

# Solid Organ Transplantation is a Reality for Patients with HIV Infection

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Recent policies, guidelines, and laws reflect promising preliminary outcomes among transplant recipients with HIV infection, and ethical analyses suggest that it is not justifiable to deny solid organ transplantation based solely on HIV-infection status. These studies consistently describe stable HIV disease following liver and kidney transplantation. Despite good graft survival, kidney allograft rejection occurs frequently, and serious non-AIDS-defining infections requiring hospitalization are common following antirejection therapy. Profound interactions between immunosuppressants and antiretroviral drugs require careful monitoring, dose adjustment, and highly effective communication between the patient and a multidisciplinary group of health care providers. Despite these scientific and policy advances, many health care providers and patients remain unaware of ongoing progress in this field. The implications are critical, as late referral for liver transplant evaluation increases the pretransplant mortality risk. Because important patient selection and clinical management questions remain, it is critical that ongoing studies are completed quickly.

## Introduction

With reductions in AIDS-related mortality, patients with HIV infection are dying and experiencing significant morbidity from end-stage liver and kidney disease and are, thus, potential transplant candidates [1–7]. Several authors argued as early as 2002 that advances in the management of HIV disease make it unethical to deny solid organ transplantation to this population based upon futility arguments alone [8–10]. In the past

year, health policy groups from Spain and the United Kingdom and the United States Veteran's Administration have published guidelines describing the selection and management of HIV-infected liver and kidney transplant candidates and recipients [11–13]. The California senate passed an Assembly Bill (AB228) prohibiting third-party payers from declining coverage for transplantation based upon HIV status alone. Despite these policy advances, many health care providers and patients remain unaware of ongoing progress in this field. Delays in referral for transplant evaluation result in potentially avoidable deaths [4,6].

Before recent publications described favorable outcomes among HIV-infected transplant recipients taking highly active antiretroviral therapy (HAART), the understandable concern was that the immunosuppression required to prevent graft rejection would accelerate HIV disease progression. Preliminary studies consistently suggest that HIV disease is stable following liver and kidney transplantation [14,15,16•,17•,18•,19•]. In all of the published literature, only three patients developed an AIDS-defining opportunistic infection or neoplasm, including a case each of cytomegalovirus and *Candida* esophagitis [15,16•]. A third patient with Kaposi's sarcoma and multicentric Castleman's disease was in complete remission at 31 months post-transplantation [20]. CD4+ T-cell counts have also been stable over time, except following the treatment of kidney rejection with thymoglobulin [14,19•,21•]. Despite significant drug interactions and modifications in immunosuppressant dosing, HIV RNA has been well-controlled in all the published studies describing patients on antiretroviral therapy.

Recent publications also address questions about the impact of HIV infection and antiretrovirals on graft function and about the pharmacokinetic interactions between antiretroviral and immunosuppressant agents. Despite good graft survival rates, kidney allograft rejection occurs much more frequently than in recipients who are HIV-negative [14,16•]. Potent antirejection therapy is associated with the development of serious non-AIDS-defining infections requiring hospitalization [21•]. Characterizing the

complex interactions between immunosuppressant and antiretroviral agents has enabled the management of these drugs through careful monitoring and frequent dose adjustments [22•]. Recognizing the need for additional data to guide clinical practice, a study sponsored by the National Institutes of Health is ongoing at 20 transplant centers in the United States ([www.HIVtransplant.com](http://www.HIVtransplant.com)).

### Kidney Transplant Outcomes

Overall, studies of kidney transplant recipients demonstrate patient and graft survival rates that are comparable to those in the general transplant population [14,16•,18•,19•]. They also illuminate the difficult balance of preventing allograft rejection without developing immunosuppressant-associated infectious complications or nephrotoxicity. Despite good graft survival and function, the infectious consequences of potent rejection therapy are significant [21•]. Fortunately, AIDS-defining opportunistic complications are rare even though CD4+ T-cell counts can be profoundly suppressed for months following the use of thymoglobulin. HIV viremia remains under good control in the face of complex drug interactions in most transplant recipients.

A recent prospective analysis of 40 kidney transplant recipients from Drexel University largely supports the good patient and graft survival rates described in a prior retrospective review of 47 patients with HIV infection identified in the United States Renal Data System [18•,19•]. Another prospective study of both kidney and liver transplant recipients in the HAART era was initiated in 1999 [14]. Twenty-nine subjects, including 18 kidney recipients, were subsequently enrolled at four transplant centers through 2003 [16•]. There are four additional published cases in the HAART era of HIV-infected kidney transplant recipients from the University of Pittsburgh and one case from Switzerland [23,24]. In all of these studies and case reports, patient and graft survival rates were similar to those seen in HIV uninfected recipients, there were few AIDS-defining opportunistic infections, and CD4+ T-cell counts and HIV RNA levels remained relatively stable in the post-transplant period.

Unexpectedly high rejection rates were seen in the earlier prospective study [14,15,16•]. Fortunately, there have been few graft losses, and renal function is generally preserved despite these rejection episodes. Rejection episodes were less common, but renal function perhaps poorer, in the recent prospective study where more aggressive immunosuppressant regimens were used [19•]. The higher median creatinine in this study may have resulted from renal toxicity related to calcineurin inhibitors and/or calcineurin metabolites or

use of more marginal extended criteria donors. Potent antirejection therapy has not been associated with the development of AIDS-defining opportunistic infections, despite profound and prolonged suppression of CD4+ T-cell counts [21•]. Therapy with thymoglobulin is associated, however, with an increased risk for serious infections requiring hospitalization. Identifying the etiology of these rejection episodes is a priority of ongoing research studies.

### Liver Transplant Outcomes

Similar to the studies of HIV-infected kidney recipients, liver transplant recipients have had favorable outcomes overall [17•,20,25–29]. Despite high rates of lamivudine-resistant hepatitis B in this population, hepatitis B virus (HBV) infection appears to be easily controlled post-transplant [25,30]. The outcomes of hepatitis C virus (HCV) and HIV co-infected liver transplant recipients have been less consistent across transplant centers; appropriate patient selection and post-transplant management strategies remain uncertain among this population [17•,25]. A case of Kaposi's sarcoma and multicentric Castleman's disease responded to therapy in a liver transplant recipient who is reported to be alive and well nearly 3 years post-transplant [20].

A multisite analysis of 24 liver transplant recipients with HIV infection from the Universities of Pittsburgh, Miami, California at San Francisco, Minnesota, and King's College in London was led by investigators at the University of Pittsburgh [17•]. The cumulative survival at years 1, 2, and 3 (87%, 73%, and 73%) was similar to age and race matched HIV-negative recipients from the United Network for Organ Sharing (UNOS) database (87%, 82%, and 78%). Although HCV infection was associated with poorer survival in this analysis (50% vs 100% in those without HCV,  $P = 0.023$ ), as it is among HIV-negative transplant recipients, the difference in survival between HCV monoinfected and HCV-HIV co-infected individuals did not reach statistical significance at the  $P < 0.05$  level ( $P = 0.058$ ).

Additional reports of liver transplants, some of which were included in the Pittsburgh-led analysis, include 14 cases from King's College in London, 12 cases from Germany, 11 cases from the US prospective multisite study of kidney and liver transplants described previously, eight cases from Spain, and one case from The Netherlands [14,16•,20,25–29]. Five of seven HCV co-infected patients from King's College died, three from HCV-associated cirrhosis and one in the setting of significant HCV recurrence, a median of 161 days post-transplantation. There was no recurrence of HBV infection among four patients in this cohort. Deaths reported from the other European and US liver

transplant studies include three from recurrent HCV, one from hepatic artery thrombosis and sepsis, one from chemotherapy-induced liver damage, one due to rhizopus infection more than 4 years post-transplant, one from postoperative pancreatitis, and one from a procedural complication. An avoidable death resulted from a severe rejection episode precipitated by HAART discontinuation leading to very low immunosuppressant levels. This case reinforces the importance of communication among all health care providers prior to making changes in medication regimens.

### When Should Patients with End-stage Liver or Kidney Disease be Referred for Evaluation?

The natural history of HCV infection is accelerated in the context of HIV infection. It appears that the death rate is higher among HIV-infected than uninfected transplant candidates undergoing evaluation or awaiting an organ; delays in referral result in unnecessary mortality during the pretransplant evaluation process [4,6]. It is critical that HIV clinicians, hepatologists, and patients are aware that liver transplantation is an option for patients with HIV infection at an increasing number of transplant centers (see study referral sites at [www.HIVtransplant.com](http://www.HIVtransplant.com)). Patients should be referred for liver transplantation evaluation following any clinical decompensation with hepatic encephalopathy, ascites, or variceal bleeding. Patients with cirrhosis and evidence of liver synthetic dysfunction with low albumin and an elevated prothrombin time may be referred as well.

End-stage renal disease and dialysis also are associated with substantial morbidity and mortality in HIV-infected and uninfected patients [31–33]. Potentially eligible patients on hemodialysis or peritoneal dialysis should be referred for kidney transplant evaluation. Patients with a creatinine clearance or glomerular filtration rate of less than 25 mL/min who have not yet initiated dialysis should be referred for evaluation; they will start to accumulate time on the UNOS transplant waiting list when their glomerular filtration rate is less than 20%.

### Managing Complex Drug Interactions

The immunosuppressant medications cyclosporine, tacrolimus, and sirolimus and protease inhibitors interact pharmacokinetically due to metabolism by cytochrome p4503A enzymes [22,34–36]. Immunosuppressant doses necessary to achieve adequate levels are much lower in patients taking protease inhibitors, and often require further reductions over time. Efavirenz is a P4503A inducer that might require increased

immunosuppressant dosages. When both a protease inhibitor and a non-nucleoside reverse transcriptase inhibitor are used, immunosuppressant dosages are similar to those used with protease inhibitors alone. Inadequate immunosuppressant levels result in rejection and high levels cause significant toxicities. Thus, all medication changes, including those involving antibiotics, antifungals, and other agents that are metabolized by the hepatic P450 system, should always be discussed with the transplant team prior to implementation.

In general, the antiretroviral regimen that makes most sense from an HIV suppression perspective should be continued post-transplant. Whenever possible, atazanavir should be avoided because proton pump inhibitors (PPI) are nearly universally used indefinitely following transplantation, and PPI-use is contraindicated in patients on atazanavir. The additive myelotoxicity of zidovudine and the post-transplant immunosuppressive and prophylactic medications makes this a less desirable agent for use following transplantation. Also, it is reasonable to limit the use of zidovudine and stavudine when mycophenolate mofetil is used due to the *in vitro* antiretroviral antagonism between these agents [37–39].

Management of the HIV and HBV co-infected patient requires virologic suppression and avoidance of drug resistance with both viruses. Lamivudine, emtricitabine, and tenofovir have activity against and can thus generate resistance with, both HIV and HBV. Adefovir and entecavir are active against only HBV and do not select for HIV drug resistance mutations. Fortunately, HBV-HIV co-infected patients who are at high risk of having lamivudine resistance HBV usually experience ongoing suppression of HBV in the post-transplant period [25,30]. In addition to antivirals, high dose hepatitis B immune globulin is used indefinitely following transplantation.

### Solid Organ Transplantation for Patients with HIV Infection: No Longer “If,” but “Who” and “How”

HIV disease progression among HIV-infected patients who received transplants prior to the HAART era was probably accelerated due to advanced HIV-associated immunosuppression and less sophisticated infection prophylaxis than currently available [40–46]. Thus, solid organ transplantation should be offered to otherwise eligible individuals with relatively intact immune systems and controllable HIV viremia. Currently accepted HIV-specific criteria for transplantation are likely to evolve with increasing experience with HIV and transplantation (Table 1).

**Table 1. Current HIV-specific selection criteria in multisite study of liver and kidney transplantation in patients with HIV infections**

All candidates	Kidney candidates	Liver candidates
Excluded OI history: progressive multifocal leukoencephalopathy, chronic intestinal cryptosporidiosis (> 1 month), lymphoma (Burkitt's, immunoblastic or brain)	CD4+ T cell $\geq$ 200/mL  Children: 1–2 years-old: CD4 % $\geq$ 30; 2–10 years-old: CD4 % $\geq$ 20%  On HAART	CD4+ T cell $\geq$ 100/mL or $\geq$ 200/mL if there is a history of opportunistic complication  Children: 1–2 years-old: CD4 % $\geq$ 30; 2–10 years: CD4 % $\geq$ 20%
Documented multidrug-resistant fungal infection not expected to respond to available oral antifungal agents	HIV RNA undetectable using an ultrasensitive assay	HIV RNA undetectable using an ultrasensitive assay or if not on HAART or recently started or reinitiated HAART. May have detectable viral load, if an HIV clinician confidently predicts HIV suppression post-transplant.

HAART—highly active antiretroviral therapy; OI—opportunistic infection.

For kidney transplant candidates, CD4+ T-cell counts should be greater than or equal to 200 cells/mL prior to transplant. For liver transplant candidates who have never had an AIDS-related opportunistic infection, the CD4+ T-cell count should be greater than or equal to 100 cells/mL prior to transplant. They should be greater than 200 cells/mL for those with an opportunistic complication history. Many patients with end-stage liver disease experience a decline in their CD4+ T-cell count in the days and weeks prior to transplantation. The CD4+ T-cell requirement may be applied to any point in the 3 to 4 months prior to transplantation, and allowed to decline below this level as the individual gets closer to transplant. Because interferon treatment of HCV causes a transient decline in CD4+ T-cell count, the level prior to initiation of HCV therapy may be more appropriate to consider for transplant eligibility.

Generally, HIV RNA should be undetectable in those on HAART. Although most studies and programs exclude patients with highly drug-resistant HIV and detectable HIV RNA but stable CD4+ T-cell counts from transplantation, it may be reasonable to consider such patients on a case-by-case basis. Patients who have never been on antiretrovirals and have never had detectable HIV RNA may not need to initiate antiretroviral therapy prior to or following transplantation, although there is a risk of uncontrolled viral replication in the context of post-transplant immunosuppression [23]. For liver transplant candidates who are unable to tolerate or have recently initiated HAART, an experienced HIV clinician should confidently predict post-transplant HIV RNA suppression with HAART, based upon review of the antiretroviral treatment, HIV RNA and antiretroviral resistance test history.

AIDS-related opportunistic infections or cancers must be completely treated prior to transplant. Cur-

rent studies continue to exclude those diseases for which there is no reliable therapy should they recur post-transplant (eg, progressive multifocal leukoencephalopathy and chronic cryptosporidiosis). Kaposi's sarcoma (KS) is a challenging area because of the seriousness of post-transplant KS that often results in sacrifice of the allograft. Fortunately, there is one case in the literature of a man with a history of KS that did not recur following transplantation and one case of de novo KS that resolved in the post-transplant period [47,48]. We know of two other such cases, both with good outcomes. Many centers allow patients with a history of cutaneous, but not systemic, KS to be listed for transplant.

Following transplantation, opportunistic infection prophylaxis will include both standard post-transplant prophylaxis and HIV-related prophylaxis. Communication between transplant and HIV clinicians is critical in this area as neither are likely to have all the necessary expertise to prophylax against and diagnose opportunistic complications associated with both HIV and post-transplant immunosuppression, particularly outside of a study setting. Patients with a prior history of opportunistic infection should receive secondary prophylaxis based upon CD4+ T-cell counts, regardless of the etiology of the decline [49]. Secondary prophylaxis should also be reinstated in the immediate post-transplant period and in the case of treatment for acute rejection regardless of CD4+ T-cell count. Of note, *Pneumocystis carinii* pneumonia prophylaxis should continue for life regardless of CD4+ T-cell count. HIV-infected transplant recipients with low CD4+ T-cell counts should receive macrolide prophylaxis against *Mycobacterium avium* complex with weekly azithromycin as it has less potent drug interaction potential than clarithromycin. Patients with CD4+ T-cell counts below 50 cells/mL should have biannual ophthalmologic exams to screen for cytomegalovirus

retinitis. Those with cytomegalovirus viremia should also have regular dilated fundoscopic exams regardless of CD4+ T-cell count.

Pretransplant health care maintenance includes up-to-date Pneumovax and hepatitis A and B vaccines; purified protein derivative screening and appropriate treatment (this can be initiated pre-transplant and completed post-transplant); dental screening and care; and cervical pap smear and/or colposcopy screening. Both women and men with HIV are at increased risk of developing human papillomavirus-associated anorectal cancers [50]. They should be screened with anal pap smears and colposcopy where available. Skin cancer is common following transplantation, requiring dermatologic monitoring. There is controversy about the rejection potential associated with influenza vaccination in the context of transplantation.

## Conclusions

The goals of the ongoing multicenter study of HIV-infected patients who undergo kidney or liver transplantation include: 1) providing patients and clinicians with information regarding the HIV-specific risks of transplantation and 2) providing clinicians with information necessary to manage complex drug interactions and assess and manage post-transplant complications. The study is also exploring underlying basic science mechanisms related to HIV, viral co-pathogens, drug interactions, and the alloimmune response that may explain patient outcomes and thus impact clinical management. The study is currently enrolling up to 125 liver and 150 kidney transplant recipients at 20 transplant centers ([www.HIVtransplant.com](http://www.HIVtransplant.com)). Significant progress has been made in demonstrating good overall short-term patient and graft outcomes in this population, and we can conclude that patients with HIV infection should have access to solid organ transplantation. Many important clinical and pathogenesis related questions remain to be addressed in well-designed studies. Clinicians caring for patients with HIV infection should refer those with end-stage liver and kidney disease for transplant evaluation as outlined previously. The primary care provider should be prepared to work intensively with the transplant team in the evaluation and management of these patients.

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