk posed by different populations is underscored, advocating for robust safety measures, including universal nucleic acid testing (NAT), to protect both donors and recipients. Balancing the elimination of discrimination with enhanced blood safety practices is crucial to ensure non-maleficence and equity for all stakeholders involved in the blood donation process in Colombia. The article emphasizes the importance of protecting individuals and communities at greater risk of defenselessness and insecurity within the evolving landscape of blood donation protocols.

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**ARTICLE** (ÉVALUÉ PAR LES PAIRS / PEER-REVIEWED)

# Vulnerability and Blood Donation: Enhancing Safety While Combating Stigma in Colombia

Michel Andrés García-Otálora[a], Boris Julián Pinto Bustamante[a,b], María José Ochoa-Cómbita[b], María Alejandra Pardo-Cubillos[b], Miguel David Quintero-Consuegra[c]

**Résumé**
En 2022, la Cour constitutionnelle colombienne a ordonné la suppression de l'exclusion de 12 mois du don de sang pour les donneurs masculins potentiels qui ont déclaré avoir eu des relations sexuelles avec d'autres hommes au cours de l'année écoulée dans les lignes directrices nationales pour la sélection des donneurs de sang, afin de lutter contre la stigmatisation et la discrimination à l'encontre des diverses identités de sexe et de genre. Cet article explore la dynamique complexe de ce mandat et examine la tension entre les valeurs morales privées, telles que l'autodétermination et la liberté d'expression, et les valeurs publiques, telles que la non-malfaisance, l'égalité et l'approche de la vulnérabilité. L'analyse se penche sur les défis posés par le système d'hémovigilance colombien, les schémas épidémiologiques du VIH et le manque d'études à l'appui de ces changements de lignes directrices. Les contraintes structurelles et logistiques liées à la minimisation des risques transfusionnels sont mises en évidence, soulignant la nécessité d'améliorer les mesures de sécurité. Les implications de la réduction des délais d'ajournement pour les groupes à haut risque ne disposant pas de protocoles de test adéquats sont également abordées. La nécessité d'études nationales pour déterminer le risque réel posé par les différentes populations est soulignée, en plaidant pour des mesures de sécurité solides, y compris le test universel d'acide nucléique (TAN), pour protéger à la fois les donneurs et les receveurs. Il est essentiel de trouver un équilibre entre l'élimination de la discrimination et l'amélioration des pratiques de sécurité du sang afin de garantir la non-malfaisance et l'équité pour toutes les parties prenantes impliquées dans le processus de don de sang en Colombie. L'article souligne l'importance de protéger les individus et les communautés les plus exposés au risque d'absence de défense et d'insécurité dans le cadre de l'évolution des protocoles de don de sang.

**Mots-clés**
orientation sexuelle, maladies infectieuses, autonomie du patient, transfusion sanguine, Colombie, bioéthique

**Abstract**
In 2022, the Colombian Constitutional Court mandated the removal of the 12-month deferral for blood donation for potential male donors who reported having had sexual relations with other men in the past year in the national guidelines for blood donor selection, aiming to combat stigma and discrimination against diverse sex-gender identities. This article explores the complex dynamics of this mandate, and examines the tension between private moral values, like self-determination and freedom of expression, with public values, such as non-maleficence, equality and vulnerability approach. The analysis delves into the challenges of Colombia's hemovigilance system, the epidemiological patterns of HIV, and the lack of supporting studies for these guideline changes. Structural and logistical constraints in minimizing transfusion risks are highlighted, emphasizing the need for improved safety measures. The implications of reduced deferral times for high-risk groups without adequate testing protocols are also addressed. The necessity for national studies to determine the actual risk posed by different populations is underscored, advocating for robust safety measures, including universal nucleic acid testing (NAT), to protect both donors and recipients. Balancing the elimination of discrimination with enhanced blood safety practices is crucial to ensure non-maleficence and equity for all stakeholders involved in the blood donation process in Colombia. The article emphasizes the importance of protecting individuals and communities at greater risk of defenselessness and insecurity within the evolving landscape of blood donation protocols.

**Keywords**
sexual orientation, infectious diseases, patient autonomy, blood transfusion, Colombia, bioethics

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## INTRODUCTION

In 2021, in the city of Cali, Colombia, two men took legal action after being denied the opportunity to donate blood at a hospital blood bank. Their case was based on the argument that existing regulations — specifically, Resolution 3212 of 2018 issued by the Ministry of Health and Social Protection (MHSP) and the Technical Guidelines for the Selection of Blood Donors established by the National Institute of Health (INS) — discriminated against them. At the time, these guidelines mandated a 12-month deferral period for men who have sex with men (MSM), given their significantly higher prevalence of HIV infection (estimated to be 36-42 times higher than that of the general population) (1,2).

The plaintiffs argued that this policy reinforced stigma and discrimination, particularly against gay, bisexual, and other MSM, and transgender individuals. Their claims were upheld by both the Eighth Family Court of Cali and the Superior Court of Cali, which ruled that the deferral guidelines were discriminatory. In 2022, the case was reviewed by the Constitutional Court, which reaffirmed its previous stance from Judgment T-248 (2012) and ruled in favour of eliminating donor selection criteria based on sexual orientation, instead advocating for an individualized risk assessment approach (3).



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While this decision represented an important step toward eliminating discrimination, it also raised significant concerns regarding the safety of blood recipients, who have no choice in their transfusion. Unlike donors, recipients rely on rigorous clinical and technical protocols to ensure that the blood supply is as safe as possible. Colombia has an estimated population of 52.6 million inhabitants and is served by 83 blood banks (29 public and 54 private). In 2023, these blood banks collected 999,545 blood donations from non-remunerated volunteers, yielding a national rate of 26.5 donations per 1,000 people. All blood banks adhere to guidelines established by the National Institute of Health, which manages the national hemovigilance program that gathers data from both blood banks and healthcare facilities that perform transfusions. It is important to note that, until 2025, the universal implementation of nucleic acid testing (NAT) for the detection of infectious agents potentially transmitted by transfusion was not mandatory in Colombia.

Given the unique epidemiological characteristics of HIV in Colombia and the challenges of implementing universal screening measures such as NAT, the absence of national studies validating the impact of these changes introduces a critical uncertainty: Could this policy modification increase the risk of transfusion-transmitted infections?

This article examines the implications of the Constitutional Court's ruling by analyzing four key aspects: 1) the evolution of donor selection policies in Colombia, 2) the functioning of the national blood system and current screening practices, 3) the epidemiological dynamics of HIV in Colombia, including risk factors and preventive strategies, and 4) the ethical and public health considerations surrounding this issue. We explore the balance between rights such as self-determination and non-discrimination and the fundamental principles of non-maleficence, equity, and the protection of vulnerable populations.

For the purposes of this article, we clearly distinguish between sexual orientation and sexual behaviour. An individual who identifies as gay or bisexual (orientation) may not engage in high-risk behaviours (e.g., they might be abstinent), meaning their risk profile differs from someone classified based solely on behaviour. This distinction is crucial because donor deferral policies may affect these groups differently depending on whether the criteria are based on identity or on behaviour.

Ultimately, we argue that while eliminating discriminatory practices in blood donation is a necessary step toward social equity, it must be accompanied by robust safety measures to ensure the protection of blood recipients. The principle of non-maleficence demands that any change in donor selection criteria be guided by scientific evidence and supported by comprehensive risk mitigation strategies, including the potential implementation of universal NAT testing. Without these safeguards, well-intended reforms risk unintentionally increasing recipient vulnerability rather than protecting public health.

## FROM EXCLUSION TO INDIVIDUALIZED RISK ASSESSMENT: CHALLENGES OF BLOOD DONOR SELECTION CRITERIA IN COLOMBIA

The evolution of blood donor selection criteria in Colombia reflects a gradual shift from exclusionary policies to a more individualized risk assessment approach. This section examines key regulatory changes over the years, highlighting both advancements in reducing discrimination and persistent challenges in balancing inclusivity with blood safety.

In 1996, the MHSP introduced Resolution 901 (4) which adopted the Manual of Technical, Administrative, and Procedure Standards for blood banks. This document outlined the initial requirements to be eligible as a blood donor in the country. It also established a permanent deferral for individuals who disclosed having engaged in male homosexual relations within the last 15 years. In 2012, the Constitutional Court in Colombia issued Judgment T-248 (5) which established:

> among the risk factors that should be considered when qualifying a blood donor, sexual orientation should not be mentioned, but rather risky sexual behaviours, such as sexual intercourse without any kind of protection or with strangers, promiscuity, not having a permanent partner, etc.

In 2013, the INS published the Guide for the Selection of Blood Donors in Colombia with the aim to standardize and update the criteria for accepting or deferring potential blood donors across all blood banks operating in the country. Within this guide, question twelve was defined as follows: "Have you had sexual relations with individuals of the same sex? If the answer is affirmative, MSM since 1977 must be permanently deferred" (6).

At that time the Colombian guideline was aligned with the Guidelines on the Assessment of the Suitability of People for Blood Donation issued by the World Health Organization (7) and the Food and Drug Administration (8) of the United States, which recommended an indefinite deferral for all MSM (since 1977) from donating blood due to concerns regarding the potential transmission of HIV through transfusion.

Following the analysis, the Constitutional Court emphasized the need for the MHSP to review existing regulations regarding the reception and supply of blood components. The aim was to eliminate sexual orientation as a criterion for assessing the risk of transmitting infections like HIV and instead focus on investigating specific sexual risk behaviours. Additionally, the court ordered modifications to Resolution 901 to remove as exclusion criteria sexual orientation and belonging to the MSM population. These changes were intended to align the regulations with the understanding that HIV risk is not determined by gender identity or sexual orientation, but rather by individual risk practices.

To comply with the order of the constitutional court, in 2018 the MHSP issued Resolution 3212 (9). There, the behaviour of permanent deferral for MSM was changed to a deferral for 12 months, from the last sexual contact. In accordance with Resolution 3212, the INS published the Technical Guidelines for the Selection of Blood Donors in Colombia in 2018. This document updated the donor selection guide from 2012 and modified question twelve: “Have you had sexual relations with individuals belonging to any of the key populations, such as sex workers, people who inject drugs, street dwellers, men who have sex with men, and transgender women?”

If the answer was affirmative, a deferral period for twelve months after the last sexual contact with any member of these key populations was established (10). The Court established that the phrasing of the question assumed that having sexual relations with individuals from certain key populations (e.g., sex workers, MSM, transgender women) inherently carried a risk, without explicitly addressing actual risky behaviours. Therefore, this question generalized risk based on population group rather than behaviour. This was considered discriminatory by the court because it implies that all individuals within these groups were high-risk, rather than assessing risk based on specific sexual behaviours (e.g., multiple partners, unprotected sex, or sex with partners with known infections).

The implementation of a 12-month deferral period aligned with the policies adopted by various countries at that time, including the United States (11), Great Britain, Australia, and others (12). In Canada, for example, the lifetime deferral implemented in 2013 was later amended to a five-year deferral, allowing men to donate if they had refrained from sexual contact with another man for at least five years. This deferral period was subsequently shortened to one year in 2016 and further reduced to three months in 2019. In 2022, Canada removed the sexual orientation criterion and introduced a gender-neutral questionnaire focusing on sexual risk behaviour (13).

In August 2022, the INS issued an updated version of the Technical Guidelines for the Selection of Blood Donors (1) in response to the decision by the Superior Court of the Judicial District of Cali and the Constitutional Court Judgment T-171 (2022). The court determined that the 12-month deferral period for blood component donation by MSM, as stated in the 2018 INS Guidelines, could potentially violate fundamental rights when applied. As a result, the INS modified question twelve: “Have you had sexual relations with individuals belonging to any of the following populations: sex workers, homeless people, or individuals who inject drugs?”

On October 12, 2023, the MHSP issued Resolution 1676 of 2023 (14), thereby rescinding Resolution 3212 of 2018. Despite the persistence of epidemiological data highlighting an HIV epidemic concentrated in MSM, psychoactive substance users, transgender women, sex workers, homeless individuals, transgender men, and incarcerated individuals, this resolution omits any mention of populations with a prevalence of HIV infection greater than 1%. Instead, it introduces the following statement:

> It is incumbent upon individuals to practice solidarity self-selection. After receiving information about the requirements for blood donation, individuals are encouraged to assess their health status, habits, and behaviors that may constitute risk factors. Through this process, they can make a ‘voluntary, autonomous, conscious, and responsible decision’ to donate blood. The Ministry, the National Institute of Health, and Blood Banks will actively promote self-selection as a supportive behaviour.

Currently, after completing the donor selection questionnaire, there is a second step called self-exclusion. Here, potential donors are urged to think about the information they’ve provided to ensure the safety of blood components and recipients. Some blood banks still remind donors that providing false information during self-exclusion could be considered “spreading of HIV or hepatitis B,” according to Article 370 of the Penal Code. It’s crucial to note that Article 370 was declared unenforceable by Constitutional Court Ruling C-248 in 2019 (15). However, Article 369 (spread of epidemic) remains in effect.

Resolution 1676 of 2023 (14) also delineates certain criteria identifying individuals at risk for blood donation, including those engaged in specific sexual behaviours:

> [...] g) Individuals involved in any of the following risky sexual behaviours:
> - Having engaged in sexual relations (vaginal, anal, or oral) with more than two people within the last 12 months.
> - Changing sexual partners within the last 6 months.
> - Having sexual relations with individuals diagnosed with HIV, hepatitis, HTLV I-II viruses, and other biological agents known, through scientific evidence, to be sexually transmitted within the last 12 months. [...]
>
> [...] The deferral period for blood donation, when one or more of these risk factors are identified, shall align with the guidelines outlined in the ‘Technical Guidelines for the Selection of Blood Donors in Colombia’ established by the National Institute of Health. [...]
>
> [...] The questions and information solicited during the blood donor eligibility assessment shall focus on the risk factors defined in this resolution, without delving into matters of sexual orientation or gender identity. Blood banks, during the interview, must adhere to the questions stipulated in the ‘Technical Guidelines for the Selection of Blood Donors in Colombia. [...]’

> [...] The language employed throughout the blood donor selection process must be rooted in respect for human dignity, confidentiality, and the safeguarding of human rights. It should eschew any form of stigmatization or discrimination, seeking only information relevant to the fundamental technical purpose of ensuring blood safety. Furthermore, the reasons for deferring a donation in specific cases should be explained, guiding referred individuals to their respective health-promoting entities. [...]

In essence, the Resolution 1676 of 2023 advocates for the individualization of behaviours rather than generalization. This line of reasoning was supported by initiatives such as the FAIR screening criteria, promoted by the UK group For the Assessment of Individualized Risk (FAIR), which updated and emphasized the importance of assessing individual risk behaviours during the donor selection process. The aim of FAIR is to ensure a safe and equitable blood donation screening system that treats all individuals equally, regardless of gender identity or sexual orientation (16).

Resolution 1676 of 2023 (14) is significant for its endorsement of supportive self-selection and the individualization of cases. Nevertheless, within the Colombian context, certain instances highlight the inherent vulnerability of this approach. For example, in Colombia, it is regulated that a man can donate a maximum of four whole blood donations per year, with a minimum interval of three months between donations, while a woman can donate up to three times per year, with a minimum interval of four months between each donation. However, between 2018 and 2019, over 4,000 cases were documented in which individuals made whole blood donations at various blood banks within a period of fewer than 30 days, which violates national policy (17). Despite being informed, these people persisted in donating, prompting the need for strategies that can only be effectively implemented through a national framework, as opposed to relying solely on an individualistic approach. The identification of these cases raises concerns about the absence of studies quantifying whether these individuals belong to key populations or the general public. This critical limitation must be addressed as a priority before widespread national measures are implemented. While the primary intention is to reduce discrimination against specific groups, there is a risk of unintentionally amplifying the vulnerability to blood recipients. Recognizing that, in the Colombian context, a decrease in blood collections below 17.3 donations per 1,000 people is associated with higher mortality in vulnerable groups (18), it becomes imperative to meticulously evaluate both the positive and negative aspects of behaviours that may be in conflict at the present moment.

While Resolution 1676 of 2023 represents a significant step toward eliminating discriminatory deferral policies and emphasizing individual risk assessment, its reliance on self-selection raises concerns about enforcement and potential gaps in donor safety. The next section will explore the evolution of the Colombian hemovigilance system and the current challenges, particularly in light of legal changes.

## NATIONAL HEMOVIGILANCE SYSTEM AND ITS CHALLENGES

This section outlines the evolution of serologic and NAT in blood donation screening, emphasizing its role in reducing transfusion-transmitted infections. While many countries have mandated NAT to enhance detection sensitivity, Colombia has yet to implement universal NAT screening, with less than 10% of blood banks adopting the practice. Understanding these testing strategies and their impact on the window period is crucial for evaluating the effectiveness of current screening policies and their implications for donor eligibility criteria.

Since the enactment of Decree 1571 in 1993, all blood units collected in Colombia are required to undergo serologic screening to identify HIV 1-2, hepatitis B surface antigen (HBsAg), antibodies against Hepatitis C Virus (HCV), and *Treponema pallidum*. Subsequently, Resolution 1738 of 1995 mandated the inclusion of serologic screening for antibodies against *Trypanosoma cruzi*, while Resolution 437 introduced mandatory screening for the presence of antibodies against hepatitis B core antigen (Anti-HBc) and Human T-Cell Lymphotropic Virus (HTLV). In 2023, most blood banks (95.2%) employed Chemiluminescent Immunoassays (CLIA), Amplified Electrochemiluminescence (ECLIA), or Chemiluminescent Magnetic Immunoassay (CMIA) HBsAg, Anti-HCV, Anti-*T. cruzi, T. pallidum*, Anti-HBc, and anti-HTLV I-II. The remaining 4.8% relied on fourth generation Enzyme-Linked ImmunoSorbent Assay (ELISA) (19).

The implementation of NAT aimed at detecting HIV, HBV, and HCV to reduce serologic window periods in blood donors started in 1997 in Germany (20). The window period refers to the time between the initial infection with a specific agent and the point at which the infection can be reliably detected by specific blood tests. The window period for HIV detection using NAT is approximately 3 to 9 days post-exposure, while for HCV is 1-7 days post-exposure (21). Conversely, for HBV, NAT can identify the virus within 10 to 23 days following exposure (22). In contrast, the window period extends from 18 to nearly 45 days for CLIA in HIV infections, and for HCV and HBV, CLIA can detect the viruses within 18 to 90 days post-exposure. Finally, the window period for HIV, HCV, and HBV with the ELISA test spans from 23 to 90 days after exposure (22). During this window period, the individual may be infected but still test negative (23). By the end of the 20$^{th}$ century, ten nations had adopted HCV detection through NAT in 100% of collected units, with four and three countries doing the same for HIV-1 and HBV, respectively. By 2010, 33 countries had extended their NAT testing protocols to include 100% of collected units for HCV and HIV, while 31 countries incorporated the same for HBV (20,24).

An international survey on NAT of blood donations from 1999 to 2009 showed that a total of 272,520,696 donations underwent screening using HIV-1 NAT, 303,196,074 underwent screening using HCV NAT, and 114,286,214 underwent screening using HBV NAT (20). Among these, 244 (0.9 per million) tested positive exclusively for HIV-1 through NAT, 680 (2.2 per million)

tested positive exclusively for HCV through NAT, and 1,884 (16.5 per million) tested positive exclusively for HBV through NAT. Consequently, there were 2,808 donations contaminated with viruses that tested negative in serologic screening, highlighting the potential transfusion of these units without the implementation of NAT (20).

Notably, in Latin America, Brazil stands out as the only country enforcing mandatory NAT screening on all collected blood donations (25). While other countries in the region have blood banks conducting NAT, the requirement to apply these tests to 100% of collected units is not obligatory. In the case of Colombia, the MHSP conducted a systematic review in 2016 to explore the introduction of NAT in blood banks (21). However, their findings did not deem it a mandatory requirement for widespread implementation, considering the prevailing characteristics of the Colombian blood donor population. At that time, 94% of blood donors were voluntary unpaid and 6% were family/replacement, and the selection process adhered to existing donor selection guidelines. This handbook prohibited the acceptance of populations identified by the MHSP with HIV prevalence exceeding 1%, where MSM and transgender women were included (26).

In 2018, the Institute for Health Technology Assessment (IHTA) conducted a comprehensive study evaluating the cost-utility of integrating NAT for the detection of HBV, HCV, and HIV into the conventional screening process for blood donations in Colombia (27). The findings of the study suggested the incorporation of NAT testing into the routine blood donation processing. This recommendation gained significance when considering clinical, ethical and social dimensions. Beyond the economic advantages derived from preventing infections in blood recipients, the decision to prioritize NAT testing was underscored by the imperative to safeguard the quality of life for individuals at risk.

Countries that have reduced deferral times for MSM typically implemented NAT across 100% of collected blood units simultaneously (28). However, the situation in Colombia presents a contrast. At the onset of the lawsuit initiated by the couple in Cali, less than 6% of the country's blood banks were conducting NAT procedures (29). As of November 2023, Colombia had not enforced the requirement for the inclusion of NAT in collected blood units, as noted by Bermúdez-Forero (30). Out of the 83 blood banks, only ten had integrated NAT for screening HIV, HBV, and HCV, comprising 12.4% of the total.

## BEHAVIOUR OF HIV INFECTION IN COLOMBIA. TRANSFUSION-TRANSMISSIBLE INFECTIONS AND CURRENT LIMITATIONS

In this section, we review epidemiological studies conducted in Colombia on the incidence and prevalence of HIV, as well as the use and availability of antiretroviral therapy and post-exposure prophylaxis. The aim is to highlight the challenges the country faces in controlling the disease and the potential risks associated with relaxing restrictions in blood donor selection.

In 2002, the MHSP initiated studies to identify key populations in the country regarding HIV. In 2016, the MHSP published reports on the prevalence of HIV in MSM (26) and transgender individuals (31). The prevalence of HIV in the general population fluctuated between 0.2 to 0.6%, while in MSM it was between 5.6% and 24.1%. These studies revealed that Colombia was experiencing a concentrated HIV epidemic in MSM, psychoactive substance users, transgender women, sex workers, homeless individuals, transgender men and incarcerated individuals.

A 2019 study (32), which included a sample of 1301 individuals, aimed to assess the magnitude of the HIV epidemic and associated sexual behaviours among MSM aged 18 years and older in three Colombian cities (Bogotá, Medellín, and Cali), found that among participants queried about anal sex with a stable partner in the last 12 months, 92.8% acknowledged its occurrence. Regarding the frequency of anal sex (penetrative or receptive) in the last 30 days, 82.3% reported 1-5 instances, and 0.3% reporting none. Notably, 32.6% of participants consistently used condoms[1] during anal sex in the past 30 days, while 48.8% admitted to never using them. Conversely, when it came to anal sex with casual partners in the last 12 months, 91.8% of participants confirmed engagement. Importantly, 74.4% of participants disclosed using condoms during their last anal sex encounter with a casual partner. Of all participants, 3.3% reported taking pre-exposure prophylaxis (PrEP). The study determined a prevalence of HIV among MSM of 11.4% in Medellín, 23.4% in Cali, and 26.4% in Bogotá.

The 2023 report from the High-Cost Account in Colombia (35), highlighted that 62.12% of new HIV cases belonged to key population groups (i.e., people who inject drugs, transgender people, especially women, sex workers, MSM, people deprived of liberty, people living with HIV), with MSM accounting for 53.65% of these events.

It's essential to note that PrEP is a medication-based preventive strategy used to prevent HIV infection. When used correctly, PrEP is a highly effective method to significantly reduce the risk of HIV infection from sex. Additionally, studies have shown that individuals with an undetectable viral load cannot sexually transmit HIV. However, it is important to note that this does not apply to transfusion (36).

In 2015, the WHO recommended the use of tenofovir, in 2021, the dapivirine ring, and in 2022, long-acting injectable cabotegravir (37). In the Americas, 80% of PrEP users are in Brazil, where programs are free and easily accessible. In Chile, PrEP is distributed free to high-risk individuals under the National HIV/AIDS Plan. Peru confirmed the viability and safety of

[1] Condoms are 99% effective with perfect use but significantly less effective with typical use, with failure rates comparable to withdrawal. For instance, Smith et al. (33) reported that condom use reduces the risk of seroconversion by 63% to 72% in MSM, while Weller & Davis-Beaty (34) found a reduction of up to 80% in heterosexual couples.

tenofovir disoproxil fumarate alone, or in combination with emtricitabine in vulnerable populations through the iPrEx trial. In Mexico, despite a high intention to use PrEP, access is restricted due to cost. In Colombia, HIV prevention strategies focus on condom use and not sharing needles but do not fully reflect current advancements in combined prevention, including PrEP (29).

Colombia's "Clinical Practice Guidelines Based on Scientific Evidence for the Care of HIV/AIDS Infection in Adults, Pregnant Women, and Adolescents," effective since 2021 (38), recommend three PrEP options: a) Daily Tenofovir disoproxil fumarate/Emtricitabine or Tenofovir alafenamide/Emtricitabine for individuals over 12 at substantial risk of HIV; b) Dapivirine rings for women over 18 at substantial risk, subject to availability; c) Maraviroc for individuals over 18 at substantial risk when Tenofovir disoproxil fumarate/Emtricitabine or Tenofovir alafenamide/Emtricitabine are not viable, though not approved by INVIMA (National Regulatory Agency for Medicines) for prophylaxis. As of March 2025, only the first recommendation is available in the country. The use of lenacapavir is not yet available in the country.

In Colombia, only physicians can prescribe antiretroviral drugs, including PrEP (39) and one study showed that only 16.4% of physicians had any previous PrEP experience (40). Additionally, before enrolling in the PrEP program, an individualized assessment of the risk of HIV infection is required, considering social and access conditions (evaluated by a social worker) and the risk of conditions associated with or contraindicating antiretroviral prophylaxis. This assessment includes reviewing renal function, hematological profile, bone health, serologies for hepatitis, syphilis screening, and testing for HIV and other sexually transmitted infections (STIs).

Although PrEP reduces the risk of HIV transmission, a 2020 study involving 20 healthcare providers in Colombia identified several barriers to its effective implementation (41). Health Service Providers (the insurance companies of the health system) do not adequately transfer resources for PrEP implementation to Health Institutions. The lack of local studies on PrEP effectiveness in serodiscordant couples adds uncertainty. In rural areas, barriers include the cost and complexity of medications, limited availability of providers and service hours, and the absence of a national regulatory framework. PrEP is not included in the Mandatory Health Plan, complicating its administration and funding. Additionally, misinformation about approved medications, the stigma associated with HIV, and the lack of training for rural health professionals hinder PrEP acceptance and use. Adherence issues, negative perceptions about funding, and regional and economic inequalities are critical factors that need to be addressed.

According to AIDSinfo data, in 2021, 598 people received PrEP in Colombia, and in 2022 this number increased to 1,636, a rate of 3.2 per 100,000 inhabitants. This rate is low compared to other countries, in the same year: United States (114.7), Guatemala (89.7), Brazil (25.9), Canada (24.8), and Mexico (6.0) (42).

In 2022, a study on PrEP and its acceptance among transgender women found that 62.7% wanted to use it in the next 12 months, although only 26.6% had heard of PrEP. Participants reported difficulties attending medical check-ups and paying for PrEP and had concerns about changes in sexual behaviour and PrEP effectiveness (43). Another study identified seven main barriers to PrEP implementation from the perspectives of transgender women and gay/bisexual men: low awareness of PrEP, vulnerable social contexts, substance use affecting adherence, stigma, disapproval from partners, lack of training for health professionals, and discrimination in the healthcare system (44).

In Colombia, the HIV incidence rate has surged by 43% since the onset of the COVID-19 pandemic. In 2020, the rate stood at 23.5 cases per 100,000 inhabitants but by November 2023 it had escalated to 33.6 cases per 100,000 inhabitants (45). The cities registering the highest case numbers, along with their respective incidence rates, are as follows: Bogotá D.C., reporting 3,455 cases with an incidence rate of 8.4 per 100,000 women and 82.1 per 100,000 men; Medellín, documenting 1,385 cases with an incidence rate of 14.3 per 100,000 women and 97.2 per 100,000 men; Cali, recording 1,251 cases with an incidence rate of 18.2 per 100,000 women and 96.8 per 100,000 men (33). Despite findings by Scully (46), Bala et al. (47), and Saura et al. (48) establishing a higher risk of HIV infection in women compared to men, the latest HIV infection data reveal frequencies 9.8 (Bogotá D.C.), 6.8 (Medellín), and 5.3 (Cali) times higher in men than in women across the country's three major cities. The data suggest that men, specially MSM, may account for over 50% of new HIV cases in Colombia, which supports the possibility that this group continues to experience a disproportionately high risk of infection compared to other populations.

Despite the extensive measures implemented to enhance the safety of blood components for transfusion recipients, instances of HIV transmissions through transfusion have been identified (49,50,51). A notable case involves a repetitive voluntary donor whose actions in 2014 (17) resulted in the transmission of three HIV infections. Analysis of the accumulated data on transfusion-transmitted infections indicates that, during this period, one transfusion-transmitted infection occurred for every 160,755 transfused patients in Colombia (52). This figure represents a ninefold higher risk of transmission compared to rates reported in the United States and European countries (53).

It is worth noting that the national hemovigilance program in Colombia is still in the consolidation phase (49), and estimates indicate substantial underreporting of adverse reactions among donors and recipients, ranging from 60% to 95% (54). Additionally, there's a lack of post-transfusion monitoring for blood recipients to detect seroconversion caused by transfusion-transmissible agents. Moreover, blood banks currently cannot distinguish between blood components from the heterosexual

population and key populations like MSM or transgender women. Consequently, it's currently not possible to determine a distinct residual risk of transmitting viral agents to recipients based on these groups.

It is crucial to differentiate between the absence of evidence and a lack thereof. Studies conducted in the US (55) and France (56) have not identified an increased residual risk of HIV among heterosexual men and MSM, prompting a reconsideration of deferral policies for individuals from key populations. Notably, these countries conducted feasibility studies before modifying donation guidelines. However, in Colombia, these findings were applied without considering the differing epidemiological evidence across countries. One notable difference is the widespread implementation of NAT for all donations in the US and France. To the best of the authors' knowledge, there are no studies conducted in Colombia that quantify the residual risk of HIV or measure changes in reactivity and positivity rates of HIV tests conducted in blood banks between the heterosexual population and MSM or other key populations who self-identify as such during the donation selection process.

In Brazil, a multicentre study (57) found a strong association between a history of male-male sexual intercourse and having an HIV-positive sexual partner with being an HIV-positive blood donor. At the XII Colombian Congress of Blood Banks and Transfusion Medicine in October 2022, several blood banks presented evidence indicating an increase in transfusion-transmissible infections among blood donors, both before and after the 2021 changes to donor selection guidelines promoting non-discrimination towards the LGBTIQ+ population (58). Urbina et al. conducted a comparative analysis between the global residual risk per million donations from January 2011 to December 2015 and October 2021 to August 2022, revealing an increase from 5.11 to 12.43, representing a 2.4-fold rise after the Constitutional Court ruling (59).

As of the end of 2022, Colombia boasted a population of approximately 52 million people (60). The country maintained a network of 84 blood banks, comprising 29 public and 55 private establishments, which collected 963,423 blood donations in the course of the year (61). In 2022, after screening 56,769 donations, two donors were found to be in the window period (non-reactive serological tests but NAT-positive results), with one testing positive for HBV and the other for HCV. It was calculated that, maintaining that rate, screening one million donations would result in 53 window period cases. In 2023, after screening 77,173 donations, four donors were identified in the window period — exhibiting NAT-positive results despite negative serological tests — with two testing positive for HIV and two for HCV. It was estimated that, if 100% of the collected units had been screened with NAT, there would have been 52 similar cases per million donations, 50% of them for HIV (30). However, it remains unclear whether these infections indeed occurred or were false negatives.

The increase in transfusion-transmissible infections among donors, as observed after the 2021 changes to donor selection guidelines, raises important considerations. On one hand, the data suggest that Colombia's screening system is effective in identifying and removing potentially infectious donations when NAT is implemented. However, NAT is not mandatory, and only a few blood banks have voluntarily adopted it. This means that NAT-positive but CLIA/ELISA-negative cases can only be detected if NAT were applied universally across all blood banks. The rise in residual risk per million donations also highlights a critical question: does the potential increase in donors, following reduced deferral restrictions, justify the associated costs of additional screening and the potential risk of undetected infections? This trade-off underscores the need for a nuanced approach that balances inclusivity, blood safety, and financial sustainability, particularly given the existing gaps in confirming whether detected cases represent true infections or false negatives.

## VULNERABILITY AND RIGHTS-BASED APPROACH

This section integrates a vulnerability and rights-based approach to underscore that eliminating sexual orientation-based exclusions in blood donation must be paired with rigorous safety measures to protect blood recipients, who are inherently vulnerable due to their lack of choice in transfusions. By drawing on feminist ethics and distinguishing between dispositional, situational, and pathogenic vulnerabilities, this text clarifies that addressing stigma and discrimination alone is insufficient when the healthcare system's safety protocols — such as universal NAT testing — remain inadequate. Consequently, the analysis strengthens the main argument by emphasizing that a balanced approach is necessary: safeguarding individual rights should not come at the expense of the principle of non-maleficence and the equitable protection of recipients.

Mackenzie, Rogers and Dodds (62) have proposed, from the perspective of feminist ethics, understanding the notion of vulnerability as one of the sources of moral obligations and duties of justice. In this regard, they propose a taxonomy of three sources of vulnerability (inherent/intrinsic, situational, and pathogenic) and two states of vulnerability (dispositional and occurrent). This taxonomy acknowledges the ontological vulnerability intrinsic to the human condition according to its life cycle (such as the need for food), while also allowing for the identification of context-specific (or situational) forms of vulnerability (social, economic, environmental, etc.). Pathogenic vulnerability arises when interventions aimed at mitigating vulnerability have the opposite effect, exacerbating the risk situation. This type of vulnerability can also manifest as paternalism or as violence and arbitrary discrimination. Dispositional vulnerability refers to a predisposition to be vulnerable under certain conditions (risk factors that need to be identified and intervened). Occurrent vulnerability refers to a form of vulnerability that is already present and requires immediate action, such as a person needing attention during an emergency. By distinguishing between these sources and states, we can identify responsibilities toward the "more than ordinarily vulnerable" and potential interventions to mitigate their effects. Intrinsic, situational, and pathogenic vulnerabilities are intertwined dimensions.

The concept of risk groups emerged during the North American epidemic in the 1980s, but has evolved to "key populations." The Joint United Nations Program on HIV/AIDS (UNAIDS) introduced this concept to identify groups that are highly vulnerable

to HIV and frequently experience inadequate access to services, compared to the general population (63). Although the specific key populations may vary depending on local epidemic dynamics, they generally encompass:

- People who inject drugs
- Transgender people, especially women
- Sex workers
- MSM
- People deprived of liberty
- People living with HIV

These groups encountered barriers in accessing promotion, prevention, and treatment services. Several factors contributed to their heightened vulnerability. These included the pervasive presence of stigma and discrimination, manifested through various means such as the criminalization of certain behaviours and practices, acts of violence (both from state and non-state actors), and the implementation of policies and restrictive laws. The purpose of labelling these groups as key populations was to concentrate efforts on preventing, controlling, and treating HIV infections (64). According to the UNAIDS report (2021) (63) the frequency of HIV infection was estimated to be 35 times higher among people who inject drugs compared to the general population. Among transgender individuals, particularly women, the infection rate was 34 times higher. Female sex workers were found to be 26 times more likely to contract HIV, while MSM faced a 25 times higher risk compared to the general population.

Within the spectrum of HIV transmission, different activities exhibit varying levels of risk, related to intrinsic and situational vulnerability. HIV can be transmitted through specific body fluids: semen, blood, human milk, pre-seminal fluid, and vaginal or rectal fluids. The primary routes of HIV transmission include anal or vaginal sex, sharing needles, syringes, or other drug injection equipment, and mother-to-child transmission. Epidemiological studies have shown that over 90% of new HIV cases are acquired through sexual acts. For instance, orogenital interactions without ejaculation carry a risk ranging from 0.01% to 0.05%. This risk increases to 0.05% to 1% for activities such as vaginal intercourse (with or without ejaculation), orogenital intercourse with ejaculation, and anal intercourse without ejaculation. The highest level of risk, approximately 1% to 3%, is associated with anal receptive intercourse with ejaculation (65), particularly in unprotected anal intercourse practices (66). This heightened risk is attributed to factors such as the greater density of lymphoid follicles in the rectal mucosa, the presence of intraepithelial pockets facilitating virus replication, and the increased susceptibility of rectal epithelial cells to abrasions. Of course, risk accumulation occurs with multiple partners, particularly in the absence of regular testing. Although the practice of anal sex is not exclusive to MSM, as it is also practiced among heterosexual couples, its prevalence is higher in the former group.

From a vulnerability approach, it is crucial to optimize the MSM risk management processes in the selection of blood component donors, considering the different dimensions of vulnerability mentioned. The Constitutional Court of Colombia, by eliminating references to sexual orientation and gender identity as risk factors, sought to eliminate the discrimination that perpetuates the stigmatization of certain groups. However, this action does not fully address the complexities of vulnerability. Dispositional vulnerability, which refers to the predisposition of certain individuals or groups to be more susceptible to specific risks, is evident in recipients of blood components, who critically depend on the safety of transfusions. We suggest that, from a rights-based perspective, it is important to move beyond selection criteria that reinforce the stigma against individuals and groups with greater vulnerability to HIV and other STIs. We propose addressing dispositional vulnerability as a characterization that helps identify opportunities for intervention to mitigate and prevent the materialization of risk, rather than as a category that fosters stigma and unjustified discrimination. We advocate for an active policy based on affirmative actions, rather than a punitive and discriminatory approach.

Additionally, situational vulnerability, which is contextually specific, affects both donors and recipients. MSM and other risk groups face both situational and pathogenic vulnerability due to stigma and discrimination that may lead them to conceal risky behaviours during the donor selection process. At the same time, blood recipients are in a vulnerable situation due to deficiencies in the Colombian healthcare system, such as the limited availability of NAT, pathogen inactivation processes for all collected blood units, and PrEP. This situation increases the risk of infection transmission through transfusions, which is particularly dangerous for those in critical condition or with compromised immune systems.

Understanding the dynamics of HIV infection acquisition necessitates an exploration of the interconnected social determinants that contribute to vulnerability. For instance, inequity (46) and gender-based violence disproportionately affect women, particularly in contexts where asserting condom use is challenging within patriarchal cultural norms (47). Additionally, forced displacement (67), socioeconomic inequality (68), educational gaps in understanding risk factors and practices (69), racial and gender discrimination (70), insufficient public policies addressing substance use disorders with a collective health and harm reduction approach (71), poverty (72) alongside the criminalization of individuals and communities with diverse gender identities, collectively amplify situational and pathogenic vulnerability to HIV infection (73).

The Constitution of Colombia guarantees that all individuals are born free and equal before the law, receiving equal protection and treatment from authorities, and enjoying the same rights, freedoms, and opportunities without discrimination based on sex, race/ethnicity, national or familial origin, language, religion, or political or philosophical opinion. However, it does not establish a right to donate blood. The Constitutional Court Judgment T-171 of 2022 describes the practice of donation as an intention of solidarity or an act of empathy (74). Decree 1571 of 1993 characterizes it as a duty of social solidarity (75). Thus,

under Colombia's legal framework, donating blood cannot be regarded as a legal or moral right. Instead, what must be ensured during the blood donation process is that potential donors are treated without discrimination based on their sexual orientation. This conclusion aligns with Franklin's perspective (76), as he has analyzed the interaction between rights, responsibilities, and expectations of the actors involved in blood component donation and transfusion. His analysis concludes that, although there is no explicit right to donate, rights, duties, and responsibilities are recognized for both donors and other participants in the process, with a special emphasis on the rights of patients receiving transfusions.

In other contexts, such as South Africa, where the pattern of HIV transmission differs from that of Colombia, the right of MSM to donate blood was established several years ago. However, some authors express their disagreement and advocate for prioritizing the rights of recipients (77). Another study highlights that, for many MSM, blood donation represents an act of citizenship that reflects values such as altruism and solidarity. For this reason, they advocate for a risk-based individualization approach rather than deferral based on sexual orientation. Nevertheless, there is no consensus within these communities regarding the "right to donate" (78).

At this point, it is important to draw a distinction. One meaning of the term "discrimination" refers to the ability to distinguish or discern, that is, the capacity to differentiate between various elements. In this sense, a discriminatory practice (understood as an exclusionary selection) can be either arbitrary or reasonable, depending on the strength of the justifications that support it in each case (79). A selection practice that discriminates between certain groups or practices is considered reasonable when it is based on fair, objective, proportional, and transparent criteria, while respecting fundamental rights (for example, in the case of blood donation, a person carrying a bloodborne condition). Conversely, selection based on criteria such as race/ethnicity, social status, age as an isolated factor, disability, sexual orientation, or gender identity may be arbitrary, according to the specific context. In the case of blood component donor selection, the Constitutional Court ruled that discrimination based on sexual orientation and gender identity constituted an unjustified practice.

In 1991, the Constitution of Colombia was updated to declare and protect the fundamental rights of the population (80). The request by the Constitutional Court to remove any mention of sexual orientation as a criterion for blood donation exclusion aimed to guarantee rights in the realm of private moral values, such as:

a) Self-determination: According to Article 18, freedom of conscience is guaranteed, where no one shall be harassed for their convictions or beliefs, nor compelled to reveal them or act against their conscience.

b) Freedom of expression: Article 20 ensures that everyone has the freedom to express and disseminate their thoughts and opinions, and to receive truthful and impartial information.

Article 16 of the current Constitution states that all individuals have the right to free development of their personality, with no limitations other than those imposed by the rights of others and the legal order. However, this protection of individual rights conflicts with essential public values due to several deficiencies in the Colombian healthcare system:

a) Non-maleficence: Article 11 declares that the right to life is inviolable. In Colombia, as described before, NAT for collected blood has not been fully implemented, pathogen inactivation techniques are not used, and there is a growing HIV epidemic concentrated in specific populations such as MSM. The lack of complete coverage of antiretroviral therapy for diagnosed HIV patients and the unavailability of free PrEP increase the risk of HIV transmission through blood transfusions.

b) Equality: According to Article 13, all people are born free and equal before the law and must receive the same protection and treatment from authorities. However, a patient undergoing a transfusion, especially in conditions of vital urgency, loss of consciousness, intellectual disability, or under 18 years of age, cannot choose whether to accept the transfusion. Allowing blood donation from a group with a high prevalence and incidence of HIV without adequate measures to reduce the transmission risk violates the principle of equality, endangering the lives of vulnerable recipients, such as pediatric patients, who may receive infected blood due to the HIV window period.

c) Vulnerability: The state has an obligation to provide special protection to people in circumstances of manifest weakness, according to Article 13. Not taking measures to reduce the risk of HIV transmission through transfusions exposes the most vulnerable to fatal consequences, contravening this constitutional mandate.

Therefore, while eliminating sexual orientation-based exclusion for blood donation aims to protect individual rights, this measure must be accompanied by significant improvements in blood donation safety practices. Implementing universal NAT and ensuring access to antiretroviral therapies and PrEP are essential steps to balance individual rights with public health protection and equity. Only then can we ensure the rights of all actors involved in the donation process and the safety of blood recipients, without compromising the integrity and lives of the most vulnerable members of our society.

## CONCLUSIONS

While it is crucial to address practices that perpetuate stigma and discrimination against individuals based on their sexual orientation or gender identity, it is equally important to safeguard the safety of blood component recipients and uphold the

principle of non-maleficence. Unlike donors, recipients do not always have a choice in whether they receive a transfusion; they rely entirely on clinical criteria and technical guidelines to ensure that both donation and transfusion processes are safe.

The risk of HIV and other STIs is driven not by an individual's sexual orientation or gender identity but by specific high-risk behaviours. In light of this, we support the Constitutional Court's decision to review and modify donor selection criteria to eliminate discrimination against historically marginalized groups. However, given the unique epidemiological characteristics of the HIV epidemic in Colombia and the challenges inherent in ensuring the safety of the blood supply, the absence of studies validating these modified criteria raises significant concerns. These concerns are twofold: there is the potential for an increased risk of transfusion-transmitted infections, and there is the economic cost associated with implementing comprehensive safety measures — such as universal NAT testing — to mitigate such risks.

A clear cost-benefit trade-off emerges in this context. On one hand, broadening the donor pool by eliminating discriminatory deferral criteria may result in an increased supply of blood components. On the other hand, if these changes are not accompanied by robust safety practices — most notably, the universalization of NAT testing — the risk of undetected window period infections may rise, potentially compromising recipient safety. Economic considerations, including the cost of additional NAT testing, must be carefully balanced against the imperative to protect patients from transfusion-transmitted infections.

Pathogenic vulnerability arises when measures intended to reduce risk inadvertently exacerbate it. Therefore, while eliminating criteria based on sexual orientation is an essential step toward achieving equality and equity, it must be coupled with the universal implementation of rigorous safety measures and a continuous reassessment of associated risks. Only by integrating these strategies can we ensure that efforts to increase the blood supply do not inadvertently compromise its safety, thereby upholding the principles of non-maleficence, justice, and equitable care for both donors and recipients.

In conclusion, before implementing nationwide changes in blood donation policies, it is imperative to consider the complexity of the risks involved. We disagree with the Constitutional Court's decision which, in the absence of studies demonstrating a differential risk in the detection of infections between MSM and heterosexual individuals, assumes that both groups present the same risk. Although we agree that sexual orientation and gender identity alone do not determine the likelihood of acquiring infections potentially transmissible by transfusion, lifting the donor restriction without robust comparative studies is premature. Colombian epidemiological evidence — which shows that six out of ten new HIV cases occur among MSM and that the prevalence of HIV in men is 4.3 times higher than in women — indicates that specific sexual behaviours, such as anal intercourse, present a higher probability of transmitting infections like HIV compared to other practices, such as vaginal intercourse. Therefore, it is crucial to conduct studies that quantify and compare these risks to ensure that any modifications in donor criteria are accompanied by adequate safety measures, thereby safeguarding both the health of recipients and the integrity of the blood supply. In the absence of such studies, the widespread incorporation of NAT testing in all blood banks should be mandated to reduce the immunological window periods and mitigate the potential increased risk of transmission of infectious diseases that could result from removing one of the donor selection filters.

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