

# Gender-neutral donor deferral policies: experience in Argentina implementing individual risk-assessment policies

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## Vox Sanguinis

**Background** In Argentina, with the aim of moving to a safe supportive and inclusive National Blood System, in September 2015 the Ministry of Health stipulated that eligibility criteria for blood donation should only take into account the so-called 'risk practices', focusing on a 'gender-neutral' policy. The aim of this study is to demonstrate the impact of such regulation on the prevalence of STI in the population of blood donors in Argentina, through the analysis of the scientific evidence obtained from 174 074 donors from a large central region of the country, focused on a regional Blood Bank for a 6-year period (pre- and post-entry into force of the regulations).

**Materials and Methods** To analyse the evolution of prevalence rates of STI, two periods of 3 years each were evaluated: The first period (P1) lasted from 16 September 2012 to 15 September 2015 (prior to the entry into force of the law) and the second one (P2) from 16 September 2015 to 15 September 2018 (after the entry into force of the law).

**Results** A total of 82 838 subjects were enrolled in P1 and 91 236 in P2. The results show a significantly lower prevalence of HCV ( $P = 0.029$ ), HBV ( $P = 0.028$ ) and syphilis ( $P = 0.001$ ) in P2, while no difference was observed for HIV infection ( $P = 0.60$ ).

**Conclusion** This study evidenced that the implementation of a 'gender-neutral' policy based on individual risk-assessment deferral criteria maintained the safety of blood supply and decreased the prevalence of STI among blood donors.

**Key words:** blood donor deferral, men who have sex with men, sexually transmitted infections, transfusion-transmitted infections.

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## Introduction

Donor eligibility criteria for men who have sex with men (MSM) are under continuous evaluation. Based on epidemiological and scientific evidence, debates on this topic focus on the maintenance of current levels of safety and reduction of HIV transmission risk, to ensure adequate quality of blood supplies [1].

Currently, in several countries, blood donor eligibility criteria regarding MSM have been reformed and deferral policies in many jurisdictions are nowadays based on a period of abstinence from MSM, while in other countries, they are based on donor sexual activities considered of high risk [2]. Nevertheless, there are changes to indefinite deferral policies, but not all countries have changed this policy [3]. Nowadays, in Australia, MSM are deferred from blood donation when the risky behaviour occurred within the previous 12 months [4]. However, the Australian Red Cross Blood Service is now attempting to shorten this deferral period to 6 months, as the Japanese Red Cross has recently done [2]. In the same direction, in

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2001, the criteria for blood donor eligibility in Italy were changed from permanent deferral of MSM to individual risk assessment of sexual behaviour [5]. In December 2015, the U.S. Food and Drug Administration (FDA) released revised guidelines regarding deferral criteria for MSM blood donors, changing its policy from indefinite deferral to a 12-month postponement since the last sexual contact with another man [6]. In this sense, time-based deferrals have been already reduced from 12 months to 4 in the Netherlands, Denmark and France and to 3 months in England, Scotland, Wales and Canada [7,8].

In Argentina, with the aim of moving to a safe, supportive and inclusive National Blood System, in September 2015, the Argentinean Ministry of Health released a regulation ruling that selection criteria of the National Blood System for blood donors should rely on a paradigm shift replacing the category 'risk group' for 'risk situation' [9]. The new donor eligibility criteria should only take into consideration the so-called 'risk practices', focusing in a 'gender-neutral' policy. In this sense, the 2015 regulation established that 'the incorporation of information regarding diverse situations and/or sexual practices considered of "high risk" in the donor selection process, propitiating the self-exclusion and/or professional consultation in case of doubt, is considered more adequate than a deep investigation regarding sexual orientation or gender identity' [9]. Thus, the legislation recognizes that sexual orientation does not determine the risk of acquiring an infection but risky situations, like unprotected sexual practices, do. Therefore, blood donor deferral criteria are based on individual risk assessment to identify any personal behaviour that could make the donor interviewer suspect a risk for sexually transmitted infections (STI) that could be transfusion-transmitted (TTI) as well. Prior to this regulation, the blood donor selection criteria established a 12-month deferral for MSM without inquiring about the safety of their sexual practices. This represents a paradigm shift in the Argentinean transfusion medicine, since the so extended practice that excluded MSM just because of their sexual orientation, gender identity or expression was rejected. Nowadays, the question about having sex with MSM has been excluded from the situations that involve a 12-month deferral [9]. Also, donor interviews have to avoid questioning about sexual orientation. Following this change, the current attention focuses on those situations that could increase the risk of acquiring TTI, no matter the sexual preferences.

The aim of this report is to show the impact of the new regulation on the prevalence of STI in the population of blood donors in Argentina, through the analysis of scientific evidence obtained from 174 074 donors from a large central region of the country and focused on a regional

Blood Bank during a 6-year period (pre- and post-entry into force of the regulations).

## Materials and methods

To analyse the evolution of prevalence rates for STI, two periods of three years each were analysed: the first period (P1) lasted from 16 September 2012 to 15 September 2015 (prior to the entry into force of the law) and the second one (P2) from 16 September 2015 to 15 September 2018 (after the entry into force of the law). Prevalence rates for TTIs are donation-based.

The study was developed in a blood bank of Córdoba, a large province of Argentina. This Blood Bank centralizes different blood transfusion services (BTSS) working all over the 165 321 km<sup>2</sup> of the province. Serological and molecular pre-transfusion screenings of almost 50% of the blood units collected throughout the province are performed in this centre. Thus, the donor population of this blood bank is not circumscribed to a particular area but distributed in a large region of the centre of the country; Córdoba province is the second most populated region of Argentina.

Blood donors' data were obtained from the Blood Bank Information System. Personal information regarding sex, age, personal identification number (PIDN), current residence, status of replacement or altruistic/repeat donor, donor qualifications or clinical data, pre- or post-donation self-exclusion and serological/molecular studies was recorded in the database system and analysed. Even when a unique database number was assigned for every individual donation, donors PIDN allowed to link multiple donations and discriminate between first-time/repetitive donations. Blood donors are classified as repeat donors if they had donated blood at least three times during the same year without evidence of previous blood donations, or when they had donated blood at least once in the last 12 months and had previous altruistic donations within the last 24 months. Replacement donors were those who were required to give blood urgently for a relative or close friend.

In both periods, potential donors filled a questionnaire to collect any relevant information about epidemiological features, clinical conditions and any practice that would place them at risk of carrying TTIs. With the purpose of avoiding discrepancies between BTSS and confusion in blood donors, in Argentina, donor selection is standardized by the Plan Nacional de Sangre of the Ministry of Health of Argentina. Compelling with that, all blood banks use the same documents for donor qualifications: donor information form, pre-donation self-exclusion document, personal questionnaire and post-donation self-exclusion documents, which are available for free on the

web and can be downloaded from the government website (see reference [9]).

The candidates were face-to-face interviewed by trained healthcare personnel, who decided if they were eligible to donate blood according to the donor selection criteria defined by the active law.

Serological screening of blood donors was performed as follows: detection of antigens and antibodies against HIV (HIV Ag/Ab, Abbott, Wiesbaden, Germany) by chemiluminescence assay (ARCHITECT HIV Ag/Ab combo reagent kit, Abbott), detection of antibodies against HCV by anti-HCV (anti-HCV reagent kit ARCHITECT, Abbott, Wiesbaden, Germany), detection of HBsAg (ARCHITECT AgHBs reagent, Abbott, Sligo, Ireland) and anti-core (ARCHITECT core reagent kit, Abbott, Wiesbaden, Germany) and detection of antibodies to *Treponema pallidum* (ARCHITECT Syphilis TP, Abbott, Wiesbaden, Germany). By protocol, all reactive samples are retested from the primary tube and the donation bag sample. Furthermore, a second sample is obtained from reactive donors for retesting.

Córdoba province has effective regulations that establish the compulsory use of NAT at regional level, making it mandatory for all blood banks in the province since 2010, based on Decree N° 1047/ Resolution N° 618 [10]. NAT was introduced in our blood bank in 2006 [11]. Molecular screening of all blood donors was performed with COBAS TaqScreen MPX Version 2.0 test (Roche Molecular Systems, Cobas TaqScreen MPX: Roche Diagnostics GmbH, Mannheim, Germany) for detection of HIV-1 RNA Group M, HIV-1 Group O RNA, HIV-2 RNA, HCV RNA, and HBV DNA in minipools of six. Samples included in reactive minipools are afterwards tested individually to identify the reactive one.

By protocol, when a sample results repeatedly reactive by serology and molecular tests, a second sample is requested from the donor to confirm the identity of the primary sample. When only NAT is reactive, a careful follow-up is performed to confirm infection.

### Statistical analysis

Chi-squared test was applied to investigate any correlation between prevalence rates and sex or period of study. The statistical package R version 3.2.4 software (R Core Team) was used for statistical analyses. In all cases, significance level was 5%.

### Results

Demographic data and the evolution of prevalence rates for STI were analysed, and results are shown in Tables 1 and 2, respectively. Total numbers of donors enrolled in

P1 were 82 838 and 91 236 in P2. Age distribution and standard deviation between the two periods were identical ( $36 \pm 11$  years), and the proportion of donors by gender in both periods was similar (Table 1). Proportion of first-time/repeat donors was 80%/20% for P1 and 77%/23% for P2, respectively. These proportions are concordant with those reported for Córdoba by the provincial blood programme authorities (Visintín G. personal communication, June 14, 2019).

The results show a significantly lower prevalence for HCV ( $P = 0.029$ ), HBV ( $P = 0.028$ ) and syphilis ( $P = 0.001$ ) in P2, while no changes were observed for HIV infection ( $P = 0.605$ ).

Rates of infection were compared among female donors showing absence of significant variations for HIV ( $P = 0.165$ ), HBV ( $P = 0.427$ ), HCV ( $P = 0.084$ ) or syphilis ( $P = 0.151$ ) between both periods (Table 2). On the other hand, comparison among male donors revealed that while rates did not vary significantly for HIV ( $P = 0.155$ ), there was a significantly lower prevalence for HCV ( $P = 0.045$ ), HBV ( $P = 0.006$ ) and syphilis ( $P = 0.001$ ) in P2 (Table 2).

In P1, donors who tested HIV or HCV positive by NAT were also positive by serology while five male donors tested HBV positive only by NAT. In P2, donors who tested positive for HBV by NAT were also positive by serology, including one male and one female with recent infections (Reactive HBV NAT and HBsAg and nonreactive anti-core) while two serological window periods (SWP), one for HCV and other for HIV, were detected by NAT.

Results for SWP and recent infections detected in P1 and P2 were confirmed by complementary assays and/or sero-conversion of donors by follow-up. All of them were first-time replacement donors.

### Discussion

Herein, we demonstrate the effectiveness of the paradigm shift from 'risk group' to 'risk practice'. We investigated the rates of STI in an Argentinean blood donor population before and after the implementation of the mandatory regulation of the Healthy Ministry, which introduced a 'gender-neutral' individual risk-practice deferral policy. The comparison of STI rates obtained through six years in this survey shows that donor selection criteria focusing on identification of individual risk practices allowed to defer those who were not eligible based on high risk of TTI, preserving the safety of blood supply.

Deferral donor criteria based on the risk-group model undermines the right of access to health care and is not a good model in terms of sustainability of the blood supply system. Moreover, it promotes discrimination because in a 'risk-group' paradigm-based model, some people cannot

**Table 1** Blood donor demographic data

	Age			Sex (%)		Type of donor (%)	
	Median	Mean	Standard Deviation	Male	Female	First Time/ Replacement	Repeat
P1	35	36	±11	66	34	80	20
P2	36	36	±11	63	37	77	23

**Table 2** HIV, HBV, HCV and Syphilis prevalence rates in a blood donor population of Argentina

STI		Period 1 (n = 82 838)	Period 2 (n = 91 236)	P value <sup>a</sup>
HIV		69 (0.084%) <sup>b</sup>	70 (0.076%) <sup>b</sup>	0.605
	M	60 (87%)	55 (79%)	0.155
	F	9 (13%)	15 (21%)	0.165
HBV		44 (0.053%) <sup>c</sup>	29 (0.031%) <sup>b</sup>	0.028
	M	38 (86%)	22 (76%)	0.006
	F	6 (14%)	7 (24%)	0.427
HCV		45 (0.055%) <sup>b</sup>	30 (0.033%) <sup>b</sup>	0.029
	M	27 (60%)	18 (60%)	0.045
	F	18 (40%)	12 (40%)	0.084
Syphilis		1539 (1.86%) <sup>b</sup>	1514 (1.66%) <sup>b</sup>	0.001
	M	1060 (69%)	1030 (68%)	0.001
	F	469 (31%)	486 (32%)	0.151

F, female donors; M, male donors; STI, sexually transmitted infections.

<sup>a</sup>Independent chi-squared test. In all cases, significance level was 5%.

<sup>b</sup>Reactive donors.

donate or may feel forced to lie in order to donate blood. Besides, a model based on the concept of 'risk group' establishes a 12-month deferral for MSM without inquiring about the safety of sexual practices. It has been demonstrated that the risk should be assessed individually rather than impute a risk status just because of the membership of specific groups [7]. In this sense, although HIV prevalence is higher in homosexual men, this fact does not determine that a MSM is certainly infected.

Last decades, evidence-based studies supporting MSM deferral policies based on individual risk assessment have been disclosed. In a study by Seed *et al.* [4], the authors did not find any evidence that the implementation of a 12-month deferral for MSM resulted in an increased risk for blood transmission of HIV in Australia. Recently, a review by Haire *et al.* [7], also in Australia, concluded that the reduction of the deferral period to 3 months does not increase the risks of HIV transmission. Moreover, a study by Suligoj *et al.* [5] in 2013 demonstrated that after the change of donor screening criteria introduced in Italy in 2001, no significant increase in the proportion of MSM compared to heterosexuals was observed among HIV antibody-positive blood donors. Modelling studies performed

in the US, Canada, UK and France evaluating several scenarios predicted negligible risk increments (less than 1 in 1 million units) when changing to a 12-month deferral period [2,8].

Even though our data are in agreement with the mentioned reports [2,4-5,7,8], local epidemiological context is complex and different. In this sense, during recent years, there has been an increase in the incidence of STI. According to a report released in December 2018 by the Ministry of Health of Argentina, the rate of syphilis cases in young people and adults tripled between 2013 and 2017 [12]. This rate has been growing steadily, reaching its highest growth in 2018 with a rate of infection of 51.1 people per 100 000 inhabitants (Fig. 1) [13]. Likewise, the rate of syphilis positivity in pregnant women increased from 2% to 3.2% between 2013 and 2017 [12] reaching 4% during 2018 [13] (Fig. 2). Like for blood donors, syphilis screening is mandatory in pregnant women, but through a nontreponemal test. The yearly comparison of syphilis rates between both populations (Fig. 2) evidences a decrease in the incidence of this infection in donors. Considering this particular scenario, the lower prevalence of syphilis demonstrated in this

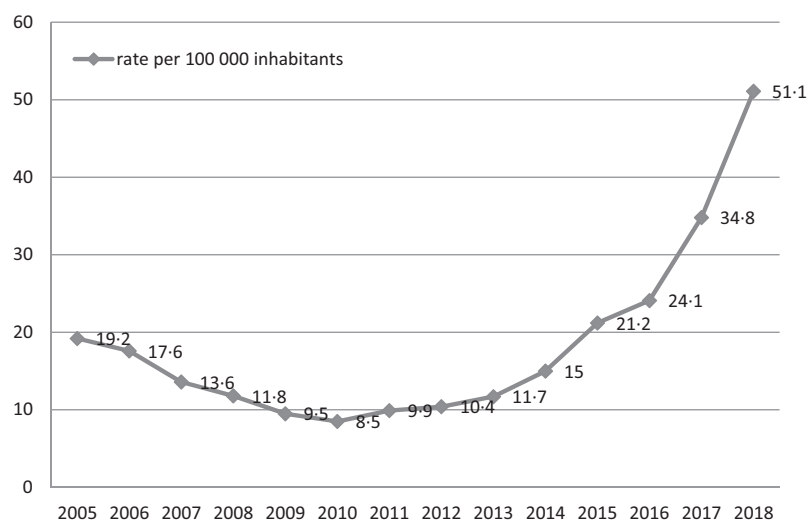
study during P2 reveals the great importance of individual risk assessment to identify risk practices in blood donors. Moreover, along with this fact, we demonstrated a significant decrease of other STI as HBV and HCV during P2. In this regard, in a previous publication, our group reported the usefulness of NAT in the reduction of the risk of HBV transmission with a frequency of 1 in 56 072 [11]. We also found a high frequency of HBV recent infections (1/33 643) [11]. Herein, we are communicating the detection of 5 SWP for HBV infections in P1 and 2 HBV recent infections in P2, which is concordant with the significantly lower prevalence of STI found in P2.

On the other hand, the SWP for HCV and HIV detected in P2 reflects the current epidemiological context of the country. In this regard, the increase in syphilis rates in the general population and pregnant women during recent years in Argentina is a direct indicator of an increase in risky sexual practices, which has direct impact on the acquisition of other STI. Thus, despite the higher rates expected for these pathogens in regional blood banks, the lower prevalence detected for syphilis, HCV and HBV, especially the lower frequency of HBV recent infections, during P2 reinforce the fact that current donor selection measures based on individual risk factors minimize the risk of acquiring TTI. This solid evidence demonstrates that deferral of blood donors should not be based on donor sexual identity or orientation but on the assessment of individual risk practices. A time deferral for MSM without inquiring about sexual practices reinforces stigma and their exclusion is not scientifically justified. For this reason, we agree with the concept that

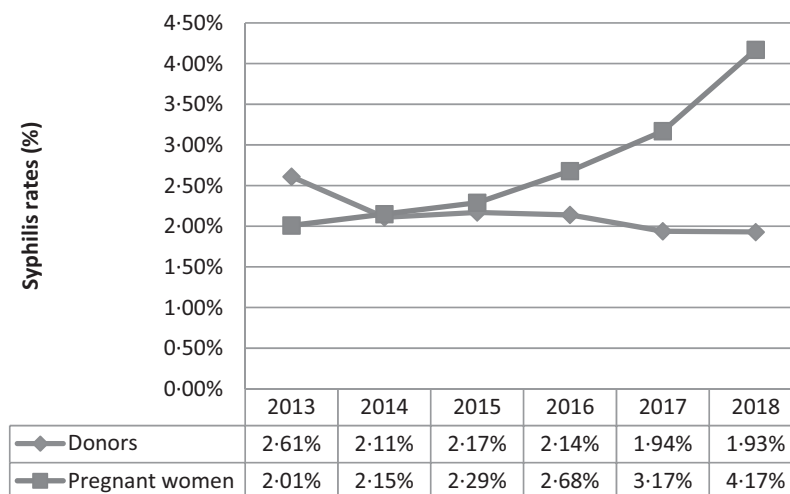
sexual orientation does not determine the risk of acquiring an infection; however, engagement in risky situations, like unprotected sex, does.

It is necessary to reinforce gender-neutral deferral policy with the use of highly sensitive techniques. It has been already discussed that WP for blood-borne infections should be taken into account in the calculation of deferral period [7,8]. In Argentina, only Córdoba province has effective regulations that establish the compulsory use of NAT, making it mandatory for all blood banks in the province [10,11]. The introduction of NAT testing for all blood donations in Córdoba by Ministerial regulation occurred after transmission of HIV during SWP to two recipients in 2008. Until 2007, there were at least six trials with final judgement in Argentina related to transfusion-transmitted HIV during SWP. Although there is not national regulation, different blood banks across the country have already incorporated NAT into regular pre-transfusional screening. Our findings demonstrate that it would be necessary to promote unified effective regulations in order to set up the compulsory use of NAT throughout the country.

Scientific evidence provided herein, along with preexisting information reported in other countries [2,4-5,7,8], support the feasibility of a system based on a 'gender-neutral' deferral and the paradigm shift from 'risk group' to 'risk practice', which is more extensive and inclusive. Furthermore, based on the rates yielded by our survey, we can assure that the change from time-based deferral policies to strategies based on individual risk assessment does not compromise transfusion safety and reduces the risk of STI transmission through blood and blood components.



**Fig. 1** Evolution of syphilis rates in the Argentinean general population (2005–2018). Data provided by the National Health Surveillance System (Sistema Nacional de Vigilancia de Salud, SNVS), published in the Bulletin on HIV, AIDS and STIs in Argentina N°36 by the Ministry of Health, 2019 [13].



**Fig. 2** Evolution of syphilis rates in blood donors compared to pregnant women. Data provided by the informatics system of the blood bank and the National Health Surveillance System (Sistema Nacional de Vigilancia de Salud), published in the Bulletin on HIV, AIDS and STIs in Argentina N°35 by the Ministry of Health, 2018 [12].

Unlike estimations expressed by Haire *et al.* [7], we are convinced that it is responsibility of the Blood Department to conduct probing and intimate questioning on sexual practice since individual face-to-face donor interview is critical to exclude donations from individuals at risk of TTI, but also provides an opportunity to educate and motivate people to become regular responsible donors. A sustainable and responsible blood donation system must ensure that donors engaged in sexual practices with high risk for STI are capable to identify the risk themselves and refrain from donating blood. Studies on unreported deferrable risk among donors demonstrate that the personal perception of risk is key to non-compliance with donor selection criteria [3]. Inadequate level of awareness of risk behaviour in the blood donor population has already been discussed [5]. Thus, education of the potential blood donor population is a key to generate blood donors with self-perception of the risks, understood

as the ability to identify exposure to factual unsafe practices.

Finally, we are convinced that based on the principle that 'nobody contracts or transmits an infection because of what he/she is, but for what he/she does', harmonization of deferral criteria for all donors regardless sexual identity allows to maintain the safety of blood supply. In this sense, we are sure that the key formula to achieve sustainable and inclusive blood supply systems is to continue working to train specialists in identifying individual risk practices in the blood donor population. This, in addition to the education of the general population, would ensure safe and sufficient supply of blood and blood products from responsible donors for future generations.

## Conflict of interests

The authors declare no conflict of interests.

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