

Recommendations for the prevention, monitoring, and treatment of infectious complications post-hematopoietic cell transplantation

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ABSTRACT

This chapter outlines recommendations for the control and management of infections following hematopoietic cell transplantation. Given the complexity and scope of the subject, the authors chose a format that considers the various interventions available to prevent, minimize, or—when appropriate—treat infections relevant to the hematopoietic cell transplantation setting. We consider the active and collaborative involvement of the transplant infectious disease specialist in transplantation centers to be essential in ensuring the best possible care for this vulnerable population.

Keywords: Cell Transplantation; Infections; Febrile Neutropenia; Vaccination.

INTRODUCTION

In the current version of the Recommendations for the Prevention and Treatment of Post-Hematopoietic Cell Transplantation (HCT) Infections, we have maintained the previous format, with tables depicting the following sections:

- Pre-transplant screening;
- Prophylactic measures;
- Laboratory monitoring;
- Management of febrile neutropenia;
- Empirical and preemptive antimicrobial therapies;
- Antimicrobial therapy for documented infectious events;
- Post-transplant revaccination program.

In addition to the bibliographic update, new topics have been added to the current version, such as the management of refractory or resistant cytomegalovirus (CMV) infection, viral hepatitis including hepatitis E virus (HEV), human T-cell lymphotropic virus (HTLV), syphilis, malaria, among others. In the current version, we have updated the vaccination schedule, including respiratory syncytial virus (RSV) and dengue vaccines, highlighting the availability of vaccines and RSV monoclonal antibody for children up to 2 years of age. Availability was noted in both the public and private sectors. Additionally, we have included specific steps that healthcare professionals should follow before referring a patient to begin the revaccination program.

We would like to highlight the relaxation of mandatory pre-HCT screening for COVID-19. Any changes that arise based on local or regional epidemiological data will be notified through technical notes on the Brazilian Society of Cellular Therapy and Bone Marrow Transplantation (SBTMO) website.

The strength of recommendations and quality of evidence were based on the grading system of the European Society of Clinical Microbiology and Infectious Diseases (ESCMID), as shown in Fig. 1.

Strength of recommendation	Quality of evidence
• Grade A: ESCMID strongly supports the recommendation for use • Grade B: ESCMID moderately supports the recommendation for use • Grade C: ESCMID marginally supports the recommendation for use • Grade D: ESCMID is against the use of the recommendation	• Level I: evidence from at least one properly designed randomized, controlled trial • Level II: evidence from at least one well designed clinical trial, without randomization; from cohort or case-controlled analytical studies (preferably from more than one center); from multiple time series; or from dramatic results of uncontrolled experiments • Level III: evidence from opinions of respected authorities, based on clinical experience, descriptive case studies, or reports of expert committees

Source: Elaborated by the authors.

Figure 1. Grading system of the European Society of Clinical Microbiology and Infectious Diseases (ESCMID).

PRE-TRANSPLANT SCREENING

The control and management of post-HCT infections begin with the pre-transplant evaluation, when mandatory actions must be taken to prepare the candidate for HCT. Table 1 outlines these actions and recommendations, adapted to our country's epidemiology.

Table 1. Pre-transplant screening for autologous or allogeneic hematopoietic cell transplantation (HCT).

Pre-transplant assessment	References
Assessment: Colonization by multi-drug-resistant (MDR) microorganisms. Method: Surveillance cultures (nasal, methicillin-resistant <i>Staphylococcus aureus</i>—MRSA; anal, vancomycin-resistant <i>Enterococcus</i>, carbapenem-resistant Enterobacterales, extended-spectrum beta-lactamase, <i>Pseudomonas aeruginosa</i>) to reduce intra-hospital transmission and eventually to guide empiric antibiotic therapy in febrile neutropenia. Studies evaluating the clinical usefulness of surveillance cultures to detect colonization by resistant gram-negative and gram-positive bacteria showed high negative predictive values and variable positive predictive values, indicating that infection by MDR organisms is unlikely in patients not colonized. Recommendation: Perform cultures of nasal and anal swabs on admission to evaluate colonization by MRSA and MDR gram-negative organisms. Weekly cultures should be obtained in centers with high incidence of colonization/infection by a MDR organism (BII).	1–11
Assessment: Previous infections. Method: Medical history, physical examination, imaging tests, and review of previous events. Certain infections such as tuberculosis, malaria, Chagas and invasive mold fungal disease (IFD) may recur. Recommendation: Attention to recurrent infectious events, MDR pathogens, and latent or persistent infections (BII).	12,13
Assessment: <i>Clostridioides difficile</i> infection (CDI). Method: In children < 2 years old, asymptomatic colonization rates are high. In this population, testing should only be conducted in cases of strong clinical suspicion. Recommendation: Screening for asymptomatic colonization is not recommended (DII). Testing should only be performed when clinical signs and symptoms are compatible with CDI (AII).	14
Assessment: Serologic screening for syphilis. Method: Perform treponemal tests (e.g., fluorescent treponemal antibody absorption test—FTA-ABS, <i>Treponema pallidum</i> haemagglutination assay—TPHA/<i>Treponema Pallidum</i> particle agglutination—TPPA, enzyme-linked immunosorbent assay—ELISA/chemiluminescent microparticle immunoassay—CMIA) and non-treponemal tests (e.g., venereal disease research laboratory—VDRL, rapid plasma reagin—RPR). Screening is mandatory for both donors and recipients as required by Brazilian regulations. Recommendation: Syphilis screening should be performed within 15–30 days prior to HCT, except when repeated to establish a baseline serologic status in the final pre-transplant evaluation (typically 7–10 days before conditioning). Syphilis does not contraindicate HCT. However, positive results require confirmatory testing using different methodology and infectious diseases specialist consultation to assess disease activity and ensure adequate treatment according to national guidelines before cell infusion (AIII).	15,16
Assessment: Risk stratification for invasive fungal disease (IFD). Method: Look at all factors associated with an increased risk for IFD and apply appropriate measures for low- and high-risk patients (anti-mold prophylaxis for high-risk patients). The most important risk factors for IFD in the pre-engraftment period are the duration of neutropenia, severity of gastrointestinal mucositis, and T-cell depletion. In the post-engraftment period, graft-versus-host disease (GVHD) requiring treatment with corticosteroids or other agents, cytomegalovirus reactivation and graft failure are the most important risk factors. Recommendation: Apply a risk stratification strategy to define the appropriate strategy: no antifungal prophylaxis if the risk is low (e.g., autologous HCT without mucositis), anti-Candida prophylaxis if the risk for invasive candidiasis is high but the risk for mold infection is low (e.g., autologous HCT with mucositis). In mold infections, two strategies may be applied depending on the risk: fluconazole + serial (twice or three times/week) serum galactomannan or anti-mold prophylaxis (AII).	17–26
Assessment: Previous viral infection. Method: Medical history and specific serologies (herpes simplex virus, cytomegalovirus, Epstein-Barr virus, human immunodeficiency virus, hepatitis C virus—HCV, hepatitis B virus, human T-cell lymphotropic virus). Comments (evidence): Order HBsAg, anti-HBs, anti-HBc e anti-HCV serology for recipient and donor and nucleic acid test (NAT)/polymerase chain reaction (PCR) for donor. It is crucial screening viral hepatitis for proper prophylaxis or treatment (AII). Anti-hepatitis E virus serology has no role in the evaluation of donors or patients. Human T-cell lymphotropic virus (HTLV)-positive donors are ineligible. In general population, asymptomatic HTLV-1 positive individuals have a 3–5% risk of developing adult T-cell leukemia/lymphoma (ATLL). The risk is expected to be higher in HCT recipients.	13,15,27–29
Assessment: Dengue, chikungunya, Zika. Method: Inquiry about the epidemiological risk. Serological screening of donor/recipient is not recommended. Comment (evidence): Check whether the candidate and/or donor come from an endemic or epidemic region; or had a recent travel to such regions. If symptomatic, collect NAT (and/or NS1 antigen test in the case of dengue virus. If positive, wait 30 days for stem cell harvesting or transplant (AII). If the donor has recently had severe dengue, stem cell harvesting should be postponed for six months.	30,31
Assessment: Respiratory virus infections before admission. Method: Immunofluorescence assay (IFA) or multiplex PCR in respiratory samples before admission. Comment (evidence): Visitors and healthcare professionals with respiratory symptoms are prohibited from entering the HCT unit (BII). HCT candidates or recipients with respiratory symptoms should be tested by IFA/multiplex PCR. Rapid NAT tests are preferred to support timely decisions regarding hospital admission, infection control, modification or postponement of chemotherapy or conditioning procedures, and antiviral treatment (when indicated). IFA is rapid and specific, but negative results cannot rule out infection. Management of asymptomatic patients is challenging because they may be post-symptomatic (after clinical recovery, often associated with prolonged viral shedding), pre-symptomatic (if recently exposed) or truly asymptomatic. Screening of asymptomatic candidates upon admission is controversial but encouraged if available (CIII). Screening tests should include SARS-CoV-2, respiratory syncytial virus, influenza (INF) A, INF B, hMPV, and parainfluenza virus, and postponement of HCT is recommended in case of a positive result (AII). In other respiratory virus infections, if postponement of HCT is not possible, consider reduced-intensity conditioning (BIII).	32

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Pre-transplant assessment	References
Assessment: Yellow fever. Method: There is no recommendation for serological screening of donor/recipient. Check if the donor has been recently vaccinated. If so, wait 30 days for stem cell harvesting or HCT. Comment (evidence): Yellow fever vaccination is recommended nationwide as a public health policy. In HCT recipients, yellow fever vaccination is safe. Approximately 30% of individuals vaccinated before transplantation retain antibodies after HCT (BII). Depending on the current epidemiological situation (e.g., spreading epidemics), consider vaccination <i>before</i> HCT of donor and recipient, taking into account the safety of vaccination on a case-by-case basis (CIII).	33–38
Assessment: Latent tuberculosis infection (LTBI). Method: Epidemiological and/or diagnostic investigation of LTBI. Diagnostic methods are the tuberculin skin test (TST) or interferon gamma release assays (IGRA), e.g., the QuantiFERon TB test (QFT-TB). Comment (evidence): Active tuberculosis (TB) should be ruled out in patients with TST ≥ 5 mm or reagent IGRA. The investigation of active TB should include medical history, physical examination, epidemiological links, bacteriological tests, radiological findings, and other complementary tests, if needed. In a population vaccinated with <i>Bacillus Calmette-Guérin</i> (BCG), the IGRA test is recommended because it does not show cross-reactivity with <i>Mycobacterium bovis</i>, which is present in BCG (BII).	13,39,40
Assessment: Chagas disease. Method: Serological screening of donor and recipient is mandatory. Enzyme immune assay (EIA), IFA, or hemagglutination inhibition assay (HIA). Perform two different tests. If discordant, repeat with Western blot or chemiluminescence. Inquiry donor/recipient about residence in an endemic area, houses that favors the presence of the vector, blood transfusion before 1992, having family members or a mother with Chagas positive serology. Comment (evidence): False negative serology may occur. In such cases, the information acquired in the survey must be valued, and the recipient should be monitored after HCT (AII).	33,41,42
Assessment: Toxoplasmosis. Method: Serological screening of donor and recipient (IgG and IgM) is mandatory (AII). In HCT candidate with pre-transplant positive IgM (whatever the IgG title), PCR should be performed. If the recipient is PCR-positive, the patient should be treated and HCT postponed (if possible) until the end of treatment plus two negative tests (BIII). If the donor tests positive for IgM, a PCR test for toxoplasmosis is recommended. If the donor tests positive on the PCR test, the donation should be postponed until two negative tests, seven days apart (BIII). Comment (evidence): Reactivation of latent cysts is the primary mechanism of toxoplasmosis following HCT; hence, patients at high risk are those who are seropositive before transplantation. The mean incidence of <i>T. gondii</i> infection was 9.6% (range 6.4–32.5) in R-positive patients, 0.4% in R-negative patients (0.0–3.3), and 5.5% (4.0–18.5) in series in which R-positive and R-negative were both included. PCR screening is a sensitive method of early detection of reactivation in R-positive patients.	43–45
Assessment: Strongyloidiasis. Method: Investigation by stool examination, and/or serology, or empirical therapy. Comment (evidence): In general, serological and stool tests have low sensitivity. Empirical pre-HCT therapy with ivermectin 200 $\mu\text{g/kg/d}$ for two days is recommended. Repeat treatment after two weeks. Alternative schedule is albendazole 400 mg 12/12 h for seven days (AII).	46,47
Assessment: Malaria. Method: Investigation of epidemiological risk in donor and candidates: previous history of malaria, and individuals who live in or have traveled to endemic areas. Serology to investigate previous malaria is not recommended (BII). In Brazil, deferral of the donor due to a previous history of malaria is not recommended, unless an alternative donor is available. Donor deferral is only indicated in case of malaria due to <i>Plasmodium malariae</i>. If epidemiological risk exists, the presence of parasitemia should be investigated before HCT or before donor stem cell harvesting. In the case of positive parasitemia, the donor or candidate must be referred for treatment. In such cases, the donor will be ineligible to donate for at least 12 months after recovery. If parasitemia testing is unavailable and postponing the transplant or searching for an alternative donor is not possible, the transplant team, along with infectious diseases specialists, must define the strategy to avoid the risk of transmission (BIII). If previous malaria was properly diagnosed, the information of <i>Plasmodium</i> species may be available at institutional data base (currently Pasteur Institute). Comment (evidence): Transmission of malaria by HCT is rare but well-documented and has occurred with both bone marrow and peripheral blood stem cells (PBSC). Some red blood cells may be collected during the apheresis of PBSC, and merozoites may survive during the freezing process.	48–52

Source: Elaborated by the authors.

PROPHYLACTIC MEASURES

For certain infections, the best control strategy is prophylaxis, based on factors such as frequency, infection severity, or the availability of safe and effective antimicrobial agents.

In Table 2, we describe infectious events for which prophylaxis is—or may be—the strategy to be adopted.

Table 2. Prophylactic measures.

Prophylactic measures	References
Intervention: Antibacterial prophylaxis during the pre-engraftment period; ciprofloxacin or levofloxacin. Evidence summary: Clinical trials and meta-analyses have shown that the use of quinolones in the prophylaxis of neutropenic patients reduces the incidence of febrile neutropenia and bloodstream infections in patients with an expected duration of neutropenia > seven days. However, in patients with baseline colonization by quinolone-resistant gram-negative bacteria, quinolones do not prevent infection. Recommendation (evidence): In adults, quinolone prophylaxis could be considered in autologous and allogeneic HCT recipients during neutropenia, provided that the frequency of colonization and / or infection by resistant gram-negative bacteria is not frequent (less than 30–40%) (AI). In children, current evidence does not support the routine use of antibacterial prophylaxis in pediatric patients with cancer, including those with acute leukemia and those undergoing HCT (DII). Limited benefit, concerns regarding antimicrobial resistance, microbiome disruption, adverse effects (Australasian Consensus Guidelines, 2024), and the lack of robust pediatric-specific evidence (European Conference on Infections in Leukemia guidelines, Infectious Diseases Society of America guidelines) are the main reasons to contraindicate antibacterial prophylaxis in children. In high-risk children, prophylaxis could be considered (CII). Taken together, these consensus guidelines state that, in children, antibacterial prophylaxis should not be implemented routinely, but rather individualized based on the patient's risk factors, local epidemiology, and institutional policies for the rational use of antimicrobials.	53–67
Intervention: Antibacterial prophylaxis in late post-engraftment phase; oral penicillin. Alternatives: macrolides, quinolones, amoxicillin, or second generation cephalosporin. Evidence summary: Allogeneic hematopoietic cell transplantation (HCT) recipients with chronic graft-versus-host disease (GVHD) usually have impairment in B-cell immunity, including deficit in complement function and hypogammaglobulinemia. These immunodeficiencies increase the risk of infection caused by encapsulated bacteria. Recommendation (evidence): Check if <i>Haemophilus influenzae</i> B (Hib) and pneumococcal vaccines (PCV and PPV23) are updated. Prophylaxis should be considered in patients with chronic GVHD to prevent infection by encapsulated bacteria or in cases of recurrent respiratory infections in the context of hypogammaglobulinemia (BII).	61
Situation: Prophylaxis for <i>Clostridioides difficile</i> infection (CDI). Evidence summary: Regarding environmental prevention measures, be aware that handwashing with soap and water is recommended after caring for CDI patients because alcohol-based hand rubs do not effectively eliminate spores. Recommendation: There is no recommendation for primary prophylaxis against CDI. In high-risk patients for recurrent CDI, especially those with a previous history of CDI, and concomitant broad-spectrum antibiotic therapy, secondary prophylaxis with oral vancomycin 125 mg twice daily may be considered until discontinuation of antibiotic treatment.	14,68,69
Intervention: Immunoglobulin replacement to prevent bacterial infection. Evidence summary: One multicenter double-blind randomized trial compared intravenous immunoglobulin or placebo in the prevention of complications after allogeneic HCT. The frequency of infection was similar in the two arms, including in patients with chronic GVHD. Recommendation: Measurement of serum levels of immunoglobulins should be performed in patients who develop bacteremia or recurrent sinopulmonary infections. In patients with low IgG serum levels, immunoglobulin replacement should be considered, especially if the patient has been adequately vaccinated. An alternative to immunoglobulin replacement is the start of antibacterial prophylaxis, starting immunoglobulin replacement to those who fail antibiotic prophylaxis (BIII).	60,70,71
Intervention: Primary antifungal prophylaxis. Evidence summary: Invasive fungal disease (IFD) in allogeneic HCT occurs mainly in two periods: pre-engraftment (neutropenia) and post-engraftment (GVHD-related immunosuppression), reflecting different risk profiles. During pre-engraftment, <i>Candida</i> spp. predominates, and fluconazole remains appropriate for patients at low/moderate mold risk when combined with an active mold-directed diagnostic strategy, such as serial galactomannan (GM) and computed tomography when indicated. Mold-active prophylaxis should be reserved for selected high-risk patients. None of the three randomized trials of micafungin versus fluconazole showed a significant reduction in the incidence of invasive aspergillosis in the micafungin arm. Similarly, the rates of IFD were similar in randomized studies comparing voriconazole versus itraconazole, or fluconazole versus voriconazole with serum galactomannan monitoring. After engraftment, mold-active prophylaxis is recommended for steroid-treated (acute and/or chronic) GVHD. Posaconazole is preferred, but given limited access and oral suspension availability in some settings, voriconazole is a supported alternative, and isavuconazole may be considered second line, especially with QTc prolongation or contraindication/intolerance to posaconazole/voriconazole. Recommendation (evidence): In both autologous and allogeneic HCT, a risk stratification strategy can be employed, taking into consideration the main risk factors for IFD. In allogeneic HCT, for patients at very high risk for mold infections in the pre-engraftment period, voriconazole (BI) is the agent of choice since there are no studies evaluating posaconazole or isavuconazole. If risk assessment indicates a moderate risk for mold infection, fluconazole + active monitoring with serial serum galactomannan is a good alternative (BI). In patients with GVHD, posaconazole (AI) is the agent of choice, but its use may be limited by availability, formulation, absorption concerns, drug interactions, or inability to ensure adequate exposure. Therefore, the best-supported alternative is voriconazole. Isavuconazole is a second-line option in selected patients, particularly in cases of QTc prolongation or intolerance/contraindication to posaconazole or voriconazole. In autologous HCT, the agent of choice for anti-<i>Candida</i> prophylaxis is fluconazole (AI). Therapeutic drug monitoring is recommended for azoles in situations of variable absorption, drug interactions, organ dysfunction, or inadequate clinical response, to ensure adequate exposure and reduce toxicity (AI-AII).	72–80

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Prophylactic measures	References
Intervention: Prophylaxis for herpes simplex virus (HSV) and varicella-zoster (VZV). Recommendation: Acyclovir or Valacyclovir. Comment (evidence): Beginning in conditioning up to one year after bone marrow transplant or up to six months after the end of immunosuppression, whichever comes last (allogeneic HCT) (AI).	81,82
Intervention: Prophylaxis for cytomegalovirus (CMV). Recommendation: Letermovir. Comment (evidence): Indicated for adult CMV IgG positive allogeneic HCT recipients. Perform CMV quantitative polymerase chain reaction (qPCR) before prophylaxis (less effective if DNAemia is present). Letermovir should be started as soon as possible and no later than day +28 and kept at least until day +100 (AI). Available pediatric data demonstrate favorable pharmacokinetics, efficacy in reducing CMV reactivation, and a good safety profile. In 2024, the U.S. Food and Drug Administration (FDA) approved its use in children ≥ 6 months of age and ≥ 6 kg. However, letermovir is not approved for pediatric use in Brazil yet. Therefore, its use should be individualized and based on a case-by-case assessment, considering clinical risk and local experience (BII). Extended letermovir prophylaxis should be considered in patients at high risk for CMV-CS: human leukocyte antigen (HLA) mismatched or cord blood HCT, use of PT-CY, T-cell depletion (e.g., anti-thymocyte globulin, alemtuzumab), patients on steroids, patients with ongoing GVHD, patients with previous episodes of CMV DNAemia. Prophylaxis can continue to at least 200 days after transplantation (AI). Letermovir dose should be adjusted if concomitant use of cyclosporine. Acyclovir or valacyclovir prophylaxis for HSV/VZV should be maintained (AI).	83–88
Intervention: Prophylaxis for hepatitis B virus (HBV). Recommendation: Entecavir or tenofovir from the first conditioning day (if not in use) to one year after autologous HCT and two years after allogeneic HCT or six months after the end of immunosuppression (whichever comes later). Lamivudine may be considered only in settings in which entecavir and tenofovir are unavailable or contraindicated. Monitor with monthly transaminases, and, if increased, request HBV DNA (AII). After the discontinuation of prophylaxis, monitor with HBV DNA every three months (AII). Comment (evidence): Indicated in the presence of any serological marker of previous HBV infection: all HBsAg-positive recipients (allo and auto); anti-HBc positive donors with negative HBV DNAemia; and HBsAg-negative with anti-HBc-positive recipients. Recipients previously treated with depleting anti-CD20, anti-CD38, or anti-CD19 antibodies are in higher risk for HBV reactivation. Attention to autologous patients treated with immune biological drugs after HCT. As the risk of reactivation persists, maintenance of antiviral treatment may be necessary.	27,28,89
Intervention: Prophylaxis for hepatitis E virus (HEV). Recommendation: Ribavirin for recipients with HCT from a HEV RNA-positive donor. Comment (evidence): Although data are limited and reports of HEV transmission through blood or organs remain rare, the use of an HEV-positive donor may be acceptable when no better alternative exists. In such cases, close monitoring of the recipient is essential, and ribavirin therapy can be considered (CIII).	28,90–92
Intervention: Prevention of respiratory viruses (RV). Recommendation: HCT candidates and recipients should be advised to avoid contact with symptomatic individuals (AII), avoid crowds in public places, and adhere to individual protection measures according to epidemiological risk (AIII). Surgical masks are recommended in the HCT unit and for patients after discharge, especially in the first few months or in cases of severe immunosuppression, at any time post-transplant (AII). HCT should be postponed in symptomatic patients (AII). Ideally, only patients who tested negative in pre-HCT RV screening can be admitted for transplantation (AII). Daily surveillance of respiratory symptoms is crucial (AIII). Rapid diagnosis and precautions implementation according to specific diagnosis (AII). In units with high-efficiency particulate air rooms, the positive pressure should be reverted or turned off if RV are diagnosed (AII). Comment (evidence): Post-exposure prophylaxis with oseltamivir (75 mg once daily for 10 days) is recommended for exposure to the influenza virus within the first 48 hours, regardless of vaccination history. Recently, nirsevimab, a monoclonal antibody for RSV prophylaxis was approved in children up to 2 years of age and is available in public healthcare system (special immunobiologics reference centers). Nirsevimab should be administrated yearly, from February to August (RSV season in southeast region of Brazil).	32,93,94
Intervention: Prevention of hemorrhagic cystitis (HC) caused by <i>Polyomavirus hominis</i> tipo 1 (BKPyV). Recommendation: Hyperhydration (BII) and bladder irrigation (CII). Careful reduction of immunosuppression may be considered. Comment (evidence): HC prophylaxis is based on hyperhydration and bladder irrigation to reduce urothelial damage, which occurs mainly in myeloablative conditioning with cyclophosphamide, busulfan and total body irradiation (BII). Asymptomatic BKV viruria is frequent after HCT ($> 60\%$), and there is no correlation between viral load and hematuria severity. Monitoring of BKV in urine or blood is not recommended. Fluoroquinolones are not recommended because of the ineffectiveness in viral replication and severity of HC, and the risk of increasing resistance to quinolones (DII).	95,96

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Prophylactic measures	References
Intervention: Prophylaxis of TB reactivation. Management: Prophylaxis with isoniazid (INH) for six to nine months is strongly recommended for recipients with LTBI, after ruling out active TB. The diagnosis of LTBI should be made before HCT by TST or IGRA. Alternative is short-term regimen based on rifapentine + isoniazid (3HP) once a week for three months (lower hepatotoxicity and a higher treatment completion rate compared to isoniazid). In transplant patients, drug interactions may limit its use, and there is little information on its effectiveness. Thus, INH remains the preferred regimen. Comment (evidence): Prophylaxis with INH has been controversial due to the late occurrence of TB and adverse events (in general, rare). Main risk factor is active chronic GVHD. Maintain prophylaxis for six months or until the condition stabilizes (BII).	40,97–99
Intervention: Prophylaxis for toxoplasmosis and pneumocystosis. Conduct: All seropositive (R-positive) patients before transplant should receive primary <i>Toxoplasma gondii</i> prophylaxis: trimethoprim (TMP)/sulfamethoxazole (SMX) oral or intravenous (first choice) (AII). Dapsone–pyrimethamine as alternative (BI). Comment (evidence): TMP/SMX is active against <i>T. gondii</i>, <i>Pneumocystis jirovecii</i> (All adults; AI children), <i>Listeria</i> and <i>Nocardia</i>. In adults, recommended regimens include 80/400 mg daily, 160/800 mg daily, or 160/800 mg three times weekly. In children, the most used regimen consists of 5 mg/kg/day of the TMP component administered in two divided doses on three days per week. In allogeneic HCT recipients, SMX-TMP used for PJP prophylaxis also provides protection against toxoplasmosis. Half of the cases of toxoplasmosis occur before d +30. Thus, prophylaxis should start soon after engraftment and maintained until d +180 or more in patients who continue to receive IS and/or have chronic GVHD. The duration of <i>T. gondii</i> prophylaxis should be at least six months and extended during immunosuppression; or until the CD4 cell count significantly increases, in patients who no longer receive immunosuppressive drugs (BII).	43,44,100

Source: Elaborated by the authors.

LABORATORY MONITORING

For some infectious agents, the best strategy is preemptive therapy guided by biomarkers that are sensitive, specific, and have a high positive predictive value for the development of disease. This strategy requires monitoring for infections. Table 3 describes the infections for which monitoring is necessary and how to carry it out.

Table 3. Laboratory monitoring.

Laboratory monitoring	References
Situation: Early diagnosis of invasive aspergillosis. Evidence summary: Galactomannan (GM) is released from the cell wall of <i>Aspergillus</i> (and a few other molds) when hyphae are growing and can be detected very early during invasive aspergillosis in the bronchoalveolar lavage (BAL) and, a little later, in the serum. The performance of GM in the serum is high in neutropenic, but not in non-neutropenic patients. In addition, the use of mold active azoles reduces its sensitivity. Recommendation: In neutropenic patients not receiving mold active agents (azoles, echinocandins), obtain serum GM twice or three times/week (AII). One or more positive tests (optical density > 0.5) should trigger the investigation of aspergillosis with chest computed tomography scan. In neutropenic patients receiving prophylaxis with an echinocandin or a mold-active azole, serum GM should be obtained in three consecutive days by clinical demand (persistent or recurrent fever, clinical symptoms or images in chest or sinuses computed tomography scan). This strategy also applies for non-neutropenic patients (AII).	101–107
Situation: Control of response to the treatment of invasive aspergillosis. Evidence summary: The kinetics of serum GM strongly correlates with outcome, with persistently positive tests predicting poor outcome and fast normalization of GM being associated with clinical response and better survival. Recommendation: Patients with invasive aspergillosis in whom serum GM was the basis for the diagnosis, should have serial (twice or three times/week) serum monitoring with serum GM, especially in the first two weeks of treatment.	102,107
Situation: Cytomegalovirus (CMV) monitoring. Method: Perform quantitative polymerase chain reaction (qPCR) (AII) or pp65 antigenemia (AG) (BII) at least once a week from conditioning up to D +100. Recommended in all CMV seropositive allogeneic recipients (R+). Recipient-/donor- do not require monitoring, to guide preemptive therapy, and during letermovir prophylaxis (AI). Extended monitoring is recommended for at least another three months after the end of letermovir prophylaxis, and in patients at higher risk (see topic 7 in Table 2) (BII). Comment (evidence): When using qPCR, monitoring should be carried out keeping the same type of sample, the same method of DNA extraction and quantification (including World Health Organization quantification standard) (AII), and the results must be available within 48 hours. Monitoring with AG should start after engraftment. Letermovir blips (single test low-level DNA positivity in plasma or whole blood samples occurring especially early during letermovir prophylaxis) are common; interruption of letermovir prophylaxis is not recommended unless there are repeated positive samples showing increasing viral load (BII).	85,108

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Laboratory monitoring	References
Situation: Monitoring of Epstein-Barr virus (EBV). Method: qPCR weekly from D +0 until D +100. Validated <i>in house</i> assays and commercial kits have been used. Monitoring may be extended, at least monthly, in case of graft-versus-host disease (GVHD) using immunosuppression or previous reactivation of EBV during the first year (BII). Comment (evidence): Recommended for groups at risk for post-transplant lymphoproliferative disease: T-cell depletion (<i>in vivo</i> or <i>ex vivo</i>), donor/recipient EBV serology mismatch, cord blood transplant, HLA mismatch, splenectomy, second HCT, severe acute or chronic GVHD, high or rising EBV viral load, and treatment with mesenchymal stem cells (AII). EBV reactivation is more frequent in matched unrelated donor <i>versus</i> haploidentical HCT. Main risk factor for EBV reactivation is anti-thymocyte globulin use (BII).	109,110
Situation: Monitoring of HHV-6 reactivation. Method: qPCR. Comment (evidence): Routine HHV-6 DNA screening is currently not recommended for pre-emptive or prophylactic therapy (DII). HHV-6 is associated with acute GVHD and is frequent in haploidentical HCT. Based in recent data, some HCT centers may choose to perform monitoring in this group of patients (BII).	111–113
Situation: Adenovirus monitoring (ADV). Method: qPCR in feces or blood weekly. Comment (evidence): In high-risk groups, <i>e.g.</i>, children with cord blood HCT or unrelated donor, severe GVHD (grade III–IV); severe lymphopenia (< 200/L) (IIA children). Adults with cord or haploidentical HCT; severe GVHD (grade III–IV); severe lymphopenia (< 200/L); alemtuzumab treatment (BII adults). In feces, viral load above 10⁶ copies/gram of feces predicts viremia and indicates the time to start blood monitoring. In the absence of stool screening, blood monitoring can begin immediately after transplantation and be maintained until D +100 (BIII children, CIII adults).	114–116
Situation: Monitoring Human T-cell lymphotropic virus (HTLV)-1 positive recipients. Method: qPCR in blood. Comment (evidence): In general population, asymptomatic HTLV-1 positive individuals have 3–5% risk of developing adult T-cell leukemia/lymphoma (ATLL). The risk is higher in solid organ transplant recipients, older age, increased proviral load in blood, and a family history of ATLL. Due to the lack of data in HCT recipients, there are no evidence-based recommendations regarding the need or the frequency of HTLV-1 monitoring post-HCT (CIII). Adapted from observational studies and the known kinetics of HTLV-1 infection, some experts suggest a baseline viral load before HCT followed by monthly measurements up to day 100 and less frequent follow-up thereafter (every six months or annual) (CIII). Clinical monitoring for neurological symptoms and atypical lymphocytosis is advised.	29,117
Situation: Monitoring of Chagas disease. Method: Qualitative polymerase chain reaction (PCR) in decreasing frequency. Comment (evidence): Recommended in donors and/or recipients with positive Chagas serology. In Brazil, Chagas seroprevalence in HCT recipients is around 0.5%. PCR monitoring should start on admission, then weekly for two months, every other week between two and six months of HCT and annually after six months. If benznidazole is introduced preemptively, monitor marrow and hepatic toxicity. There is no benefit of prophylaxis compared to preemptive therapy (BII).	33,41,118
Situation: Monitoring of malaria. Method: PCR is the method of choice due to higher sensitivity. Microscopy (thick and thin blood films) or rapid diagnostic tests can be done if PCR is not available. Comment (evidence): Recipient monitoring after HCT is recommended if donor or recipient has a previous history of malaria or live in endemic areas. Monitoring is recommended weekly for two months.	49,119

Source: Elaborated by the authors.

MANAGEMENT OF FEBRILE NEUTROPENIA

Febrile neutropenia is a frequent and predictable event during the first few weeks post-transplant, or later in cases of poor neutrophil engraftment or graft failure. Managing febrile neutropenia requires knowledge of local epidemiology to select appropriate antibiotic regimens. Table 4 outlines the key issues regarding the management of febrile neutropenia in HCT recipients.

Table 4. Management of febrile neutropenia.

Febrile neutropenia	References
Intervention: Procedures before starting empiric antibiotic therapy. Evidence summary: The initial assessment of febrile neutropenia (FN) patient comprises history, physical examination, and blood cultures. The history should include comorbidities, underlying disease and its status, and the more recent chemotherapy regimen. Signs and symptoms should guide the physical examination looking especially for the most common sites of infection as skin, respiratory and gastrointestinal tract. Blood cultures from peripheral vein and any available long-term catheter are recommended. Additional tests should be ordered only as clinically indicated. Routine urine cultures are not recommended. Recommendations: Obtain medical history, perform clinical exam, and obtain at least two sets of blood cultures from peripheral vein and catheters (AII).	120,121

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Continuation.

Febrile neutropenia	References
Intervention: Empiric antibiotic therapy. Evidence summary: Studies conducted in the late 1990s established monotherapy as standard of care for the empiric antibiotic regimen in FN, usually with cefepime, piperacillin-tazobactam or a carbapenem (imipenem, meropenem). The routine use of carbapenem in the initial empiric antibiotic regimen has been discouraged because of its association with pseudomembranous colitis, selective pressure with the emergence of carbapenem-resistant organisms and a higher interference in the gut microbiome, increasing the risk of severe graft-versus-host disease (GVHD). In patients with colonization by resistant gram-negative bacteria (such as extended spectrum beta-lactamase or carbapenem-resistant enterobacteria, there is a risk of bacteremia by the same colonizing agent. In such circumstances, there is a rationale for choosing an empiric antibiotic regimen that is active against the colonizing bacteria since inappropriate anti-gram-negative coverage in FN is associated with higher mortality rates. Regarding the empiric use of anti-methicillin-resistant <i>Staphylococcus aureus</i> (MRSA) antibiotics in the initial regimen, epidemiologic studies do not support this strategy because infection by gram-positive organisms is not associated with early death; inappropriate anti-gram-positive coverage is not associated with higher mortality even if shock is present. Furthermore, patients with negative nasal swabs for MRSA have a very low probability of developing infection by MRSA (99% negative predictive value). Recommendations: Cefepime or piperacillin-tazobactam are good options as empiric antibiotic therapy in FN; the choice between these two antibiotics should be based on local epidemiology and potential of toxicity of each antibiotic (AI). A carbapenem should not be used routinely as empiric antibiotic therapy in febrile neutropenic patients. If a regimen other than cefepime or piperacillin-tazobactam with a broader spectrum of activity is used as empiric therapy because of colonization by multi-drug-resistant gram-negative organisms, hypotension, or other severe clinical condition, a de-escalation approach (switch to cefepime or piperacillin-tazobactam) should be employed if blood cultures do not grow resistant gram-negative bacteria (AII). There is no indication for the empiric use of an anti-MRSA agent in FN (BII). An anti-MRSA may be considered in patients who are colonized by MRSA and have an infection that usually does not have microbiologic documentation, such as skin and soft tissue infection.	12,120,122–132
Intervention: Modification of empiric antibiotic regimen in FN. Evidence summary: Adjustment in the empiric regimen is usually recommended based on the results of blood cultures. Although frequently prescribed, the addition of anti-MRSA antibiotic (vancomycin or teicoplanin) did not show any benefit in persistently febrile neutropenic patients, in randomized controlled trials. On the other hand, a change in the betalactam is usually considered in patients who present new clinical signs of infection or clinical deterioration. In patients with typhilitis, anaerobe bacteria may be involved in the infection. In a prospective cohort study, FN patients with abdominal symptoms (abdominal pain, diarrhea, perianal pain) received either cefepime plus metronidazole, piperacillin-tazobactam or meropenem monotherapy. The 28-day mortality rate was lower in patients receiving metronidazole. Recommendations: Modification in the empiric regimen is not indicated based on persistent fever only (BIII). By contrast, a change in the betalactam to a regimen of broader gram-negative spectrum is recommended in case of clinical deterioration or the appearance of new clinical signs of infection, even if the patient is afebrile (BIII). If the betalactam was changed empirically to a regimen with broader spectrum, a de-escalation to the original antibiotic regimen should be undertaken after 48–72 hours if there is no documentation of infection caused by a gram-negative organism exhibiting resistance to the first regimen (BIII). Adjustment in the antibiotic regimen should be undertaken according to results of blood cultures, including de-escalation to an antibiotic with narrow spectrum (BIII). An anti-anaerobe antibiotic should be started in FN patients who present with clinical manifestations suspicious of typhilitis or perianal pain (BII).	133–136
Intervention: Discontinuation of antibiotics in FN. Evidence summary: A randomized study evaluated 157 neutropenic patients who were afebrile after 72 hours of empiric antibiotic therapy, did not have any documentation of infection, and had normal vital signs. In one group, antibiotics were continued and in other discontinued. Patients who discontinued the antibiotic regimen had less days on antibiotics, with no negative impact on the number of days with fever or mortality. Similar observations were reported in cohort studies. Recommendations: The duration of antibiotic therapy should be guided by documentation of infection and neutrophil recovery. Antibiotics should be discontinued if neutropenia resolves, and there was no documentation of infection, even if the patient is still febrile (AII). If there was a documentation of infection during FN, the antibiotic regimen should be adjusted and maintained until resolution of the documented infection (AII). In persistently neutropenic patients, empiric antibiotic regimen should be discontinued after four days if patients did not have any documentation of infection and have normal vital signs (AI). Antibiotics should be continued in patients who persist neutropenic and febrile (AII).	123,137,138

Source: Elaborated by the authors.

EMPIRICAL AND PREEMPTIVE ANTIMICROBIAL THERAPIES

Table 5 outlines the management of suspected fungal infections with empirical therapy, and the management of viral or parasitic infections with preemptive intervention.

Table 5. Empirical and preemptive antimicrobial therapies.

Empirical and pre-emptive therapies	References
Intervention: Empiric or preemptive antifungal therapy. Evidence summary: For many years, empiric antifungal therapy was considered standard of care in high-risk neutropenic patients with persistent fever after four to seven days of broad-spectrum antibiotics, based mainly on older studies with limited diagnostic tools. With the introduction of serum galactomannan (GM) and early chest computed tomography (CT), preemptive strategies became feasible. In a randomized study of high-risk febrile neutropenic adults, including acute leukemia and HCT recipients receiving fluconazole prophylaxis with serial serum GM monitoring, preemptive therapy was non-inferior to empiric therapy for six-week survival and reduced the use of non-prophylactic antifungal agents. Similar findings were reported in children. A preemptive strategy requires rapid access to serum GM, timely chest CT, and close clinical reassessment. If these tools are not promptly available, empiric antifungal therapy remains appropriate. However, if chest CT is not suggestive of mold infection and serum GM remains negative, discontinuation of the antifungal agent should be considered. Recommendations: If serum GM and chest CT are available in real time, a preemptive strategy is recommended in high-risk neutropenic patients with persistent fever (AI). The choice of antifungal agent should be guided by the suspected pathogen, prior prophylaxis, local epidemiology, drug interactions, organ dysfunction, and clinical severity. For suspected or probable invasive aspergillosis, voriconazole or liposomal amphotericin B are preferred options; isavuconazole may also be considered when available. Echinocandins may be appropriate for empiric therapy when invasive candidiasis is the main concern, but they should not be used as monotherapy for suspected invasive aspergillosis. Consultation with an infectious diseases specialist is strongly recommended.	139–142
Situation: Preemptive therapy for cytomegalovirus (CMV). Recommendation: Ganciclovir (GCV) or valganciclovir are recommended (AI). Oral valganciclovir should not be used in patients with severe gastrointestinal graft-versus-host disease (GVHD) (AII). Foscarnet can be used during neutropenia (AI) and is an alternative therapy for resistant or refractory CMV infections, particularly in the central nervous system (CNS) and eyes, but it is associated with clinically significant toxicity (BII). Preemptive maribavir can be considered for patients with neutropenia who cannot be treated with valganciclovir (BI) or patients with renal function impairment for whom foscarnet (BII) is not appropriate. The duration of preemptive therapy is ≥ 14 days and may be suspended after that period with a negative quantitative polymerase chain reaction (qPCR) result. Granulocyte colony-stimulating factor can be used in case of hematopoietic toxicity by GCV. Valganciclovir can be used in place of GCV IV or foscarnet, except in patients with severe gastrointestinal GVHD (BII). Doses need to be adjusted to the patient's renal function (AII). Comment (evidence): Preemptive therapy should be introduced after detection of CMV DNAemia by qPCR or AG positivity (≥ 1 positive cell). The qPCR cut-off for the introduction of GCV must be defined locally according to the standardized kit and may vary according to the patient's risk. High risk = cord, haplo, T cell depletion, and HLA mismatch (lower cut-off). Low risk = remaining hematopoietic cell transplantations (HCTs) or using letermovir (highest cut-off). If DNAemia is on the rise or increases after two weeks, the possibility of viral resistance or tolerance should be considered. In this situation, maribavir is preferred (AI). Alternatively, consider increasing the dose of ganciclovir (7.5–10.0 mg/kg every 12 h as tolerated), if CMV disease is not present (CIII). Maribavir is also an alternative for ganciclovir when reactivation occurs in the engraftment period and foscarnet is not tolerated. Poor response to preemptive maribavir is expected in CNS or eye involvement (AI), acute GVHD, high CMV viral load ($> 9,000$ IU/mL), the use of T-cell depletion and a CMV D+/R-serostatus. In such situation, an infectious diseases consultation is advised (BII). The addition of intravenous immunoglobulin is not recommended unless CMV pneumonia is diagnosed. During preemptive therapy, suspend prophylactic Acyclovir.	85,108,143,144
Situation: Preemptive therapy for Epstein-Barr virus (EBV). Recommendation: In high-risk patients, consider the dynamics of EBV viral load. If there is a one-log increase in EBV DNAemia within a seven-day period, reduce/discontinue immunosuppression, if possible (AII). Consider rituximab (one to four doses, until negative EBV qPCR) in patients who do not respond to immunosuppression reduction or develop EBV end-organ disease or post-transplant lymphoproliferative disease (AII). Comment (evidence): In addition to enlarged lymph nodes, the target organs of EBV diseases are the CNS (encephalitis), the liver, and the lungs. More than 90% of recipients with EBV DNAemia respond to IS reduction (AII). To date, there are no studies that indicate a viral load cut-off to start preemptive therapy. The cut-off should be defined locally, according to the experience of the HCT team and diagnostic assay used. The load of EBV DNAemia did not correlate with the severity of EBV encephalitis, according to a recent Brazilian study (AII). EBV qPCR results should be readily available to evaluate viral load increase.	109,110,145
Situation: Preemptive therapy for HHV-6 (if HHV-6 is monitored). Recommendation: Consider therapy with GCV or foscarnet for 21 days in few conditions. Comments (evidence): Preemptive therapy is indicated in risk groups with: HHV-6 positive in cerebrospinal fluid and compatible neurological condition excluding other causes; HHV-6 DNAemia in the presence of delayed engraftment (platelets, neutrophils), myelosuppression or engraftment failure, with no other explanation (CIII); and proven HHV-6 lower respiratory tract infection (rare).	111,146
Situation: Preemptive therapy for adenovirus. Recommendation: Reduce immunosuppression (AII) and initiate cidofovir therapy (BII). Comment (evidence): In patients with disseminated disease, cidofovir may be administered at 3–5 mg/kg once weekly for two or three weeks, followed by maintenance dosing every two weeks. An alternative regimen is 1 mg/kg three times per week (BII). Adequate hyperhydration and concomitant use of probenecid are recommended to mitigate nephrotoxicity.	115,116

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Empirical and pre-emptive therapies	References
Situation: Preemptive therapy for Chagas. Recommendation: Benznidazole 5 mg/kg/day for 60 days in case of Chagas reactivation. The cut-off to start preemptive therapy has not been established. Comment (evidence): The reactivation rate of Chagas disease is approximately 30% in recipients of allogeneic HCT with positive Chagas serology.	118
Situation: Preemptive therapy for malaria. Recommendation: If parasitemia is detected during malaria monitoring, preemptive malaria treatment should be started. Treatment is based on <i>Plasmodium</i> species and drug resistance patterns, according to geographic regions of presumable malaria acquisition. If the diagnosis of malaria is confirmed without species determination, <i>P. falciparum</i> treatment must be initiated immediately because this can be a life-threatening condition. <i>P. vivax</i>, <i>P. ovale</i>, and <i>P. malariae</i> infections should be treated with chloroquine. In donors, candidates, and recipients with vector-borne <i>P. vivax</i> and <i>P. ovale</i> infections, a 14-day course of primaquine needs to be added to chemotherapy regimen to eradicate hypnozoite forms that remain dormant in the liver and may cause relapses. Comment (evidence): An infectious diseases specialist should be consulted to define malaria therapy and doses, the management of CNS complications, and intensive care unit need.	119

Source: Elaborated by the authors.

ANTIMICROBIAL THERAPY FOR DOCUMENTED INFECTIONS EVENTS

Not all prevention or control strategies are 100% effective, and infection occurs despite them. Furthermore, there are unpredictable situations, such as epidemic outbreaks, that result in many potentially severe and fatal events. Table 6 describes the treatment of established infections that could not be prevented by prophylactic, empirical, or preemptive measures, or that occurred unpredictably.

Table 6. Antimicrobial therapy for documented infections events.

Treatment of documented infections	References
Situation: Bacterial infections. Conduct: Clinical and laboratory diagnosis of the disease; specific treatment. Comment (evidence): The choice of therapy should be guided by syndrome and isolated agent (including susceptibility test). There is no indication of expanding the antimicrobial spectrum beyond what is necessary to treat documented infectious syndrome in non-neutropenic situations.	147
Situation: <i>Clostridioides difficile</i> infection (CDI)-related diarrhea. Method: Use diagnostic algorithms in accordance with the European Society of Clinical Microbiology and Infectious Diseases (ESCMID) recommendations, combining specific tests for toxin detection and sensitive tests for toxigenic strains: NAT associated with toxin detection, or toxin detection + glutamate dehydrogenase (GDH). If GDH positive and toxin negative, confirm with NAT. Recommendation (evidence): Discontinue other concomitant antibiotics whenever feasible. Vancomycin 125 mg orally, four times daily, for 10 days (AII). For severe or fulminant CDI, vancomycin orally or via nasogastric/gastroenteric administration plus IV metronidazole (AII). In refractory and carefully selected cases, fecal microbiota transplantation may be considered. Although studies show favorable results in improving dysbiosis and suggest a potential impact on graft-versus-host disease (GVHD), they are not consistent regarding its efficacy in the acute phase of the disease. In these cases, and in cases of ileus, toxic megacolon, consult an infectious diseases specialist. Bezlotoxumab and fidaxomicin are currently not available in Brazil.	14,148–150
Infection: Syphilis. Evidence summary: Donor: a previously treated infection (serofast state = persistent low titers [1:1–1:4] after adequate treatment) does not contraindicate donation. Ensure that adequate prior treatment is documented, there is no evidence of active disease, and baseline venereal disease research laboratory (VDRL)/rapid plasma regain (RPR) is recorded for traceability. In untreated or active disease, donation should be postponed until treatment has been initiated. In urgent situations, collection may proceed after donor therapy has started, with formal justification; recipient treatment should be considered according to exposure risk and clinical context. Recipient: if previously treated (serofast state), hematopoietic cell transplantation (HCT) may proceed without delay after documentation of treponemal and non-treponemal tests before conditioning. In untreated or active syphilis, initiate treatment before conditioning whenever feasible. HCT may proceed after treatment initiation if clinically stable and without secondary, disseminated, neurologic, otological or ocular disease. In disseminated disease or severe systemic symptoms, consider postponing HCT until improvement. Recommendation: Early syphilis (primary, secondary, and early latent) should be treated with benzathine penicillin G; doxycycline or ceftriaxone may be alternatives when appropriate. Late latent syphilis, syphilis of unknown duration, and tertiary syphilis without neurologic/ocular/otological involvement should be managed as late syphilis, preferably with benzathine penicillin G. Neurosyphilis, ocular syphilis, or otosyphilis requires intravenous crystalline penicillin G; ceftriaxone may be an alternative in selected cases. Because dosing and duration depend on stage, allergy, pregnancy, organ involvement, and timing of HCT, consult an infectious diseases specialist. After treatment, repeat clinical evaluation and VDRL/RPR at three, six, nine, and 12 months.	151,152

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Treatment of documented infections	References
Infection: Invasive aspergillosis. Evidence summary: Three randomized trials established voriconazole, posaconazole, and isavuconazole as first line in the treatment of invasive aspergillosis. An alternative to azoles is lipid amphotericin B, but there are no randomized trials comparing lipid amphotericin B with azoles. Deoxycholate amphotericin B is not recommended, since it was associated with higher mortality rate compared with voriconazole. Recommendations: Voriconazole, isavuconazole or posaconazole (intravenous, not available in Brazil) are considered first line therapy in invasive aspergillosis (AI). Liposomal amphotericin B is an alternative (BII), especially if infection occurs in patients receiving anti-mold azole. The duration of treatment should be individualized.	153–155
Infection: Mucormycosis. Evidence summary: There is no randomized trial exploring different antifungal agents in the treatment of mucormycosis, and recommendations are based on small cohorts and expert opinion. The largest experience is with lipid amphotericin B (liposomal or lipid complex). Isavuconazole is an option as primary therapy and posaconazole as salvage therapy. The role of combination therapy is uncertain since a matched cohort study did not show improved outcomes with combination therapy. Surgical debridement and improvement in immunity are considered of paramount importance in the treatment of mucormycosis. Recommendations: Lipid amphotericin is the drug of choice as first line therapy in mucormycosis (AII). The optimal daily dose has not been established, and recommendations are based on the opinion of experts. Isavuconazole is an alternative for primary therapy (BII). Early initiation of treatment is of great importance, as are surgical debridement and attempts to improve immunity.	156–159
Infection: Fusariosis. Evidence summary: There is no randomized trial exploring different antifungal agents in the treatment of fusariosis. In the largest cohort, primary therapy in 206 patients was mostly deoxycholate or lipid amphotericin B and voriconazole. The outcome of patients treated with deoxycholate amphotericin B was poor, whereas treatment response was similar in patients treated with lipid amphotericin B (liposomal or lipid complex) and voriconazole. Combination therapy did not improve outcomes. In neutropenic patients, recovery of neutropenia is the most important prognostic factor. Recommendation: Lipid amphotericin B and voriconazole are considered first line therapies for invasive fusariosis (AII). In neutropenic patients, attempts to accelerate neutrophil recovery should be undertaken (AII).	160
Situation: cytomegalovirus (CMV) disease. Recommendation: Intravenous ganciclovir (GCV) for at least 14 days is recommended for CMV disease (AII). Foscarnet may be used instead of GCV in cases of toxic effects or antiviral resistance (AIII). Cidofovir or the combination of foscarnet and GCV at full doses may be used as second- or third-line therapy (BII). Intravitreal injections of GCV or foscarnet may be used to treat CMV retinitis in combination with systemic therapy (BII). Cidofovir is an option for the treatment of CMV retinitis (BII). Valganciclovir can be used as a substitute for intravenous GCV or foscarnet (except in patients with severe gastrointestinal GVHD (BIII)). Comment (evidence): The addition of intravenous immunoglobulin (IVIG) can be considered for the treatment of CMV pneumonia (CIII). For other manifestations of CMV disease, the addition of IVIG is not recommended (BII). All doses need to be adjusted to the patient's renal function.	85,108
Situation: Refractory/resistant cytomegalovirus (CMV)-CS (infection or disease). Recommendation: Maribavir (AI). Foscarnet (BII). Foscarnet + GCV in full doses (third line) (CII). CMV-specific T cell therapy, if available (BII). Comment (evidence): Maribavir is effective for treatment of resistant or refractory CMV infection and disease and is associated with lower risk for side-effects than the other alternatives (AI). Foscarnet is an alternative therapy for resistant or refractory CMV infections, particularly in the CNS and eyes, but is associated with clinically significant toxicity (BII). Combination therapy for resistant or refractory CMV infections could be considered (BII). The combination of maribavir with valganciclovir or GCV should not be used (DII). CMV-specific T cell therapy is an alternative with growing prospects in Brazil (BII). Maribavir has no activity against herpes simplex virus or varicella-zoster. Therefore, proper antiviral prophylaxis against these viruses should be maintained.	85,108,144,161
Situation: Disease due to Epstein-Barr virus (EBV) and post-transplant lymphoproliferative disease (PTLD). Recommendation: Reduce IS and rituximab 375 mg / m² one/week for up to four weeks (AII). An alternative is the transfer of adaptive immunity by infusion of donor lymphocytes or EBV specific T-cell therapy (CII). Comment (evidence): In cases of disease (hepatitis, pneumonitis, or central nervous system disease) due to suspected or confirmed EBV or PTLD (with biopsy), therapy should be started as soon as possible (AII). Factors of good prognosis are age < 30, benign disease, absence of acute GVHD, reduced IS at diagnosis, and drop in viremia after initial therapy.	109,110,162
Situation: HHV-6 treatment. Recommendation: Consider therapy with GCV or Foscarnet for 21 days in few conditions. Comments (evidence): HHV-6 positive in cerebrospinal fluid and compatible neurological condition excluding other causes (AII); HHV-6 DNAemia in the presence of delayed engraftment (platelets, neutrophils), engraftment failure, or myelosuppression with no other explanation (CIII); and proven HHV-6 lower respiratory tract infection (BII). Other HHV-6 end-organ diseases have been poorly documented, and no recommendation can be done at this moment.	111,146,163

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Treatment of documented infections	References
Situation: Influenza A or B. Recommendation: Oseltamivir. Comment (evidence): Oseltamivir should ideally be started within the first 48 hours of symptom onset at a dose of 75 mg twice daily for five to 10 days in all individuals with suspected or confirmed influenza virus infection (AII). Due to the high risk of complications, treatment in HCT recipients remains recommended even when initiated later in the course of illness. Oseltamivir may be discontinued if diagnostic tests rule out influenza. For severely immunocompromised patients presenting with severe influenza, administration of a double dose of oseltamivir (150 mg twice daily) should be considered.	32,164
Situation: Respiratory syncytial virus (RSV). Recommendation: Supportive therapy consider the use of ribavirin in high-risk patients (BIII). Consider IVIG as an adjuvant (BIII). Careful evaluation of reducing corticosteroid treatment (CIII). Comment (evidence): Consider immunodeficiency score to define low risk (score 0–2), medium risk (3–6) and high risk (7–12). The following factors are considered in the score: neutropenia < 500; lymphopenia < 200; age > 40; GVHD using steroids; myeloablative conditioning and within the first year of HCT (BII). High risk of complications comprises a patient with RSV or RSV pneumonia detected before engraftment, lymphopenia < $0.3 \times 10^9 / L$ (most important), GVHD using IS, or neutrophils < $0.5 \times 10^9 / L$.	32,165,166
Situation: COVID-19 / SARS-CoV-2 infection. Recommendation: Oral nirmatrelvir/ritonavir (Paxlovid) may be indicated up to five days after symptom onset in patients with mild to moderate COVID-19 who do not require supplemental oxygen, but with factors contributing to severe disease (such as anti-CD20 or GVHD therapy). For patients with contraindications to Paxlovid (especially difficult-to-manage drug interactions), there is benefit from treatment with intravenous remdesivir up to seven days after symptom onset. Comment (evidence): In severe or critical cases, combinations of antivirals, convalescent plasma, and immunomodulators (such as tocilizumab or baricitinib) may be used. Dexamethasone is indicated in cases of COVID-19-related inflammation in patients requiring O₂ support. Equivalent doses of alternative corticosteroids may be used when clinically indicated, particularly in patients already receiving corticosteroid therapy for GVHD or other transplant-related complications.	167,168
Situation: Adenovirus (ADV). Recommendation: Supportive care. There is no specific treatment for respiratory conditions. Comment (evidence): If the allogeneic patient has an adenovirus upper respiratory tract infection, it is important to assess for concomitant viremia using a blood polymerase chain reaction (PCR) test. Treatment with intravenous cidofovir should be considered if ADV blood loads rise above 1,000 copies per mL (BII).	116,169
Situation: Parainfluenza, rhinovirus, metapneumovirus, coronavirus. Recommendation: If documented before HCT, postpone conditioning (BII). Supportive therapy and IVIG if hypogammaglobulinemia (< 400 mg/dL). Careful evaluation of reducing corticosteroid treatment (CIII). Comment (evidence): If recurrent or severe respiratory infections with IgG hypogammaglobulinemia < 400 mg / dL, IVIG replacement may be performed. Perform IgG dosage monthly.	32,170
Situation: BKPyV hemorrhagic cystitis. Recommendation: Supportive treatment. Antiviral treatment is controversial. Comment (evidence): There is no effective antiviral for BKPyV hemorrhagic cystitis. Treatment is based on supportive therapy (hyperhydration, bladder irrigation, platelet transfusions to reduce bleeding, and pain management). Treatment with cidofovir IV is controversial (absence of randomized controlled studies), but it may be an option although there is uncertainty regarding efficacy, doses, and risk-benefit in the face of renal side effects. Intravesical cidofovir can be used in severe cases, after evaluation by an infectious disease specialist.	95,96
Situation: Viral hepatitis. Method: Antiviral therapy according to diagnosis. Referral to an infectious disease specialist is strongly recommended. Comment (evidence): Targeted investigation for hepatitis A, B, C, D and E is recommended when there is unexplained elevation of liver enzymes, compatible epidemiological history, serology or biomarkers of any of them in the recipient or donor. The investigation should include HEV RNA PCR, since HEV transmission from HCT donors is possible (BIII).	28
Situation: Tuberculosis. Conduct: Rifampicin (R), isoniazid (H), pyrazinamide (Z) and ethambutol (E) for two months + RH four months (2RHZE/4RH). Meningoencephalitic and osteoarticular tuberculosis (TB) require more prolonged treatment (2RHZE/10RH). In HCT recipients, therapy may be prolonged according to clinical response. Comment (evidence): The most common form is pulmonary, with symptoms similar to the immunocompetent host (fever, weight loss and persistent cough). Clinical suspicion can be masked in patients with lung GVHD (investigate TB always). Acid fast bacilli show low sensitivity (60%), and culture is the gold standard for TB diagnosis (but may take 30 days). Currently, PCR is preferred yielding fast results and allowing prompt introduction of treatment. There are molecular tests that already detect resistance to rifampicin (AII).	40,171
Situation: Pneumocystosis. Conduct: Sulfamethoxazole-trimethoprim. Comment (evidence): The consensus recommends diagnostic confirmation by specific tests. Full dose therapy should be administered for at least 14 days. Secondary prophylaxis should be maintained for the duration of IS (AII). Corticosteroid use may be necessary in cases of hypoxemia. Alternatives are pentamidine (BII), primaquine + clindamycin or atovaquone (CIII).	172

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Treatment of documented infections		References
Situation: Toxoplasmosis.		
Conduct: Pyrimethamine plus folinic acid (due to hematological toxicity of pyrimethamine) associated with a second active agent: with sulfadiazine (All) or clindamycin in patients intolerant to sulfadiazine (All). As an alternative regimen, trimethoprim (TMP)-sulfamethoxazole (SMX) (TMP 10–20 and SMX 50–100 mg/kg/day, orally or intravenously, divided every 12 hours), with or without clindamycin, may be used, particularly when pyrimethamine is unavailable or oral administration is not feasible (All). Minimum duration of therapy is six weeks or until clinical resolution, or both, and two negative PCR tests in blood, seven days apart, or one quantitative polymerase chain reaction (qPCR) negative in a previously qPCR positive cerebrospinal fluid. Longer courses might be required if clinical disease or radiological findings are extensive or response is incomplete at six weeks (BII).		43,44,46
Comment (evidence): Non-specific presentation. Investigate neurological and ocular conditions. Treatment recommendations are mainly derived from studies in human immunodeficiency virus (HIV) patients. Pyrimethamine is the most effective agent and is usually combined with a second drug, along with folinic acid to reduce myelotoxicity. The initial treatment should be at least six weeks, with longer courses if incomplete response. TMP/SMX has demonstrated similar efficacy to pyrimethamine-sulfadiazine and is recommended as an alternative regimen, with or without clindamycin, particularly if pyrimethamine is unavailable or the oral route is not feasible. Steroids may be cautiously used in cases of severe ocular involvement, CNS disease with raised intracranial pressure, or rapid clinical progression. We strongly suggest calling the infectious diseases specialist.		
Situation: Malaria.		
Conduct: The same as described for preemptive therapy.		119
Comment (evidence): In donors, candidates, and recipients with vector-borne <i>P. vivax</i> and <i>P. ovale</i> infections, a 14-day course of primaquine needs to be added to chemotherapy regimen to eradicate hypnozoite forms that remain dormant in the liver and may cause relapses.		

Source: Elaborated by the authors.

POST-TRANSPLANT REVACCINATION PROGRAM

HCT recipients lose immunity to infections or vaccines acquired over their lifetime and require revaccination starting three months post-transplant, even though a weaker serological response to vaccination is expected. Brazil provides free vaccines to immunocompromised patients, facilitating access to a comprehensive revaccination program with well-established safety criteria. Table 7 describes the revaccination program post-HCT.

Table 7. Post-transplant revaccination program.

General recommendations ^{38,173–190}						
In general, vaccines are safe and effective in protecting against infections or reducing the risk of complications arising from them. Effectiveness depends on the functionality of immune system reconstitution; Predictors of vaccination failures are allogeneic hematopoietic cell transplantation (HCT), time since HCT, rituximab use, acute graft-versus-host disease (GVHD) under treatment, low level of immunoglobulin, anti-thymocyte globulin use, lymphopenia below 200/mm ³ ; The revaccination program unfolds in two stages: inactivated vaccines, which are administered starting on day 90; and live attenuated vaccines, which begin to be administered after the second year post-transplant for patients without active chronic GVHD and not using immunosuppressive drugs; Ideally, we recommend preparing two referral letters for vaccination centers: one letter with inactivated vaccines to begin on day 90, and another letter with live attenuated vaccines to begin on day 270, according to the inclusion criteria for live-attenuated vaccines. This measure avoids errors in administering live-attenuated vaccines outside the safe and appropriate period; Before referring the patient to begin the revaccination program, the healthcare professional should investigate time since HCT (do not start inactivated vaccines before day 90 or live-attenuated vaccines before day 270); IVIG in the last two months (if yes, wait 60 days to proceed with vaccination); anti-CD20/CD19 in the last six months (if yes, wait at least six months to proceed with vaccination); and corticosteroids dose ≥ 1 mg/kg/day. If so, wait until the dose is reduced to less than 1 mg/kg/day before proceeding with the administration of inactivated vaccines, or until the complete discontinuation of immunosuppressant to administer live attenuated vaccines.						
Inactivated vaccines – start day 90						
Vaccine	Start	Doses	Interval	Chronic graft-versus-host disease (cGVHD)	Children	Available
Pneumococcal conjugate vaccine (PCV)13	3–4 months	3	1–2 months	4 th dose	Idem	Public
PCV15	3–4 months	3	1–2 months	4 th dose	Idem	Private
PCV20	3–4 months	3	1–2 months	Unknown	Idem	Private
Pneumococcal polysaccharide vaccine 23	1 year	1	> 8 weeks after PCV	Idem	> 2 years old	Public

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Continuation.

Vaccine	Start	Doses	Interval	Chronic graft-versus-host disease (cGVHD)	Children	Available
<i>Haemophilus influenza</i> b (Hib)	3–4 months	3	1 month	Idem	Idem	Public
Diphtheria, tetanus, pertussis vaccine (DTP)-Hib	6 th month	3	1 month	Idem	Idem	Public
Diphtheria, tetanus, acellular pertussis (DTPa)	6 th month	3	1–2 months	Idem	Idem	Private
Inactivated poliovirus vaccine (IPV)	6 th month	3	1–2 months	Idem	Idem	Public
Meningococcal conjugate vaccine (MCV) (C)	6 th month	2	2 months	Idem	Idem	Public
MCV (B)	6 th month	2	1 month	Idem	Idem	Private
MCV (ACWY)	6 th month	2	1 month	Idem	Idem	Public (special immunobiologics reference centers)
Hepatitis B virus (HBV)	6 th month	3	0–1–6 months	Idem	Idem	Public
Hepatitis A vaccine (HAV)	6–12 months	2	6 months	Idem	Idem	Public
Human papillomavirus vaccine (HPV) 4	6–12 months	3	0–2–8 months	Idem	Idem	Public
HPV 9	6–12 months	3	0–2–8 months	Idem	Idem	Private
Recombinant herpes zoster vaccine	D50–D70	2	1–2 months	No data	No data	Private
Trivalent influenza vaccine	6 th month	1	Annual	2 doses	< 9 years–2 days	Public
High-dose influenza vaccine	6 th month	1	Annual	2 doses	No data	Private
Tetavalent influenza vaccine	6 th month	1	Annual	2 doses	No data	Private
Respiratory syncytial virus	≥ 1 year	1	to be defined	No data	No data	Private
COVID-19	Access updated data on the groups covered by the National Immunization Program (PNI), vaccine availability, and schedules at https://www.gov.br/saude/pt-br/assuntos/covid-19					
Attenuated vaccines – start day 270, if possible						
Vaccine	Start	Doses	Interval	cGVHD	Children	Available
Measles, mumps, rubella (MMR)	24 months	1	1 month (children)	No	2 doses	Public
Yellow fever vaccine (YFV)	24 months	1	-	No	> 9 meses	Public
Live-attenuated varicella vaccine (LAVV)	24 months	1	1 month (children)	No	2 doses	Public
Live attenuated zoster vaccine	Do not use. Contraindicated in HCT recipients					
Dengue vaccine	24 months	2	3 months	No	Idem Private	Public
Vaccine-specific comments						
PCV13	In general, children respond better to PCV13, but have more fever and local reactions than adults (AI).					
PPV23	After three or four doses of PCV13/15. Not necessary if PCV20 was used. Those who have already received PPV23, can take one dose of PCV13 after ≥ six months. If gammaglobulinemia < 3 g/L, severe GVHD, or rituximab for less than six months, maintain with prophylactic antibiotics + IVIG and delay PPV23 due to poor response (BI).					
Hib	Cord blood and non-myeloablative transplantation have the same response rate (BII). cGVHD does not interfere in the response (AII).					
DTPa	Public for children < 7 years old. The adult formulation (dTpa) is poorly immunogenic. Use DTPa for adults and children (BII).					
IPV	For children < 7 years old, use PENTA acellular (DTPa/HBV/Hib) and HEXA acellular (DTPa-IPV-HBV/Hib) (AII).					
INF	Annually, for life, or at least up to six months after the end of IS. In adults, INF-HD (one or two doses) is preferred because is more immunogenic. Children < 9 years old at the first vaccination or those with chronic GVHD should receive two doses (one month apart) (AII).					

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Vaccine-specific comments	
RSV	Few data in HCT recipients. RSV vaccine is safe and induces weak response in HCT (BII) recipients—seroconversion around 35%, T-cell response around 70%. Better response after the first year of HCT. Number of doses and the need of annual vaccination is unknown. In children ≤ 2 years old, consider nirsevimab yearly, from February to August. Available in special immunobiologics reference centers.
MCV	ACWY: At basic health units, only for 11 and 12 years of age. B: Adults up to 50 years old: two doses with an interval of one to two months between them. Adults ≥ 50 years old: the use is off-label (BII).
HAV	Serology (IgG) is recommended to evaluate specific antibodies and the need of vaccination. More than 90% of HCT recipients maintain antibodies for up to five years. The response to HAV vaccine in HCT recipients is poor ($\sim 30\%$) (BII).
HBV	Vaccinate after six to 12 months of HCT. Attention to the pediatric dose of the vaccine. Age and chronic GVHD decrease vaccine response (AII).
HPV	For HCT recipients from 9 to 45 years old, three doses, for both sexes (BII). HPV9 will be available soon in Brazilian public healthcare system as well.
RZV	Safe and effective in autologous HCT (AI). Few data on effectiveness in allo-HCT. Preliminary data showed seroconversion rate of $\sim 50\%$ (BII). The response is better if vaccination is done later, although it is most needed in the first six months of HCT.
LAVV	The attenuated varicella vaccine may be indicated in children (two doses) and in varicella-zoster seronegative adults (one dose) (BII).
MMR	In case of measles outbreak, MMR can be anticipated to the 12 th month of HCT and in patients with mild IS (BII).
YFV	To date, there are no reports of serious adverse events in HCT recipients vaccinated against yellow fever. Consider vaccination before transplantation, since 30% of vaccinees maintain antibodies after HCT (BIII).
DENV	No data in HCT recipients. However, HCT recipients may receive live-attenuated vaccines provided that the necessary safety requirements are met (CIII). Available in special immunobiologics reference centers and basic health units for children 10–14 years old, and in private clinics from 4 to 60. Currently only Qdenga (Takeda) is available in Brazil.

Source: Elaborated by the authors.

CONCLUSION

The prevention and management of infectious complications before and after HCT require a series of measures that must be developed and adjusted locally—with the participation of an infectious disease specialist—and implemented according to established protocols at HCT centers.

CONFLICTS OF INTEREST

Nothing to declare.

DATA AVAILABILITY STATEMENT

Data sharing is not applicable.

AUTHORS' CONTRIBUTIONS

Substantive scientific and intellectual contributions to the study: Nucci M, Machado CM, Gandolpho L, Breda GL, Garnica M, Ramos JF, Mendes AVA and Carlesse F. **Conception and design:** Machado CM. **Acquisition of data:** Nucci M, Machado CM, Gandolpho L, Breda GL, Garnica M, Ramos JF, Mendes AVA and Carlesse F. **Manuscript preparation:** Nucci M, Machado CM, Gandolpho L, Breda GL, Garnica M, Ramos JF, Mendes AVA and Carlesse F. **Manuscript writing:** Nucci M, Machado CM, Gandolpho L, Breda GL, Garnica M, Ramos JF, Mendes AVA and Carlesse F. **Critical revision:** Nucci M and Machado CM. **Final approval:** Machado CM.

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