HBV, HCV, HIV and Kidney Transplantation

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Objectives

• Prevalence of hepatitis B (HBV), hepatitis C (HCV) and human immunodeficiency virus (HIV) in ESRD population
• Transplant evaluation of patients with these viral infections
• Kidney transplantation in patients with HBV, HCV or HIV
  • Immunosuppression
  • Outcomes
  • New developments
HBV, HCV, HIV Infections

• Chronic HBV, HCV or HIV infections: were relative contraindications to kidney transplant in the past

• Concerns:
  • Effects of immunosuppressive drugs on viral replication, leading to acceleration of liver injury and progression to hepatocellular failure/death
  • Development of *de novo* GN in the graft
  • Serious opportunistic infections/malignancy
Case #1

- 54 year old AA male, on dialysis since 2007, blood group O
- Has polycystic kidney disease, **HIV positive**-diagnosed in 1993, and **hepatitis B surface antigen positive**
- Came in for kidney transplant evaluation
Case #1

What would be your recommendation?

• A-Transplant is contraindicated in this setting; no listing
• B-Advise to accept only a living donor kidney
• C-List for DD kidney transplant if no cirrhosis on liver biopsy and if patient is stable on antiretrovirals
• D-List for DD kidney transplant-no need for a liver biopsy, and advise to accept HIV/HbsAg positive kidney
Hepatitis B (HBV)

• The prevalence of chronic HBV infection: differs between regions
  • Low rates (≤2%) in Western Europe and the U.S
  • Intermediate rates (2–8%) in Mediterranean countries and Japan
  • High rates (8–20%) in Southeast Asia and Sub-Saharan Africa

• Successful vaccination in CKD/ESRD patients, improved infection control in dialysis units, and widespread use of EPO rather than blood transfusions for anemia
HBV Serologic Markers
Consensus Guidelines

• Positive HbsAg/HBV DNA/HbeAg: active infection
• Positive HbcAb IgM: a marker of acute or reactivated infection
• Positive HbsAb: immunity (anti-Hbs>10 IU/mL protective)
• Positive HbcAb: in the absence of HBsAg, could be a false positive result, past exposure with resolved infection, or rarely chronic HBV infection with detectable HBV DNA

Huprikar S, et al. AJT 2015
Transplant Evaluation of Patients with HBV

- All candidates should be screened
- Obtain serologies and HBV viral load
- All candidates who are HbsAg positive: must be referred to Hepatology
  - Most patients require a liver biopsy-to make sure that they do not have cirrhosis or portal hypertension
  - Assess the need for treatment
Impact of Pre-existing HBV Infection on Outcomes

- 1346 HBsAg+ recipients from UNOS database 2001-2007
- 5 yr death-censored graft survival 85.2% and patient survival 85.3% in HbsAg+; no significant difference from HBV- patients
- 5-yr cumulative incidence of hepatic failure higher in HBV+ recipients (1.3% vs 0.2%; $P < 0.001$)-still low, 5x risk of severe liver disease in HBV+ recipients

Reddy P, et al. CJASN 2011
HBV Therapies
Consensus Guidelines

- Effective HBV therapies have improved outcomes significantly
  - **Lamivudine** was the primary antiviral agent used for the treatment of chronic HBV both before and after transplantation
  - **New agents**: potent oral nucleoside analogs with a high genetic barrier to resistance such as **entecavir and tenofovir** (very low resistance rates (<1%) in treatment naive patients)

Huprikar S, et al. AJT 2015
# Antiviral Treatments for HBV Infection

<table>
<thead>
<tr>
<th>Drug</th>
<th>Anti-viral potency</th>
<th>Barrier to resistance</th>
<th>Side effects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adefovir</td>
<td>+</td>
<td>++</td>
<td>Nephrotoxicity, diabetes insipidus, Fanconi syndrome</td>
</tr>
<tr>
<td>Lamivudine</td>
<td>++</td>
<td>+</td>
<td>Lactic acidosis, pancreatitis</td>
</tr>
<tr>
<td>Emtricitabine</td>
<td>++</td>
<td>+</td>
<td>Lactic acidosis, anemia, leukopenia</td>
</tr>
<tr>
<td>Telbivudine</td>
<td>+++</td>
<td>+</td>
<td>Neuropathy, myopathy, elevated creatinine kinase</td>
</tr>
<tr>
<td>Entecavir</td>
<td>+++</td>
<td>+++</td>
<td>Lactic acidosis, transaminitis</td>
</tr>
<tr>
<td>Tenofovir</td>
<td>+++</td>
<td>+++</td>
<td>Nephrotoxicity, Fanconi syndrome, lactic acidosis, osteomalacia</td>
</tr>
</tbody>
</table>
Use of HBV-positive Donors (HbsAg negative and anti-HbcAb positive)

- UNOS database from 1994-1999: multivariate regression analyses—neither donor nor recipient anti-HbcAb status influenced the risk of graft failure or patient death

- Anti-HbcAb positive kidneys resulted in a higher incidence of anti-Hbc antibody seroconversion; was not associated with a higher incidence of HbsAg detection

Fong TL, et al. Transplantation 2002
• HBV vaccination is recommended for all non-immune (anti-Hbs antibody negative) transplant candidates and recipients
• HBV DNA with or without HbsAg should be monitored every 3 months for 1 year posttransplant
• HBIG is not recommended

Huprikar S, et al. AJT 2015
Case #2

- 56 yo AA male; on dialysis since 1/2015; blood group B
- Has history of diabetes, hypertension, and hepatitis C
- Came in for kidney transplant evaluation
- No potential living donors
Case-Hepatitis C

- HCV viral load 6.3 log-never been treated
- s/p liver biopsy: stage 2 fibrosis, no evidence of cirrhosis; no varices
- Liver enzymes, serum albumin and platelets are normal
- Waiting time for a DD kidney in the region: average 5 years
Case-Hepatitis C

What would you recommend for this patient to do?

• A-List for DD kidney transplant and start treatment with interferon and ribavirin
• B-List for DD kidney transplant and start treatment with DAAs
• C-List for DD kidney transplant; no HCV treatment now; advise to accept HCV positive kidneys and offer HCV treatment with DAAs posttransplant
• D-Kidney transplant is contraindicated in this setting; no listing
Hepatitis C (HCV)

• Estimated to affect approximately 170 million individuals worldwide
• Prevalence of HCV in patients with ESRD (worldwide 5% to 60%) far exceeds that of the general population (5-10% in the US)
• HCV-infected patients with CKD has an increased mortality and an accelerated rate of progression to ESRD
• Liver failure and hepatocellular carcinoma are the major long-term complications in chronic HCV-infected patients
• Patients co-infected with HIV have an increased mortality and overall worse prognosis

HCV and Kidney Transplant

• KDIGO (2008): all kidney transplant candidates should be tested for HCV infection via antibody screening or nucleic acid testing (NAT)

• All patients who are HCV NAT positive should be referred to Hepatology for liver biopsy to assess the degree of hepatic disease severity prior to transplantation

• Updated recommendations from 2017-ongoing

Transplant Evaluation of Patients with HCV

- Liver enzymes and HCV viral load correlate poorly with disease activity and liver fibrosis in advanced CKD
- Liver biopsy remains the “gold standard”
- Transient elastography (FibroScan) is emerging as a highly reproducible noninvasive technique—but liver stiffness is affected by central venous pressure
Meta-analysis (overall mortality): Patients with HCV infection on waiting list had **2.19 times higher** risk for death than patients who had kidney transplantation.

Transplant provides a survival benefit for HCV+ patients.

Benefit of kidney transplantation—approx **55% lower risk of death at 5 years**.

Waiting list group had **higher risk of cardiovascular diseases**.

Survival advantage particularly in HCV patients aged **45 years or older**.

*Ingsathit A, et al. Transplantation 2013*
• Meta-analysis: 18 observational studies; 133,530 renal transplant recipients
• Increased all-cause mortality in HCV+ patients due to cardiovascular dz
• HCV+ patient outcomes are inferior to HCV-
• Meta-regression showed that living donor rate had a favorable influence on patient (P = 0.031) and graft survival (P = 0.01), diabetes had a detrimental role on patient survival (P = 0.001)

• The link between HCV and **lower graft survival after kidney transplant** was demonstrated irrespective of reference year, country of origin or size of the study group

• **Causes of graft loss**: increased risk of new onset diabetes after transplant, recurrence of HCV-associated glomerulonephritis and chronic rejection/transplant glomerulopathy/TMA

*Fabrizi F, et al. J Viral Hepatitis 2014*
Immunosuppression in Patients with HCV

- UNOS database; 3708 HCV+ and 75,629 HCV- kidney transplant recipients
- Increased mortality risk for HCV+ kidney transplant recipients compared with HCV- recipients, particularly among younger age groups
- With HCV positive serology, the use of induction therapy was not associated with an increased mortality risk

• A lower mortality risk with induction was observed beyond the first 2 years after tx
• The choice of CNI (CsA or Tac) and use vs nonuse of steroids had no effect on patient mortality
• The use of MMF (yes vs no) was associated with a significantly reduced mortality rate

Use of HCV-positive Kidneys

- HCV+ organs to HCV+ recipients
- Overall shortage of suitable donor kidneys/long waiting times; not every center accepts these kidneys
- Usually limited to recipients who are viremic with genotype 1
- Risk of superinfection with other HCV genotypes
- With new direct-acting antivirals to cure HCV, no need to limit to genotype 1 recipients
• 162 HCVR+ received a kidney from HCVD+ (group 1) and 306 from HCVD− (group 2)

**Similar patient survival:** Five- and 10-year patient survival was 84.8% and 72.7% in group 1 vs. 86.6% and 76.5% in group 2 (p = 0.250)

**Decreased graft survival:** Five- and 10-year graft survival was 58.9% and 34.4% versus 65.5% and 47.6% respectively (p = 0.006)

**Decompensated chronic liver disease** was similar: 10.3% versus 6.2%.

Morales JM, et al. AJT 2010
Treatment of HCV

- KDIGO guidelines: treatment of HCV in all kidney transplant candidates—interferon based; low response rate and poor tolerability
- Treatment with interferon after transplant is not recommended—increased rejection risk
- New interferon-free direct acting antiviral (DAA) regimens—cure rates up to 90% and efficacious posttransplant as well—new treatment recommendations are underway

DAA Agents for Treatment of HCV - Targeting the Essential Proteins for HCV Replication

DAA-Based Regimens in HCV

Treat pretransplant

- Can remain active on the waitlist during therapy
- Cure of HCV is likely
- Prevent disease transmission
- Avoids drug-drug interactions with immunos
- Possible decreased risk:
  - Progressive liver disease
  - Posttransplant GN
  - New onset diabetes posttransplant

Do not treat pretransplant

- Efficacious and safe posttransplant
- Potential drug-drug interactions
- Cure eliminates HCV+ organ
  - Longer waiting time
  - Increased kidney discard rate

Sawinski et al. Transplantation 2015
Treatment of HCV

- Reactivation of hepatitis B infection following successful therapy of HCV infection with DAA-based therapy
- In patients with HCV and CKD, serum markers of HBV infection (HBsAg, HBV DNA) should be obtained prior to antiviral therapy
HCV Treatment

- The optimal timing of antiviral treatment: depends on the availability of a living donor or of an HCV+ kidney graft—shorter time to transplantation
- Issues: the extent of liver disease (severe disease calls for urgent DAA tx to halt worsening of liver disease+avoid the need for a liver transplant) and the HCV genotype (complexity of treatment in late CKD and dialysis)
- Awaiting the update of the KDIGO recommendations on HCV in CKD/posttransplant
- Patients might need to be treated if they have symptomatic vasculitis or if they are kidney recipients
- Patients with no significant fibrosis treatment may be postponed to the posttransplantation period

Pol S, et al. NDT 2017
FDA Approval
(Glecaprevir and Pibrentasvir)

- (HCV) genotypes 1-6 without cirrhosis (liver disease) or with mild cirrhosis, including patients with moderate to severe CKD or on dialysis
- Adult patients with HCV genotype 1 infection who have been previously treated with a regimen either containing an NS5A inhibitor or an NS3/4A protease inhibitor but not both
- Total of 8 weeks; headache, fatigue and nausea
- Contraindicated in patients taking the drugs atazanavir and rifampin
All patients cleared the virus quickly while on therapy, and 100% have achieved a sustained virologic response at 12 weeks after completion of DAA therapy.

Most commonly used regimen: sofosbuvir 400 mg + simeprevir 150 mg daily.

20 consecutive kidney recipients.

88% were infected with genotype 1; 50% had biopsy-proven advanced hepatic fibrosis on most recent liver biopsy.

60% had failed treatment pretransplant with interferon-based therapy.

Sawinski, et al. AJT 2016
Use of DAAs Posttransplant

<table>
<thead>
<tr>
<th>DAA</th>
<th>CYP3A4 Inhibition</th>
<th>Adjust Dose for eGFR &lt; 30 mL/min</th>
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</thead>
<tbody>
<tr>
<td>NS3 Protease Inhibitors</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Boceprevir</td>
<td>+++</td>
<td>–</td>
</tr>
<tr>
<td>Telaprevir</td>
<td>+++</td>
<td>–</td>
</tr>
<tr>
<td>Simeprevir</td>
<td>+</td>
<td>–</td>
</tr>
<tr>
<td>Paritaprevir (ritonavir boosted)</td>
<td>+++</td>
<td>–</td>
</tr>
<tr>
<td>NS5A</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ledipasvir</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>Ombitasvir</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>NS5B Nucleoside Inhibitor</td>
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<tr>
<td>Sofosbuvir</td>
<td>–</td>
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<tr>
<td>NS5B N006Fn-Nucleoside Inhibitor</td>
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<td>–</td>
</tr>
<tr>
<td>Dasabuvir</td>
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</table>

- DAA-immunosuppressive drug-drug interactions are very important
- CNI levels have been shown to fluctuate during and even after DAA treatment is completed
- Need for careful monitoring of kidney function and CNI drug levels both during and after therapy
- Combined efforts by hepatologists and transplant nephrologists

*Sawinski D, et al. Transplantation 2015*
HCV-positive Donors and HCV-negative Recipients

- Limited data across all organ transplants
- Wait time for transplant might be shorter by accepting an organ from an HCV-infected donor
- People injecting drugs to be the main source of HCV-viremic donors in next decade
- US data suggest that currently there are 300–500 additional (unrealized) opportunities for donation among HCV-viremic deaths and the trend increasing

Levitsky J, et al. AJT 2017
Transplanting Hepatitis C Kidneys into Negative Kidney Recipients (THINKER)

- Open-label, single-group, pilot trial at the University of Pennsylvania; (ClinicalTrials.gov number, NCT02743897)
- 10 patients received HCV-infected kidneys (median age: 59 years; half were men and 2 were black; median time from eligibility to transplantation was 58 days)
- Patient had detectable HCV RNA on day 3 posttransplant

Goldberg DS, et al. NEJM 2017
THINKER STUDY

• Nine had HCV genotype 1a infection; none had identifiable NS5A resistance
• Patients were treated with elbasvir–grazoprevir posttransplant
• All recipients were cured of HCV (sustained virologic response 12 weeks after the end of treatment)
• Proteinuria (at an estimated level of 2 g per day of urinary protein excretion) in one patient (FSGS on biopsy)

Goldberg DS, et al. NEJM 2017
The efficacy, safety, and tolerability of DAA therapy make transplantation of HCV-viremic donors into HCV-negative recipients feasible to study.

The transplantation of organs from HCV-viremic donors into nonviremic recipients should only be conducted under IRB-approved protocols with multistep informed consent processes.

Individuals likely to suffer clinical deterioration while waiting for an organ offer should be considered first, as the risk of remaining on the waitlist may outweigh the risk of donor-derived HCV infection.

Levitsky J, et al. AJT 2017
Hepatitis C

What would you recommend for this patient to do?

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- C-List for DD kidney transplant; no HCV treatment now; advise to accept HCV positive kidneys and offer HCV treatment with DAAs posttransplant
- D-Kidney transplant is contraindicated in this setting; no listing
HIV and Kidney Transplantation

- With HAART use, decline in HIV-related deaths; number of patients living with HIV increased.
- HIV is the third-leading cause of ESRD in African Americans after diabetes and hypertension.
- Kidney transplantation is now offered as an acceptable treatment option for HIV+ ESRD patients.
- High incidence of acute rejection.
- Increased risk of delayed graft function.
Evaluation of HIV Positive Candidates

- All patients are required to have:
  - CD4 count >200/mm³
  - An undetectable HIV viral load on stable antiviral therapy for at least 6 months prior to transplant
  - No significant opportunistic infections
  - Evaluation by Transplant Infectious Diseases
HIV and Kidney Transplantation

Locke J, et al. JASN 2015
• **PS:** similar for HIV-monoinfected recipients and HIV negative/HCV negative controls both at 5 years and 10 years

• **HIV/HCV coinfected recipients had worse PS** compared with HIV-negative/HCV positive controls

*Locke J, et al. JASN 2015*
Graft Survival-HIV+ Patients
(SRTR; 2002–2011; 510 adults, median follow-up: 3.8 years)

• GS: similar for HIV-monoinfected recipients and HIV negative/HCV negative controls both at 5 years and 10 years
• HIV/HCV coinfected recipients had worse GS compared with HIV-negative/HCV positive controls

Locke J, et al. JASN 2015
**HIV-Choice of Immunosuppression**  
*(SRTR: 2003-2011 data, 516 adults)*

<table>
<thead>
<tr>
<th>Induction therapy</th>
<th>HIV-negative (n=93,027)</th>
<th>HIV-positive (n=516)</th>
<th>P</th>
</tr>
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<tbody>
<tr>
<td>None</td>
<td>21.4</td>
<td>35.1</td>
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<tr>
<td>ATG</td>
<td>43.5</td>
<td>25.8</td>
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<tr>
<td>IL-2 inhibitor</td>
<td>23.1</td>
<td>33.5</td>
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</tr>
<tr>
<td>Alemtuzumab</td>
<td>12.0</td>
<td>5.6</td>
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<table>
<thead>
<tr>
<th>Maintenance therapy</th>
<th>HIV-negative (n=93,027)</th>
<th>HIV-positive (n=516)</th>
<th>P</th>
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</thead>
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<tr>
<td>None</td>
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<td>9.3</td>
<td>&lt;0.001</td>
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<tr>
<td>CNI-based</td>
<td>89.0</td>
<td>83.7</td>
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<tr>
<td>Sirolimus-based</td>
<td>6.1</td>
<td>7.0</td>
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<table>
<thead>
<tr>
<th>Induction therapy</th>
<th>Rejection (1 year, RR)</th>
<th>95% CI</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>Reference</td>
<td></td>
<td></td>
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<tr>
<td>ATG</td>
<td>0.39</td>
<td>0.18–0.87</td>
<td>0.02</td>
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<tr>
<td>IL-2 inhibitor</td>
<td>1.11</td>
<td>0.66–1.86</td>
<td>0.7</td>
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<tr>
<td>Alemtuzumab</td>
<td>1.6</td>
<td>0.8–3.2</td>
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</table>

<table>
<thead>
<tr>
<th>Maintenance therapy</th>
<th>Rejection (1 year, RR)</th>
<th>95% CI</th>
<th>P</th>
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<tbody>
<tr>
<td>CNI-based</td>
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</tr>
<tr>
<td>Sirolimus-based</td>
<td>2.15</td>
<td>1.2–3.87</td>
<td>0.01</td>
</tr>
<tr>
<td>Neither CNI or sirolimus-based</td>
<td>1.21</td>
<td>0.58–2.54</td>
<td>0.6</td>
</tr>
</tbody>
</table>

- HIV-positive patients had a **1.77-fold higher risk of AR** at 1 year compared with their HIV-negative counterparts (15% vs 8%).
- Among HIV-positive and HIV-negative patients receiving ATG induction therapy, the risk of AR was 1.16 and was not statistically different.
- HIV-positive patients that received **ATG induction had a 2.6-fold or 61% lower risk of AR at 1 year** compared with no induction therapy.
- Sirolimus-based therapy had a **2.2-fold higher risk of AR at 1 year**.

*Locke J, et al. Transplantation 2014*
• 830 HIV+ kidney transplant recipients (from 2000-2014, SRTR)
• HIV+ recipients who received induction spent fewer days in the hospital, had lower rates of DGF, less graft loss, lower rates of AR (with ATG induction), and a trend toward lower mortality
• Induction therapy was not associated with increased infections

Impact of Antiretroviral Therapies on Outcomes

- 332 HIV+ kidney transplant recipients
- Protease inhibitor (PI)-based regimens; associated with 1.8-fold increased risk of allograft loss (greatest risk observed in the first post-transplant year); 1.9-fold increased risk of death as compared to non-PI regimens
- Suggests- whenever possible recipients should be converted to a non-PI regimen prior to transplant

Sawinski D, et al. AJT 2017
HIV Medications and Immunosuppression

- Profound drug-drug interactions, especially with protease inhibitors
- Frequent drug level monitoring of CNIs
- New integrase inhibitors, CCR5-antagonists and fusion inhibitors cause significantly less pharmacokinetic interactions
- Must work closely with a Transplant Infectious Diseases expert
HIV and Kidney Transplantation

- Prospective, nonrandomized study of kidney transplantation in **27 HIV-infected patients** (CD4 count > 200 and undetectable HIV RNA level)-all on antivirals; **received HIV positive kidneys** - results at 5 years
- Patient survival: 84% at 1 year, 84% at 3 years, and 74% at 5 years; graft survival: 93%, 84%, and 84%
- Rejection rates were 8% at 1 year and 22% at 3 years.
- HIV infection remained well controlled, with undetectable virus in blood after the transplantation

*Muller E, et al. NEJM 2015*
Kidney as a Reservoir for HIV after Transplantation

- Protocol biopsies from 19 recipients with HIV-1 who did not have detectable levels of plasma HIV-1 RNA at transplantation
- HIV-1 infected the kidney allograft in 68% of these patients; HIV-1 infection was detected in either podocytes predominately (38% of recipients) or tubular cells only (62% of recipients)
- HIV-1 can re-infect kidney allografts after transplantation despite undetectable viremia, and this infection might influence graft outcome
- Close monitoring of proteinuria is needed after transplantation

HIV Organ Policy Equity Act (HOPE Act)

- Enacted on November 21, 2013
- Allows for the development and publication of criteria for research relating to transplantation of organs from donors infected with HIV into individuals who are infected with HIV
HIV-Infected Waitlist Candidates

- 1636 HIV+ and 72,297 HIV- kidney transplantation candidates
- HIV+ waiting list candidates: more often young (<50 years old: 62.7% vs 37.6%), men (75.2% vs 59.3%), black (73.6% vs 27.9%), had longer time on dialysis (2.5 yrs vs 0.8), coinfected with HCV (9.0% vs 3.9%), and were less likely to remain active on the waiting list (37.7% vs 49.4%)

HIV-Infected Waitlist Candidates

- Waitlist mortality among HIV+ candidates was similar compared with HIV- candidates
- Likelihood of living donor kidney transplantation was 47% lower
- A trend toward lower likelihood of deceased donor kidney transplantation
- Disparities in access to transplantation among HIV+ kidney waitlist candidates

Retransplantation (re-KT) in HIV+ Recipients

- SRTR data (2004-2013); 22 HIV+ vs. 4127 HIV-negative adult re-KT
- HIV+ re-KT recipients: more commonly AA (63.6% vs. 26.7%, p < 0.001), infected with hepatitis C (31.8% vs. 5.0%, p < 0.001) and had longer median time on dialysis (4.8 years vs. 2.1 years, p = 0.02)
- HIV+ re-KT recipients: had 3.11-fold increased risk of death and 1.96-fold increased risk of graft loss compared to HIV- re-KT recipients

Shelton BA, et al. AJT 2017
Case #1

- 54 year old AA male, on dialysis since 2007, blood group O
- Has polycystic kidney disease, HIV positive-diagnosed in 1993, and hepatitis B surface antigen positive
- Came in for kidney transplant evaluation
Case #1

What would be your recommendation?

- **A**- Transplant is contraindicated in this setting; no listing
- **B**- Advise to accept only a living donor kidney
- **C**- List for DD kidney transplant if no cirrhosis on liver biopsy and if patient is stable on antiretrovirals
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Summary

• HBV positive recipient outcomes have improved significantly with vaccination and antiviral therapy
• HbcAb positive organs can be used safely in most patients
• Treatment of HCV with interferon-free regimens is now possible; long-term studies needed
• HIV+ kidney transplant recipients have excellent patient and allograft survival