Men who have sex with men and ethical analysis of blood donors screening in Brazil

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Abstract The scope of this study is the ethical analysis of Resolution no 153⁄2004 of Brazil's National Health Surveillance Agency, concerning human rights involving the deferral for men who have sex with other men (MSM) in blood donation during one-year period. The Mann & Gostin`s model that utilizes human rights as parameter for evaluating health public policies was used for ethical analysis. The study showed that the national blood policy purpose is clear and accurate related to transfusional safety, as well as there are effectiveness evidences of laboratorial and epidemiological screening measures. Still, it was found that there isn`t strict restriction of MSM's human rights. Considering that the current national blood policy of MSM temporary exclusion is consistent with human rights norms and principles, this study concluded that mentioned resolution should remain unchanged.

Key words: Blood. Donation. Screening. Male homosexuality. Human rights

This article aims to ethically analyze the constraint of donating blood relative to men who have sex with men (MSM), established by Resolution RDC 153, of June 14, 2004, from the National Agency of Sanitary Surveillance (Anvisa) [1], through the use of the referential of human rights, applicable to the evaluation of policies and programs on public health, as developed by Mann and Gostin [2]. Aiming to contextualize the problematic, following are explained the events that conditioned the adoption of such measure.

History goes back to the beginning of the epidemic's immunodeficiency syndrome (AIDS) at the end of the 70s, and its dissemination mainly through sexual and blood routes [3-5]. This fact prompted the adoption of a new transfusion policy worldwide, with the introduction of various procedures in the hemotherapic services to ensure the safety of blood transfusion, focusing mainly in preventing transmission of infectious diseases such as AIDS [3-6].

The first cases of patients infected by the human immunodeficiency virus (HIV) through blood transfusion were detected in the beginning of the epidemic, with a high fatality rate [3,4,5]. At that time, the rapid world expansion of AIDS was associated with transfusions of blood products, as happened in France, in the period from 1985 to 1993, when the administration of blood products caused the infection of 1927 recipients and the death of 250 hemophiliacs [6-8]. In Brazil, the situation was also quite complicated, since we were facing the problem of blood commercialization [9.] However, despite these difficulties and the fact that we had not the same amount of resources as those available in developed countries, accidents of so serious nature did not happen in the country.

These serious blood transfusion problems have forced governments and the global scientific community to work apace with the aim of improving the production of blood products, with improved methods of viral inactivation. The same did not happen with the blood components, which do not usually go through that process, being necessary to adopt other measures. New procedures were implemented for laboratory screening of HIV and other infections, from which blood transmission was reduced but not eliminated. This residual probability of transmission is mainly due to the possibility of the existence of donors in the so-called *immunological window* stage, the initial period of the infection in which the diagnostic tests are negative [10]. To reduce this residual risk two other measures were included: the possibility of self-exclusion and epidemiological screening, with which there was a significant reduction of transfusion transmission[10]. This strategy was implemented in most hemotherapy services in the world[6]. The DRC 153 1, currently prevailing, determines the exclusion, for the period of one year, of MSM donors and their sexual partners.

In recent years, in Brazil [11], as in other countries [5], several groups that advocate the gay rights began discussions and questioned Anvisa and the Ministry of Health about the provision in the mentioned resolution as to the epidemiological screening, which makes it impossible for MSM to donate blood temporarily. These groups advocated the repeal of the norm on the justification that it would be discriminatory and based on homophobic prejudice.

In parallel, since the end of the 80s the number of lawsuits against the state, regarding transmission through transfusion of HIV infection and other microorganisms, has been

increasing. Most of their decisions were in favor of applicants based on the principle of the protection of the right to health of the human person and accountability of the state. As an example, there is the first lawsuit brought by the family of cartoonist Henfil against the Union and the State of Rio de Janeiro [12].

Given this conflicting scenario around the regulation in question, this paper aims to examine the current national policy of blood, specifically with regard to the temporary exclusion of MSM from blood donation. In order to further study the problem, the work presents contribution so that the governmental decision-making within the framework of the national blood policy be performed at the light of the human rights applicable to the field of public health.

Normative grounds about the screening of blood donators and MSM

This topic aims at investigating the norms that in Brazil were targeted to regulate the screening of blood donors, and also present an outlook of the norms adopted in other countries.

In the 80s, after the progress of the epidemic AIDS and accidents in blood transfusion and blood products, France, the United States of America (USA) and other countries adopted strict criteria as the exclusion of donors [7,13]. In September 1985, the Food and Drug Administration (FDA) made the following recommendation: *All men who have had sex with men at any time since 1977, are permanently excluded as blood donors* [6,14]. England, USA, Canada, Australia and the European Blood Alliance (network of national blood organizations that provide important services in the member states of the European Union) and also most developed countries, with minor exceptions, followed the recommendation from FDA [6,13-16] - based on statistical information and scientific evidence which showed that MSM have higher risk of HIV infection than the general population [13,15,17] .

Brazil, unlike other countries, kept less strict criteria, which could be noticed from the national legislation that addressed the issue. Law 7649 [18] of January 25, 1988, regulated by Decree 95721[10] of February 11, 1988 defined the requirement of laboratory proof to detect the following infections: hepatitis B, syphilis, Chagas disease, malaria and AIDS. Ordinance 721 [20] of the Ministry of Health, of August 9, 1989, determined the exclusion of the sexual partners of individuals exposed to risk factors for AIDS. Ordinance 1376 [21] of the Ministry of Health, of November 19, 1993, established the exclusion of individuals with definitive serology positive for HIV and / or history of belonging or having belonged to risk groups for AIDS and / or having as sex partner individuals which fall in that group.

From RDC 343 [22] of Anvisa, of December 13, 2002, the Brazilian norm became less severe, disabling only for one year the MSM donors and their sexual partners. This same determination is maintained by RDC 153 [1]. However, the norm is not restricted to the donation by homosexual women, in addition to disqualify the donation for other causes - the elderly and minors of age, suffering from anemia, infectious illness, patients being treated with certain medications - and in many other situations, as those listed in item B.5.2.7.2, "d" in Annex I, called *Situations with increased risk* (people who have had sex for cash or drugs, victims of rape, inmates, sexual partners of patients in a program of hemodialysis etc.).

Thus, due to serious accidents with the transmission of HIV and other infections through blood transfusion, Brazil adopted several legal measures to ensure safety transfusions, but less stringent that most countries that followed strictly the recommendation made by the FDA. It is noteworthy that the national blood policy also includes many other temporary or permanent exclusions, in the donation of blood, which shows the concern with the safety of donors (including the elderly, pregnant, sick people etc.) and of blood receptors (infections transmission and others) based on the risks of transfusion and technology available.

The referential of human rights in the ethical evaluation of public health practices

The practice of blood transfusion involves a series of ethical issues involving the analysis of moral accountability, both in relation to donors and the recipients. The government deliberations on the subject should always consider the ethical, notably those arising from the comparison of the best public policy for the donation of blood with respect, protection and realization of human rights . Ethical considerations of the problematic, object of this study will be made from the human rights framework, applied to public health, as designed by Mann and Gostin [2]. These authors propose an analytical instrument that enables health professionals its systematic application to assess the effects of policies on public health on human rights.

The referential adopted unfolds in seven different phases and is intended to verify if the policy / program is ethically acceptable and appropriate to the perspective of humans rights: 1) to clarify the purpose of the public policy ; 2) to evaluate the effectiveness of the policy; 3) to determine if the public health policy has clearly defined the target populations; 4) to examine the impact of the policy on human rights; 5) to determine whether the policy is the less restrictive option to attain the goal proposed; 6) to verify if the coercive measure of public health is the most effective alternative and the less restrictive alternative , based on the significant risk pattern; 7) to verify whether the restrictive measure is indeed necessary to prevent a significant risk and warrant reasonable procedures to affected people.

First, we shall analyze the purpose of the policy of temporary restriction of blood donation by MSM, which is the blood transfusion security. It should be remembered that despite the great technological advances in recent years, the transfusion therapy is not free of risks, and the transmission of infectious diseases is a major one among them. Thus, the main objective of the sanitary norm, applied to blood transfusions, components and derivatives, is to reduce and if possible eliminate health risks to both the donor and the receiver. The laboratory and epidemiological screenings, including the temporary exclusion of MSM have been introduced for this purpose, especially concerning the infections transmitted by blood [6, 10, 12]. In addition, several studies demonstrate the greater risk of the MSM contracting STD / AIDS [6,11,14,17] Therefore, there is a precise and clear objective that leaves no room for speculations.

In the evaluation of the effectiveness of the measures adopted by the blood policy at the national and international level, like the laboratory and epidemiological screening and new techniques of viral inactivation, it was observed a great impact in the reduction of the risks of infection transmission through blood transfusions, especially after the

serious problems occurred in the inception of the epidemics. Such reduction shows that the measures as rather reasonable to the proposed objectives.

In fact, in the world dimension, up to 1987, the HIV transmission through the blood system was originated from full blood transfusions, hemocomponents, plasma and coagulation factors. For example, before the implantation of the serological screening and the treatment of blood viral inactivation, 12,000 persons in the USA were infected by the HIV from blood transfusions [23]. Studies performed between 1985 and 1991, in that country, show that the risk of HIV transmission was of approximately one case per 60,000 transfused units [6]. After the adoption of preventive measures and the progress of viral inactivation techniques, it was verified that such residual risk was expressly reduced: in the USA [24] it was of 1/450,000 to 1/660,000 in the period of 1992-1993, and in Canada [16], 1,43/1,000,000, similar to most other developed countries [8,24-26].
In regions under development , like the Middle East and North of Africa, the HIV soroprevalence in individuals of multiple blood transfusions was reduced from 270/10,000, in the period of 1987-1989, to 7/10,000 in 1995 [27].

The result of the measures adopted in Brazil as from 1988 [20], such as the obligatoriness of blood tests to detect infections and the possibility of self-exclusion and the epidemiological screening was successful, as shown by the drastic reduction in the rates of HIV transmission via blood [9,28-30]. In 1984, the two sub-categories – transfusions and hemophiliac – corresponded to 26.66% and 66.67% of the total number of AIDS cases via blood transmission in Brazil, and the remaining 6.67% were credited to the sharing of needles and syringes (UDI) [29]. In 1992, percentages changed with the reduction of transmission from transfusions (6.90%), particularly among the hemophiliacs (2.22%) [29]. In the year of 2000, the sub-category UDI prevailed (99,33%), further reducing the transfusion transmission (0.29%), as well as the dissemination among hemophiliacs (0.38%) [29,30].

When analyzing the policy of blood donation exclusion as regards the target populations, we verify that they are well defined, including not only MSM but also other populations with characteristics that raise the transfusion risk to the donors themselves, such as the elderly, bearers of anemia of cardiovascular, infectious diseases and many other included in item B.5, called *Criteria for the selection of donators*. The restriction on the blood donation also applies to all cases typified in item Added r*isk situations* (item B.5.2.7.2., sub item “d” of Annex I of RDC 153/2004) [1], since in any of them the HIV transmission risk increases to the receptors. Therefore, the resolutions is not only limited to MSM, reaching a greater (and differentiated) part of the population.

Examining the blood policy in relation to human rights of MSM, it is observed that the degree of intrusion does not cause significant violation of their rights. Thus, there is no severe restriction of freedom or privacy of the human person. It is only prohibited to them to donate blood for a limited time. It is known that the right to liberty or privacy is not absolute, all societies impose certain restrictions, especially when there is interference in the rights of others and / or perspective of imminent harm to public health. In this case, such constraint is justified by the high benefits to the population through confirmation of the drastic reduction in the transmission of infections by blood. Thus, the collective benefits outweigh the limited restriction on the human rights of some.

One must consider, moreover, that currently there is no alternative to achieving the objective proposed by the national blood policy, since there are technical and operational limitations and there are no laboratory tests capable to completely eliminate the risk of transmission of infections via blood. As new technologies are discovered, the constraint of the donation by MSM and other population groups should be reassessed. The countries that have more technological resources use more sensitive laboratory tests , that detect infections earlier than those held by blood centers in Brazil. Despite such advantages, developed countries continue adopting measures for epidemiological screening, which are even more strict than ours, permanently excluding the MSM since 1977 [6,13,14,16].

Recent studies indicate that the risk growth due to failure to detect HIV infection in the blood screening process, in case the standard is relaxed or excluded the question about sexual orientation, would be 50% - 500% higher than if it remained. Szwarcwald and Barbosa in 1998, made an estimate on the risk in two situations [31]. In the first, the question on MSM remains in the screening process. In the second, there is no screening. In the first situation, each 100,000 donors, in average, 1.4 would have a recent infection and not detected by the routine process. In the second one, at each 100,000 donors, in average, 2.1 would have undetected infection - which means an increase of 50% in biological risk.

Research carried out in the U.S.A., Canada and England demonstrate that the risk of HIV transmission would increase by 8% -60% is the norm in force (permanent exclusion of MSM donors since 1977) was changed for the exposure by MSM for one year (like current Brazilian norm), and this risk would increase by 500% if that selection was excluded [15,32,33]. These studies also showed that a change in the criterion to the period of one year would not bring any significant benefit as to the increase on donors. In the U.S., Spencer estimated that the change of the norm in that direction would increase the number of blood donations in only 12 new donors / years, in a total of 200,000 donors per year [34].

It is important to emphasize that the risks associated with the donation of contaminated blood are great: the receiving patient will most likely be infected. As for AIDS, the probability of infection of a blood receiver HIV infected is of 70% - 90% of the cases [23,27] and a single infected donor can transmit HIV and other infections to various receptors [23].

Besides the high risk of infection by contaminated blood, the health situation of receptors should be considered. Potential receptors, i.e., any person who needs to undergo elective or emergency surgery, accident victims, patients under chronic use of blood products - as those in hemodialysis programs – and patients with hematological diseases, among others, are expected to have secured their right to health. It should be registered that the infections that can be transmitted by blood produce chronic, serious and even lethal pictures, are difficult to manage therapeutically, cause serious changes in the quality of life of patients, and will only worsen the pre-existing picture . That is the case of AIDS, hepatitis B and C, infection by HTLV I / II etc.

According to the studies presented, if in this moment the norm becomes less stringent residual risk would increase, indicating therefore, the need to keep it unchanged, at least for now. The measures adopted, both laboratory and epidemiological screening and the

possibility of self-exclusion, are necessary and still constitute the area less restrictive and more effective norms for the attainment of the objective proposed by the national blood policy. Through them we can enhance the security of blood receivers, prevent significant risks to their health associated with the acquisition of chronic and even lethal diseases, which would greatly deteriorate the quality of life of patients and their families.

If the State fails in the execution of their duties related to norms on human rights, by not adopting the measures appropriate to ensure blood of quality, irreversible damage may occur to the health for transfused individuals. In addition, there are the indirect costs that the State will have to pay for medical services and hospital care of patients with diseases transmitted through contaminated blood. It should be noted, however, that other State liability resulting from these screening mechanisms , is to ensure that persons directly responsible for addressing the donor, and particularly the interviewers are properly trained to perform the work with due respect to human dignity - thus avoiding unnecessary constraints. That way we would at the same time maximizing population's access to secure health procedures, without harming individual human rights.

Final considerations

According to current legislation, the blood donation must be a voluntary, anonymous, not paid and altruistic act. Last quality is relevant, as there is evidence of misuse of purpose by candidates to the donation, which decharacterizes their altruistic character, thus increasing the risk of transfusion. According to recent survey with MSM, they seek for different medical services , among them the blood centers, not with the adequate purpose, to donate blood, but with the intent to perform tests to discard HIV infection [35]. This behavior increases the transfusion risk because many of these MSM may be undergoing the immunologically window stage, without the detection of the presence of HIV by the laboratory tests applied. Considering that laboratory tests only do not ensure the elimination of the transfusion risk, the more efficient are the complementary measures, such as epidemiological and clinical screening and the possibility of self-exclusion, the lower will be the residual transfusion risk . In such a circumstance it is indispensable to underline the high possibility of infection of recipients of contaminated blood (70% -90%).

It can be predicted that, according to the studies described, any eventual change of the norm, with the aim of making it less stringent, may lead to the increase of cases of transmission of infectious diseases, not just AIDS, which would lead to an increase of risks. As a consequence, there will be a growth in the number of lawsuits against the state, elevation of the value of indemnities and demand for high-cost medications for treatment of HIV infection and other infections of contaminated recipients, besides the enormous social cost. It should be considered that the diseases transmitted by blood, for example, AIDS, hepatitis B and C, have a great impact on public health, are difficult to handle, display serious complications and its treatment, in most cases, does not lead to healing and creates great costs, both for families and for the public health system . In eliminating the MSM screening, there is the possibility of a requirement by blood receptors to know the precedence of the bags, alleging their right to receive blood of quality. The physicians, in turn, aware of the risks of blood transfusion, if the screening

was suspended, would be subject to the ethical dilemma of deciding between the need for transfusion and the risks of the transfusion.

In conclusion, the ethical analysis of the national policy on blood donation, as refers to the MSM, reveals that the same is ethically acceptable and appropriate from the perspective of human rights and the process of epidemiologic screening of MSM for blood donation should not become less rigorous. Since the situation is dynamic and considering the accelerated development of the new technologies and changes in the epidemiological patterns, these issues should remain in continuous evaluation, including the previous careful analysis and studies well carried out on the possible consequences of risk transfusion.

Resumo

Análise ética da triagem dos doadores de sangue no Brasil e em homens que fazem sexo com outros homens

Este trabalho tem como escopo a análise ética da Resolução da Diretoria Colegiada (RDC) 153/2004, da Agência Nacional de Vigilância Sanitária do Brasil, quanto aos aspectos de direitos humanos que envolvem a vedação, aos homens que fazem sexo com homens (HSH), de doação de sangue pelo prazo de um ano após a última relação. Na análise ética empregou-se o modelo proposto por Mann e Gostin, que utiliza os direitos humanos como parâmetro de avaliação de políticas públicas em saúde. O estudo demonstrou que o propósito da política nacional de sangue é claro e preciso quanto a garantir a segurança transfusional, assim como que há evidências da efetividade das medidas de triagem laboratorial e epidemiológica. Ainda, verificou-se que não há severa restrição dos direitos humanos da população de HSH. Considerando que a atual política nacional de sangue de exclusão temporária de HSH coaduna-se com as normas e princípios dos direitos humanos, concluiu-se que a referida resolução deve permanecer inalterada.

Palavras-chave: Sangue. Doações. Triagem. Homossexualidade masculina. Direitos humanos.

Resumen

El análisis ético del *screening* de donadores de sangre en el Brasil y hombres que hacen sexo con otros hombres

Este trabajo tiene por finalidad el análisis ético de la Resolución n. º 153⁄2004, de la Agencia Nacional de Vigilancia Sanitaria del Brasil, sobre los aspectos de los derechos humanos que envuelven la exclusión de los hombres que hacen sexo con hombres (HSH) de la donación de sangre, por el período de un año. Para el análisis ético se usó el modelo propuesto por Mann y Gostin, que utiliza los derechos humanos como parámetro de evaluación de las políticas públicas en salud. El estudio demostró que el propósito de la política nacional de sangre es claro y preciso en lo referente a garantizar la seguridad en transfusiones, bien como que hay evidencias de la efectividad de las medidas del *screening* de laboratorio y epidemiológica. También se verificó que no hay severa restricción de los derechos humanos de la población de HSH. Considerando que la actual política nacional de sangre de exclusión temporaria de HSH es consistente con las normas y principios de los derechos humanos, se concluye que la referida resolución debe permanecer inalterada.

Palabras-clave: Sangre. Donación. Selección. Screening. Homosexualidad masculina. Derechos humanos.

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Received: 4.28.2010 Approved: 10.21.2010 Final approval: 10.26..2010

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