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TRANSPLANT INFECTIOUS DISEASE

ORIGINAL ARTICLE

Brazilian perspective: antimicrobial stewardship in solid organ transplant

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Abstract

Background: The incidence of multidrug resistant organisms (MDROs) infections among solid organ transplant (SOT) patients is very high in Brazil.

Methods: This review will discuss antimicrobial use and resistance in SOT in Brazil, highlighting the main barriers and facilitators for implementation of an antimicrobial stewardship programme (ASP).

Results: The most common group of MDROs is carbapenem-resistant Gram-negative bacteria and vancomycin-resistant Enterococcus. Carbapenem-resistant Enterobacterales (CREs) are the most frequent MDROs and have been reported as donor-derived as well. Although ASPs are mandatory in the country, there is a lack of information regarding ASPs in SOT recipients. The main barriers for the implementation of ASPs in Brazilian hospitals are lack of electronic medical records, absence of national guidelines specific to SOT recipients, lack of recommendations on surveillance culture to evaluate colonization and transmission of donor-derived MDROs, limited availability of rapid diagnostic tests, and insufficient pharmacist and clinician time allocated to ASP activities in some SOT centers.

Conclusions: The incidence of MDRO infections caused mainly by VREs and CREs is very high in the country. There is limited data regarding antimicrobial use among SOT recipients in Brazil. The absence of antimicrobial stewardship national guidelines specific to SOT recipients is one of the main barriers for the implementation of ASPs in Brazilian hospitals.

KEYWORDS
antimicrobial resistance, antimicrobial stewardship, Brazil, solid organ transplant

1 | Introduction

Antimicrobial resistance (AMR) is a major global public health priority, considered an important threat of the 21st century.[1] The emergence of AMR has led to treatment failures, serious illnesses, increases in healthcare costs, and high mortality.[1,2] Approximately 700,000 deaths per year occur due to AMR across the globe.[2] Although AMR occurs naturally, it has been greatly accelerated by the overuse of antimicrobials in healthcare units, especially in hospitals, as the need for broad-spectrum antimicrobials is real, and due to the vulnerability of patients.[3,4]

Brazil is the largest country in Latin America, at 8.5 million square kilometers (3,300,000 sq mi) and with over 211 million people. It is classified as an upper-middle income economy by the World Bank, having the twelfth largest gross domestic product (GDP). Brazil's *Sistema Único da Saúde* (SUS) is one of the largest public health systems in the world. More than three-fourths of Brazil's population rely exclusively on it for health services. Currently, there are 6,820 hospitals operating in Brazil.

Brazil has one of the largest public solid organ transplant (SOT) program in the world, with an average of 5,900 kidney transplants and 2,000 liver transplants performed per year before the COVID-19 pandemic.[5] Despite the large absolute number of transplants performed in the country, data from the Brazilian Organ Transplant Registry pointed out that there is a deficit between the number of transplants needed and the number of transplants performed yearly in the country[5] (Table 1, Figure 1).

Additionally, in Brazil, the proportion of multidrug resistant organisms (MDROs) among healthcare-associated infections (HAIs) is high, especially in highly complex hospitals, where transplant recipients are usually attended. Gram-negative bacteria are the microorganisms most often isolated from HAIs. For example, *K. pneumoniae* caused nearly 18% of intensive care unit (ICU) bloodstream infections (BSIs) in São Paulo, followed by *A. baumannii*, which corresponded to 10% of the agents of these infections.[6] National data reported carbapenem-resistance in 63% of *K. pneumoniae* and 84% of *A. baumannii* isolated from BSIs identified in ICUs.[7]

2 | Antimicrobial resistance in SOLID ORGAN TRANSPLANT

Patients submitted to organ transplantation are at increased risk for infections due to their immunocompromised status, surgical procedures, and the use of numerous invasive devices. Furthermore, they have a greater risk of infections caused by multidrug resistant pathogens.[8] These infections can worsen the outcome of transplanted patients as there are limited antimicrobial treatment options, an increased risk of toxicity, and drug interactions.[8]

Antimicrobials are commonly used in situations where indications are not very clear and sometimes not even recommended. One possible explanation for this overuse is the erroneous and common belief that the benefits of prescribing always overcome potential hazards such as collateral effects or AMR.[9] For immunocompromised patients, as they exhibit greater morbi-mortality to infections, this imbalance is even more pronounced.

In this scenario, the incidence of MDRO infections among SOT patients is very high in Brazil. The most common group of MDROs is carbapenem-resistant Gram-negative bacteria and vancomycin-resistant Enterococcus.[10] Carbapenem-resistant Enterobacterales (CREs) are the most frequent MDROs reported and despite some hospitals having reported that only 5%–7% of HAIs in transplanted patients were due to CREs, recent data showed that more than 30% of early infections after liver transplant were caused by CREs.[11–13] Graft-derived CRE infections have been reported as well, and a high rate

TABLE 1 Estimated annual number of transplants needed vs. performed in Brazil (Brazilian Transplant Registry, ABTO)[5]

	Cornea	Kidney	Liver	Heart	Lung
Estimated number of transplants needed based on the current Brazilian population 210,147,125 per year	18,913	12,609	5,254	1,681	1,681
Transplants performed per year	7,127	4,805	2,050	307	65

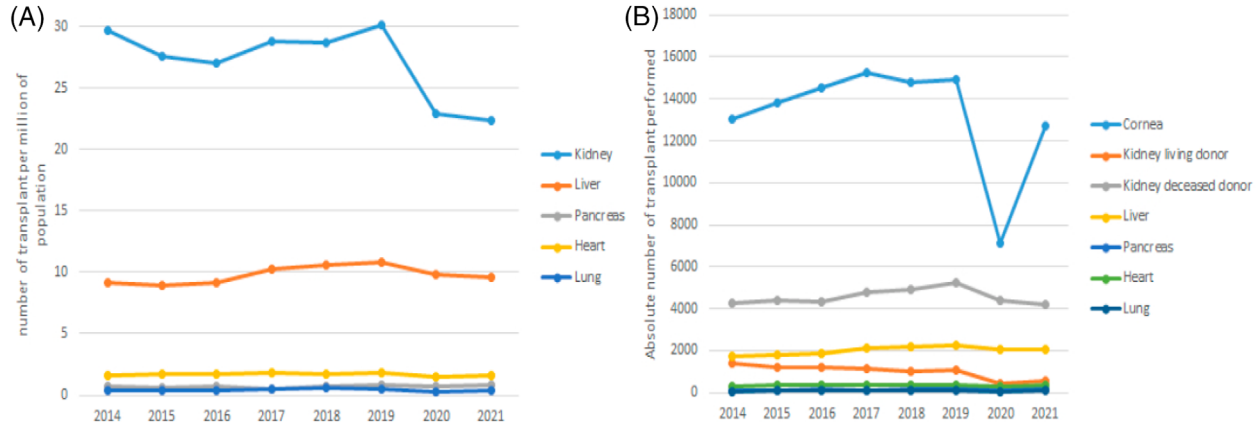

FIGURE 1 (A) Absolute number of solid organ transplants performed by type of organ from 2014 to 2021 (Brazilian Transplant Registry, ABTO). (B) Number of solid organ transplants performed by type of organ per millions of people from 2014 to 2021 (Brazilian Transplant Registry, ABTO)[5]

of graft loss and mortality are associated with those infections.[14,15] Another MDRO with a high mortality rate among SOT recipients is *A. baumannii*; those infections usually occur early after transplant, and the 30-day mortality rate is reported in up to 46% of Brazilian hospitals.[14,15]

3 | Antibiotic usage and antimicrobial stewardship in SOT

In the multidrug-resistant scenario and with the vulnerability of SOT patients, antimicrobial stewardship programs (ASPs) are important to limit adverse events related to abusive use, the main one being the increase in MDRO.[16] Despite this, studies on ASPs in SOT patients and their strategies are still scarce in the literature, especially in Latin America.

In Brazil, there's a federal law since 1998 which describes the minimum requirements of an Infection Control Committee, and the presence of ASPs is mandatory. However, it is one among many low- and middle-income countries that has struggled to implement a robust antimicrobial management program. For instance, more than 50% of Brazilian hospitals do not have an ASP.[17]

The quality of ASPs in Latin American hospitals varies greatly. A systematic review pointed out that in only 59% of the hospitals at least one action related to ASP was identified. In addition, only 31% of studies indicate the presence of an ASP with face-to-face audits and feedback.[18] It is known that ideally the ASP team in a SOT service should contain an infectious diseases specialist with experience in transplantation and a clinical pharmacist.[18,19] In Brazil, pharmacists with experience in infectious diseases are generally not uniformly present in hospitals. In São Paulo, only 59% of the evaluated ASPs had a pharmacist on the team.[20]

Sato et al. evaluated a sample of 28 ASPs in hospitals in the state of São Paulo and found that 100% had antibiotic therapy and surgical prophylaxis guidelines, *Clostridioides difficile* diagnose, and antifungal usage, but with highly variable face-to-face auditing, consumption data, and feedback strategies.[20]

Although there has been progress in infection control practices, surgical site infections (SSIs) remain one of the most common healthcare-associated infections. SSIs are a significant issue in transplant recipients with higher rates of SSIs among SOT recipients than among non-SOT recipients who undergo comparable clean or clean-contaminated procedures.[21,22]

SSIs account for most infections in the early post-transplant period in part due to the complexity of these operations, immunosuppression, and patient comorbidities. The spectrum of organisms implicated in SSIs in SOT recipients is more diverse than the general population due to other important factors such as underlying end-stage organ failure, immunosuppression, prolonged hospitalizations, organ transportation, preservation, and previous exposures to antibiotics in donors and recipients that could predispose to infections with MDRO.[21,22]

SSIs occur in 4%–26% of organ transplant procedures. In liver transplantation, SSI occurs in 11%–20% of procedures. In simultaneous pancreas–kidney transplantation, SSI rates range from 30% to 46%. SSI in kidney transplantation occurs in 7.5% of procedures.[21] Data from the municipality of São Paulo, taken in 2020 from 19 hospitals, totaling 1,987 transplants, showed that the SSI rate was 5.49 and that the highest rates were among liver (10.42) and heart (6.74) transplants (number of lung ($N = 36$), pancreas ($N = 42$), and bowel transplants ($N = 1$) were very small which led to high infection rates that cannot be valued).[23]

Prevention of SSIs requires multidisciplinary approaches that include optimized surgical techniques, preparation of the instrumentation, use of sterile barriers and, obviously, appropriate antimicrobial prophylaxis.[21,22]

Although the basic principles of surgical antibiotic prophylaxis are the same as that of non-transplanted surgical patients, there are some peculiarities that need to be highlighted. Specific antibiotic regimens and durations vary widely across transplant centers and SOT procedures, and the quality of the evidence supporting specific practices varies.[22] Currently, there are no formal recommendations on perioperative antibiotic prophylaxis in SOT outside of the "Clinical practice guidelines for antimicrobial prophylaxis in surgery" by the Infectious Diseases Society of America, American Society of Health-System Pharmacists, Surgical Infection Society, and Society for Healthcare

Epidemiology of America (IDSA/ASHP/SIS/SHEA guidelines).[24] A recent review by Anesi et al. proposes changes and more structured formal recommendations for antimicrobial prophylaxis in transplantations as there is a need to address the unique circumstances of the transplant population in many parts of the world such as recipient colonization with a MDRO pre-transplantation or the presence of a ventricular assist device (VAD) prior to heart transplantation.[25]

Very few studies have evaluated infection control bundles and antimicrobial stewardship in liver, kidney, pancreas, and simultaneous pancreas–kidney transplantation.[26–28] In a Brazilian study that evaluated kidney transplantation from 2009 to 2012 comparing surgical antimicrobial prophylaxis with cephalosporin (70%) versus amikacin (28%). The only factor associated with a reduction in the incidence of SSI was amikacin use due to a high frequency of ESBL producing isolates and CREs.[29]

A point prevalence survey (PPS) of antimicrobial use that included antifungal usage and resistance, conducted in 53 countries in 2015, including Latin America countries, showed the highest prevalence of antimicrobial use in transplant wards compared to medical, surgical, and ICUs.[30] Since infection is considered a common complication after SOT and antimicrobial prophylaxis has altered its incidence and severity, high rates of antimicrobial prescribing in this population may be partially justified by the need of antimicrobials to prevent opportunistic bacterial, fungal, and viral infections.[30] Another study carried out in 18 Brazilian hospitals from different regions using PPS to evaluate antimicrobial including antifungal use found that 52% of patients were on antimicrobials on the day of the PPS, but only one hospital included SOT patients, a kidney transplant ward.[31] Yet SOT programs in Brazil usually include infectious diseases specialist with experience in transplantation, there are no metrics data to assess antimicrobial prophylactic use in this specific population, such as control prophylaxis adherence rates and antimicrobial agents used for prophylaxis or treatment consumption rates.

As described by other countries, although the implementation of ASPs in hospitals is mandated by the Brazilian regulatory agency, there are no specific requirements for transplant centers.[17] This may explain the paucity of information regarding ASPs and metrics used in SOT populations in Brazil.

4 | Barriers and facilitators of implementing an antimicrobial stewardship programme

There is limited data regarding the implementation of antimicrobial stewardship programmes (ASPs) among SOT recipients in Brazil. Although some studies have included SOT patients, the efficacy, safety, and optimal intervention strategies have not been widely evaluated. The majority of existing data is extrapolated from non-immunocompromised hosts, and thus, their validity in the setting of SOT recipients remains unverified.[32] The main cited barriers in the implementation of ASPs among SOT recipients were diagnostic uncertainty of infectious syndromes, the delay in the turnaround of diagnostic test results, and clinician fears of graft loss.[16]

One of the major problems of the country is the lack of electronic medical records in many hospitals and national AMR and antibiotics usage databases. Although AMR rates are reported at the state and national level, they are focused on the HCAI acquired in ICUs and specific surgical procedures such as orthopedic procedures. There is no specific data on antibiotic usage and ASPs in SOT. Another major problem is the lack of pharmacists with clinical training in the country. The ASP teams are predominantly composed of physicians and microbiologists. Another point that may make the implementation of ASPs difficult, particularly in our country, is the absence of national guidelines specific to SOT recipients, lack of recommendations on surveillance culture to evaluate colonization and transmission of AMR derived from the donor, limited availability of rapid diagnostic tests, and insufficient pharmacist and clinician time allocated to ASP activities in some SOT centers.[33] Reported facilitator to establish and maintain ASP is the incorporation of a multidisciplinary team, with a transplant infectious disease physician and an immunocompromised-host infectious diseases pharmacist.[34] Members of the ASP team rounding together in person, in a "handshake stewardship" strategy, have shown to be an effective and sustainable ASP approach.[34–37]

Although SOT-specific process and outcome measures related to ASPs have not been defined, examples of metrics used to evaluate program interventions have been described. Currently, recommended AMS metrics already reported by hospital-based ASPs, such as antimicrobial consumption, appropriateness of prescribing, AMR patterns and incidence of *Clostridioides difficile* infections, are also applicable to the SOT population.[35] Valuable outcome measures to consider in reporting the impact of an ASP in this population include detection and avoidance of adverse events, graft injury, and drug–drug interactions. Antimicrobial consumption and costs are common process measures in transplant-specific ASPs and in antifungal stewardship programs for immunocompromised populations.[16,36,37]

Then, an ideal ASP in SOT should be mandatory and include the following metrics: guideline adhesion, antimicrobial use (antibacterial, antiviral, and antifungal) including surgical prophylaxis, serum level and de-escalation as well as adverse events, graft injury, and drug–drug interactions. AMR and *C. difficile* rates, cost, interventions, and targets for reducing antibiotic use and AMR (Figure 2).

In conclusion, there is limited data regarding the implementation of ASPs among SOT recipients in Brazil. The incidence of MDRO infections caused mainly by VREs and CREs is very high in the country. The main barriers for the implementation of ASPs in Brazilian hospitals are lack of electronic medical records, absence of national guidelines specific to SOT recipients, limited availability of rapid diagnostic tests and insufficient pharmacist and clinician time allocated to ASP activities.

AUTHOR CONTRIBUTIONS

Sections were divided between authors, with at least two authors contributing to one paragraph. Each author group performed at least one non-systematic review of the available literature and drafted the

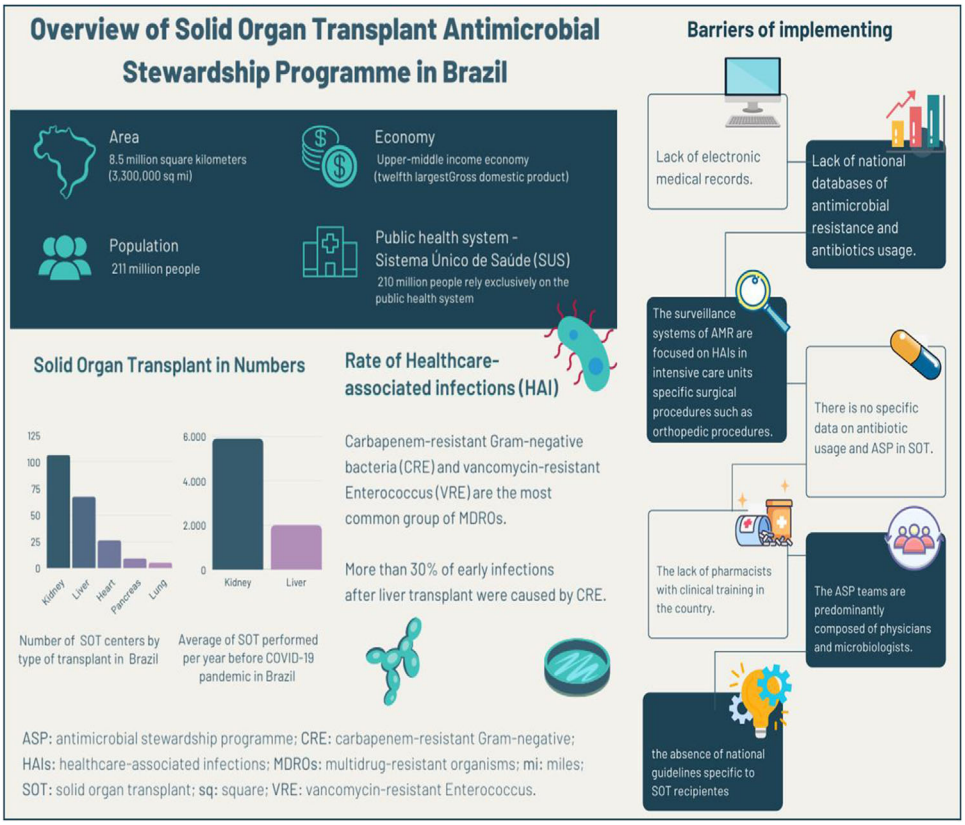

FIGURE 2 Overview of solid organ transplant antimicrobial stewardship programme in Brazil

section(s) accordingly. All authors critically reviewed the final version of the manuscript.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest that could be perceived as prejudicing the impartiality of the research reported.

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