Transplantation in People With HIV

Updated: September 12, 2024
Reviewed: September 12, 2024

Panel's Recommendations and Key Considerations
• People with HIV who are eligible for solid organ transplant (SOT) or hematopoietic cell transplant (HCT) should have equitable access to transplant (AII). • People with HIV should be managed by a multidisciplinary team before, during, and after transplant (AIII). • Transplant candidates with HIV should be up-to-date on their vaccination schedule (AIII).
Antiretroviral Drug Considerations Before Transplant
• In preparation for transplant, HIV providers should review the transplant candidate's antiretroviral (ARV) history, efficacy of the current ARV regimen, prior HIV drug resistance results, ARV adherence, and the potential for drug–drug interactions (AIII). • All ARV regimen changes should be guided by ARV history, along with current and prior HIV drug resistance testing results (AIII). • If switching to an alternative ARV regimen is necessary, changes should be completed several weeks before the transplant whenever possible to minimize drug–drug interactions in the post-transplant period and to assure tolerability and efficacy of the new regimen before transplant (BIII). • Tenofovir alafenamide (TAF) is preferred over tenofovir disoproxil fumarate (TDF) in transplant candidates and recipients due to the lower risk of affecting renal function and bone mineral density (AII). • To avoid significant drug–drug interactions between ARV drugs and anticipated immunosuppressive therapies, chemotherapies (for HCT), and prophylactic regimens for opportunistic infections, the following should be considered: o Unboosted second-generation oral integrase strand transfer inhibitor (INSTI)–based regimens (i.e., with bictegravir or dolutegravir) are preferred in most people with HIV needing transplant (AII). o In general, potent cytochrome P450 (CYP) 3A4 inhibitors—including pharmacokinetic boosters, such as ritonavir (RTV) or cobicistat (COBI), and protease inhibitor (PI)-containing regimens—should be avoided (AII). o In general, non-nucleoside reverse transcriptase inhibitors (NNRTIs) such as nevirapine (NVP), efavirenz (EFV), and etravirine (ETR), which are CYP3A4 inducers, should be avoided (AII).
Maintenance of Viral Suppression
• HIV viral suppression should be maintained before and after transplant (AIII).* • HIV providers with appropriate expertise should design alternative ARV regimen(s) that are likely to achieve viral suppression if post-transplant regimen changes are necessary (AIII).
Immediately Post-Transplant
• Immediately post-transplant, renal or hepatic function may fluctuate; close monitoring of these organ functions is recommended to ensure appropriate dosing of ARV drugs and other concomitant medications to avoid potential drug toxicities (AIII). • Interruption of antiretroviral therapy (ART) post-transplant should be avoided (AIII). • If interruption is necessary, all components of an oral ART regimen should be stopped simultaneously to avoid exposure to an incomplete regimen. The period of interruption should be kept to a minimal duration (AIII). • If a person cannot swallow pills, providers should consider using oral liquid formulation if available; alternatively, some pills can be crushed or dissolved for administration orally or via an enteral tube (AIII).

Post-Transplant
• Therapeutic drug monitoring for immunosuppressive drugs should be performed to guide dosing adjustments, especially before, during, and after the start or switch of ARV drugs that may interact with immunosuppressive drugs (AII). • The burden of medication increases significantly post-transplant. Providers should continue to evaluate for potential drug–drug interactions and overlapping toxicities with the addition of new medications (AIII). o When feasible, providers should consider consolidating ART using fixed-dose combination tablets and/or single-tablet regimens to minimize pill burden and bolster adherence (AIII).
Hepatitis B Virus or Hepatitis C Virus Coinfection
• All donors and recipients should be screened for hepatitis B virus (HBV) and hepatitis C virus (HCV) with a serological and/or nucleic acid amplification test, according to transplant guidelines (AIII). • Transplant candidates and recipients who are nonimmune to HBV (as measured by HBV surface antibody [HBsAb]) should be vaccinated, ideally before transplant (AIII). • HBV serology should be monitored after transplant for loss of HBsAb in order to guide the need for revaccination per professional society and transplant center guidelines (AIII). • Transplant recipients with active HBV infection should be treated with ARV regimens with anti-HBV activity before transplant and indefinitely after transplant (AIII). Use of nucleos(t)ide reverse transcriptase inhibitors (NRTIs) with activities against both HIV and HBV is strongly recommended unless contraindicated or not tolerated (AIII). • For management of recipients with HIV without HBV who receive an organ from a donor with markers of HBV infection, see guidance in the HBV-Positive and HCV-Positive Donors section below and follow appropriate institutional protocols. • All transplant candidates and/or recipients with HCV infection should be treated with direct-acting antivirals against HCV (AII).
Rating of Recommendations: A = Strong; B = Moderate; C = Weak *Rating of Evidence: I = Data from randomized controlled trials; II = Data from well-designed nonrandomized trials or observational cohort studies with long-term clinical outcomes; III = Expert opinion*
* In some cases, it may be necessary to interrupt ART due to intolerance of or inability to administer ARV drugs pre-transplant, such as in end-stage liver disease or when enteral access is limited. In these situations, the HIV provider should design a regimen that will result in viral suppression after transplant and resume therapy as soon as feasible.

General Principles When Managing People With HIV Before and After Transplant

Below are some key principles to follow when caring for people with HIV before and after transplant.

- Ensure that people with HIV have equitable access to transplant.
- Utilize a multidisciplinary approach.
- Maintain HIV viral suppression.
- Select or maintain an antiretroviral (ARV) regimen to minimize drug–drug interactions.
- Be aware of changes in renal or liver function.
- Perform therapeutic drug monitoring (TDM) of immunosuppressants for all transplant recipients.
- Consider pill burden.
- Consider and address hepatitis B virus (HBV) and hepatitis C virus (HCV) coinfection.

- Prevent infectious complications post-transplant with updated vaccination and antimicrobial prophylaxis.

Outcomes of Transplant in People With HIV and the Importance of Equitable Access to Transplant

Before the introduction of potent antiretroviral therapy (ART), people with HIV were systematically denied solid organ transplantation (SOT).[1] When performed, SOT was linked to unfavorable outcomes,[2] partly attributed to the use of older antiretroviral (ARV) regimens that included protease inhibitors (PI), which interact with immunosuppressive medications, such as calcineurin inhibitors or mTOR inhibitors.[3] SOT also had unfavorable outcomes in people with HIV and HCV coinfection before the era of direct-acting antivirals (DAAs) for HCV treatment.[4] The use of PIs also affects the choice of DAAs for HCV treatment. In the era of integrase strand transfer inhibitors (INSTIs) with fewer drug–drug interactions and the widespread availability of DAAs for HCV, recent cohorts have shown a reduction in the disparity of transplant outcomes between people with and without HIV.[5-7]

In people with end-stage renal disease (ESRD), those with HIV are less likely to be referred for kidney transplant than those without HIV. With the use of potent ART, kidney transplant in people with HIV is associated with a survival benefit over chronic hemodialysis, with high rates of recipient and graft survival at both 1 and 3 years post-transplant.[8] Lower but acceptable rates of recipient and graft survival have been reported with long-term (between 5 and 15 years) follow-up when comparing kidney and liver transplantation outcomes in people with HIV compared with recipients without HIV. This difference was primarily driven by lower rates of survival in people with HIV/HCV coinfection before the use of DAAs for HCV treatment.[6,9] In retrospective studies conducted in the post-DAA era, rates of recipient and graft survival in liver transplant recipients with HIV/HCV appear to be similar to people with HIV without HCV.[5,6] Acute rejection rates for kidney transplant recipients are higher in people with HIV than in recipients without HIV.[10]

Hematopoietic cell transplants (HCTs) in people with HIV are now the standard of care in people with hematologic malignancies for which HCT is indicated.[11] In most reported prospective and retrospective studies in the combination ART era, HIV status does not appear to impact the outcome of autologous or allogeneic HCT with respect to nonrelapse mortality. Allogeneic HCT is particularly intriguing due to its potential to significantly reduce HIV reservoirs or even achieve a cure, particularly when complete chimerism is achieved and the donor is CCR5delta32 homozygous. It is important to note that acute and even life-threatening viral rebound can occur if ART is discontinued after HCT. Planned ARV interruptions should only be attempted in the setting of a clinical trial.[11-16]

Given the improved outcomes and benefits to quality of life and other measures associated with transplantation, transplant eligibility should be equitable between people with and people without HIV **(AII).** Infectious complications and malignancy risk remain a concern post-transplant. For discussion of transplantation from donors with HIV to recipients with HIV, see Solid Organ Transplant Considerations From Donors With HIV below.

Multidisciplinary Approach

With the complexity of care required before, during, and after transplant in people with HIV, a multidisciplinary team approach is recommended, including transplant-specific specialists such as nephrologists, hepatologists, hematologists, infectious disease and HIV specialists, transplant

surgeons, pharmacists, nurses, and social workers **(AIII).** This approach is to ensure favorable outcomes and to effectively prevent and manage adverse events.

Antiretroviral Therapy Before, During, and After Transplant

This section of the guidelines will focus on special considerations for ART use before, during, and after SOT or HCT in people with HIV.

Maintain HIV Viral Suppression

Before and after a transplant, it is crucial to ensure that HIV suppression is maintained **(AIII).** This involves continuing ART as prescribed and closely monitoring viral load. Consistent adherence to ART is essential to prevent HIV viral rebound and maintain overall immune health. However, interruption of ART may be necessary in certain situations, such as intolerance of or inability to take oral ARV drugs pre-transplant, which may occur in some people with end-stage liver disease or when enteral access is limited post-transplant. In these situations, an ART regimen that will result in viral suppression after transplant should be resumed as soon as feasible**.**

Antiretroviral History and Review of Drug Resistance Testing Results

Before transplant and before starting, stopping, or changing any ARV drug, it is essential to review the person's ART history and any current and previous drug resistance testing results. This review guides the selection of an appropriate ARV regimen that will maintain or result in viral suppression.

If a person with wild-type HIV achieves and maintains viral suppression after starting ART, it is generally safe to assume that no drug resistance mutations have developed during that time. However, for people who have experienced virologic failure in the past, it is important to thoroughly review their resistance test results and their clinical and virologic responses to previous regimens when designing a new treatment plan.

Cumulative resistance test results encompass all previous and current test results, including genotypic, proviral DNA genotypic (if available), phenotypic, and tropism assays. Proviral DNA genotypic resistance testing can be considered in people with HIV who have suppressed viral loads and no prior drug resistance or unknown ART history information. In individuals with multiple treatment failures, proviral DNA genotypic testing may be useful but should be interpreted with caution. For additional information on proviral DNA assays, refer to the Drug Resistance Testing section.

Using the ART history and resistance results, one should be able to design at least one future suppressive regimen if changes are necessary.

Minimize Drug–Drug Interactions

Transplant recipients require multiple medications to prevent organ rejection, graft versus host disease (GVHD), and opportunistic infections, and to manage post-transplant complications. Polypharmacy can result in a complex array of drug–drug interactions. Consultation with a pharmacist with expertise in transplant, oncology, and/or HIV is recommended to aid with assessing and managing these challenging drug interactions.

Transplant-related drug interactions are commonly mediated by the cytochrome P450 (CYP) enzyme system. Below are some key principles for managing these drug–drug interactions.

- Use an ARV regimen with the lowest potential for drug interactions with medications used post-transplant, such as immunosuppressants, certain chemotherapeutic agents (for HCT recipients), azoles, corticosteroids, and acid-reducing drugs.
- Unboosted, oral, second-generation INSTI-based regimens (i.e., bictegravir or dolutegravir [DTG]) are preferred for most people with HIV needing transplantation **(AII).**
- In general, potent CYP3A4 inhibitors, including pharmacokinetic (PK) boosters such as ritonavir or cobicistat and PI-containing regimens, should be avoided **(AII).**
- In general, non-nucleoside reverse transcriptase inhibitors (NNRTIs) (e.g., efavirenz, etravirine, nevirapine), which are CYP3A inducers, should be avoided **(AII).** Among NNRTIs, doravirine (DOR) has fewer drug–drug interactions; however, experience with DOR in the transplant setting is limited.
- To minimize interactions in the post-transplant period and to assure tolerability and efficacy of the new regimen before transplant, whenever possible, any necessary ARV switches should be completed several weeks before the transplant **(BIII).**
- Therapeutic drug monitoring (TDM) of immunosuppressants is recommended for all transplant recipients; this is particularly important when drug–drug interactions with ARVs are expected **(AII).** Consultation with a pharmacist is recommended.

Drug Interactions Between Antiretroviral Drugs and Immunosuppressants

Immunosuppressants such as cyclosporine, sirolimus, and tacrolimus are mainstays of therapy post-transplant to prevent organ rejection or GVHD and are metabolized by CYP3A4.[17] These immunosuppressants have a narrow therapeutic window for efficacy and toxicity, and their drug concentrations may be impacted by ARV drugs that are CYP3A4 inhibitors or inducers because significant changes in their exposure may occur. There are limited data and experience evaluating interactions between newer ARV drugs and immunosuppressants, including a lack of published studies or case reports.[18-20] Immunosuppressant dose and target drug levels depend on the type of transplant, time since transplant, transplant center-specific protocols, transplant recipients' medical conditions, and other factors. Table 17a provides information regarding expected interactions based on available data and theoretical estimates. Safe and effective use of immunosuppressants should be guided by TDM.

Table 17a. Drug Interactions Between Antiretroviral Drugs and Immunosuppressants Used Post-Transplant

	Overview of Interaction Potential	Tacrolimus	Sirolimus	Cyclosporine
NRTI	↔ NRTI ↔ Immunosuppressant	Initiate standard doses. Monitor renal function if used with TDF.	Initiate standard doses. Monitor renal function if used with TDF.	Initiate standard doses. Monitor renal function if used with TDF.

Table 17a. Drug Interactions Between Antiretroviral Drugs and Immunosuppressants Used Post-Transplant

	Overview of Interaction Potential	Tacrolimus	Sirolimus	Cyclosporine
NNRTI	↔ NNRTI With EFV, ETR, and NVP • ↓ Immunosuppressant expected With DOR (A Weak Inducer) • ↓ Immunosuppressant possible With RPV • ↔ Immunosuppressant	Initiate standard doses and adjust based on TDM. With EFV, ETR, and NVP • May need higher doses With RPV • Monitor QTc with RPV.	Initiate standard doses and adjust based on TDM. With EFV, ETR, and NVP • May need higher doses With RPV • Monitor QTc with RPV.	Initiate standard doses and adjust based on TDM. With EFV, ETR, and NVP • May need higher doses. With RPV • Monitor QTc with RPV.
PI (With COBI or RTV as PK Booster)	↔ PI ↑ Immunosuppressant requiring dose reduction and/or extending dosing interval	↑ ↑ Tacrolimus Switch to a non-PI/c or PI/r-based regimen. If not possible, consider initiating tacrolimus 0.5 mg PO every 5–7 days. Adjust based on TDM.	↑ ↑ Sirolimus Switch to a non-PI/c or PI/r-based regimen. If not possible, consider initiating sirolimus 1–1.5 mg PO once weekly. Adjust based on TDM.	↑ CsA Consider initiating reduced dose of CsA at 5% to 20% of standard daily dose. Adjust based on TDM.
INSTI	↔ INSTI For BIC, CAB, DTG, or RAL • ↔ Immunosuppressant With EVG/c • ↑ Immunosuppressant with EVG/c	For BIC, CAB, DTG, or RAL • Initiate standard doses and adjust based on TDM. With EVG/c • ↑ ↑ Tacrolimus expected • Switch to a non–EVG/c-based regimen. If not possible, consider initiating tacrolimus 0.5 mg PO every 5–7 days. Adjust based on TDM.	For BIC, CAB, DTG, or RAL • Initiate standard doses and adjust based on TDM. With EVG/c • ↑ ↑ Sirolimus expected • Switch to a non–EVG/c-based regimen. If not possible, consider initiating sirolimus 1–1.5 mg PO once weekly. Adjust based on TDM.	For BIC, CAB, DTG, or RAL • Initiate standard doses and adjust based on TDM. With EVG/c • ↑ CsA expected • Consider initiating reduced CsA at 10% to 20% of total standard daily dose. Adjust based on TDM.
Capsid Inhibitors	↔ LEN expected ↑ Immunosuppressant expected	No data to guide dosing Adjust based on TDM.	No data to guide dosing Adjust based on TDM.	No data to guide dosing Adjust based on TDM.

Table 17a. Drug Interactions Between Antiretroviral Drugs and Immunosuppressants Used Post-Transplant

	Overview of Interaction Potential	Tacrolimus	Sirolimus	Cyclosporine
CCR5 Antagonist, Fusion, Attachment, and Post-Attachment Inhibitors	↔ ARV drugs expected ↔ Immunosuppressant expected	Initiate standard doses. Adjust based on TDM.	Initiate standard doses. Adjust based on TDM.	Initiate standard doses. Adjust based on TDM.

Key: ↔ = No clinically significant change; ↓ = decreased; ↑ = increased; ↑ ↑ = greatly increased; ARV = antiretroviral; BIC = bictegravir; CAB = cabotegravir; CCR5 = chemokine co-receptor 5; COBI = cobicistat; CsA = cyclosporine; DOR = doravirine; DTG = dolutegravir; EFV= efavirenz; ETR = etravirine; EVG/c = elvitegravir/cobicistat; INSTI = integrase strand transfer inhibitor; LEN = lenacapavir; NRTI = nucleos(t)ide reverse transcriptase inhibitor; NNRTI = non-nucleoside reverse transcriptase inhibitor; NVP = nevirapine; PI = protease inhibitor; PI/c = cobicistat-boosted protease inhibitor; PI/r = ritonavir-boosted protease inhibitor; PO = orally; QTc = QT corrected for heart rate; RAL = raltegravir; RPV = rilpivirine; RTV = ritonavir; TDF = tenofovir disoproxil fumarate; TDM = therapeutic drug monitoring

Drug Interactions Between Antiretroviral Drugs and Other Transplant-Related Medications

Transplant recipients often require other medications that may interact with ARV drugs via the CYP450 system or through decreased oral absorption due to altered gastric pH. These include azole antifungals, chemotherapy drugs, corticosteroids, and acid-reducing agents. A summary of these commonly encountered interactions can be found in Tables 24a to 24g. The table below is not comprehensive and is meant to highlight commonly used drug classes in transplant recipients with HIV.

Table 17b. Drug Interactions Between Antiretroviral Drugs and Medications Commonly Used in Transplant Recipients

Drug Class	Examples	Effects of Interactions
Azole Antifungals	Isavuconazole Itraconazole Posaconazole Voriconazole	CYP Inhibition (e.g., With RTV or COBI as PK Booster, Azoles)[a] • ↑ Azole concentration, ↑ toxicities • ↑ ARV concentration possible, ↑ toxicities CYP or Glucuronidation Induction (e.g., EFV, NVP) • ↓ Azole concentration, ↓ efficacy
Chemotherapy	Busulfan Cyclophosphamide Etoposide[b]	CYP Inhibition or Induction (e.g., With RTV or COBI as PK Booster) • ↑ or ↓ Chemotherapy concentration with RTV, ↑ toxicities, or ↓ efficacy • ↑ Chemotherapy concentration with COBI, ↑ toxicities CYP Induction (e.g., EFV, ETR, NVP) • ↓ Chemotherapy concentration, ↓ efficacy

Table 17b. Drug Interactions Between Antiretroviral Drugs and Medications Commonly Used in Transplant Recipients

Corticosteroids	Dexamethasone	Dose-Dependent CYP3A4 Induction • ↓ ARVs that are metabolized by CYP3A4
	High-dose Prolonged Use Prednisone/Prednisolone	CYP3A4 Inhibition (e.g., With RTV or COBI as PK booster) • ↑ Steroid concentration, ↑ toxicities
Acid-Reducing Medications	PPI, H2 Antagonists	Increase in Gastric pH • ↓ Absorption of certain ARVs, including ATV or RPV. See Table 24a and 24b for recommended timing of administration if concomitant therapy is needed.

Key: ARV = antiretroviral, ATV = atazanavir; COBI = cobicistat; CYP = cytochrome P450; CYP3A4 = cytochrome P3A4; EFV = efavirenz; ETR = etravirine; H2 = histamine 2; NVP = nevirapine; PK = pharmacokinetic; PPI = proton pump inhibitor; RPV = rilpivirine; RTV = ritonavir

[a] CYP inhibition by azoles can ↑ concentrations of immunosuppressants and certain cancer chemotherapy drugs.

[b] The listed are frequently used conditioning therapy pre-hematopoietic transplants that have potential interactions with ART. For other chemotherapeutic agents, consult a clinical pharmacist with expertise in transplant-related drug–drug interactions.

Considerations When Switching Antiretroviral Drugs Due to Drug–Drug Interactions

To minimize immediate interactions in the post-transplant period, whenever possible, any necessary ARV drug switches should be completed several weeks before the transplant **(BIII).** Waiting at least five half-lives would allow for adequate elimination of any interacting ARV drugs and/or PK booster prior to transplant. Switching ART by at least several weeks before transplant also allows clinicians to assess the tolerability and efficacy of the new regimen. Clinicians should be aware that discontinuation of certain ARV drugs may reverse previously stable drug interactions, therefore other comedications may need to be adjusted. For example, a person's immunosuppressant dose may need to be increased if the clinician is discontinuing a PI-based ARV regimen or the dose may need to be decreased if the clinician is discontinuing certain NNRTI-based regimens.

Changes in Renal or Hepatic Function

Following a kidney or liver transplant or after HCT, there may be abrupt changes in renal or hepatic function that may require dose adjustments of one or more drugs, including certain ARV drugs. All NRTIs except for abacavir (ABC) primarily undergo renal elimination and should be adjusted for dynamic changes in renal function. During the post-transplant period, it may be necessary to use individual components of ARV drugs instead of single-tablet regimens or fixed-dose combinations to allow for appropriate dose adjustments. Tenofovir alafenamide (TAF) is preferred over tenofovir disoproxil fumarate (TDF) because it has a lower risk of affecting renal function **(AII).** Because the rate of renal or hepatic function recovery can differ among recipients and immediate fluctuations may occur post-transplant, regular monitoring of organ function is important to ensure appropriate dosing of ARV drugs and minimize adverse effects or reduced efficacy (refer to Appendix B, Table 12 for ARV dosing in renal and hepatic insufficiency).

Alternative Methods for Antiretroviral Drug Delivery Post-Transplant

Interruption of ART post-transplant should be avoided **(AIII)**. If interruption is necessary, all components in an oral ART regimen should be stopped simultaneously to avoid exposure to an

incomplete regimen. The period of interruption should be kept to a minimal duration **(AIII).** If an ARV regimen includes both oral and long-acting injectable drugs (e.g., lenacapavir [LEN] or ibalizumab [IBA]) and interruption of the oral drugs is necessary, the oral ARV drugs should be resumed as soon as feasible to avoid monotherapy with the injectable agent.

If a transplant recipient cannot swallow pills immediately post-transplant, providers should consider using oral liquid formulation if available, or crushing and administering ARV drugs (if possible) to administer orally or via an enteral tube **(AIII).** Only a few ARV drugs are available in liquid formulations (Appendix B, Tables 1–12). Although PK data are limited, some ARVs can be temporarily crushed or dissolved and immediately administered orally or via an enteral tube until the recipients are able to swallow whole tablets (see more on Crushing and Liquid Antiretroviral Formulations). For people who require administration of crushed ARVs over an extended period of time, more frequent HIV viral load monitoring is recommended. If adequate oral absorption is a concern, TDM of certain ARV drugs may be considered.

Pill Burden and Post-Transplant Medication Management

Medications required for preventing graft rejection or opportunistic infections following SOT or HCT add significant pill burden and potential cost through medication copays. The complex medication schedule may also lead to medication errors and increased risk for suboptimal adherence. When renal and liver function are more stable, switching to single-tablet regimens or a fixed-dose combination ARV regimen (e.g., TAF or TDF with lamivudine [3TC] or emtricitabine [FTC]), dosed separately pre-transplant, can help reduce pill burden. Assisting transplant recipients with medication coordination, such as using a single pharmacy for dispensing all medications; attempting to synchronize refills to minimize trips to the pharmacy; and utilizing services such as adherence packaging, medication delivery, and refill reminders can also facilitate adherence. Medication and adherence counseling for transplant recipients and caregivers at each medical encounter is essential to ensure safe and effective therapy.

Impact of Medications on Adverse Effects and Comorbid Conditions

Close monitoring and prompt management of drug-associated adverse events is critical for all transplant recipients. Transplant medications, ARV drugs, and other medications may have some overlapping effects that can increase the risk or severity of toxicity. This overlap may have both short-term and long-term effects. Electrolyte disturbances may occur with sirolimus, tacrolimus, and cyclosporine. Of note, TDF may cause Fanconi syndrome, which could exacerbate the electrolyte disturbances. Similarly, nephrotoxicity associated with tacrolimus may also increase with concomitant TDF use.[21] All immunosuppressants are associated with side effects, such as nausea, vomiting, and diarrhea. These gastrointestinal side effects may be worsened when combined with ARV drugs, particularly PIs. While some of these adverse effects may be mitigated with symptomatic treatment, risk can be lowered pre-emptively by avoiding PIs and using TAF over TDF whenever possible.

In the long-term, people undergoing transplant are at high risk of developing new cardiovascular disease, diabetes, or osteoporosis.[22-24] If those conditions were present before transplant, they may worsen post-transplant. ARVs and/or transplant medications may play a role in the worsening of these conditions. Dyslipidemias associated with sirolimus or tacrolimus may be compounded by lipid disturbances associated with PIs or NNRTIs, such as efavirenz.[25,26] Cardiovascular events have been associated with ABC in some studies.[27] Fracture risk may be increased if corticosteroids are used in

combination with TDF.[28] Since TDF may negatively impact bone mineral density,[28] TAF is preferred over TDF **(AII).** Management of comorbid conditions in transplant recipients is highly individualized. Clinicians must consider the risks and benefits of adjusting stable ARV regimens versus using other medications to manage complications. If ARV regimens are adjusted post-transplant, selecting agents that have minimal impact on transplant-related comorbidities is helpful in optimizing therapy. (For more information, see Table 21. Antiretroviral Therapy-Associated Adverse Effects That Can Be Managed With Substitution of Alternative Antiretroviral Agents)

Considerations for Long-Acting Antiretroviral Drugs

Several important factors should be considered when making decisions to initiate or continue transplant candidates on long-acting (LA) injectable ARV drugs, including cabotegravir (CAB) and rilpivirine (RPV) (typically used together as a complete ART regimen), IBA, and LEN. Experience with these LA ARV drugs in transplant candidates is limited, and these agents have not been studied in the setting of severe hepatic disease, ESRD, or post-transplant. The impact of fluctuations in renal function, hepatic function, and fluid shifts that may occur around the time of transplant on the PK of these LA ARVs is largely unknown. Additionally, it should be noted that because LA ARVs may be difficult to obtain in the hospital, administration must be carefully timed to avoid any medication access issues and treatment interruptions.

The benefits of initiating LA CAB/RPV pre-transplant should be weighed against potential risks. People who are stable on LA CAB/RPV prior to transplant may be maintained on their regimen and monitored closely. For individuals with very low platelet counts or who require anticoagulation, intramuscular (IM) injections of LA CAB/RPV may need to be postponed. In these cases, initiation of a bridging regimen with oral CAB and oral RPV until IM injections can be resumed may need to be considered. If oral CAB is not available, DTG may be used in its place.

Although there are occasions when a transplant recipient may not be able to take oral medications immediately post-transplant, in general, this should be resolved within a few days. There are no data on temporarily switching to LA CAB/RPV as a bridging strategy in this instance and, therefore, this strategy is not advised.

IBA and LEN are two LA ARV drugs approved for use in people with multiple drug-resistant HIV. IBA is given as an intravenous infusion every 2 weeks, whereas LEN is given as a subcutaneous injection every 6 months. These drugs should not be started post-transplant just to reduce pill burden without other indications for their use. Transplant candidates on ARV regimens containing LEN or IBA likely have very limited alternative treatment options and should continue these LA ARV drugs as scheduled, in combination with any oral ARVs that are part of their complete regimen.

Because LA ARV drugs have very long half-lives, abruptly stopping any oral ARVs can lead to functional monotherapy with the LA ARV drugs, which may result in viral rebound and resistance. Therefore, the oral background regimen should be continued. People undergoing transplant who are maintained on these medications should be monitored closely for adverse events, drug interactions, and HIV viral load suppression. Drug interactions are an especially important consideration with LEN, which is a moderate CYP3A4 inhibitor (see Table 17a). There is a prolonged period of drug interaction risk due to the extended presence of LEN in the body. Clinicians may inadvertently miss these interactions if they are unaware that LEN is part of the ARV regimen, as clinic-administered

injectable LA ARV drugs are often listed separately from other ambulatory prescription medications in electronic health records.

Prevention of Infectious Complications Post-Transplant

Vaccination

Vaccination is a critical tool for preventing infections in all transplant recipients; however, the timing and some aspects of the approach to vaccination differ between SOT and allogeneic bone marrow transplant (BMT) candidates.

Timing of Vaccination

After registering as a transplant candidate and before SOT, there is typically a waiting period that provides an opportunity to assess vaccination status and update the vaccination record. It is important to consult the Centers for Disease Control and Prevention for up-to-date and specific vaccination recommendations, which include those for individuals with end-stage organ disease or immunocompromising conditions. Following an allogeneic BMT, vaccination plays a crucial role in restoring immune function and protecting against infectious diseases. Notably, the goal of vaccination in allogeneic BMT is to induce immune responses by the new engrafted donor immune system, not the pre-existing (recipient) one. However, vaccination strategies can vary based on the recipient's specific condition, transplant protocols, and recommendations from the transplant center. After allogeneic BMT, vaccination schedules are typically planned in phases, starting after the initial recovery period. Following that, vaccines are usually administered sequentially based on the transplant recipient's immune reconstitution status.

General principles for both SOT and allogenic BMT include the following:

- Vaccine recommendations for both SOT and BMT candidates and recipients should follow the same guidance as those recommended for those without HIV.
- In addition to reviewing standard pre- and post-transplant vaccine strategies described by the American Society of Transplantation Infectious Diseases Community of Practice, the need for additional vaccines based on HIV status (e.g., meningococcus) and/or exposure-related risk factors (e.g., mpox) should be assessed (see Immunization section of the *Guidelines for the Prevention and Treatment of Opportunistic Infections in Adults and Adolescents With HIV*).
- For people without HBV infection, HBV vaccination is important to maximize options for ARV simplification strategies that may involve tenofovir-sparing regimens.
- Inactivated vaccines, which do not contain live pathogens, are generally considered safe after BMT. These include vaccines such as influenza, COVID-19, pneumococcal, HBV, tetanus, and diphtheria, as well as the new recombinant zoster vaccine.
- Live vaccines—including the varicella-zoster virus (VZV) and measles, mumps, and rubella (MMR) vaccines—should be avoided in SOT recipients while on immunosuppressants and may not be recommended immediately after BMT due to the recipient's weakened immune system. The decision to administer live vaccines is based on the individual's clinical condition and time since transplantation.

Pre-transplant Screening for Infection Risk and Antimicrobial Prophylaxis

Prior to transplant, transplant candidates should undergo a detailed assessment for infection risk, including history of prior infections, travel history, and environmental exposures. Due to the increased risk of reactivation of latent infections (e.g., tuberculosis, Strongyloides), transplant candidates with HIV who are at risk for these latent infections should undergo screening to guide pre-transplant treatment to prevent reactivation and disease post-transplant. Active opportunistic infections are a contraindication for transplantation. Additionally, both HIV and the immunosuppression associated with transplant are risk factors for anogenital or cervical human papillomavirus-related malignancies.[29] Prophylaxis against bacterial, fungal, and viral diseases is a standard of care at transplant centers and is tailored to factors such as serostatus (e.g., cytomegalovirus) or geographic risk (e.g., coccidioidomycosis). Clinicians should also be aware of the risk for donor-derived infections, especially in the early transplant period.

For more information regarding the prevention and treatment of opportunistic infections and donor-derived infections, refer to the *Guidelines for the Prevention and Treatment of Opportunistic Infections in Adults and Adolescents With HIV* and center-specific protocols.

Recipient Considerations

HBV and HCV Coinfection

Due to overlapping risk factors, HBV and HCV coinfection is common in people with HIV. Both HBV and HCV are causes of cirrhosis that may lead to the need for liver transplant, and are also associated with extrahepatic manifestations such as diabetes mellitus, polyarteritis nodosa, membranoproliferative glomerulonephritis, and cryoglobulinemic vasculitis, which may contribute to ESRD.[30,31] Immunosuppression and chemotherapy (in cases of HCT) associated with transplant may result in loss of control of either HBV or HCV. Flares of active HBV or HCV following liver transplant begin with rises in HBV or HCV viral load, often followed by elevations in liver transaminases,[32,33] and can result in shortened graft survival. In those with only markers of prior HBV infection (core antibody [HBcAb] positive) and without evidence of active replication, HBV may reactivate from a latent state. Rarely, fibrosing cholestatic hepatitis results in rapidly progressive liver disease in transplant recipients.[34-38]

Assessment for HBV and HCV coinfection should occur at entry into HIV care and periodically for those at risk; status should be updated during the pre-transplant period. Transplant candidates or recipients who lack immunity to HBV (as indicated by negative HBV surface antibody [HBsAb]), including those with HBsAb loss, should receive vaccination regardless of HBcAb status and ideally before SOT.[39] Despite repeated attempts at vaccination, some people with end-stage organ disease or immunosuppression do not respond serologically and thus may be at risk for flares. Those undergoing allogeneic HCT generally undergo vaccination after the procedure.[40] For additional information regarding ARV drugs for people with HIV/HBV coinfection, refer to the Hepatitis B Virus/HIV Coinfection section.

Candidate/Recipient Considerations

Candidate/recipient is HBsAg positive. In people with active HBV (HBV surface antigen [HBsAg]–positive) coinfection, it is important to include either TAF or TDF as part of the ARV regimen, with the goal of suppressing both viruses. Both TAF and TDF are active against HBV, and

either can serve as the only active agent for HBV, although they are often used in combination with 3TC or FTC in people with both HIV and HBV. If TAF or TDF cannot be included, another potent anti-HBV drug—entecavir—should be initiated. Entecavir has weak anti-HIV activity and is not considered part of the ARV regimen but can induce nucleoside resistance mutation (M184V) and thus should never be used without a fully active ARV regimen.[41] Due to the low barrier to resistance and high likelihood for viral rebound, the use of 3TC or FTC as the only anti-HBV drug in individuals with HBV/HIV coinfection **is not recommended.**

Maintaining regimens with anti-HBV activity before transplant and indefinitely after transplant is recommended for transplant recipients with HIV and active HBV infection due to the risk of HBV reactivation and the potential for severe liver damage, including fulminant liver failure.

Candidate/recipient is HBcAb positive, HBsAg negative, and HBsAb negative or positive. The risk of HBV reactivation in the transplant recipient depends on the type of transplant, the depth of immunosuppression, and the presence of HBsAb. For liver transplant recipients who are HBcAb positive without evidence of active HBV (negative serum HBsAg and HBV DNA), reactivation risks are considered negligible due to removal of the potential liver reservoir. By contrast, in non-hepatic transplant recipients with markers of past infection, reactivation may occur in up to approximately 5%, usually during the first year, when immunosuppression is most intense and in the absence of protective levels of HBsAb.[42] This risk can be further abrogated if anti-HBV agents are already part of the ART regimen and by boosting HBsAb levels with vaccination. For non-hepatic transplant recipients not already on agents with anti-HBV activity, periodic prophylaxis or monitoring (regular measurements of transaminases and if newly elevated, rapid HBV DNA) strategies may be deployed to the highest-risk recipients per institutional protocol.[43,44]

Candidate/recipient is HCV RNA positive. All transplant candidates and/or recipients with HCV infection should be treated with DAAs against HCV **(AII),** preferably prior to transplant. Exceptions to this principle might include select candidates awaiting liver transplant, with a short waiting time for transplant (e.g., high Model for End-Stage Liver Disease, or MELD, score),[45] or select candidates for non-liver transplants who elect to defer treatment to remain eligible for donor organs from HCV viremic donors,[46-48] per discretion of the transplant providers. For those deferring treatment for HCV before transplant, treatment should be initiated early in the post-transplant period.[49-51] Additional considerations for the care of people with HIV and HCV, including fibrosis assessment, are found in the Hepatitis C Virus/HIV Coinfection section.

Donor-Related Considerations

HBV-Positive and HCV-Positive Donors

Organs from donors with serologic or virologic markers of HBV or HCV infection may be considered when recipients have given informed consent and providers have determined that benefits outweigh potential risks.[52,53] Antiviral treatment for recipients prior to transplantation can help prevent or manage post-transplant infection. Additionally, monitoring for donor-derived transmission and close follow-up of the recipient post-transplantation are necessary to detect and manage any potential infection.

Donor is HBcAb and/or HBsAg positive. To expand the size of the donor pool, use of HBcAb positive/HBsAg negative organs has become common practice.[54] More rarely, donors who are HBsAg positive are also utilized.[55] Without prophylaxis or recipient immunity (presence of surface

antibody), the risk of HBV transmission from such donors is present for non-hepatic organs and is extraordinarily high for liver transplants. Strategies to mitigate the risk of donor-derived HBV include pre-transplant vaccination, nucleos(t)ide therapy, and—particularly for liver transplant recipients who receive HBsAg-positive organs—hepatitis B immunoglobulin.[56] Anti-HBV agent prophylaxis may be deployed for moderate to high-risk recipients, with the highest risk (liver transplant recipients) receiving lifelong nucleos(t)ide analogues. Organ recipients with HIV may continue on regimens that already include tenofovir; those on tenofovir-sparing regimens pre-transplant may require the addition of anti-HBV agents such as tenofovir or entecavir. 3TC or FTC alone is not preferred for this indication.

Donor is HCV antibody or HCV RNA positive. The safety of using organs from HCV antibody-positive donors in both HCV viremic and aviremic recipients has been established, especially with early initiation of antivirals in the post-transplant setting.[45-48,51,57-62] Although untreated chronic HCV infection may have an accelerated course in people with HIV and SOT, early and effective treatment abrogates this risk substantially. Transplant candidates with HIV without current HCV infection should consider accepting HCV viremic organs if prompt DAA therapy is available at their center (see the Hepatitis C Virus section for more information).

Solid Organ Transplant Considerations From Donors With HIV

Kidney transplantation demonstrates survival benefit compared to dialysis for people with HIV and ESRD.[63] Previously, the use of organs from donors with HIV was banned. After a successful study of transplanting kidneys from donors with HIV into recipients with HIV in South Africa, the U.S. HIV Organ Policy Equity (HOPE) Act was approved in 2013, amending the law to allow transplantation of organs from donors with HIV into recipients with HIV (HIV D+/R+) under research protocols.[64]

For transplant candidates, eligibility criteria for HIV D+/R+ transplantation are the same as standard transplant criteria. For donors, federally mandated research criteria require that donors do not have active opportunistic infections.[65] Organs from donors with any CD4 lymphocyte cell count or viral load are allowed; however, transplant teams need to consider the likelihood of any ART resistance in the donors and justify whether an ART regimen in the recipient will be effective and tolerated.[65] To date, INSTI resistance has been rare in deceased donors with HIV.[66]

Early studies have shown excellent outcomes of HIV D+/R+ kidney and liver transplantation.[64,67] Based on this, the federal Advisory Committee on Blood and Tissue Safety and Availability has recommended to the U.S. Department of Health and Human Services that HIV D+/R+ kidney and liver transplantation be moved outside of research and into clinical care.[68] Due to the paucity of outcome data, HIV D+/R+ heart or lung transplantation remains under research protocols for now.[68] HIV D+/R+ kidney transplantation has been shown to decrease wait times for transplant.[69] SOT candidates with HIV may therefore consider being listed at a center currently offering organs from donors with HIV, if feasible.

As organ allocation in the United States occurs at a national level, all people with HIV may register as organ donors regardless of their distance from these centers, as their organs would only be directed to transplant candidates with HIV.[70] In addition, people with HIV may be living organ donors under HOPE Act research protocols.[68,71]

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