Meeting Summary:

Solid Organ Transplantation in HIV Positive Patients

Multi-Site Trial Planning Meeting

Hotel Sofitel, 1914 Connecticut Avenue NW
Washington, D.C.
August 12-14, 2000

This document is a companion piece to the Briefing Book
Please contact Charlie Everett at: ceverett@psg.ucsf.edu if you need a copy.

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  and Transplantation

The Emmes Corporation
  Dr. Donald Stablein, President
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SPECIFIC AIMS

- To evaluate the impact of kidney and liver transplantation, and post-transplant immunosuppression, on HIV disease progression and markers of immune function and activity.
- To evaluate the impact of HIV infection on graft function and survival.
- To describe the pharmacokinetic interactions between immunosuppressive agents and the hepatically metabolized antiretroviral (ARV) agents.

Review of Current Protocols for Kidney and Liver

- Common inclusion/exclusion criteria
- Kidney vs. liver: differences in eligibility
  - CD4, viral load, antiretroviral use
- Medication regimens
  - antiretrovirals, immunosuppressives, prophylaxis (transplant and HIV)
- Clinical and laboratory follow-up
- Special studies and donor issues

Common Eligibility Criteria

- No history of opportunistic infection or neoplasm
  - except fluconazole sensitive candida esophagitis
- No h/o aspergillus, TB, cocci, resistant fungal infections, specific neoplasia, recent flu or RSV
- No age limitations (peds ok)
- Monitoring (including biopsies) and treatment of HCV co-infection

Eligibility Criteria Differences

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<td>CD4 &gt;/= 200</td>
<td>CD4 &gt;/= 100</td>
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<tr>
<td>VL &lt; 50</td>
<td>VL &lt; 50 on stable ARV regimen or</td>
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<tr>
<td>Stable ARV regimen</td>
<td>Detectable viral load off ARVs but ability to predict full suppression post-tx</td>
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Medication Regimens

- Immunosuppressive Protocols
  - Cyclosporine-based therapy
  - Prednisone
  - Anti-metabolites: MMF or imuran
  - Standard rejection therapy
- Antiviral therapy
  - Optimize suppression of HIV-1 RNA
  - Minimize development of resistance
  - Avoid AZT, D4T (MMF interactions)
- Prophylaxis
  - pneumocystis, cytomegalovirus, fungal infections
  - MAC, TB
  - HCV: interferon and ribavirin
  - HBV: HBIG and lamivudine

Clinical Follow-Up Schedule

- 5 year follow-up
- Min. 6 GCRC visits (12-24-hour) at Week 1, 4, 6 months, and 1, 2 and 5 years + + +
  - --> weekly (x 4)
  - --> every other week (x 4)
  - --> monthly (x 2)
  - --> every 8 weeks (x 4)
  - --> every 12 weeks for the next two years
  - --> every 6 months for the final two years

Current Sub-Study Elements

- Immunology Studies
  - HIV
  - Transplant
- Virology Studies
  - HIV
  - HCV, HBV
  - HPV
  - HHV8
- Pharmacology Studies
**Immunology Studies: HIV**

- **Immunophenotyping**  
  - (T and B cells, naive vs memory, activation state)
- **LPA**  
  - (PTH and recall antigens)
- **Cytokine flow cytometry (CFC)**  
  - (to CMV and staph enterotoxin B)
- **NK cell function**
- **Soluble activation markers**  
  - neopterin, beta-2-microglobulin
- **CAF** (CD8 mediated antiviral response)
- **CMV, EBV and HHV6 ELISAs**
- **Thymus CT**

**Immunology Studies: Transplant**

- LPA against alloantigen (donor)
- Donor reactivity  
  - (MLC, CML and CFC)
- Chimerism studies

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**Virology Studies**

**HIV, HCV, HBV**

- Plasma and tissue HIV-1 RNA quant (bDNA)
- Plasma and tissue HCV RNA quant. (bDNA)
- HCV genotype and quasispecies
- Plasma and tissue HBV DNA quantification (bDNA and PCR)

**HHV8 and HPV**

- HHV8: Ab, cell associated and plasma viral load, cellular immunology, saliva
- HPV: cytology and biopsy with colposcopy

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**Pharmacology Studies**

- Trough CSA and prograph levels
- ? MMF levels
- Full pK of protease inhibitor and NNRTI  
  - HPLC assays
- Urine tox for illegal and prescription drugs

**Donors**

- Living related
- Cadaveric
- High Risk
ELIGIBILITY: No Changes From Proposed Protocol

1. **Protocol vs. Registry**
   Goal is to design a study protocol that can establish safety and appropriateness of procedure.

2. **CD4 Count**
   - Kidney: minimum 200 for previous 3 months
   - Liver: minimum 100 for previous 3 months

3. **HIV viral load**
   - Kidney: < 50 for previous 3 months
   - Liver: retain flexibility on VL criteria. Likelihood of post transplant viral suppression based on previous ARV history +/- resistance tests, to be decided by a three-person committee on a case-by-case basis.
   - Add: undetectable VL without any ARV therapy ok

4. **Opportunistic infections/neoplasms**
   No history of OI. Evaluate this criterion as study progresses, particularly with respect to history of PCP for sulphato-tolerant patients.

**HEPATITIS C: Consensus Document in Process** (see Appendix C, page 32)

- Not an absolute exclusion.
- Algorithm for disease staging, pre-transplant treatment options, and post-transplant monitoring and management to be distributed among consultants, with final review by all meeting attendees by Sept. 15th. (David Oldach, lead)
MEDICATION REGIMENS

1. Immunosuppressives: Kidney

Regimen: Prednisone, mycophenlyate plus calcineurin inhibitor of choice (cyclosporine or tacrolimus).
+/- anti-CD 25

Rejection: No absolute recommendations or prohibitions.
Sirolimus in steroid resistant or refractory rejection.
Avoid OKT3.

Delayed Graft Function:
Consider treatment with sirolimus until a calcineurin inhibitor can be initiated. Other considerations for management of ATN include anti-CD25 antibodies.

2. Immunosuppressives: Liver

Regimen: Calcineurin inhibitor of choice
Rapid steroid taper
Low threshold for mycophenalate use
Avoid IL-2 receptor inhibitors

Rejection: No absolute recommendations or prohibitions.
Sirolimus in steroid resistant or refractory rejection.
Avoid OKT3

3. Antiretrovirals – MMF interactions
   • No mandated exclusion of AZT and D4T in those on MMF, but ensure patients and providers are aware of potential antagonism and encourage alternatives when appropriate.
   • Consider merits of NNRTI vs. PI based regimen on case by case basis.
   • M. Roland to prepare a briefing packet for referring HIV providers

4. Prophylaxis – HIV and Transplant
   • see consensus document prepared by Marla Keller on page 8

5. PEP in the OR
   • Plan appropriate PEP drugs before surgery
LAB/STUDIES - see Appendix B, page 29

1. Clinical: Accept page 28 in briefing book. All core studies for all sites. See protocol details regarding monitoring frequency in those patients with and without evidence of past disease of pathogen exposure. HIV RNA will be local.

2. Immunology: Accept page 30 in briefing book. Some transplant-specific immunology labs need to be local, but the chimerism and alloreactivity labs will be centralized in the Stock lab. There should be further discussion at each site with report back on intentions regarding optional labs. TRECS available at M. Sinai; funding will be provided for this assay by B. Murphy.


4. Funding: Funding for optional studies and specimen storage is being identified and pursued. Sites will be queried in the coming weeks regarding needs for storage and shipping, as well as special studies planned at individual sites.
Consensus Document-Opportunistic Infection Prophylaxis
Prepared by Marla Keller

Pneumocystis carinii pneumonia (indicated for all patients for life)

Preferred: Bactrim 1 double strength tablet (160 mg trimethoprim, 800 mg sulfamethoxazole) daily or Bactrim 1 single strength tablet (80 trimethoprim/400 sulfamethoxazole) daily

Alternatives: Bactrim DS 1 tab tiw or Dapsone 50 mg bid or Dapsone 100 mg qd (Dapsone contraindicated if G6PD deficient)

If Bactrim & Dapsone allergic, consider Atovaquone 1500 mg daily or Aerosolized Pentamidine 300 mg via Respirgard II nebulizer monthly

Strategies for managing mild reactions include discontinuation of the drug and resuming it at a lower dose or rechallenging with gradual dose escalation: Bactrim suspension for dose escalation (8 mg trimethoprim/40 mg sulfamethoxazole) 1 cc qd x 3d, 2 cc qd x 3d, 5 cc qd x 3d, 1 single strength qd

Toxoplasmosis (indicated for Toxo IgG + and CD4 count <100)

Preferred: Bactrim DS 1 tab qd or Bactrim SS 1 tab qd
Alternatives: Dapsone 50 mg daily + pyrimethamine 50 mg weekly + leucovorin 25 mg weekly, Atovaquone 1500 mg qd with or without pyrimethamine 25 mg qd + leucovorin 10 mg qd

Mycobacterium avium complex (indicated for CD4 count <50)

Azithromycin 1200 mg weekly is preferred. If unable to tolerate, consider Clarithromycin 500 mg bid, although must consider drug interactions with immunosuppressive agents. If unable to tolerate a macrolide, consider Rifabutin 300 mg qd.
Cytomegalovirus, Herpes simplex virus and Epstein Barr virus

CMV negative recipient/negative donor: Acyclovir 400 mg bid x 1 year

CMV negative or positive recipient/positive donor: Gancyclovir 5 mg/kg IV qd while hospitalized the 1 gram PO tid x 3 months

If CD4 >100, change to Acyclovir 400 mg bid x 9 months
If CD4 <100, continue Gancyclovir 1 gram PO tid

CMV positive recipient/negative donor: Gancyclovir 5 mg/kg IV qd while hospitalized then change to Acyclovir 400 mg bid x 9 months

If CD4 <100, change to Gancyclovir 1 gram PO tid

Alternative option is no treatment while hospitalized and Acyclovir 400 mg bid x 1 year with close monitoring for CMV with PCR or antigenemia testing (per standard transplant protocol)

EBV negative recipient/positive donor: Gancyclovir 5 mg/kg IV qd while hospitalized then change to Gancyclovir 1 gram PO tid x 1 year

Reduce the dose of Gancyclovir for prophylaxis and treatment for undialyzed patients with renal dysfunction (Transplantation 2000 Feb 15;69(3):389-94)

Candidiasis: Mycelex troches for 3 months

+PPD (indicated for TST reaction ≥ 5 mm or previous +TST reaction without treatment or contact with a person with active tuberculosis)

Preferred: INH 300 mg qd + pyridoxine 50 mg qd x 9 months or
INH 900 mg + pyridoxine 100 mg biw x 9 months or
Rifampin 600 mg + pyrazinamide 20 mg/kg qd x 2 mo

Alternatives: Rifabutin 300 mg qd + pyrazinamide 20 mg/kg qd x 2 mo or
Rifampin 600 mg qd x 4 months

Rifampin should not be administered with protease inhibitors or nonnucleoside reverse transcriptase inhibitors. Rifabutin can be administered at one-half the usual daily dosing (i.e., reduce from 300 mg to 150 mg qd) with nelfinavir, indinavir and amprenavir. Rifabutin should not be used with the protease inhibitor hard-gel saquinavir or the nonnucleoside reverse transcriptase inhibitor delavirdine. Information is lacking regarding coadministration of rifabutin with soft-gel saquinavir or nevirapine.

Consider dose adjustment of all medications based on creatinine clearance and risk of hepatotoxicity.
Kidney Transplants in HIV Infected Patients

- Randomization not practical
- Questions

Does renal transplantation benefit recipients? - Time varying covariate
When transplanted, do recipients have adequate function to justify the procedure? - Single arm trial versus external standard

Projects

- 85% Government
- NIH Institutes
  - NCI
  - NEI
  - NHLBI
  - NIAID
  - NICHD
  - NIDDK
  - NIDCD
  - NIDA

Projects (Continued)

- Disease Areas
  - Oncology
  - Infectious Disease
  - Vaccine Development
  - Transplantation
  - Autoimmune Disease
  - Ophthalmology

Services

- Protocol Development
- Data Collection Activities
- Data Systems Design
- Data Quality Control
- Administrative Support
- Analysis and Reporting

Design Assumptions

- 5 Year Study
- 3 Year Accrual Period
- 75 patients ie 2/month
Monitoring Plan

• Truncated Sequential Probability Ratio Test SPRT (Wald 1954)
• 1-Year Graft Survival
• Ho: 75% versus Ha: <75%
  – Ho: 75% versus Ha: 60%
• Test Statistic
  – Total Time on Study and # of Graft Failures

Monitoring Plan (Cont)

• Assume exponential failure times
• Uniform patient entry
• Observe graft failures through the one year time point
• Construct truncated bounds, if trial does not terminate, choose the null

Operating Characteristics

- 75% 1-year GraftSurv
  – Size=.10
- 60% 1-year GraftSurv
  – Power=0.88
  – 43 patients
  – 22 Months

SPRT Designs

- 80v60
- 80v65
- 75v60

• Donald Stablein, Principal Investigater
• Matthew McIntosh, Statistician
• Ilene Blechman-Krom, Protocol Monitor
• Ann Limberger, Protocol Monitor
HIV & Transplantation:

- Will immunosuppression to prevent organ rejection in the HIV+ patient result in:
  - Synergistic Immunosuppression…

- Or can we exploit antiretroviral activities of immunosuppressive medications to achieve
  - Synergistic Antiretroviral Activity?

Mycophenolate & Antiretroviral Nucleoside Analogues (NRTIs)

- Mycophenolate mofetil, an inhibitor of inosine monophosphate dehydrogenase, reduces intracellular GTP pools in cells lacking the purine salvage pathway…

- Mycophenolate has intrinsic antiretroviral activity in-vitro, through its inhibition of T-cell activation…

Mycophenolate & Anti-Retroviral Agents: Purine Biosynthesis
MA/ABC inhibit multi-drug resistant HIV-1

MM / ABC Salvage Trial

- Phase I, 20 week trial
- ABC 300 mg BID + MM 250 mg BID + at least two other antiretroviral agents
- Inclusion Criteria:
  - HAART & salvage rx failure.
  - Genotype: 3 or more RT mut.(ABAC)
  - or multidrug resistance mut.
  - and NNRTI or PI resistance

Baseline Parameters and Therapy, ABC/MM Salvage RX Pilot Study

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<tr>
<th>PI-#</th>
<th>Baseline Regimen</th>
<th>Baseline CD4</th>
<th>Baseline Viral Load</th>
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**Conclusion**

Mycophenolate Mofetil at daily doses between 500 mg and 1500 mg was well tolerated and without evidence of significant toxicity. Two volunteers developed significant adverse events (CMV retinitis and HSV esophagitis) at a daily dosage of 2000 mg. Causal association with high dose MM cannot be excluded.

The use of MM and ABC in combination with additional anti-retroviral agents was associated with a temporal decrease in plasma HIV RNA levels in heavily experienced anti-retroviral-treated patients.

The use of MM and ABC alone failed to demonstrate significant in vivo anti-viral activity in patients with multi-RT resistant virus. Although in vitro data demonstrated the ability of the addition of Mycophenolic acid to Abacavir to “restore” susceptibility of abacavir-resistant mutant viruses, this observation failed to translate clinically when tested directly in vivo.

Whether or not MM will impact the durability of abacavir-induced viral control in volunteers prior to the development of abacavir resistance remains to be determined.
Antiretroviral Drug Interactions:

PI/NNRTI and Immunosuppressives

*Initial UCSF Study Patient Experience*

Presented by Laviero Mancinelli, PharmD., University of California, San Francisco
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1. Protocol Development:
   - Revised protocol and informed consents will be distributed to all sites for review and IRB submission by Sept. 15th

2. Liver Study:
   - UCSF ARI currently fundraising for data management add-on for Emmes. Sites should plan on enrolling at same time as kidney.

3. Optimal lab studies and storage:
   - Funding sources to be explored. Sites will be queried regarding local lab resources and monetary needs for shipping and storage.

4. National DSMB:
   - We will use the DSBM for kidney trials—CCTAT

5. Site Coordinators/Data Managers:
   - Lawrence Kerr will review funding requests ASAP. Funding decisions will be made in conjunction with Emmes.

6. Educational Programs/Best Practices:
   - Will coordinate web-based educational resources and consider further educational meeting.
   - Sites are encouraged to share key clinical experiences for inclusion in a developing Clinical Guidelines in the Management of the HIV Positive Transplant Recipient Manual (send them to M. Roland and L. Carlson)

7. Facilitating ongoing dialogue:
   - Consider list-serve
   - Protocol and site information on website
   - Conference calls to include: Surgeons, HIV Clinicians, Hepatologists, Nephrologists, Pharmacologists, Clinical Coordinators, Data Managers

8. Referrals between sites:
   - Facilitate via contact information on website
9. Ethical and Policy Issues:
   - UCSF will host a policy forum and write up the results

10. R01/P01 preparation:
   - The subject of a future meeting—possible writing retreat
   - February 2001?
   - UCSF ARI to coordinate

*****************************************************

Timeline to begin implementation of the common protocol:

- Emmes—data collection tools (CRFs) to be ready at earliest by end of September
- Revised protocol and consent forms—distributed by Sept 15
- Start-up—Nov 15
Appendix A-1: Background and Patient Data Slides
Presented by Peter Stock

**HIV AND END STAGE RENAL DISEASE**

HIV-associated nephropathy (HIVAN) — most common cause of ESRD in seropositive patients

Characteristic lesion:
- **glomerular** — focal sclerosis (FSGS)
- prominent retraction of the glomerular tuft
- visceral epithelial cell hypertrophy
- tubulointerstitial — infiltrating mononuclear cells
- interstitial edema
- fibrosis
- microcystic tubule dilatation

**NEED FOR ORGAN TRANSPLANTATION IN HIV + POPULATION**

- 750,000-1,5 million people infected with HIV, with 40,000 new cases added each year.
- Renal failure
  - HIV associated nephropathy (HIVAN)
- Liver failure
  - Hepatitis B
  - Hepatitis C

Risk factors:
- transfusion, IVDA, multiple sexual partners

**HIV AND HIV-ASSOCIATED NEPHROPATHY**

- Incidence of HIV nephropathy has increased by 30% each year since 1991
- In 1995, HIV nephropathy became the third leading cause of ESRD in Blacks
  - HIV incidence in White men whose risk factor was sex with other men (MSM)
  - HIV incidence in Blacks and women
  - in AIDS-related deaths in men and women of all racial/ethnic groups
- Number of patients at risk for the development of HIVAN increasing at a dramatic rate

**RENEAL COMPLICATIONS IN HIV + POPULATION**

- HIV-associated nephropathy (HIVAN)- FSGS
  - Rapid progression to ESRD (weeks to months)
  - predeliction in Blacks: genetically determined response to glomerular injury versus genetically determined susceptibility to viral infection
- Membranoproliferative glomerulonephritis
- Rapidly progressive glomerulonephritis
- IgA nephropathy
- Amyloid

**WHY NOW?**

- Epidemiological data show decreased incidence of opportunistic infections and hospitalizations with use of HAART.
- HAART in immunosuppressed HIV positive transplant recipients will further improve allograft and patient survival.
- Immunosuppressive agents commonly used in transplant have anti-HIV effects.

**POTENTIAL HIV + CANDIDATES FOR RENAL TRANSPLANTATION**

- Dependent on the stage of HIV infection when HIVAN occurs
- Several series show HIVAN occurs in otherwise asymptomatic individuals before the development of opportunistic infections
- Two series demonstrated rapid progression to the development of AIDS defining condition within 1 year of the diagnosis of HIVAN (< average time between seroconversion and AIDS-defining condition 8-10 years)
HIV POSITIVITY AND END-STAGE LIVER DISEASE
Similar risk factors: IVDA, transfusion, sexual

Hepatitis C infection:
- Incidence in U.S.: 18% (3.9 million)
- Most common indication for OLT (~25%)
- 90% of HIV infected hemophiliacs and people with IVDA are co-infected
- HIV infection accelerates HCV progression (higher proportion of ESLD in HCV infected hemophiliacs with HIV than without)
- HCV viral RNA levels correlate with decreasing CD4 counts.

Hepatitis B infection:
- Estimated incidence of 140,000-320,000 infections per year (about 50% symptomatic)
- Depending on geographic location, up to 20% co-infected with HBV

SHOULD ALL HUMAN IMMUNODEFICIENCY VIRUS-INFECTED PATIENTS WITH END-STAGE RENAL DISEASE BE EXCLUDED FROM TRANSPLANTATION?

TRANSPLANTATION, MAY 15, 1998
VIEWS OF U.S. TRANSPLANT CENTER

- Transplant Center Response Rate: 149/248 (60%)
- Is HIV testing required for prospective recipients? YES 100%
- Would a patient who refuses HIV testing be considered for transplantation? YES 12% NO 84% UNSURE 4%
- Would an HIV-infected ESRD be considered for cadaveric transplantation? YES 9% NO 91% UNSURE 3%
- Would an HIV-infected ESRD be considered for living donor transplantation? YES 5% NO 91% UNSURE 4%

HISTORICAL DATA IN HIV + TRANSPLANT RECIPIENTS

- Several initial reports demonstrating worse outcomes following solid organ transplantation seropositive patients.
  - Drummer et al. Transplantation 1989
  - Poliet al. Transplantation 1989
  - Ragni et al. NEJM 1990
  - Teckis et al. Transplantation 1990
- Several reports suggesting adverse effects of HIV infection > 8 yrs, HIV undetectable, no OIs.

HIV AND MORTALITY FROM ESLD

- + in AIDS-related deaths from infection and malignancy
- 1 in mortality from ESLD
- Study from Tufts University, 50% of deaths in HIV + people in 1998, 1999 attributed to ESLD
- Study from Case Western University, Hepatic failure-related death: 0-2% 1995 20% 1997
- Study at MCP Hahmemann found that HCV was among three most common causes of death for people with HIV

HUMAN IMMUNODEFICIENCY INFECTION PATIENTS WITH ORGAN TRANSPLANTS: REPORT OF CASE AND REVIEW

RENAI
- 6/11 functioning at a mean follow-up time of 31
- 27% with progression to

LIVER
- 5/7 patients died within 18
- 3/5 deaths were AIDS
- Poor liver results related:
  - Severe co-morbidity of viral
LIVER TRANSPLANTATION IN HIV-POSITIVE PATIENTS — POSSIBLE INTERACTION BETWEEN TACROLIMUS AND NELFINAVIR

Söderdahl et al. — Huddinge Hospital, Sweden

- Patient transplanted for HCV on PI-HAART with negative HIV (risk factor: multiple transfusions for hemophilia A)
- Tacrolimus-based immunosuppression — no rejection
- Tacrolimus dose — 0.5 mg/week
- Recurrent HCV — 4.1 million copies/ml 8 weeks following transplantation
- No detectable HIV — survival to 1 year at time of presentation. Patient cured from hemophilia A.

LIVER TRANSPLANTATION IN HIV-POSITIVE PATIENT — POSSIBLE INTERACTION BETWEEN TACROLIMUS AND NELFINAVIR

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RESULTS FROM KING’S COLLEGE HOSPITAL (cont.)

- No opportunistic infections
- 3 patients with HCV
  - All with rejection
  - All with severe recurrence and died with cholestatic hepatitis at 6, 15 and 25 months
    - CD4 counts pre-op >500, 280, 160
    - CD4 counts prior to death 87, 5, 10

AN OBSERVATIONAL STUDY OF FRENCH LIVER RECIPIENTS INFECTED WITH HIV-1

BOUSCARAT ET AL. CLINICAL INF. 1994:19

- 11 patients underwent OLT between 1985-1987 found to be infected with HIV-1
- CSA-based immunosuppression
- 8/11 patients had acute rejection
  - 5/8 required anti-T cell preparations
  - 3/5 had rapid progression to AIDS and death
- 7-year survival rate: HIV + 36%
  HIV - 70%

JK-39 Y/O Female 8 Years S/P OLT For Fulminant Hepatic Failure (HEP B)

- OLT July 1992 (31 y/o)
- Jan. 1994 — HEP C +, HIV +
- Immunosuppression ↓ 2 HIV +
- FK, prednisone
- FK triggered rejection episode
- Rejection tx with steroid bolus, T FK
- 1996 - initiated on anti-viral therapy EPIVIR, ZERIT (3TC, d4T)
  no protease inhibitors
- 1996-2000
  - No detectable HIV viral load
  - Negative Hep B staining on liver biopsy
  - No detectable HCV by PCR
  - No opportunistic infections
  - Normal LFT’s

SL-51 Y/O MALE - OLT FOR HEP B

9/97 → ascites, LFT’s ↑
  liver biopsy → CAH, cirrhosis
  serologies → Hep B Ag +
  HIV +

1/98 → TIPS for ascites
  worsening encephalopathy S/P
  TIPS

2/98 → SBP

4/98 → severe encephalopathy
  hepatorenal syndrome (BUN 105)

4/29/98 → CVVH initiated
  → HIV regimen nelfinavir, d4T,
  lamivudine
  → encephalopathy improved with
PM - 15 Y/O Male with ESLD 2° to Hep C/HIV. Both viruses acquired during transfusion (Age 2) forkx ALL.

- Massive ascites, fatigue
- Proteinuria, GFR 80 ml/minute
- Renal biopsy: membranoproliferative GN
- No detectable viral load on HAART
- HCV viral load 9 million copies/ml

PM-POST COURSE

- Immediate resolution ascites with normalization of renal function and function.
- Resolution 30.0 → 2.0 over 2
- Discharge from hospital
- Tolerates virals (2 NRTI, 1 PI) ↓ in HIV viral load to
- Tolerates interferon , with ↓ in HCV viral load from 120 million → 30 million copies over 4

PM - (cont.)

Due to waiting list issues, underwent a living donor (L) lobe liver transplant (donor-mother)

Post-op Course:
- Severe preservation injury → C/W small-for-size graft
- Progressive renal insufficiency - inability to administer CSA
- Immunosuppressive therapy - Rapamycin, CellCept, prednisone
- Inability to administer Ribaviron 2° renal insufficiency and major hemolysis
- Ability to administer to interferon (effects on regeneration)
- Inability to administer anti-virals 2° to poor hepatic function
- Liver biopsy → continued P.I.
- Periportal infiltrates
- Total bilirubin to >30
- ~ 1 month post-op → re-transplant liver and kidney

SL (cont.) →

COURSE

- Extubate on POD#4 + continued intermittent confusion performed 2° to altered mental status (no significant
- Required CVVH X 2 days, then HD. HD required until
- Immunosuppressa with " Given a single dose Zenapa (IL-2R inhibitor) 2° to renal
- On POD#4 (5/6), a sputum culture from 4/26/98 grew culture started on a 4 drug anti-TB regimen. subsequently identified as:
- Discharged on 6/27 wks post-
  - Normal LFT’s
  - No HepB
  - No HepC

SL (cont.) → POSTOPERATIVE COURSE

- 7/29 - readmitted c/o dizziness and
- MRI showed multiple lesions in cerebral the gray-white matter
- Progressive in mental status, with lesions in brain MRI c/w JC
- PCR of CSF positive for JC
- 9/1 (3 months post-op) respiratory support and the patient

CW-Living Related Transplant

- Received kidney from nephew (issues informed
- ESRD 2° to
- No h/o OI, CD4 >200, tolerating
- Pretx screening-non-therapeutic anti-dosing
- Uncomplicated post-op DC’ed POD#4
- No , continued undetectable tolerating HAART, normal renal
WHAT IMMUNOSUPPRESSION?

The Effect of Cyclosporin on the Progression of Human Immunodeficiency Virus... Schwartz et al. Transplantation

Retrospective review of 53 patients with infection to infected blood...

Progression to AIDS at 5 years:
- 90% (n=13) - no CSA
- 31% (n=40) - Regimens with CSA

CLINICAL TRIALS OF CYCLOSPORINE IN HIV INFECTION

Hypothesis:
1. HIV pathogenesis is in part mediated by up regulation and over-activation of the immune system.
2. Cyclosporin will decrease immune activation and lead to improved markers of HIV disease (CD4 T-cell counts and RNA).

PRELIMINARY FROM CLINICAL TRIALS UTILIZING CSA FOR THERAPY


- Significant preservation of CD4 + cell counts in HIV-infected persons treated with 7.5 mg/kg/day of CSA.
- No effect on total lymphocyte count or antigenemia, indicating no effect on HIV replication.

A CONTROLLED TRIAL OF CSA IN HIV INFECTION

Calabrese et al. [ACTG334 TEAM]

Abstract 373:146, 7th Conference on Retrovirus and Opportunistic Infection, Jan. 2000

Short-term preliminary results:
- Prospective randomized control trial → low dose CSA (4 mg/kg/day).
- Safe, but only a modest decrease in immune activation.

POLYMERASE SUBSTRATE DEPLETION: A NOVEL STRATEGY FOR INHIBITING THE REPLICATION OF THE HUMAN IMMUNODEFICIENCY VIRUS


- Inhibitor of inosine monophosphate dehydrogenase, therefore limiting de novo synthesis of guanine nucleotides.
- Mycophenolic acid (CellCept) → nonnucleoside inhibitor of inosine monophosphate dehydrogenase.
- Limits the rate of de novo synthesis of guanine nucleotides → in turn blocking the activity of reverse transcriptase.
- Shows strong anti-HIV activity in vitro in both human peripheral CD4 + lymphocytes and macrophages.

MYCOPHENOLATE MOFETIL - (MMF)

- Inhibitor of inosine monophosphate dehydrogenase, therefore limiting de novo synthesis of guanine nucleotides.
- Guanine nucleotides required for the proliferation of lymphocytes and monocytes → potent immunosuppression.
- Shows strong anti-HIV activity in vitro in both human peripheral CD4 + lymphocytes and macrophages.
- Combination of MMF and the nucleoside analog reverse transcriptase inhibitor abacavir has synergistic anti HIV-1 activity in vitro.
**DIRECT INHIBITION OF HIV ASSEMBLY BY CSA**  
Streblow et al. Virology 1998; 245:197

- CSA inhibits HIV-1 Gag processing.
- Inhibition results from binding of CSA to cyclophilin A.
- Cyclophilin A may be required for Gag conformational changes subsequent to assembly.

**PROPHYLAXIS FOR OPPORTUNISTIC INFECTIONS**

- *Pneumocystis carinii pneumonia* ⇒ indicated regardless of CD4 count
- *Toxoplasmosis* ⇒ indicated for toxo IgG +
  - If Toxo IgG + ⇒ Bactrim DS qd
  - If Toxo IgG - ⇒ Bactrim DS 3X/wk
- Alternatives if Bactrim allergic (or neutropenic)
  ⇒ Dapsone (contraindicated if GGPD deficient)
  ⇒ Aerosolized pentamidine
  ⇒ Atovaquone

- *Myobacterium avium complex* (indicated for CD4 count <50)
  ⇒ Azithromycin 1200 mg weekly preferred
  ⇒ Alternative Clarithomycin 500 mg BID
- **CAUTION:** Exacerbate inhibition of cytochrome P450

- *Candidiasis:* Mycelex troches X 1 year
**PROPHYLAXIS FOR CYTOMEGALOVIRUS**

- Reactivation or development of CMV disease even in non-HIV infected patients
- Replication of CMV can enhance HIV replication
- CMV - recipients: IV Gancyclovir during hospital, followed by Cytovene x 3 months. Then Acyclovir (400 mg BID) X 9 months (unless CD4 > 100 → then continue Cytovene)
- CMV + recipients: Acyclovir X 1 year

**IMPORTANCE OF PROPHYLAXIS IN THE RECIPIENT**

- Immunosuppression enhances the development of CMV disease even in non-HIV
- CMV → rejection can be triggered following CMV
- CMV directly enhances HIV
Appendix A-2: Background and Patient Data Slides
Presented by John Fung

Documented Liver Transplantation in HIV+ Patients

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<th>Year Reported</th>
<th>Number</th>
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<td>Pittsburgh</td>
<td>1990</td>
<td>6</td>
</tr>
<tr>
<td>Minnesota</td>
<td>1991</td>
<td>3</td>
</tr>
<tr>
<td>King's College</td>
<td>1996</td>
<td>1</td>
</tr>
<tr>
<td>Royal Free</td>
<td>1998</td>
<td>6</td>
</tr>
<tr>
<td>Milan</td>
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<tr>
<td>King's College</td>
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<td>4</td>
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<td>Philadelphia</td>
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</tr>
<tr>
<td>Pittsburgh</td>
<td>2000</td>
<td>5 (+2)</td>
</tr>
<tr>
<td>San Francisco</td>
<td>2000</td>
<td>2</td>
</tr>
<tr>
<td>Miami</td>
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<td>3</td>
</tr>
<tr>
<td>Bonn</td>
<td>2000</td>
<td>1</td>
</tr>
</tbody>
</table>


- 15 OLTX recipients from 1981-1988 were HIV positive.
- 6 infected before transplantation, 9 infected perioperatively.
- Cyclosporine based - 68% rejection, 65% given OKT3.
- 2.75 year mean followup, 7/15 patients alive
- 12.75 year mean followup, 2/15 patients alive
- 1/6 pre-tx HIV infection
  - survival: 5,6,9,20,44,204* mo.
- 1/9 peri-tx HIV infection
  - survival: 4,5,6,65,70,89,118*,149,180* mo.
*designates anti-HIV therapy post-OLTX

Additional Pre-HAART OLTX

- 2 HIV positive OLTX recipients done under
  - HIV+ and HBV+ transplanted in
    - anti-HIV therapy initiated in
      - survival for 102
      - death from recurrent
  - HIV+ and HCV+ transplanted in
    - no anti-HIV therapy
    - survival 7
    - death from recurrent

Recent University of Pittsburgh Experience

- All patients on antiretroviral therapy pre-transplant
- 5 liver - 2 NRTI and 1 PI
  - 4 - HCV associated liver disease
  - 1 - FHF due to nucleoside analog associated toxicity
- Minimum 3 months, maximum 2.50 years
- Tacrolimus dose - 1-2 mg/week on PI-HAART
- Compared to 2 kidney - 2 NRTI and 1 NNRTI
- Tacrolimus dose - .1 mg/kg/d on NNRTI-HAART

OLTX Experience

- One death - Status 2A, ventilator, renal failure, VREF sepsis
- Four alive, 3, 12, 21, and 30 months
  - Three with biopsy documented recurrent HCV at 6, 8 and 20 months
  - Treatment with alpha-IFN and ribavirin
  - One with clearance of HCV by bDNA
  - Normalization of ALT and AST
- All patients remain quantitatively HIV negative
Complications

- One death - non HIV related
- One episode of CMV reactivation - asymptomatic.
- One case of “fatty liver” with normal LFTs.
- One case of chronic rejection - HIV treating LMD elected to take the patient off of HAART therapy (“drug-free holiday”). The elimination of the PI caused drastic reduction in tacrolimus levels precipitating rejection.
- Two cases of rescinding the original decision to cover OLTX services by the fiscal intermediary.

CD4 T Cell Counts

HIV RNA Levels

Pharmacokinetic Considerations

- Significant interactions between PI and tacrolimus
- Significant interactions between PI and rapamycin
- Potential additive or synergistic effects of nucleoside and nucleotide analogs, e.g. HAART, MMF, ribavirin, anti-CMV, anti-HBV.

Clinical Benefit in HIV Transplant Recipients under HAART

1. No HIV disease progression, as evidenced by development of opportunistic infection
2. Survival beyond 24 months following transplantation
3. Sustained CD4+ > 200/ul post-transplantation
4. No increase in HIV RNA from baseline, post-transplantation
# Appendix B-1:
Consensus Document Lab Studies from Briefing Book

## Routine Safety Labs - Accepted

<table>
<thead>
<tr>
<th>Core</th>
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<tbody>
<tr>
<td>Cyclosporine Levels</td>
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<td></td>
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<tr>
<td>Renal/Electrolytes</td>
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<td></td>
</tr>
<tr>
<td>LFTs</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Amylase</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lipase</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CBC-diff</td>
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<td></td>
</tr>
<tr>
<td>PT/PTT</td>
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<td></td>
</tr>
<tr>
<td>CMV Ab*</td>
<td>None</td>
<td>Local</td>
</tr>
<tr>
<td>EBV/PCR*</td>
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<td></td>
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</tbody>
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## HIV Safety Labs - Accepted

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</thead>
<tbody>
<tr>
<td>CD4+/CD8+ T-cell</td>
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<td></td>
</tr>
<tr>
<td>HIV-1 RNA (bDNA/PCR)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>RPR/VDRL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Toxoplasmosis Quant.*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>G6PD (once only)</td>
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</tr>
<tr>
<td>LDH</td>
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<td></td>
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<tr>
<td>Fasting Lipid Panel</td>
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<tr>
<td>HepBSAg*</td>
<td>None</td>
<td>Local</td>
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<tr>
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<tr>
<td>HepB core Ab*</td>
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<tr>
<td>HepB DNA*</td>
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<tr>
<td>MAC-blood*</td>
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<tr>
<td>MAC-sputum*</td>
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<tr>
<td>CSF JC virus*</td>
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* See protocol comments re past infection, indications for monitoring, etc.
## Appendix B-2:
Consensus Document Lab Studies from Briefing Book

### Immunology (HIV) Labs - Accepted

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<td>Regional/ACTG ATL? **</td>
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<tr>
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<tr>
<td>Cytometry</td>
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<td></td>
</tr>
<tr>
<td>Lymphoproliferative Assays</td>
<td></td>
<td></td>
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<tr>
<td>Natural Killer Cells</td>
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<td></td>
</tr>
<tr>
<td><strong>Soluble Activation Markers</strong></td>
<td>Neopterin, B2microglobulin</td>
<td>Local</td>
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<tr>
<td>CT Thymus</td>
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<td>Local</td>
</tr>
<tr>
<td>HIV specific CTLs</td>
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<td></td>
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<tr>
<td>CAF</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CMV ELISA</td>
<td></td>
<td>UCSF/Levy Lab</td>
</tr>
<tr>
<td>EBV ELISA</td>
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<tr>
<td>HHV6 ELISA</td>
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### Immunology (Transplant) Labs - Accepted

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</thead>
<tbody>
<tr>
<td>Chimerism</td>
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<td>UCSF/Stock Lab</td>
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<tr>
<td>Donor alloreactivity</td>
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** Sites to be explored further
### Appendix B-3: Consensus Document Lab Studies from Briefing Book

#### HCV Labs - Accepted

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<tr>
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<td>HCV Ab*</td>
<td></td>
<td>Local</td>
</tr>
<tr>
<td>HCV RNA*</td>
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<td></td>
</tr>
<tr>
<td>HCV Genotype*</td>
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<td>Central?</td>
</tr>
<tr>
<td>HCV Quasispecies</td>
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<tr>
<td>Liver Biopsy*</td>
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<td>Local</td>
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#### HHV8 Labs - Accepted

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<th>Optional</th>
<th>Central vs. Local</th>
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</thead>
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<tr>
<td>HHV8 Ab</td>
<td>HHV8 Viral Load (cell-associated)</td>
<td>CA State Public Health Lab/J. Martin</td>
</tr>
<tr>
<td>HHV8 Viral Load (plasma)</td>
<td>HHV8 Cellular Immunology</td>
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<tr>
<td>HHV8 Saliva</td>
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#### HPV Labs-Not Discussed (sorry, we forgot!)

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<th>Central</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cytology?</td>
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<td>UCSF/Palefsky Lab</td>
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<tr>
<td>Biopsy?</td>
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<td></td>
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</table>

#### Pharmacology/Pharmacokinetics- Accepted

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<tr>
<th>Core</th>
<th>Optional</th>
<th>Central</th>
</tr>
</thead>
<tbody>
<tr>
<td>PI/NNRTI pK x12</td>
<td>None</td>
<td>UCSF/BenetLab</td>
</tr>
<tr>
<td>CSA pK 1,2,6 hours</td>
<td></td>
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</table>
Appendix C: HCV Diagnostic and Treatment Algorithm  
Presented by David Oldach

**NOTE:** This document does not reflect a consensus.  
A revised document will be distributed by Sept 15th with consensus recommendations for feedback from all sites.

Renal Transplantation for HCV/HIV coinfection. Break-out group discussion. 8/13/00.

1) HCV is a more aggressive disease in the setting of HIV/HCV coinfection than in HCV infection alone.
2) Patients with HCV infection alone who receive renal transplants have ~ similar (most studies) 5-year graft and patient survival rates (compared with matched renal transplant control patients without HCV). Large cohort 10 year rates are pending. However, even if patient or allograft survival is diminished in the HCV infected cohort (in 10 year or longer follow-up), the appropriate comparison group would be HCV infected patients remaining on dialysis.
3) Given these observations (#2), many centers perform renal transplantation for HCV infected patients, using varying HCV-specific qualifying criteria for clinical enrollment. Our task is to establish some agreement on qualifying criteria for renal transplantation in the setting of HIV/HCV coinfection.
4) The consensus among the transplant physicians present was that use of IFN to treat HCV infection in a renal transplant recipient was tantamount to “putting a gun to the kidney and pulling the trigger” (thank you, R. Shapiro). Thus, IFN treatment of HCV post-renal transplant is not a viable fall-back option…
5) We do not know what proportion of HCV infected HIV + renal transplant recipients will have an acceleration of their HCV related disease…but some certainly will.
6) Given the problems of #5 and the study’s intention to demonstrate safety and efficacy of renal transplantation, outright exclusion of HCV coinfected patients from consideration for renal transplantation is an option. However, at some centers, HCV prevalence among HIV infected patients is as high as 60% (or more). Thus the study would not address the important question of clinical outcomes in this patient population.
7) We assume that the proportion of HIV/HCV coinfected renal transplant recipients who will go on to develop severe HCV related liver disease post transplant can be reduced, however, if:

   a) HCV infection is evaluated, treated, and cleared, pre-transplant
   (will infection really be cleared? Will relapse occur in the setting of ‘dual’ immunosuppression?
   Can we realistically expect better than ~25% viral clearance rates with therapy? What about that other 75%?
   Should we attempt to treat and clear HCV infection, even in patients whose liver biopsies are so benign that, in the absence of proposed renal transplantation, most clinicians would not treat?)

   b) HCV liver disease is evaluated, and ‘high-risk’ candidates are excluded from consideration (unless successfully treated pre-transplant).

With these considerations in mind, we discussed the following **proposed guidelines:**

1) All candidates should have HCV antibody and serum PCR testing.
2) All HCV positive patients entering the protocol should be aware of the uncertainties above, and should be informed that they could develop essentially untreatable progressive HCV-related liver disease as a consequence of their renal transplantation. It probably makes sense for this discussion to occur before the risks of liver biopsy are undertaken, unless one is going to offer treatment regardless of transplantation status…
3) All HCV EIA (+) patients should have a liver biopsy, regardless of serum/plasma HCV RNA status
   (this assumes that PCR negative recipients will have had a positive HCV-RIBA assay for confirmation of infection).
4) Patients with ‘low risk’ biopsy results may enter the trial without prior treatment…..
HAI score less than/equal to 4
No fibrosis.

5) Patients with ‘moderate risk’ biopsy results should be offered treatment prior to transplantation….
   HAI score less than or equal to 8,
   Grade 0 or 1 fibrosis (permits limited fibrous expansion of portal tracts)

6) Patients with ‘high risk’ biopsy results may not enter the trial, unless successfully treated….
   Any HAI score >8, with or without fibrosis,
   Any HAI score, with stage 2 fibrosis (fibrous expansion of most portal tracts)

7) Patients with ‘higher risk’ biopsy results are not candidates for renal transplantation alone…
   Any HAI score > 12
   Any HAI score, with stage 3 fibrosis (occasional portal to portal bridging)

8) Patients with cirrhosis, or in transition to cirrhosis are not candidates….(rather, these patients should
   be under evaluation for possible future liver transplantation).

**Plan:** We will consult with a number of hepatology, renal, HIV and transplant
colleagues, revise the proposal, and circulate among the group for comment prior to
incorporation into revised protocol and consent.
Appendix D: Educational Resources

1. “Quick Reference Guide to Antiretrovirals”

   Note, you need to register for Medscape to access this. It is free and easy to do! This is very nice, brief, concise overview.

2. “Guidelines for the Use of Antiretroviral Agents in HIV-infected Adults and Adolescents”
   - [http://www.hivatis.org/trtgdlns.html](http://www.hivatis.org/trtgdlns.html)

3. “Guidelines for the Use of Antiretroviral Agents in Pediatric HIV Infection”
   - [http://www.hivatis.org/trtgdlns.html](http://www.hivatis.org/trtgdlns.html)

4. For questions or to find resources related to HIV and AIDS treatment, the HIV/AIDS Treatment Information Service (ATIS) is available Monday through Friday, 9 a.m. to 7 p.m. (ET) at:

   800-HIV-0440 (1-800-448-0440)
   301-519-6616 Fax
   888-480-3739 TTY
   atis@hivatis.org (E-mail)
   [http://www.hivatis.org](http://www.hivatis.org) (Web site)
Appendix E

Transplantation in HIV+ Patients Workshop – August 12-14, 2000
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### Table of Study Sites (and Potential Sites) and Personnel
(Not edited)

Cleveland Clinic (not active)

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<th>Name</th>
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<tr>
<td>HIV Physician</td>
<td>Leonard Calabrese</td>
<td><a href="mailto:Calabrl@ccf.org">Calabrl@ccf.org</a></td>
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Cornell Medical Center (not active)

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<td>Nephrologist</td>
<td>David Serur</td>
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<td>(212) 746-1578</td>
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Georgetown

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<tr>
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<tr>
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<tr>
<td>Study/Site Coordinator</td>
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<td><a href="mailto:Sachauw@gunet.georgetown.edu">Sachauw@gunet.georgetown.edu</a></td>
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Surgeon/Liver

Surgeon/Kidney

Hepatologist

Nephrologist

Study/Site Coordinator
University of Pittsburgh

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<td>Surgeon/Liver</td>
<td>Andrew Bonham</td>
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University of California, San Francisco

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<thead>
<tr>
<th>Specialty/Position</th>
<th>Name</th>
<th>Email Address</th>
<th>Phone Number</th>
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<tbody>
<tr>
<td>Surgeon/Liver</td>
<td>Peter Stock</td>
<td><a href="mailto:pgs007@itsa.ucsf.edu">pgs007@itsa.ucsf.edu</a></td>
<td>(415) 353-1117</td>
</tr>
<tr>
<td>Surgeon/Kidney</td>
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<td>(415) 353-1117</td>
</tr>
<tr>
<td>HIV Physician</td>
<td>Michelle Roland</td>
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<td>(415) 476 4082 ext.432</td>
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<tr>
<td>Hepatologist</td>
<td>Norah Terrault</td>
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<td>(415) 476-2227</td>
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<tr>
<td>Nephrologist</td>
<td>Lynda Frassetto/many</td>
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<td>(415) 476-6143</td>
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<tr>
<td>Pharmacologist</td>
<td>Laverio Mancinelli /</td>
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<td>(415) 476-5890</td>
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<tr>
<td></td>
<td>Les Benet</td>
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<td>(415) 476-3853</td>
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<tr>
<td>Study/Site</td>
<td>Coordinator</td>
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<td>(415) 715-2385</td>
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### University of Maryland

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<tr>
<td>Surgeon/Liver</td>
<td>Steve Bartlett</td>
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<tr>
<td>HIV Physician</td>
<td>David Oldach</td>
<td><a href="mailto:Oldach@umbi.umd.edu">Oldach@umbi.umd.edu</a></td>
<td>(410) 706-4609</td>
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<td>Hepatologist</td>
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### University of Miami (not active)

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<tr>
<td>Surgeon/Liver</td>
<td>Andreas Tzakis</td>
<td><a href="mailto:Atzakis@miami.edu">Atzakis@miami.edu</a></td>
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<tr>
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<tr>
<td>Hepatologist</td>
<td>Guy Neff</td>
<td><a href="mailto:Wallyneff@aol.com">Wallyneff@aol.com</a></td>
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### University of Minnesota

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<tbody>
<tr>
<td>Surgeon/Liver</td>
<td>Abhi Humar</td>
<td><a href="mailto:Humar001@umn.edu">Humar001@umn.edu</a></td>
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</tr>
<tr>
<td>Surgeon/Liver</td>
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</tr>
<tr>
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<td>612 625-6460</td>
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<tr>
<td>HIV Physician</td>
<td>Tim Schachter</td>
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<tr>
<td>Pharmacologist</td>
<td>Melissa Kamps</td>
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<tr>
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### University of Virginia

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<tbody>
<tr>
<td>Surgeon/Liver</td>
<td>Timothy Pruett</td>
<td><a href="mailto:Tp2w@virginia.edu">Tp2w@virginia.edu</a></td>
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<tr>
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<tr>
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</tr>
<tr>
<td>Pharmacologist</td>
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<td>(804) 243-6156</td>
</tr>
<tr>
<td>Study/Site</td>
<td>Terry Ryan</td>
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