



HIV infections in organ transplants in Brazil, 2024: a warning to the world

Infecções por HIV: Um alerta para o mundo em transplantes de órgãos no Brasil em 2024
Infecciones por VIH en trasplantes de órganos en Brasil en 2024: Un aviso para el mundo

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Dear editor,

The early 1980s were marked by the human immunodeficiency virus (HIV) epidemic. It is estimated that between 1981 (first records) and 2020, approximately 77.5 million [54.6-110 million] people were infected and 34.7 million [26-45.8 million] died from AIDS-related illnesses.¹

During the same period, Brazil recorded its first cases. Since then, the country has adopted strategies to combat HIV and has become a world reference in this field.² However, in 2024, the country was astonished to witness one of the most serious setbacks: *The infection of at least six individuals who received organ transplants from donors living with HIV in Rio de Janeiro.* The patients received kidneys, livers, hearts and corneas. No HIV infection was found in the patient who received the corneas.³

This is an unprecedented and extremely serious fact in the recent history of the country, considering that the National Transplantation System has strict criteria for the screening of donors. It should be noted that Brazil has one of the largest and most reliable public organ transplantation programs in the world. Approximately 95% of the transplants performed in the country take place under the Unified Health System (SUS).⁵ In 2023 alone, nearly 15,000 transplants were carried out in the country.

So what happened? Historically, donor screening was performed by large transplant centers or public reference laboratories. In Rio de Janeiro, the State Institute of Hematology - Hemorio - was responsible for serologic testing. However, a private laboratory was contracted by the Health Department of the State of Rio de Janeiro to provide this service for almost a year (between December 2023 and September 2024).

Several hypotheses have been considered to explain the occurrence of false negative results, among them the use of low quality inputs, failures in internal and external quality control processes and, in a more serious scenario, the issuance of reports without the actual performance of tests. This last hypothesis is the subject of criminal investigation in Brazil, with ongoing judicial action that verifies the conduct of the laboratory responsible for the tests, accused of issuing fraudulent reports that did not identify the presence of HIV in organs from two donors.

In Brazil, specific regulations are in place to ensure recipient safety. Ordinance No. 2.600, dated October 21, 2009, issued by the Ministry of Health, which approves the Technical Regulation of the National Transplant System, establishes mandatory criteria for the evaluation of potential deceased donors⁵.

Article 47 of the aforementioned Ordinance stipulates that, prior to graft allocation, the donor must undergo clinical evaluation, review of medical history, and serological screening. For corneal donors, testing for

HIV and hepatitis B and C is required. For organ and other tissue donors, screening should include HIV, HTLV I and II, hepatitis B and C, syphilis, and Chagas disease, while testing for toxoplasmosis, cytomegalovirus, and Epstein-Barr virus is optional⁵. The regulation also defines absolute exclusion criteria, including donors living with HIV or HTLV I/II, active tuberculosis, neoplasms (with specified exceptions), refractory sepsis, and severe infections, except for hepatitis B and C⁵.

Resolution No. 786, of May 5, 2023, issued by the National Health Surveillance Agency, establishes technical and sanitary requirements for the operation of clinical laboratories, pathology laboratories, and other services performing clinical laboratory testing. The regulation defines Quality Control (QC) as the systematic monitoring of the analytical process through the analysis of control samples, aimed at assessing the accuracy and precision of test results, using both Internal Quality Control (IQC) and External Quality Control (EQC)⁶.

External Quality Control refers to the evaluation of the accuracy and performance of the analytical process through interlaboratory comparisons conducted by a Proficiency Testing provider (also known as a Proficiency Testing program). Internal Quality Control consists of procedures performed alongside the analysis of biological material to assess the precision of the analytical system and ensure that it operates within predefined tolerance limits⁶.

This context suggests that not only are the correct and safe technical procedures no longer being followed, but also that the desire for profit may have led to damage (physical, mental and social) in the lives of the infected and their families. What seemed to be a victory - *receiving a compatible organ after years of waiting* - became the beginning of a new cycle - *living with the virus and its consequences in an already fragile body*.

The Brazilian case is not an isolated incident, but rather a stark warning to the world about the risks of neglecting transplant safety protocols. Finally, although the fact itself is concerning and demonstrates the need for attention from Brazilian authorities, it should not be able to 'call into question' Brazil's commitment to public health.

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AUTHORS' CONTRIBUTIONS

Carlos Dornels Freire de Souza contributed to the literature review, drafting of the text, manuscript revision. **Havandécio Rodrigues de Matos Júnior** contributed to the literature review, drafting of the text, manuscript revision. **Adeilton Gonçalves da Silva Junior** contributed to the literature review, drafting of the text, manuscript revision. **Rodrigo Feliciano do Carmo** contributed to drafting of the text, manuscript revision, text translation.

All authors approved the final version to be published and are responsible for all aspects of the work, including ensuring its accuracy and integrity.

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