Revista Bioética
Print version ISSN 1983-8042 | On-line version ISSN 1983-8034

Rev. Bioét. vol.29 no.2 Brasília Apr./Jun. 2021

Secrecy, anonymity and confidentiality in blood donors with HIV

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Abstract

A recent article published in this journal on confidentiality in the care of HIV/aids patients reports that, in the event of a positive result in the Screening Tests for the virus, the Blood Bank must, in addition to disposing of the blood bag, refer the donor to the reference service. Due to the implicit ethical dilemmas we have experienced, this led us to a detailed review of the respective brazilian legislation and critical analysis of the issue. People with HIV/aids are surrounded by prejudices, discrimination and negative social repercussions, so it is essential that the Blood Bank professional who will communicate this news is fully aware of the issues involving secrecy and confidentiality, and fully trained and capable to proceed adequately. We present and discuss the fundamental points of the current Brazilian legislation the theme and how we must communicate to the donor about the detection of HIV serodiagnosis.

Keywords: HIV seroprevalence. Blood donors. Confidentiality.

Resumo

Sigilo, anonimato e confidencialidade de doadores de sangue com HIV

Na ocorrência de resultado positivo para HIV em triagem sorológica para doação, o serviço de hemoterapia deve, além de descartar a bolsa de sangue, encaminhar o doador ao serviço de referência. A situação, no entanto, traz dilemas éticos implícitos, vivenciados cotidianamente pelos profissionais da área. Assim, o objetivo do presente estudo é revisar pormenorizadamente a legislação sobre o assunto, desenvolvendo reflexões necessárias. Tendo em vista que a condição de ser portador de HIV/aids está envolta em preconceitos, discriminações e repercussões sociais negativas, é fundamental que o profissional da hemoterapia responsável por comunicar a inaptidão esteja ciente do sigilo e da confidencialidade das informações e devidamente capacitado para atuar nessa situação. O artigo defende a comunicação plena da inaptidão sorológica ao doador.

Palavras-chave: Soroprevalência de HIV. Doadores de sangue. Confidencialidade.

Resumen

Secreto, anonimato y confidencialidad de los donantes de sangre con VIH

Un artículo reciente publicado en esta revista sobre confidencialidad en la atención de pacientes con VIH/SIDA informa que, en caso de un resultado positivo en la detección serológica del virus, el servicio de hemoterapia debe, además de desechar la bolsa de sangre, remitir al servicio de referencia. Debido a los posibles dilemas éticos implícitos que se experimenta a diario, esto llevó a una revisión detallada de la legislación pertinente y la reflexión necesaria. Teniendo en cuenta que la condición de tener VIH/SIDA está rodeada de prejuicios, discriminación y repercusiones sociales negativas, es esencial que el profesional de la hemoterapia que comunicará la discapacidad sea plenamente consciente de los problemas relacionados con el secreto y la confidencialidad, y esté totalmente capacitado para actuar en esta situación. El artículo presenta y discute los puntos fundamentales de la legislación actual y las debidas justificaciones que basan la opinión de que se debe comunicar completamente al donante sobre la detección de su discapacidad serológica.

Palabras-clave: Seroprevalencia de VIH. Donantes de sangre. Confidencialidad.

The authors declare no conflict of interest.

Brief history of AIDS

Active health professionals have witnessed on site the significant advances in the identification, diagnosis and treatment of AIDS since the first cases appeared in the 1980s [1]. Initially, the disease was believed to affect only homosexual men [2], but the same clinical events began to be observed in injecting drug users, hemophiliac patients, and heterosexual men and women. It became evident that such events were the result of an acquired immunodeficiency, later named "acquired immunodeficiency syndrome" (AIDS).

The identification of the human immunodeficiency virus (HIV) as the causative agent of AIDS, reported in May 1983 [3], triggered a sequence of technological and scientific achievements that leveraged the development of medicine as a whole. Since then, we have witnessed the epidemic spread of the disease and successive therapeutic achievements, from azidothymidine (AZT), to cocktails, finally reaching an undetectable viral load as a therapeutic target, with the current and much more simplified antiretroviral regimen. Despite this, and even though Brazil is one of the countries whose public health system provides all the necessary medications and clinical and laboratory follow-up, the stigma of having HIV remains.

AIDS and legislation on haemotherapy activity in Brazil

A direct effect of the appearance of AIDS was the accelerated restructuring of haemotherapy services in Brazil through the National Program for Blood and Blood Products, created in 1980 by the Federal Government, but whose effectiveness was only felt after popular pressure generated by the emergence of HIV infection cases from blood transfusion [4].

Serological tests to detect HIV in blood donors were implanted in 1985 in blood centers, but it was only after 1988 that they became mandatory for the entire Brazilian territory [5], including private haemotherapy services, through Federal Law 7.649/1988 [6]. This law, which aimed to prevent the spread of the disease through transfusion, established the obligation to register blood donors, identity document included, making blood donation an act of civil liability.

In the same year, the Brazilian Constitution [7] was promulgated, whose article 199, paragraph 4, prohibited all commercialization in the collection, processing and transfusion of blood and its derivatives. This paragraph was regulated by Law 10.205/2001 [8], which established the institutional order of haemotherapy activity in the country. The Law, in item VII of article 3, when referring to the care of the blood donor, determines that protecting and guiding the unsuitable donor candidate includes referring them to centers that promote rehabilitation or clinical, therapeutic and laboratory support necessary for their physical and emotional well-being. Article 14, which refers to the principles and guidelines of the National Blood Policy, guarantees, among others things, the right to confidentiality of results and information to the donor candidate on any anomaly identified in the laboratory tests and on the procedures that will follow.

Ministry of Health's Consolidation Ordinance 5/2017 [9] redefined the technical regulation of blood therapy procedures then in force, based on the National Health Surveillance Agency's Resolution 34/2014 [10]. This ordinance is the ultimate legal source that regulates the topics covered in this study: donor and blood donation procedures and how to deal with serological ineligibility, especially in the positive test for HIV. Article 30 establishes that blood donation must be *voluntary, anonymous and altruistic*, and Article 31 guarantees that the *confidentiality of information provided by donors before, during and after the donation process must be absolutely preserved, in compliance with other provisions provided for in the current legislation*.

According to the same Ordinance [9], to detect the presence of HIV in donors, serological tests (which detect antibodies or antigen-antibody complexes) and molecular tests (which, by means of nucleic acid technology, directly detect the presence of the virus) are mandatory. The presence of a positive or inconclusive result after repeated tests in duplicate in the same sample will imply inviting the donor to collect new samples or guidance, according to article 129, which deals with the mandatory laboratory tests in every donation to identify infectious diseases transmissible by blood [9].

Article 32 of Ordinance 5/2017 [9] determines that the donor must sign an informed consent form authorizing the performance of laboratory tests required by laws and technical standards in force. The same article provides that, in case of reactive or inconclusive results, the haemotherapy services and health surveillance agency are authorized to undertake an "active search" to repeat tests. In this sense, article 68 of the Ordinance provides that the haemotherapy service must inform the competent health authority of donor data on a monthly basis, with results of laboratory tests for blood-borne diseases, reagents in duplicate repetitions and absence of those summoned to collect new samples or receive guidance [9]. In addition to the Ordinance, according to article 99 of Resolution 34/2012 [10], the return of donors considered unsuitable to haemotherapy service aims at clarifying, repeating the tests and referring them to referral health services.

Blood donor and clinical and serological screening for HIV

In a recent article, Salvadori and Hahn [11] presented the results of an extensive integrative literature review on the topic of medical confidentiality in the care of patients with HIV/AIDS. The haemotherapy aspects addressed by the authors – notably the communication to the donor of serological ineligibility due to HIV – instigated us to reflect, and the result was this article. The objective is to further investigate this point, especially in relation to legislation and how it affects professional's actions.

As already mentioned, haemotherapy owes much of its current state to technological advances resulting from research on AIDS. Due to the strategic role of transfusion in medical therapy, it was essential to ensure safety against the transmission of AIDS and other infectious diseases through the procedure. There was, therefore, a challenge: how to guarantee the safety of transfusion if this is one of the main routes of transmission of AIDS?

Despite advances in laboratory methods, donor clinical screening remains one of the main transfusion safety measures. Screening includes applying a questionnaire that addresses the donors' history, including their sexual behavior. This questionnaire is standardized in accordance with operating procedures guides whose existence is determined by article 237 of Consolidation Ordinance 5/2017 [9].

Depending on the content of the responses to the clinical screening questionnaire, the interviewer may refuse the donation, as provided for in article 67 of Consolidation Ordinance 5/2017 [9]. In this case, the professional must inform the reason for the ineligibility, which may be temporary or definitive. Bearing in mind that the donor altruistically and voluntarily seeks the haemotherapy service, the refusal can be a source of frustration, then the decision must be communicated in an appropriate manner, with due justification.

There is a second strategy that aims to increase the safety of clinical screening: the self-exclusion vote [12]. If the interviewee has omitted relevant information due to being embarrassed by the questions, at the end of the donation they can indicate, by electronic or manual filling, without any human intermediation, that they consider the donation inappropriate for transfusion, preventing the use of the bag by the haemotherapy service.

Even with all the aforementioned care, the serological ineligibility in the tests (positive or inconclusive result of one or more tests for HIV) is feasible. In this situation, haemotherapy services must proceed according to the legislation [10]. The donor will be summoned, communicated of the cause of the ineligibility and submitted to the collection of a new sample to confirm or not the presence of HIV. In this communication, the patient must be informed that the donation has not been completed (the bag has been discarded), be referred to SUS for treatment with antiretroviral drugs (if positivity is confirmed) and receive guidance on the risks of transmission through sexual intercourse, pregnancy and future blood donations.

Secrecy and confidentiality

Human beings communicate, in person or virtually, regardless of distance, time and words: communication is inherent to the human condition [13]. Through communication, we obtain verbal and non-verbal information, some of which should be known only to the participants in the

dialogue. This is classified information or, as called by common sense, "secrets."

However, as communicating beings, keeping secrets doesn't seem natural to us. Thus, behavioral, legal and ethical mechanisms are needed to safeguard information that must not be disclosed. Professional relationships are based primarily on communication, and the information that results from it is, in principle, confidential. Professional secrecy [14], involving information from the assistant about the assisted person (for example, the physician and the patient), is ethically complex and not limited to a single precept, considering the several situations and dilemmas that threaten its preservation.

Health care is not limited to the relationship between assistant and assisted person – physician and patient, or physician and donor –, but involves other dimensions. It is necessary to consider that the information obtained is shared institutionally (in medical records, in epidemiological record systems, etc.) and socially (medical reports of distinguished people in hospital treatment, for example). Consequently, the concept of professional secrecy must be understood in a way that encompasses these dimensions.

Professional secrecy in health was already addressed in the Hippocratic Oath, which is still used today in the commencement ceremony of most medical courses: *Whatever I see or hear, whether professionally or privately which ought not to be divulged I will keep secret and tell no one* [15]. Respect for confidentiality is also one of the fundamental principles of the Code of Medical Ethics, except as provided by law [16]. In these two formulations, the professional is required to be able to judge what can or must not be disclosed, that is, confidentiality is not absolute, it depends on circumstances, and therefore it is an ethical issue.

The decisive element in the relationship between the assistant and the assisted person is mutual trust, which makes dialogue and understanding possible. Secrecy is a premise for that trust to develop. Nevertheless, depending on the circumstances, the confidentiality pact is not always explicit or formalized. A good example is the practical training of future health professionals, which involves many complex situations of professional secrecy. Students and residents, at the end of the service, inform the patient that they will meet with preceptors and professors to analyze the case (check). In this situation, the relationship includes, in addition to the patient and the student/resident, the professor/preceptor.

Likewise, the information in the medical record, despite belonging to the patient, will be available to other professionals who have institutional permission to access it (and probably most patients are unaware of this fact). The presentation of patients on ward visits or case discussions is also a time when clinical data are shared. Outside the academic environment, when evaluation by another professional is necessary, the referral letter, duly protected from being read by third parties, also contains clinical data.

The situations mentioned show that the extension of confidentiality to third parties is a consequence of the need for other professionals' opinion or action. Exclusively didactic activities are also situations in which clinical data are disclosed. Nevertheless, in these activities, it is highly recommended that pseudonyms, acronyms or just the patient's first name be used, preserving anonymity. In the professional training environment, confidentiality must be constantly taught, cited, remembered and preserved, as a form of continuing education for students, residents and professionals.

In scientific publications, as they are publicly accessible, even if anonymity or pseudonym is obligatorily used, professional secrecy can still be violated. Thus, excepting cases of definitive impossibility, authorization from the patient or legal guardian is necessary to publish the data by signing an informed consent form. In summary, as professional secrecy is agreed (implicitly or formally), it is inseparable from professional relationships, and must be preserved as much as possible, within the limits of circumstances.

Assuming that the maintenance of confidentiality is the object of judgment by the professional, considering the possibility of violation in extraordinary situations, the need for ethical precepts becomes clear. Regarding the diagnosis of HIV/AIDS, there are some assumptions: maintaining confidentiality can directly threaten the physical integrity of other people, due to the risk of becoming infected if they have sex or share syringes (in the case of injecting illicit drug users) with the patient.

In this case, one follows the lesser evil principle, pointed out by the Federal Council of Medicine (CFM) in the early years of AIDS as a reason to violate the infected patient's confidentiality [17]. Thus, it is accepted that the sexual partner of an HIV-infected individual is informed of this fact as long as the patient, having been properly alerted to the risk of contamination, refuses to communicate the diagnosis to potentially infected people [18].

At this point, it is necessary to distinguish the concepts of secrecy and confidentiality. Professional secrecy, restricted to those involved, refers to information obtained in interpersonal relationships and in documents concerning these relationships. Its nature, therefore, is relational, intersubjective. It is a pact built between people and groups or institutions, and which is the product of circumstances. Confidentiality, on the other hand, refers to data or information systems. As defined by the Brazilian Association of Technical Standards in ISSO/IEC 17799:2005 Standard, confidentiality is the guarantee that information is accessible only to authorized persons and institutions [19]. Its nature, therefore, is objective, and it can be fully submitted to regulation. Institutional and social, confidentiality is the result of planning, legislation and constant monitoring and surveillance.

Secrecy is regulated and regimented by confidentiality. Since it is a pact, it depends on a final decision: to preserve it or not. When you decide to break confidentiality, the next step is to decide who else will have access to the information, and whether this will require renegotiations, and so on, in a sequence of decisions and agreements. Therefore, professional secrecy is always an ethical decision. Confidentiality, in turn, contains a predetermined set of rules that ensures that access to information is available only to those with the right to it. In conclusion, confidentiality is institutional in nature, while secrecy is within the scope of personal relationships – the first is objective (based on information), and the latter is subjective (based on the subjects involved).

As an example, the same information can be addressed in different institutional contexts. A man, who is known to have HIV, has sex with his partner – who was not informed of the test results – without proper protection (use of condoms). Both the physician of the Basic Health Unit (responsible for the diagnosis) and the parish priest (by confession) are aware of this fact. Both are subject to confidentiality, but the health professional has already given the ultimatum: if the patient does not tell the partner within 24 hours that he is HIV positive, the fact will be communicated by default, with the protection of the Code of Medical Ethics and the laws that established the Sanitary Code (Epidemiological and Sanitary Surveillance). The priest, however, is prevented from revealing the fact by the inviolable secrecy of the confession [20]. Thus, although the information is confidential for both the priest and the physician, confidentiality – and therefore the attitudes – is different.

Confidentiality of blood donation

Blood donation must be voluntary, anonymous and altruistic [10]. However, the donor is not anonymous, since they must present an identity document when applying for donation and is called by name during the entire donation process. The person receiving the transfusion is also not anonymous, as being identified and treated by name and surname in medical services is a patient's right [21]. Anonymity is a possible concept only because, based on blood collection, the collected bags and test tubes are identified with a number or bar code. The entire process of separation, storing, examination and release of the bags is carried out with this coded and confidential identification. There is no possibility that the patient or staff will identify the donor through the test tubes and blood bags.

In the case the patient feels motivated to recompense the donor (by thanking them or delivering a gift), this will not be possible, just as it is not allowed for the donor to know the recipient identity. If, on their own initiative, the donor or the patient decides to publish an image when donating or receiving the transfusion on social networks, there is no breach of confidentiality. What happens in this case is the disclosure of the act of donating or receiving transfusion. Therefore, anonymity is associated with the process of donating blood, and not with the act of donating or receiving transfusions. The coding of examination tubes and

blood bags are the protection mechanisms so that the information remains confidential.

Upon approval in the clinical screening, every blood donation candidate must sign, after being informed of the entire content of the document, an informed consent form (article 32 of the Consolidation Ordinance 5/2017)[9], in which they expressly declare consent to the performance of all laboratory tests required by current laws and technical standards. Through the form, the candidate also accepts that their name be incorporated into the local and national donor file, and that in case of reactive or inconclusive results in laboratory screenings, or in situations of retrospective surveillance, the haemotherapy service or surveillance body is authorized to summon them or undertake active search to repeat tests. Thus, upon being called, there is no way for the donation candidate to avoid being informed of the reason for the serological ineligibility, that is, the presence of HIV, or denying it, in inconclusive cases. Considering the possibility of referral to other services to start treatment with antiretroviral drugs and the risks of sexual, gestational or breastfeeding contamination, any omission in informing the results of the tests would be unacceptable.

Once HIV or another infectious agent is detected in a donor, it is necessary to identify their possible previous donations. All blood donations are therefore subject to retrospective review if necessary. This computational concept, called "traceability"[22], guarantees that it is possible to identify, in certain circumstances provided for in the legislation, from the breach of confidentiality of the donor's identity, the respective blood components and their recipients. Traceability is a two-way process, that is, it is also possible to identify the blood components received and their donors from a recipient who suspects having acquired AIDS or another disease through transfusion. Thus, when reviewing the route of blood components in the foreseen situations, donors and patients may be called to collect blood samples and be informed of the results of the retro-surveillance.

The confidentiality of blood donation, although not named this way, can be understood through current laws and technical standards that regulate professional secrecy in the various stages of the process: clinical screening (interview, signing of the informed consent form, self-exclusion vote), serological ineligibility (donor summons, communication of the reason for ineligibility, collection of new samples and referral to a reference service for confirmation or treatment) and traceability. A fundamental and unbreakable presupposition in blood donation, confidentiality guarantees that only professionals directly involved with the unsuitable donors will be able to know their identity.

A study with blood donors with reactive serology for syphilis, viral hepatitis and HIV showed that about 40% assumed having omitted information in the clinical screening. The possibility of self-exclusion at the end of the donation was also not considered by the absolute majority of donors (98.1%)[23]. HIV seropositivity was detected in 0.03% of donations. These results show that, in addition to clinical screening, self-exclusion vote and serological screening, the most important strategy to reduce the risk of transmission of infectious diseases by transfusion, is still and always will be the population's awareness and education. There will be no absolutely safe transfusion without the donor being aware that it is an act of citizenship and love.

Final considerations

The stigma of HIV/AIDS is real, debilitating, and persists until today, when it is already known that there are no "risk groups" (the chance of becoming infected is independent of age, gender, sexual orientation or educational level), and the Unified Health System (SUS) offers effective treatment for the disease.

Regarding blood donation, procedures such as clinical and serological screening and self-exclusion vote are essential to reduce the risk of disease transmission. Laws and technical standards determine how haemotherapy services must perform these procedures. Donors with a positive or inconclusive test for HIV are summoned and communicated of the result, undergo a new blood collection to repeat the tests, and receive guidance and referrals.

Confidentiality is an ethical foundation in the health area that cares for the preservation of

the person's integrity, with special attention to patients with HIV or AIDS, due to the social stigma of the disease. Professional secrecy is a pact built on the relationships between the assistant and the assisted person, based on ethical and legal precepts and governed by confidentiality. In this sense, ineligibility due to seropositivity must be communicated to the donor with full respect, precision and clarity. Despite all the technical and technological advances in screening, efforts to educate and raise awareness of the population are still essential both to reduce the transmission of HIV via transfusion and to combat the social prejudice that surrounds carriers of this virus.

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Authors' participation
Newton Key Hokama designed the research and wrote the article. Pedro Bonequini Junior collaborated in the discussion of the study and writing the text, especially in relation to haemotherapy practice. Paula de Oliveira Montandon Hokama also participated in the discussion and revised the final text.

Received: 3.12.2020
Revised: 5.4.2021
Approved: 5.5.2021