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IDCR

INFECTIOUS DISEASES IN CORRECTIONS REPORT

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CONFERENCE COVERAGE: THE 4TH INTERNATIONAL AIDS SOCIETY (IAS) CONFERENCE ON HIV PATHOGENESIS, TREATMENT AND PREVENTION

- **Spotlight:**
  Perspective on a Rapid HIV Testing Program for Inmates at the Hillsborough County Jail in Tampa, Florida
- **HIV 101:**
  New Antiretrovirals for 2007-2008

OBJECTIVES

The reader will be able to describe the most significant studies presented at the 4th International AIDS Society Conference in regards to antiretroviral therapy.

The reader will be able to discuss the most significant studies presented at the 4th International AIDS Society Conference in regards to HIV and viral hepatitis co-infection.

The reader will be able to summarize the most significant studies presented at the 4th International AIDS Society Conference in regards to resistance and tropism testing.

The reader will be able to explain the rapid HIV testing program at the Hillsborough County Jail in Tampa, FL.

The reader will be able to identify new antiretroviral medications.

DISCLOSURES AND CREDENTIALS:

Associate Editors

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Yale University AIDS Program

David Paar, MD
Associate Professor of Medicine
University of Texas, Medical Branch

Dean Rieger, MD
Officer/Corporate Medical Director
Correct Care Solution

Karl Brown, MD, FACP
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PHS-Rikers Island

Ralf Jürgens
Consultant

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Bethany Weaver, DO, MPH
Infectious Disease Consultant
Armor Correctional Health Services

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Mayo Clinic College of Medicine
Director, HIV Clinic Disease Consultant
Division of Infectious Disease Mayo Clinic

Jim Montalto
The Corrections Connection

Layout
Jose Colon
The Corrections Connection

Distribution
Screened Images Multimedia

Managing Editor
Elizabeth Closson
IDCR

Faculty Disclosure

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Disclosures: Main Article

Rafael Campo, MD
Professor of Clinical Medicine
Division of Infectious Diseases
University of Miami School of Medicine

Disclosures: Speaker's Bureau: Abbott Laboratories, Gilead Sciences, and Merck & Co.; Advisory Board: Abbott Laboratories and Monogram Biosciences; Clinical Grants: Abbott Laboratories, Bristol-Myers Squibb, Gilead Sciences, GlaxoSmithKline, Merck & Co., and Virco.

Disclosures: Spotlight

Bethany Weaver, DO MPH
Infectious Disease Consultant
Armor Correctional Health Services
Tampa, FL

Disclosures: Speaker's Bureau: Merck & Co. and Gilead Sciences, Inc.; Consultant: Merck & Co.; Advisory Board: Merck & Co.

Conference Coverage: The 4th International AIDS Society (IAS) Conference on HIV Pathogenesis, Treatment and Prevention

Rafael Campo, MD
Professor of Clinical Medicine
Division of Infectious Diseases
University of Miami School of Medicine

Introduction

The 4th International AIDS Society (IAS) Conference on HIV Pathogenesis, Treatment and Prevention took place in Sydney, Australia, from 22-25 July 2007. As the premier summer HIV conference (alternating with its sister meeting, the International AIDS Conference), the IAS meeting is a great venue for the presentation of ground breaking HIV-related research. New data on currently available antiretroviral agents, the management of medication-associated toxicities, and the ever-evolving paradigm on when to start therapy were presented. Most exciting were presentations of data dealing with new antiretroviral agents in new drug classes. Lastly, data on antiretroviral resistance, tropism testing, and management of HIV-related morbidities and co-infections rounded out the meeting. Although there were no sessions or presentations dedicated to the care of the incarcerated HIV-infected individual, the results of a number of major studies have a bearing on how HIV is treated in prisons and jails and elsewhere.

Current antiretroviral agents and treatment strategies

The newest of the protease inhibitors (PIs), darunavir (DRV), has been seen by many as a potentially valuable addition to the HIV armamentarium especially for the treatment of antiretroviral experienced patients. The TITAN study compared DRV 600 mg/ritonavir (r) 100 mg BID (n=298) to lopinavir (LPV) 400 mg/r 100 mg BID (n=297) over 48 weeks in antiretroviral therapy (ART)-experienced, LPV-naïve patients.[1] Both groups of patients received an optimized background regimen with two or more nucleoside and/or non-nucleoside reverse transcriptase inhibitors (NRTIs/NNRTIs). Results are shown in **Table 1**. Because the lower limit of the 95% CI did not go below -12% for either of the two primary outcome measures (proportion with a viral load <400 copies/ml and <50 copies/ml at 48 weeks) for the DRV/r arm, DRV/r was shown to be non-inferior to LPV/r. In fact, because the lower limit of the confidence limits for both of these endpoints did not go below 0, DRV/r was shown to be superior to LPV/r by both criteria.

A related sub-study analyzed the response according to the number of LPV-associated resistance mutations at baseline.[2] Since none of these patients were LPV-experienced, these mutations had obviously been selected through the use of other PIs prior to enrollment in this study. Although a formal statistical analysis was not presented, the results suggested that the responses to LPV/r and DRV/r are similar in patients with virus with <6 LPV mutations (**Figure 1**). Not surprisingly, it was for virus with ≥6 LPV mutations for which DRV/r seemed to be more effective than LPV/r. These findings were similar to the ones stratified by phenotypic fold changes: The outcomes were similar as long as the LPV fold change stayed <10; for patients with LPV fold change between 10 and 40, DRV/r was more effective than LPV/r. Thus, it seems that these data can be interpreted in a relatively straightforward fashion: for patients with lower level PI resistance (<6 LPV mutations and/or <10 LPV fold change on phenotypic resistance testing) the efficacy of the two PIs is comparable; with higher level PI resistance (≥6 LPV mutations or ≥10 LPV FC) DRV/r appears more effective than LPV/r.

A very interesting study by Mallal and colleagues dealt with the prevention of hypersensitivity reactions (HSR) in patients starting Abacavir (ABC) through pharmacogenomic testing ABC-naïve subjects (n=1956) about to start an ABC-containing ART regimen were randomized 1:1 to either be monitored for HSR through standard-of-care observation or to undergo prospective testing for HLA-B*5701.[3] Previously, it had been reported that persons with this HLA type were more susceptible to HSR induced by ABC. In the prospective testing arm, those patients negative for B*5701 went on to receive the ABC; those who tested positive did not continue participation in the study. The endpoints of the study were clinically suspected (but not immunologically confirmed) ABC HSR and clinically suspected, immunologically confirmed ABC HSR. The immunological confirmation was carried out through skin patch testing, a research tool not available clinically. The incidence of clinically suspected ABC HSR was lower in the prospective screening arm than the standard-of-care arm and there were no cases of immunologically confirmed HSR in the prospective screening arm (**Figure 2**). Thus, the negative predictive value of B*5701 testing was 100%. The authors concluded that prospective B*5701 testing resulted in a "dramatic, clinically relevant and statistically significant reduction in ABC HSR". Testing for HLA-B*5701 is becoming available in clinical labs at a cost of $100 or less.

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Letter from the Editor

Dear Correctional Colleagues,

These are exciting times in HIV therapeutics. We are at the cusp of a major change in the treatment landscape of this infection with the eminent release of three new HIV medications. Two of these antiretrovirals use unique mechanisms to interrupt the virus life cycle and the third extends the utility of an older class of these drugs. Together they provide, almost literally, a new lease on life for those with multi-drug resistant HIV infection.

Too often in corrections we care for HIV-infected individuals with extensive treatment experience who have cycled in and out of prisons, jails and the streets - along the way receiving and stopping antiretrovirals. Not surprisingly, many of these individuals develop drug resistant virus that out paces the availability of active agents in the HIV armamentarium. With genotypes dripping in red, we scratch our heads, unsure what to do to help these people, many of whom are asking for another chance.

With a critical mass of recently and about to be approved potent HIV drugs it is becoming increasingly possible to craft effective regimens for those with such extensive drug resistance. In this issue of *IDCR* we highlight the features of the major new HIV therapies so that we in corrections can prepare for their arrival and apply them wisely when they do come to our formularies. We also asked Dr. Rafael Campo of the University of Miami School of Medicine, an expert in the clinical management of HIV, to report back from the International AIDS Society Meeting held in Sydney, Australia. He provides an in-depth review of the data regarding emerging and established HIV therapies as well as data presented on HIV and viral hepatitis co-infection.

As with any change to the standard existing procedures, correctional systems are tasked to consider how these developments and advances can be incorporated in a manner that best serves the needs of patients and is affordable. Over the coming months there will be continued discussions regarding the cost of newer HIV therapies and the expensive laboratory testing that, in the case of one of these drugs, is practically required prior to use.

We, as well as those who represent our interests, must make a loud and unequivocal call on the pharmaceutical and laboratory companies involved to not forget that these products will be used extensively in correctional systems. Systems with zero-sum budgets that must cover everything from bed sheets to Band-Aids. Prisons and jails that are often left behind when it comes to special pricing for low income patients. Facilities that care for a lot of drug resistant HIV-infected patients. It does no good for our colleagues in industry who spent fortunes to develop these drugs or our patients who need these drugs to survive if new these exciting HIV therapies go unused for the wont of a price that is fair and affordable.

David A. Wohl, MD
Associate Professor of Medicine
Division of Infectious Diseases
AIDS Clinical Research Unit
The University of North Carolina - Chapel Hill

P.S. New (2007) modified format on first page is made to comply with the ACCME requirements

The 4th International AIDS Society (IAS) Conference...

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Many discussions at the conference centered on the question of when to start HIV therapy. Data from four large cohort studies were presented. The specific aspects of the studies were different, but the overall message was the same: deferral of therapy is associated with poor outcomes. This conclusion was evident in CASCADE (the current CD4+ count, the nadir CD4+ count, and the time with CD4+ <350 were associated with AIDS and non-AIDS-related deaths), SMART (there was a greater risk of opportunistic infections [OIs], death/OIs, and serious non-AIDS events when ART was deferred for treatment-naïve patients), ATHENA (there was a slower CD4+ decline or better increase in CD4+ numbers if therapy was started with 350-500 vs. 200-350 CD4+ cells), and HOPS (there were fewer instances of NRTI-associated toxicities with ART initiation at higher CD4+ counts).[4-7] It seems clear that the pendulum is once more on the swing towards earlier initiation of therapy. In retrospect, the reason why clinicians had moved towards later initiation was because of the lower efficacy, lower genetic barrier, higher pill burden, and greater toxicity of the ART regimens available a few years ago. With the improvements in all these aspects of ART with modern regimens, it is appropriate that we re-examine the optimal time of starting ART.

New antiretroviral agents

The first phase III 48-week data regarding the use of maraviroc (MVC), Pfizer's CCR5 receptor blocker, in ART-naïve patients were presented at the conference (the MERIT study).[8] Patients without resistance to efavirenz (EFV), zidovudine (ZDV), or lamivudine (3TC) were randomized to one of 3 blinded treatment arms: MVC 300 mg QD vs. MVC 300 mg BID vs. EFV 600 mg QD, all with a backbone of co-formulated ZDV 300 mg/3TC 150 mg (CBV) BID. Baseline characteristics were similar for all patients. The MVC QD arm was stopped by the study data and safety monitoring board (DSMB) in January 2006 due to inferior efficacy compared to the two other arms. For non-inferiority to be established for MVC, the lower limit of the 1-sided 97.5% CI could not cross -10%; by this criterion, non-inferiority was proven for <400 c/ml but not for the <50 c/ml endpoint. This means that MVC was found not to be 'not inferior' to EFV (i.e. it was worse) with regard to achievement of a viral load less than 50 copies/mL. Despite the virologic data, the mean change in CD4+ counts was statistically superior for the MVC arm. The rates of discontinuation for MVC and EFV were similar (26.9% and 25.2%, respectively); however, the causes for discontinuation were different: lack of efficacy was higher with MVC (11.9%) than with EFV (4.2%) but adverse events were higher with EFV (13.6%) than with MVC (4.2%). How to put all this together? Taking into consideration that the lower limit of the CI was a bit more stringent than what is typically used (-12%), the efficacy was roughly comparable. While EFV seemed to be more effective from a virological suppression perspective, there is a toxicity price to pay for this higher efficacy, and at the end of 48-weeks this resulted in a wash. There is one aspect of the study that was not presented but may prove to be very important in the long run: the selection of drug resistance. If the greater number of MVC virological failures were accompanied by selection of antiretroviral resistance to MVC or other agents in the regimen but the EFV toxicity failures were not associated with drug resistance, then EFV may be associated with a lesser cost for failure and may end up being a superior drug for naïve patients. This resistance data will undoubtedly be presented at a future conference.

Another CCR5 blocker, vicriviroc (VCV), was also studied in the 48-week AIDS Clinical Trials Group (ACTG) 5211 trial.[9] ART-experienced patients with CCR5-tropic virus and taking ritonavir-containing regimens were randomized to have VCV at 5, 10, or 15 mg vs. placebo added to the failing regimen for 14 days after which an optimized background regimen (OBR) was started. Crossover from the placebo arm to the VCV arms was allowed for patients with virologic failure after week 16. The lowest dose of VCV was discontinued by the study DSMB because of lower efficacy. As reported previously, the study was eventually unblinded because of eight malignancies (two in the placebo and six in the VCV arms). The data presented suggest that the 10 mg and 15 mg arms of VCV were able to suppress viral replication (**Table 2**). It is hard to make any statements beyond that observation because of the relatively small number of patients in the study and the paucity of other available information (e.g. response according to the number of active agents in the OBR). Future studies may demonstrate that VCV is yet another CCR5 blocker with promising efficacy.

Another 48-week study of a new drug in naïve patients that generated great interest was a study of the integrase inhibitor raltegravir.[10] Antiretroviral-naïve patients (n=198) were randomized to receive either raltegravir at one of four different doses BID (100 mg, 200 mg, 400 mg, or 600 mg) vs. EFV 600 mg daily, all with a backbone of tenofovir 300 mg daily and 3TC 150 mg BID. Baseline characteristics were also similar for all patients. All patient groups experienced ≥2.2 log10 viral load decreases with similar increases in CD4+ cells. Patients receiving raltegravir achieved a viral load <50 copies/mL sooner than patients on EFV, but by week 24 and through week 48 the virological responses were similar. Drug related adverse events were similar for all groups except for the well-known association of central nervous system adverse effects with EFV. Also, there were elevations in total cholesterol and triglycerides for EFV but not for raltegravir. Thus, it can be concluded that raltegravir seems to be an efficacious and well-tolerated drug in naïve patients with an efficacy and safety profile comparable to that of EFV.

TMC-125 (etravirine), a novel NNRTI, is also undergoing intensive clinical testing. Two studies identical in design and different only with respect the region of the world where they were conducted (DUET-1 [n=612] and DUET-2 [n=591]) were presented at the conference.[11,12] Patients with documented NNRTI resistance and ≥3 PI mutations were randomized to receive TMC-125 vs. placebo plus DVR/r plus investigator-chosen NRTIs ± enfuvirtide. A 24-week (out of a planned 96-week study) efficacy analysis was presented for each of the two studies (**Table 3**). The incidence of adverse events and toxicity-related treatment discontinuations were similar for both groups in both studies. The authors concluded that TMC-125 is the first NNRTI to show efficacy in patients with NNRTI resistance as well as being well tolerated and safe.

Viral hepatitis

Studies dealing with viral hepatitis are an important component of these international conferences, especially for correctional health care providers. However, not as many studies were presented on this topic at this particular conference; nonetheless, a few abstracts contained interesting observations and are worth noting.

Most hepatitis work in recent years has focused on hepatitis C virus (HCV) since the rates of co-infection with HIV are so high. As there has been an effective vaccine for hepatitis B virus (HBV) for the last two decades, the number of HIV/HBV co-infected patients is not as large, but these patients are seen among our clinic populations and frequently pose a therapeutic challenge. An issue that complicates the management of HBV-HIV co-infection is the fact that patients may require treatment for HBV but may still have high CD4+ cell values and low HIV viral loads making treatment for HIV unnecessary. Thus, the use of agents for HBV but with activity against both viruses (e.g. lamivudine [3TC], and emtricitabine [FTC]) may lead to the selection of resistance by HIV against these agents. At a hepatitis symposium, Vicente Soriano from Madrid presented a useful algorithm for the treatment of HBV in patients who do not yet require treatment for HIV (**Figure 3**).[13] Although the algorithm is based on expert opinion and would obviously need to be individualized for any particular patient, it is a potentially useful tool for the management of these patients.

An issue that many HIV clinicians deal with frequently is diminished vaccine efficacy because of a compromised immune response. It has been clearly demonstrated that response rates to HBV vaccination are lower among HIV-infected individuals compared to those without HIV infection. Bortan and colleagues reported a retrospective study on the vaccination with recombinant HBV vaccine of HIV-infected individuals with either the standard dose (10 mcg at 0, 1, and 6 months) or a higher dose (40 mcg at 0, 1, and 6 months).[14] Although the number of patients in the study was relatively small, the results were impressive: only 26% (11 of 42) of standard dose-vaccinees developed anti-HBs titers >10 IU/L whereas 82% (9 of 11) of high dose-vaccinees developed these titers. The standard and high dose vaccinees had similar CD4+ cell counts (398 and 353, respectively) and use of ART (88% and 91%, respectively). The investigators could not identify by multivariate analysis any factors (other than vaccine dose) that were associated with an adequate anti-HBs response. These results suggest that it is possible to successfully vaccinate HIV-infected individuals against HBV infection, although a larger study would be needed in order to establish the optimal dose.

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In general, the efficacy of treatment for HCV is disappointing with long-term sustained virologic response (SVR) rates as low as 20-30% especially among patients with HCV genotypes 1 and 4. A small retrospective study from Italy suggests, however, that even in the absence of SVR there might be a significant benefit to pegylated interferon (peg-IFN) and ribavirin (RBV) treatment.[15] Twenty-five co-infected patients treated with peg-IFN and RBV for a median of 9 months but without SVR were compared to 25 co-infected and untreated patients matched for age, gender, and Child-Pugh score. After a median of 54 months of follow-up, 16% (n=4) of treated and 52% (n=13) of untreated controls, respectively, developed a study endpoint (death or development of ascites, jaundice, encephalopathy, gastrointestinal bleeding, or hepatocellular carcinoma) (p=0.02). By multivariate analysis the predictors of development of a study endpoint were use of peg-IFN therapy (adjusted RR=0.03; p=0.016) and the presence of detectable HIV RNA (adjusted RR=35.98; p=0.024). Thus, there seems to be benefit to therapy for HCV in co-infected patients - even in the absence of viral suppression.

Resistance and tropism testing

An observation regarding resistance testing with useful practical consequences was made by a group of British investigators.[16] They retrospectively studied the outcome of genotypic testing (GT) in viral load samples with <1000 copies/ml vs. >1000 copies/ml from patients on antiretrovirals with either viral failure (a viral load <50 copies/ml followed by two HIV RNA levels >50 copies/ml) or failure to suppress (HIV RNA level >50 copies/ml after being on HIV therapy for >6 months). All 66 samples with a viral load >1000 copies/ml could be amplified and sequenced; remarkably, 56 of 67 (85%) of samples with a viral load <1000 copies/ml could also be amplified and sequenced. This was the case with both low (200-1000 copies/ml) (38 of 42 samp les; 90% success rate) as well as very low (50-200 copies/ml) (18 of 25 samples; 72% success rates) viral loads. This suggests that GT can identify the selection of resistance mutations at HIV RNA levels that are much lower than what has been thought possible up until now.

The appropriate use of CCR5 receptor blockers will be dependent on the identification of the exact tropism of HIV. Use of CCR5 blockers on virus that expresses the CXCR4 receptor exclusively (X4 virus) or both CCR5 (R5 virus) and CXCR4 receptors (dual or mixed [D/M] populations) would not only be associated with decreased efficacy of CCR5 blockers but could lead to the selection of resistance to the other drugs in the regimen. There is a Food and Drug Administration (FDA)-approved phenotypic assay of tropism (Monogram Biosciences' Trofile) with a turnaround time and cost similar to that of the same company's Phenosense assay. In order to improve turnaround time and cost, several genotypic assays for tropism have been developed. These assays determine the genetic sequence of the V3 loop of gp120 (responsible for tropism) that is then matched through a variety of methods (position scor-

Table 1. 48-week virological and immunological efficacy of DRV/r vs. LPV/r plus ≥ 2 NRTIs/NNRTIs in ART-experienced, LPV-naïve patients (intent-to-treat analysis)

Week 48 parameter	DRV/r (n=298)	LPV/r (n=297)	Estimated difference between DRV/r and LPV/r (95% CI)
Viral load <400 c/ml	77%	67%	10% (2%; 16%)*
Viral load <50 c/ml	71%	60%	11% (3%; 19%)*
Mean (±SD) viral load $\log_{10}$ Δ from baseline	-1.95 (±1.24)	-1.72 (±1.34)	-0.20 (-0.39; -0.004)*
Median CD4+ cell increase	97	102	-
*P<0.01			

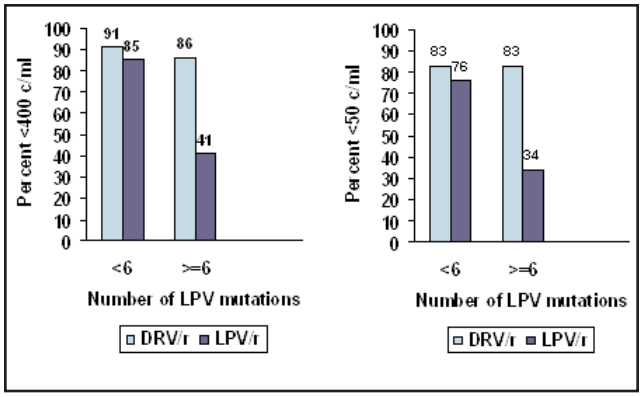

Figure 1. Virological response to DRV/r vs. LPV/r plus ≥ 2 NRTIs/NNRTIs after 48 weeks of therapy according to number of LPV-associated protease mutations at baseline

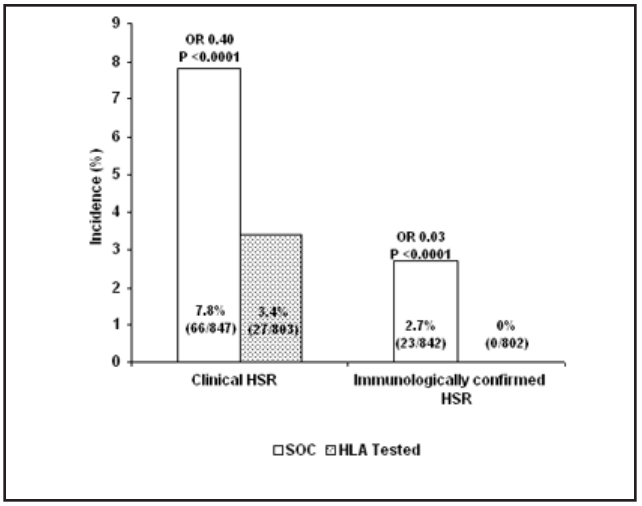

Figure 2. Clinically suspected and clinically suspected, immunologically confirmed ABC HSR (intent-to-treat analysis)

SOC = Standard of care

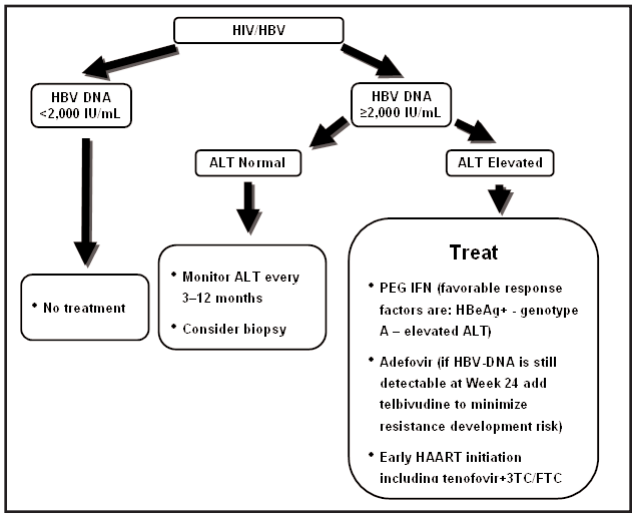

Figure 3. Treatment algorithm for HIV-infected patients with compensated hepatitis B virus infection and CD4 cell count >350/mm^3

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ing matrices, neural networks, position-based rules, etc.) to actual tropism phenotypes. A prediction of tropism is thus generated.

Low, et al. reported a study in which 920 V3 genotypes were analyzed by six different methods and the predicted tropism was then matched to the Trofile phenotype.[17] The goal of the study was to determine the sensitivity and specificity of the genotypic methods. The sensitivity of ranged from 22-50% and the specificity from 88-97% leading the authors to conclude that these methods are not yet adequate for predicting the X4 phenotypes upon which the determination of the presence of D/M populations is made. Thus, our ability to accurately predict tropism by genotypes will be currently limited for now.

Conclusions

This international conference, conducted half way around the planet, yielded data that are useful in our real world management of HIV and associated conditions. Studies of existing antiretrovirals help us refine our use of these medications while trials of newer therapies raise the prospect of continued opportunities for improving the well-being of our patients.

Table 2. Outcome of ACTG 5211 by study arm

Outcome	VCV 10 mg (n=30)	VCV 15 mg (n=30)	Placebo (n=28)
Median weeks of F/U	48	48	25
Subjects with early discontinuation (%)	11 (37%)	9 (30%)	23 (82%)
Subjects with virologic failure (%)	8 (27%)	10 (33%)	24 (86%)
Median VL Δ (log_{10} c/ml) at week 48	-1.92	-1.44	Not done
Proportion with VL <400 / <50 c/ml at week 48	57% / 37%	43% / 27%	14% / 11%
Median CD4+ cell Δ at week 48	+130	+96	Not done
Subjects with co-receptor changes (CCR5 to dual/mixed or CXCR4)	4	3	3 (2 after crossover to VCV)

Table 3. Virological and immunological outcome of the DUET-1 and DUET-2 studies at 24 weeks (intent-to-treat analysis)

Endpoint	DUET-1			DUET-2		
	TMC -125 group	Placebo group	Difference (95% CI)	TMC -125 group	Placebo group	Difference (95% CI)
<50 c/ml	56%	39%	17% (9%; 25%)*	62%	44%	18% (11%; 26%)**
<400 c/ml	74%	51%	22% (15%; 30%)*	75%	54%	21% (14%; 29%)**
Mean Δ in VL (log_{10})	-2.41	-1.70	0.57 (0.33; 0.82)***	-2.34	-1.68	0.51 (0.28; 0.74)***
Mean Δ in CD4+ count	89.0	64.4	31.7 (15.2; 48.2)	78.1	65.5	6.59 (-7.81; 20.99)
* p <0.01; ** p <0.001; *** p <0.0001						

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8. *Saag M, Ive P, Heera J, et al. A multicenter, randomized, double-blind, comparative trial of a novel CCR5 antagonist, maraviroc versus efavirenz, both in combination with Combivir (zidovudine [ZDV]/lamivudine [3TC]), for the treatment of antiretroviral naive patients infected with R5 HIV 1: Week 48 results of the MERIT study. [Abstract WESS104]. 4th International AIDS Society Meeting, July 22-25, Sydney, Australia.*
9. *ACTG 5211; phase II study of the safety and efficacy of vicriviroc (VCV) in HIV-infected treatment-experienced subjects: 48 week results. [Abstract TUAB102]. 4th International AIDS Society Meeting, July 22-25, Sydney, Australia.*
10. *Markowitz M, Nguyen B-Y, Gotuzzo E, et al. Rapid onset and durable antiretroviral effect of raltegravir (MK-0518), a novel HIV-1 integrase inhibitor, as part of combination ART in treatment of HIV- infected patients: 48-week data. [Abstract TUAB104]. 4th International AIDS Society Meeting, July 22-25, Sydney, Australia.*
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17. *Low A, Sing T, Chan D, et al. Improving HIV genotyping algorithms for the prediction of X4 co-receptor usage in clinical isolates. [Abstract WEPEA005]. 4th International AIDS Society Meeting, July 22-25, Sydney, Australia.*

HIV 101: New Antiretrovirals for 2007-2008

Drug	Mechanism of Action	Major Features and Clinical Trials Results	Refs
Raltegravir	Inhibitor of HIV-1 integrase	Inhibits the integrase enzyme responsible for integrating viral DNA into the cellular genome. Over the first 24 weeks of the BEMCHMRK 1 and 2 trials, raltegravir when added to optimized HIV therapy was found to significantly increase rates of viral suppression to <50 copies/mL compared to placebo among patients with extensive ART experience. In a smaller study of treatment for naïve patients, raltegravir was comparable to efavirenz in suppressing viremia to <50 copies/mL when both were co-administered with tenofovir/lamivudine.	1, 2
Maraviroc	CCR5 inhibitor	Blocks the CCR5 co-receptor on T-lymphocyte surface used by some strains of HIV to gain entry into the cell. Does not inhibit entry of virus tropic for the alternative CXCR4 co-receptor found on monocytes. In the MOTIVATE trials, 44% of patients with multidrug resistant HIV screened for study entry were found to have CXCR4 or dual/mixed tropic virus that would not be expected to be inhibited by maraviroc. An assay to determine if the patient harbors CCR5 tropic virus is available and is recommended prior to use of this drug. Current assay cost is $1,960. When used along with an optimized ART background, the drug was found to produce significantly higher rates of viral suppression below 50 copies/mL compared to placebo in the MOTIVATE trials. Maraviroc was inferior to efavirenz in achieving a viral below 50 copies/mL when each drug was combined with zidovudine/lamidudine in treatment for naïve patients enrolled in the MERIT trials.	3, 4, 5
Etravirine	Non-nucleoside reverse transcriptase inhibitor	This 'second generation' twice daily NNRTI has been found to be active against virus containing major NNRTI resistance mutations including K103N and Y181C. Certain mutations and accumulated NNRTI resistance can reduce effectiveness of etravirine. In the DUET trials, a significantly higher proportion of subjects with NNRTI and PI resistant HIV achieved a viral load <50 copies/mL at 24 weeks with etravirine compared to placebo when both were co-administered with darunavir/ritonavir as part of optimized therapy. Central nervous system adverse effects were no more common than that observed in patients receiving placebo during the DUET studies.	6, 7, 8

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2. *M Markowitz, B-Y Nguyen, E Gotuzzo, et al. and others (for the Protocol 004 Part II Study Team). Rapid onset and durable antiretroviral effect of raltegravir (MK-0518), a novel HIV-1 integrase inhibitor, as part of combination ART in treatment-naive HIV-1 infected patients: 48-week data. 4th IAS. July 22-25, 2007. Sydney, AU. Abstract (oral) TuAb104.*
3. *Lalezari J, Goodrich J, DeJesus E, et al. Efficacy and safety of maraviroc plus optimized background therapy in viremic ART-experienced patients infected with CCR5-tropic HIV-1: 24-week results of a phase 2b/3 study in the US and Canada. In: Program and abstracts of the 14th Conference on Retroviruses and Opportunistic Infections; February 25-28, 2007; Los Angeles, Calif. Oral 104bLB.*
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Spotlight: Perspective on a Rapid HIV Testing Program for Inmates at the Hillsborough County Jail in Tampa, Florida

Bethany Weaver, DO MPH
Infectious Disease Consultant
Armor Correctional Health Services
Tampa, FL

At the Hillsborough County Jail, where the average daily census in the first six months of 2007 was 3915 inmates with 203 bookings per day and an average length of stay of 21 days, three full-time health department employees, rotating between two facilities and funded by a federal grant, offer rapid HIV and routine syphilis testing to inmates. This is a voluntary testing program during which the staff go to the 64 open bed, direct supervision model pod and offer testing to all those who are interested. When the health department personnel arrive, an announcement is made to inform inmates they are there to offer free HIV and syphilis tests. If inmates choose to come forward for testing, the result is given face-to-face the same day. There are private rooms in each housing unit so that staff can complete a confidential pre- and post-test counseling session, including written consent for testing and provide link to care if the inmate is found to be HIV positive. The health department offers tests in the morning, performs the rapid HIV tests at the jail clinic lab, and then returns to the housing units in the afternoon to give negative results. Inmates receive HIV positive results in the clinic where there is more confidentiality and an opportunity for immediate referral to an HIV specialist and psychiatry, if indicated. Inmates sign a form stating that they received their negative or positive results, and the form becomes a permanent part of the medical record.

In the first quarter of 2007 (January-March), a total of 1013 inmates (221 females, 792 males) were tested with a total of three men identified as HIV positive and 16 cases of syphilis identified. In the second quarter of 2007 (April-June), of the 828 inmates (98 females, 730 males) tested, nine men and one woman tested HIV positive, and 13 cases of syphilis were identified.

In addition to the program described above, there are other opportunities for HIV testing at the jail. Tampa Hillsborough Action Plan (THAP), through a grant under Target Outreach for Pregnant Women's Act (TOPWA) offers rapid HIV testing to women at the jail, in a similar fashion to the program described above, two days per week. Furthermore, if an inmate requests an HIV test in writing or in the clinic when seeing a provider, the test is then offered by a certified HIV counselor. There is close collaboration between Armor Correctional Health Services, who has been contracted to provide medical services at the jail since October 2005, the Hillsborough County Sheriff's office, members of the health department, THAP, and Metropolitan Charities, who provides case management services to HIV positive inmates during and after incarceration.

Linking an HIV positive inmate to an HIV specialist on site allows the inmate the opportunity to learn about HIV/AIDS; the stage of disease based on blood work, history, and the physical exam; and risks for transmission. If appropriate, HIV treatment is initiated. In addition, the HIV specialist works with the health department to link the inmate to care in the community so that funding for medications and medical care can by accomplished upon release from custody. When possible, a three day supply of medications, a prescription for a one month supply of medications, and pertinent medical records are given to the inmate and/or case manager upon release from custody.

Overall, the HIV and syphilis testing programs are very well received by inmates and detention staff. Though inmates with HIV are not permitted to work in the kitchen, they are not segregated by HIV status, and results are given to them in a very confidential manner. Inmates are also told they can receive immediate care with an HIV specialist if they turn out to be HIV positive. There are some barriers to offering HIV testing in lockdown units, mental health units, and the infirmaries, mainly due to space and/or inability to obtain proper informed consent due to mental status, and we are working on strategies around these barriers so that we can expand this screening program. Another challenge that occasionally occurs is loss to follow-up when an inmate is released from custody prior to receiving confirmatory HIV or syphilis results, in which case the health department makes every effort to track down the individual in the community.

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Resources

4th IAS Conference on HIV Pathogenesis, Treatment and Prevention Website
http://www.ias2007.org

A Guide to Antiretrovirals The Body Pro
http://www.thebodypro.com/index/treat/antiretroviral_link.html

CDC's National HIV Testing Resource Website
http://www.hivtest.org/

CDC's Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings
http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5514a1.htm

Community HIV/AIDS Mobilization Project
http://www.champnetwork.org/

National HIV/AIDS Clinician's Consultation Center
Warmline: National HIV Telephone Consultation Services
1-800-933-3413
PEPline: National Clincian's Post-Exposure Prophylaxis Hotline
1-888-448-4911
Perinatal Hotline: National Perinatal HIV Consultation and Referral Services
1-888-448-8765
Entecavir in Hepatitis B Virus (HBV)/HIV Co-Infected Patients
Supplement to the Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents -- October 10, 2006
www.aidsinfo.nih.gov/contentfiles/EntecavirInHIV.pdf

Department of Health and Human Services
2006 Adult and Adolescent Antiretroviral Treatment Guidelines
http://www.aidsinfo.nih.gov/guidelines/

International AIDS Society-USA Panel
2006 Recommendations of the Treatment for Adult HIV Infection
http://jama.ama-assn.org/cgi/content/full/296/7/827

American Academy of HIV Medicine
http://www.aahivm.org/

Save the Dates

2007 Intensive Review in Correctional Medicine
St. Louis, MO
September 7-8, 2007
Visit: http://www.cm-institute.org

HIV Therapy, Management & Emerging Treatment Options
Live Satellite Video conference & Webcast
October 3, 2007
12:30-2:30 p.m. EST
Visit: www.amc.edu/hivconference
518.262.4674 or
ybarraj@mail.amc.edu

National Conference on Correctional Health Care
Nashville, TN
October 13-17
Visit: http://www.ncchc.org/education/national2007.html

2007 Annual Conference: Medicine in the Face of Addiction
Society of Correctional Physicians (SCP)
October 14, 2007
Nashville, TN
Visit: http://www.corrdocs.org/framework.php?pagetype=educonference&bgn=1

15th Annual HIV/AIDS Update and Border Health Summit
South Padre Island, TX
24 to 26 October, 2007
Visit: http://www.valleyaids.org

The Liver Meeting 2007
58th Annual Meeting of the American Association for the Study of Liver Diseases
Boston, MA
November 2-6, 2007
Visit: https://www.aasld.org/eweb/DynamicPage.aspx?webcode=07am

2007 United States Conference on AIDS (USCA)
Palm Springs, CA
November 7-10, 2007
Visit: http://www.cdcnpin.org/scripts/display/confdisplay.asp?confnbr=6149

AIDS in Culture IV: Explorations in the Cultural History of AIDS
Mexico City
December 9-13, 2007
Visit: www.aidsinculture.org

News and Literature Reviews

HIV Control Efforts Should Directly Address Incarceration

IDCR editorial board member, Rick Altice, in this editorial in *The Lancet*, asserts that incarceration is one of the major causes of the spread of HIV. He suggests that incarceration can lead to an increase in risk behaviors that lead to acquisition of HIV, disrupt social networks and prevent individuals from maintaining meaningful employment. Additionally, incarceration can inhibit persons with substance abuse problems from entering rehabilitation programs. While incarceration has been framed as an opportunity for a public health intervention in the HIV epidemic, it often provides inadequate treatment of the mental health and substance abuse problems that foster HIV tramsnission. Moreover, HIV-positive offenders often suffer from poor continuity of HIV care upon their release from prison. In response to this problem, Dr. Altice suggests an increase in access to treatment of substance abuse and dependence, solutions to drug-use that balance public safety and public health, advocacy for legislative changes to decriminalize drug use, and activism by communities affected by incarceration.

HIV control efforts should directly address incarceration. Altice F. The Lancet. 2007;7:568-69.

Post-Release Case Management Services and Health-Seeking Behavior Among HIV-Infected Ex-Offenders

Researchers from the Centers for Disease Control and Prevention (CDC) and Health Resources and Services Administration (HRSA) funded Corrections Demonstration Project (CDP) explored the impact of earlier post-release contact with a case manager on the post-release health-seeking behavior of formerly incarcerated HIV-infected individuals. The project, which is designed to foster inter-agency collaboration between public health departments, correctional facilities, and community-based health providers, aims to improve continuity of care for HIV-positive inmates after their release. All participants were receiving some type of case management that was initiated prior to release and continued post-release. The study consisted of 226 ex-offenders who were interviewed six months post-release. Of this group, 104 individuals (46%) were met at the gate at time of prison release by a case manager, while the remaining 122 individuals (54%) were not.

The study provided support for the important role of early post-release case management, as ex-offenders who were met at the gate demonstrated an increase in some health-seeking behavior. After controlling for health-seeking behavior before incarceration, the researchers found that ex-offenders who had been met at the gate were more likely to participate in drug or alcohol treatment and not engage in sex exchange during the six months following their release from incarceration. This exhibition of health-seeking behavior was tempered, however, by the finding that early post-release case management was not associated with reduced emergency room use or the use of street drugs. Although the reason for this finding is unclear, this study emphasizes the importance of early post-release case management in improving health-seeking behavior in ex-offenders.

Post-Release Case Management Services and Health-Seeking Behavior Among HIV-Infected Ex-Offenders. Arriola, K. et al. Journal of Health Care for the Poor and Underserved. 2007;18:665-74.

End-Stage Liver Disease in a State Prison Population

Researchers from the University of Texas Medical Branch recently conducted a study to examine the prevalence, mortality, and clinical characteristics of end-stage liver disease (ESLD) in the Texas Department of Criminal Justice (TDCJ) prison system. The study, analyzed the medical data of 370,511 inmates over a 3.5 year period. ESLD is one of the major consequences of hepatitis C virus (HCV) infection and HIV/HCV coinfection, both of which are known to disproportionately affect prison populations. The prevalence of ESLD in U.S. prisons is expected to rise as the prison-population ages, resulting in a growing number of inmates who require liver transplants.

The TDCJ prison system offers voluntary HIV testing to all inmates upon incarceration and screens all HIV-positive individuals for HCV-infection. As a result, most of the inmates in the study knew their HIV status, but those who were seronegative for HIV had only been tested for HCV if they had self-reported risk behavior or had requested a test. The study found that, of the 370,511 inmates studied, 484 had ESLD and 213 had died of ESLD during the study-period. Inmates who were Hispanic, aged 40-49 years or 50 years and older, were infected with HIV or HCV or both had an elevated risk of ESLD prevalence and mortality. Ninety percent of inmates with ESLD either had HCV monoinfection or HIV/HCV coinfection. Those inmates with HIV/HCV co-infection had higher mortality rates (64.9%) than patients with HCV mono-infection (42.8%) or patients without HCV infection (36.7%). These findings reinforce the belief that HIV/HCV coinfection accelerates the progression of HCV, resulting in increased mortality from ESLD. The growing prevalence of ESLD in the correctional setting, in combination with the high cost of liver transplants, emphasizes the need for increased HCV prevention, education, and treatment.

Baillargeon J, Soloway RD, Paar D. End-Stage Liver Disease in a State Prison Population. Ann Epidemiol. 2007 Aug 4; Epub ahead of print.

Costs of Voluntary Rapid HIV Testing and Counseling in Jails in 4 States - Advancing HIV Prevention Demonstration Project, 2003-2006

This study sought to examine the feasibility of using rapid HIV tests in prisons and jails by examining the costs and outcomes of rapid HIV testing and counseling programs in Florida, Louisiana, New York, and Wisconsin from March 1, 2004 to February 28, 2005. Correctional facilities in these states tested 17,433 individuals for HIV during this time period, resulting in 152 newly identified cases of HIV. Although the costs for these tests were extremely variable, the study found that the average cost of HIV testing for HIV-negative inmates was between $29.46 and $44.98. The cost of testing was significantly higher for HIV-positive inmates and was estimated between $71.37 and $137.72 per inmate. The discrepancy in costs relative to HIV serostatus is due to the extra post-test counseling required for individuals who test positive for HIV. Most of the cost of rapid HIV testing was due to variable costs, including time for counseling and testing, nondurable goods and supplies, and test kits. Fixed costs, such as the cost of program management, training, travel, and durable equipment, composed a smaller portion of testing costs. Average costs for testing varied greatly depending on the location of the correctional facility, as more rural facilities required public health officials and counselors to drive to distant sites. Differences in local wage rates also contributed to the variability in costs. It is hoped that this study's findings can be used to develop rapid HIV testing programs in both prisons and jails across the country.

Costs of Voluntary Rapid HIV Testing and Counseling in Jails in 4 States --- Advancing HIV Prevention Demonstration Project, 2003-2006. Shrestha, R. et al. Sexually Transmitted Diseases. 2007;34(11):000-000.

FDA Approves Novel Antiretroviral Drug

The U.S. Food and Drug Administration (FDA) approved the antiretroviral, maraviroc, for production and distribution. This FDA approval followed two controlled studies with over 1,000 clinical trial participants, 840 of which received maraviroc. The drug, which will be sold under the trade name Selzentry, received a priority review by the FDA and is the first of a new class of antiretroviral drugs that prevent HIV from entering lymphocytes by blocking the CCR5 co-receptor required by certain types of HIV to gain entry into the cell. Maraviroc is approved for use in combination with other antiretroviral drugs for the treatment of adults with CCR5-tropic HIV-1, who have been treated with other HIV medications and who have evidence of elevated levels of plasma HIV. Health care providers should exercise caution in prescribing maraviroc for treatment-naïve adults and pediatric, as it has not been adequately tested in these individuals. Maraviroc's product labeling has a boxed warning about the dangers of liver toxicity (hepatoxicity) and possibility of heart attack. Common side effects of the drug included cough, fever, upper respiratory tract infections, rash, musculoskeletal symptoms, abdominal pain, and dizziness.

http://www.fda.gov/bbs/topics/NEWS/2007/NEW01677.html

Compiled by Christine Devore, IDCR Intern

Self-Assessment Test for Continuing Medical Education Credit

This activity has been planned and implemented in accordance with the Essential Areas and Policies of the Accreditation Council for continuing Medical Education through the joint sponsorship of Medical Education Collaborative, Inc. (MEC) and *IDCR*. MEC is accredited by the ACCME to provide continuing medical education for physicians.

Medical Education Collaborative designates this educational activity for a maximum of 1 AMA PRA Category 1 Credit™. The target audience for this educational program is physcians. Physicians should only claim credit commensurate with the extent of their participation in the activity. Statements of credit will be mailed within 6 to 8 weeks following the program.

Objectives:

- The reader will be able to describe the most significant studies presented at the 4th International AIDS Society Conference in regards to antiretroviral therapy.
- The reader will be able to discuss the most significant studies presented at the 4th International AIDS Society Conference in regards to HIV and viral hepatitis co-infection.
- The reader will be able to summarize the most significant studies presented at the 4th International AIDS Society Conference in regards to resistance and tropism testing.
- The reader will be able to explain the rapid HIV testing program at the Hillsborough County Jail in Tampa, FL.
- The reader will be able to identify new antiretroviral medications.

1. The TITAN study revealed that darunavir appears to be less effective than LPV/r for patients with higher- level PI resistance (≥6 LPV mutations or ?10 LPV FC).

   TRUE or FALSE?

2. Which of the studies presented at the IAS Conference did not reveal that deferral of therapy is associated with poor outcomes?:

   A. SMART
   B. CASCADE
   C. MERIT
   D. ATHENA

3. Which of the following was found to be true in the phase III MERIT study?:

   A. Compared to the efavirenz arm, the mean change in CD4+ counts was statistically superior for the maraviroc arm.
   B. Lack of efficacy was lower with maraviroc.
   C. Adverse events were lower with efavirenz.
   D. The rates of discontinuation were similar between maraviroc and efavirenz.
   E. A and D

4. In a study by Borton and colleagues, 82% of HIV-positive patients who received high-dose HBV vaccine developed anti-HBs titers.

   TRUE or FALSE?

5. Which of the following is NOT a characteristic of the rapid HIV testing program for inmates at the Hillsborough County Jail in Tampa, Florida?

   A. This is a voluntary HIV and syphilis rapid testing program operated by three health department personnel rotating between two facilities.
   B. Health department personnel require only verbal consent for HIV testing.
   C. Inmates have to sign a form stating that they received their results, and the inmate's sero-status is documented on their medical record.
   D. If an inmate requests an HIV test in writing or in the clinic when seeing a provider, the test is then offered by a certified HIV counselor.

In order to receive credit, participants must score at least a 70% on the post test and submit it along with the credit application and evaluation form to the address/fax number indicated. Statements of credit will be mailed within 6-8 weeks following the program.

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	Excellent	***Very Good***	***Good***	***Fair***	***Poor***
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Content					
How well did this activity avoid commercial bias and present content that was fair and balanced?					
What is the likelihood you will change the way you practice based on what you learned in this activity?					
Overall, how would you rate this activity?					

II. Course Objectives

Were the following overall course objectives met? At the conclusion of this presentation, are you able to:

- The reader will be able to describe the most significant studies presented at the 4th International AIDS Society Conference in regards to antiretroviral therapy. **YES NO SOMEWHAT**
- The reader will be able to discuss the most significant studies presented at the 4th International AIDS Society Conference in regards to HIV and viral hepatitis co-infection. **YES NO SOMEWHAT**
- The reader will be able to summarize the most significant studies presented at the 4th International AIDS Society Conference in regards to resistance and tropism testing. **YES NO SOMEWHAT**
- The reader will be able to explain the rapid HIV testing program at the Hillsborough County Jail in Tampa, FL. **YES NO SOMEWHAT**
- The reader will be able to identify new antiretroviral medications. **YES NO SOMEWHAT**

III. Additional Questions

a. Suggested topics and/or speakers you would like for future activities.

b. Additional Comments

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