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ABOUT IDCR

IDCR, a forum for correctional problem solving, targets correctional physicians, nurses, administrators, outreach workers, and case managers. Published monthly and distributed by email and fax, IDCR provides up-to-the moment information on HIV/AIDS, hepatitis, and other infectious diseases, as well as efficient ways to administer treatment in the correctional environment. Continuing Medical Education credits are provided by Medical Education Collaborative (MEC). This activity is jointly sponsored by IDCR and Medical Education Collaborative (MEC). IDCR is distributed to all members of the Society of Correctional Physicians (SCP) within the SCP publication, CorrDocs (www.corrdocs.org).

FROM EVIDENCE TO ACTION ON HIV/AIDS IN PRISONS: A REPORT FROM THE XVI INTERNATIONAL AIDS CONFERENCE

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***Disclosures**: - Nothing to disclose.*

The XVI International AIDS Conference, "AIDS 2006," took place August 13-18 and attracted 26,000 researchers, physicians, front-line workers, advocates and others involved in the fight against HIV/AIDS from more than 170 countries. More than ever before,[1] issues related to HIV/AIDS in prisons were presented and discussed. On the first day of the conference, a satellite meeting organized by the United Nations (UN) Office on Drugs and Crime, the Public Health Agency of Canada and the Correctional Service of Canada debated issues related to HIV/AIDS in prisons in great depth. At the Conference itself, two oral sessions and a large number of poster presentations were dedicated to HIV/AIDS in prisons. In addition, the UN released an important guidance document on issues related to HIV/AIDS in prisons. Most activities focused on HIV prevention, although delegates also heard about efforts to make HIV treatment, including antiretrovirals, available to prisoners in developing countries.

While it is impossible to provide a detailed overview of all the prison-related developments presented at AIDS 2006, this article will highlight some of the relevant findings presented at the conference.

Prevention: Moving from Evidence to Action

Probably the most important development at the conference is an emerging consensus that there is sufficient evidence of the effectiveness of HIV prevention interventions in prisons, and that it is time to move from evidence to action and implement these interventions in prisons. This includes interventions such as condom provision that are currently the subject of much debate in the United States, as well as interventions that have been successfully introduced in other countries, but are rarely if ever discussed in the United States, such as needle and syringe programs in prisons.

Because of the importance of HIV prevention in prisons to the overall fight against HIV/AIDS, the World Health Organization (WHO) in 2005 commissioned a review of the effectiveness of HIV interventions in prisons. At one session, Dr Andrew Ball from WHO presented a summary of the main conclusions and recommendations reached by the review, which will soon be published as part of the WHO "Evidence for Action" papers series.[2] The review contains the most detailed and rigorous analysis of the evidence related to HIV/AIDS in prisons undertaken to date. In his presentation, Dr. Ball pointed out that sexual activity within prisons has been reported from around the world; that studies in several nations have shown that injecting drug use is also a reality in many prisons; that even countries that have invested heavily in drug demand and drug supply reduction efforts in prisons have not been able to stop injecting drug use; and that outbreaks of HIV infection have been documented in a number of prison systems, demonstrating how rapidly HIV can spread in prison unless effective action is taken to prevent transmission. He went on to say that HIV programs in prisons often exclude necessary interventions for which evidence of effectiveness exists, and that there is an urgent need to introduce more comprehensive programs.

Condom Provision

Dr. Ball reported that the available research and the experience of many prison systems in different parts of the world in which condoms are provided to prisoners suggest that providing condoms in prisons is feasible in a wide range of prison settings. No prison system allowing condoms has reversed its policy on condom provision, and none has reported security problems or any other relevant major negative consequences. In particular, it has been found that condom access is unobtrusive to the prison routine, represents no threat to security or opera-

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WHAT'S INSIDE

Letter from the Editor

Dear Corrections Colleagues,

For the past two decades, people from around the globe involved in the fight to combat the HIV/AIDS pandemic have gathered at two-year intervals at the International AIDS Conference (IAC). Like attendees at typical scientific meetings they trade data and share lessons learned. But those coming to an IAC also know well that there will be much more than PowerPoint presentations to see as clinicians, scientists, activists, industry representatives and policy makers mix and, at times clash as they debate strategies, set policies and launch initiatives to advance HIV treatment and prevention. Past conferences have served as watershed events in the history of HIV/AIDS ushering in the era of HAART in 1996 and focusing the world's attention on AIDS in developing countries in 2000.

The International AIDS Conference (IAC) held in Toronto in August was attended by almost 30,000 people and focused on the urgent need to deliver the promise of therapeutic and preventive advances to those affected by HIV/AIDS. A thread running through much of this conference was the plight of those living with HIV infection and incarcerated in our prisons and jails. During plenary sessions on global AIDS epidemiology, keynote speeches by policy makers and activists and in oral sessions on HIV transmission prevention, the role of incarceration in the spread of HIV and the need to provide quality HIV therapy to those imprisoned was featured. Two sessions of oral presentations were actually dedicated to this theme, reflecting the emergence of incarceration as an item on the agenda of the HIV treatment/prevention communities.

Ralf Jurgens, an IDCR board member, member of the IAC Scientific Committee and a Canadian himself, reports on presentations centering on the nexus between HIV and incarceration. In his report he provides a look at approaches to HIV transmission prevention in prisons and jails that have been explored largely outside the U.S. Some of the strategies he presents, such as those advanced by the World Health Organization (WHO), are controversial and provoke strong responses regarding feasibility and safety. Such responses are expected and, indeed, healthy. The IAC is a platform for the presentation of data that others can use and adapt to meet the needs of those they serve, what works in Moldova may not work in Mississippi but it may be of interest to a jailer in Miami. No matter where you are, join the debate by emailing your letter to editor to me at wohl@med.unc.edu or Anne Degroot at Anne_Degroot@brown.edu

Data on HIV therapeutics could also be found in Toronto and the major clinical trials findings are included in an article accompanying Ralf's report. You will also find a summary of the recent Institute of Medicine report on the ethics of research in prisons - an important report that will have considerable impact on the conduct of research studies in correctional settings

Lastly, while we were going to press the Centers for Disease Control and Prevention (CDC) made their long-awaited announcement regarding changes to their HIV testing recommendations. These changes include vastly expanding HIV testing and removal of separate written consents and extensive pre-test counseling - considered obstacles to testing. These new recommendations will have tremendous implications for HIV screening in correctional facilities and will be covered in detail in our next issue.

Sincerely,

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tions, does not lead to an increase in sexual activity, and is accepted by most prisoners and correctional officers once it is introduced. Generally, only minor incidents of misuse such as water balloons, water fights and littering were recorded.

Studies have not determined whether infections have been prevented due to condom provision in prison. However, data from a variety of settings have documented the effectiveness of condoms in preventing sexually transmitted infections and there is evidence that prisoners use condoms to prevent infection during sexual activity when they are accessible. Evidence suggests that condoms are more likely to be used if they are easily and discreetly accessible so that they can pick them up at various locations in the prison, without having to ask for them and without being seen by others.

Needle and Syringe Programs
The first prison needle and syringe program (NSP) in the world was established in Switzerland in 1992. Since then, NSPs have been introduced (or are about to be introduced) in various prison environments in 11 countries in Western and Eastern Europe and in Central Asia.

Systematic evaluations of the effects of NSPs on risk behaviors and of their overall effectiveness in prisons were carried out in at least 10 projects in Switzerland, Germany, and Spain. According to Dr. Ball, there is evidence that NSPs are feasible in a wide range of prison settings, including in men's and women's prisons, prisons of all security levels, and small and large prisons. There is also evidence that providing clean needles and syringes is readily accepted by injecting drug users in prisons and may contribute to a significant reduction of syringe sharing over time. It also appears to be effective in reducing resulting HIV infections.[3-6] At the same time, there is no evidence to suggest that prison-based NSPs have serious, unintended negative consequences. In particular, the WHO report states that they do not appear to lead to increased drug use or injecting, and needles have not been used as weapons. Evaluations have found that NSPs in prisons actually facilitate referral of drug users to drug dependence treatment programs.

Methadone Maintenance Treatment (MMT)
A wealth of scientific evidence has shown that, in the community, MMT is the most effective intervention available for the treatment of opiate dependence. MMT has been shown to be effective in improving the physical and social wellbeing of the patient and has been associated with reductions in risk behavior, illegal drug use, criminal behavior, participation in sex work, unemployment, mortality, and HIV transmission.

Dr. Ball reported that, more recently, a substantial body of research has delivered significant findings regarding the effectiveness and acceptability of MMT in prison settings:

- Adequate prison-based MMT pro grams appear to be effective in reducing injecting drug use and associated needle sharing.
- Prisoners need a daily dose of at least 60 mg of methadone and treatment is generally required for the duration of incarceration for these benefits to be realized in prison.
- Adequate prison-based MMT programs have additional and worthwhile benefits:
  - MMT in prison significantly facilitates entry and retention in post-release treatment compared to prisoners enrolled in detoxification programs;
  - Re-incarceration is significantly less likely among those prisoners who receive MMT while incarcerated;
  - MMT has a positive effect on institutional behavior by reducing drug-seeking and thus improving prison safety;
  - Although prison administrations often initially raise concerns about security, violent behavior, and diversion of methadone, these problems do not emerge once the MMT program is implemented.
- MMT may help to reduce risk of overdose for those nearing release.
- There is evidence that people who are on MMT and who are forced to withdraw from it because they are incarcerated often return to narcotic use, often within the prison system, and often via injecting. Therefore, particular efforts are needed to ensure that prisoners on MMT prior to imprisonment are able to continue this treatment while in prison.

Other Forms of Drug Dependence Treatment
Dr. Ball pointed out that, in contrast to MMT, other forms of drug dependence treatment have not usually been introduced in prison with HIV prevention as one of their objectives. There is, therefore, little data on the effectiveness of these forms of treatment as an HIV prevention strategy. However, good quality, appropriate, and accessible treatment has the potential of improving prison security, as well as the health and social functioning of prisoners, and it can reduce reoffending. Such treatment in prison can help reduce the amount of drug use in prisons and upon release. But there is a need for independent and systematic outcome evaluations of these interventions, and for examining their effectiveness in reducing injecting drug use and needle sharing.

Alternatives to Imprisonment
Ultimately, Dr. Ball said, research suggests that reducing the number of people who are in prison because of problems related to their drug use must be a priority. Studies have shown that fear of arrest and sanctions is not a major factor in an individual's decision on whether to use or deal drugs; and that there is little correlation between incarceration rates and drug use prevalence in particular countries or cities. As early as 1987, WHO, in a statement from the first Consultation on Prevention and Control of AIDS in Prisons, said that "[g]overnments may … wish to review their penal admission policies, particularly where drug abusers are concerned, in the light of the AIDS epidemic and its impact on prisons."

Prevention in Action: Examples from around the World
Other presentations at AIDS 2006 focused on how HIV prevention measures have been introduced in practice in prison environments around the world:

Morag MacDonald presented work undertaken in Ukraine to move from evidence about HIV transmission in prison to implementation of HIV prevention measures, notably needle and syringe programs.[7] In a study conducted in 2005 in seven prisons in five regions of Ukraine among 831 prisoners, between 16% and 32% of prisoners tested HIV-seropositive, and 75.5 and 91.5% of prisoners tested HCV seropositive in the two prisons in which HCV testing was also undertaken.

In addition, an HIV transmission cohort study in two prisons showed that six cases of HIV infection occurred between December 2004 and August 2005 among the 276 prisoners who were still in the cohort in August 2005. Initially, 400 who were in prison for more than six months were recruited to participate in the study. In order to assist the Ukrainian prison system with the implementation of HIV prevention measures in prisons, a partnership was struck between the Ukrainian prison system, a number of Ukrainian non-governmental organizations (NGOs), and the Canadian HIV/AIDS Legal Network. As a result of a number of joint activities, including trainings of senior staff and prison study tours with existing prevention programs, the initial resistance to implementation of pilot needle and syringe projects was overcome, and projects were scheduled to start in 2006. However, the elections in Ukraine and the following long period of political uncertainty have delayed the implementation of the pilot projects.

Anak Agung Gede Hartawan from Kerobokan Prison in Bali, Indonesia, described how the prison introduced the first MMT program in a prison in Indonesia.[8] Currently, 32 of 785 prisoners receive MMT and the program will soon be expanded to other prisons. If medically indicated, prisoners are allowed to start MMT in prison. Other prisoners are allowed to

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continue such treatment started in the community. In addition to MMT, condoms and bleach are also available in the prison.

Dumitru Laticevschi from Moldova explained how a comprehensive prevention program (including provision of condoms, bleach, needle and syringe programs, and MMT) was introduced in prisons in his country, and how this program has contributed to preventing further spread of HIV among prisoners and, ultimately, to the general community.[9]

HIV Care, Treatment, and Support

Presentations from a number of countries at AIDS 2006 showed that providing HIV therapy for prisoners is a challenge, but is necessary and feasible. The WHO review of existing studies, many of who were undertaken in the United States, showed:

- When provided with care and access to medications, prisoners respond well to antiretroviral treatment.
- Adherence rates in prisons can be high as or higher than that among patients in the community. This is also true for injecting drug users, particularly when they can access MMT.
- However, the gains in health status made during the term of incarceration may be lost unless careful discharge planning and linkage to community care are undertaken.

Presenters at the conference highlighted that, as ART is increasingly becoming available in developing countries and countries in transition, it will be critical to ensure that it also becomes available in the countries' correctional systems. Ensuring continuity of care from the community to the prison and back to the community, as well as continuity of care within the jail/prison system, is a fundamental component of successful treatment scale-up efforts. Presentations from four countries in Africa highlighted the many obstacles that exist to treatment access in prisons in Africa. Jonathan Berger from South Africa talked about the efforts his organization, the AIDS Law Project, is undertaking to ensure access to treatment in prisons, partly through litigation against the South African Department of Correctional Services, which has to date failed to provide adequate access to ART.[10] Alick Nyirenda from Zambia reported about a campaign that started in 2005 to offer voluntary HIV counseling and testing, as well as care and treatment, to prisoners. Of the first 100 prisoners tested, 64 tested HIV positive, and 15 were commenced on ART.[11] At the satellite meeting organized by the UN Office on Drugs and Crime, the Public Health Agency of Canada and the Correctional Service of Canada, presenters from Nigeria[12] and Kenya[13] also discussed the barriers they faced and the efforts they have undertaken to scale up access to HIV counseling and testing and to treatment.

Giving a Voice to (Former) Prisoners

For the first time at an International AIDS Conference, delegates were able to hear not only from researchers and staff working in prisons, but also from former prisoners, who are experts on HIV/AIDS in prisons because they live with the disease, know fellow prisoners living with HIV, know what risk behaviors prisoners engage in, and whether or not existing efforts respond to their needs and make a difference. James Motherall, a former prisoner and peer health worker in a federal prison in Canada, said that "the fight against AIDS will not be won until we can reach out to those we are angriest at, until we can extend to our prisoners the same compassion, human rights and dignity that we are prepared to extend to others".[14] Connor McCollum, another former prisoner talked about the experience of prisoners living with and/or at risk of HIV and HCV in Canadian prisons.[15] Finally, Igor Sobolev from Estonia presented the work of an NGO that has been active since 2002 in prisons, providing support to HIV-infected drug-dependent prisoners.[16]

What about the United States?

At previous conferences, research on HIV/AIDS in prisons from the United States had often been presented in oral sessions. At AIDS 2006, only a number of poster presentations highlighted new developments and findings from the United States. This was due to two factors:

- The effort made by conference organizers to include more research from developing and transitional countries, particularly in Africa, Eastern Europe and South-East Asia, which are facing serious HIV/AIDS epidemics in prisons; and
- The fact that, increasingly, the United States are seen by international experts as lagging behind other countries in the provision of evidence-based prevention interventions in prisons.

On the other hand, researchers in the United States continue to do cutting-edge research, including on interventions to improve access to care, reduce transmission risk behavior and recidivism in HIV-infected prisoners following release. Two posters presented preliminary results of the BRIGHT study, a randomized control trial in HIV-infected state prison inmates in North Carolina of a Strengths-Based Model of case management designed to bridge incarceration and release (versus standard discharge planning conducted prior to release only). Preliminary data indicate that a case management intervention for HIV-infected prisoners spanning the periods prior to and after prison release is successful in increasing access and utilization of HIV medical care, reducing emergency room utilization, and reducing early recidivism.17 Interviews with participants in the study six months after release showed that for HIV-infected prisoners, release is a time associated with great emotion and anxiety, particularly with respect to substance abuse and family relationships. This confirms that more intensive release preparation programs spanning the continuum of both pre- and post release are needed, and that these programs should not only provide HIV-related care and support services, but a broader spectrum of support including substance abuse prevention and treatment and community supports.[18]

New Resources

A final important development at AIDS 2006 was the release, by three UN agencies (the UN Office on Drugs and Crime, the World Health Organization, and UNAIDS), of "HIV/AIDS Prevention, Care, Treatment and Support in Prison Settings: A Framework for an Effective National Response".19 Consistent with the message of the sessions and presentations at the conference, the document emphasizes that "good prison health is good public health," saying that "the vast majority of people committed to prison eventually return to the wider society" and that "therefore reducing the transmission of HIV in prisons is an important element in reducing the spread of infection in society outside of prisons." The document also highlights that "protecting and promoting the health of people in prison benefits not only the prisoners, but also increases workplace health and safety for prison staff."

The document stresses, "people in prison are entitled, without discrimination, to a standard of health care equivalent to that available in the outside community, including preventive measures." It calls upon decision-makers "to acknowledge that high risk behaviors for the transmission of HIV occur within prisons - especially injecting drug use, sexual activity, and sexual abuse/violence - and to base decisions affecting prison health on evidence, recognized best practice, and legal and ethical obligations, rather than on public opinion or political expediency." It recommends implementation of comprehensive HIV/AIDS prevention and education (including condoms and sterile needles and syringes), voluntary counseling and HIV testing, HIV/AIDS care and treatment for prisoners, and drug dependence treatment programs in prisons.

Read the op-ed by Dr. Lester Wright in response to the WHO recommendations at www.idcronline.org

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Management of HIV Infection:
A summary of data presented at the XVI International AIDS Conference

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The International AIDS Conference (IAC) is increasingly becoming a global forum for the presentation of data and information related to the prevention of HIV infection as well as the effects of the disease on the lives of those with HIV/AIDS. Advances in knowledge about HIV pathogenesis and therapeutics have taken a back seat to the pressing social and behavioral dimensions of the epidemic and are now the focus of several smaller conferences and meetings. However, for those with patience, the XVI International AIDS Conference held in Toronto held a few clinical trial gems - most presented on the final day of the conference during the late breaker session. The major findings likely to have implications for the management of HIV-infected individuals in and out of prison/jail are summarized below.

Initial HIV Therapy

Efavirenz (Sustiva) versus Lopinavir/Rito - navir (Kaletra) The non-nucleoside reverse transcriptase inhibitor (NNRTI), efavirenz and the protease inhibitor (PI) co-formulated drug lopinavir/ritonavir are each anchors of the regimens listed as 'preferred' in the US Department of Health and Human Services (DHHS) guidelines for initial therapy of HIV infection. [1] Both drugs are popular but in many ways these are very different agents. Beyond their disparate targets, they differ in pill count, side effects and cost. However, they share an accumulation of clinical trial data that demonstrate their relative potency in suppressing HIV replication long term. How they stack-up against one another, though, has not been clear.

The US AIDS Clinical Trials Group (ACTG) launched study A5142 to compare these antiretroviral behemoths.[2] A total of 753 patients on antiretroviral (ART) were randomized to one of three arms: a) two nucleoside reverse transcriptase inhibitors (NRTIs) plus efavirenz; b) two NRTIs plus lopinavir/ritonavir or c) efavirenz plus lopinavir/ritonavir (a novel NRTI-sparing approach). The choice of NRTIs in the first two arms was left to the discretion of the local investigator. The study endpoints included virologic failure (lack of a ten-fold decline in HIV viral load or viral rebound during first 32 weeks of the study or failure to reach a viral load below 200 copies/mL after week 32) and regimen completion (treatment discontinuation for virologic failure or toxicity related discontinuation of regimen component).

While many thought they could predict the trial results, few did so correctly. The times to virologic failure and regimen completion were shorter with lopinavir/ritonavir than with efavirenz and the proportion of participants with a viral load below 50 copies/mL at 96 weeks was 89% for efavirenz, 77% for lopinavir/ritonavir and 83% for the combination (the comparison between efavirenz and lopinavir/ritonavir was statistically significant, p = 0.003). The differences between the arms were not as marked when looking at the proportion with viral loads less than 200 copies/mL with more patients in the lopinavir/ritonavir arm having viremia between 50 and 200 copies/mL.

The sound of the proverbial other shoe dropping came from the resistance data. While efavirenz and two NRTIs performed the best virologically, the few participants that did fail this combination were more likely to have drug resistance than those experiencing failure in the lopinavir/ritonavir. Of those who were treated with efavirenz and experienced failure, half had evidence of NNRTI resistance and a third had NRTI resistance detected. In contrast, relatively few subjects in the lopinavir/ritonavir group who had virologic failure had detectable resistance mutations (15% NRTI, 4% NNRTI and 0% PI resistance). In addition, despite the virologic results, CD4+ cell count increases were overall greater during treatment with lopinavir/riotnavir than efavirenz (268/mm^3 versus 241/mm^3, p = 0.01).

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Limited toxicity data were presented but the three regimens appeared to be similarly well-tolerated; however, hypertriglyceridemia above 750 mg/dL was observed in 14% of the NNRTI/PI arm but only 3-6% of those of those in the other two arms.

These important results suggest that virologic suppression to below the limits of assay detection are more likely with an initial regimen containing two NRTIs plus efavirenz than two NRTIs and lopinavir/ritonavir. The trade-off when using dual NRTIs and efeavirenz may be a greater risk of drug resistance among the few that do experience virologic break through and a slightly lower CD4+ cell count response. Further data on lipids and body shape will be forthcoming and will likely help to complete the comparison between these two treatment approaches.

Tenofovir/Emtricitibine (Truvada) versus Zidovudine/Lamivudine (Combivir)
After deciding whether to use a PI or an NNRTI, the clinician initiating HIV therapy must then choose which NRTIs to add to the mix. Combination formulations of NRTIs have reduced pill count and are a popular choice. Both tenofovir/emtricitabine (TDF/FTC) and zidovudine/lamivudine (ZDV/3TC) are included in the DHHS guideline for first line use and their relative efficacy and tolerability are being studied in a study sponsored by the maker of TDF/FTC, data from which was presented at the IAC.[3]

This is an open-label, 144-week trial in which 255 treatment-naïve patients were randomly assigned to open-label TDF/FTC plus efavirenz or ZDV/3TC plus efavirenz. Previously, the 48-week data were announced and demonstrated that the proportion of participants with a viral load less than 50 copies/mL at that time point was significantly higher among those receiving TDF/FTC. Importantly, failure was defined using the FDA standard for efficacy, time to loss of virologic response (TLOVR), which requires virologic suppression and no treatment-limiting toxicity. At 48 weeks, adverse effects among those assigned ZDV/3TC largely drove the difference between study arms - given efficacy was judged using the TLOVR composite endpoint.

In Toronto, an update of the data at 96 weeks indicate that the differences between the arms have narrowed with no significant difference in the proportion with a viral load less than 50 copies/mL observed between the arms using the TLOVR criteria for failure. However, there was a significant difference in the proportion with a viral load below 400 copies/mL - the main outcome of the study - favoring TDF/FTC (75% in TDF/FTC arm versus 62% in ZDV/3TC arm less than 400 copies/mL at week 96, p = 0.004). In addition, mean CD4+ cell count increases were greater in the TDF/FTC arm versus the ZDV/3TC arm (270/mm^3 versus 237/mm^3, p=0.036). Again, treatment-limiting toxicity, particularly anemia, was responsible for the relatively poorer performance of ZDV/3TC as the two regimens performed equally when only the viral suppression was considered.

Renal function was followed during the study using several measures including serum creatinine and estimations of glomerular filtration rate (GFR) and creatinine clearance (CrCl). Serum creatinine was not observed to significantly change; however, this is considered a crude assessment of renal health. CrCl as calculated by the Cockcroft-Gault equation did not demonstrate a significant difference between arms during the study; a statistically significant decrease in GFR during TDF/FTC treatment was detected using the Modification of Diet in Renal Disease (MDRD) equation. This difference was small (decline from 110 to 100 mL/min/1.73m^2 in TDF/FTC arm versus gain of 3 mL/min/1.73m^2 in the ZDV/3TC arm, [p =0.006]) and remained stable during the course of the study. The Cockcroft-Gault equation includes weight while the MDRD does not but does consider race as a variable. Note, patients had to have relatively normal renal function to be eligible for participation in this study. As previously demonstrated, DEXA assessed limb fat was seen to decline in the ZDV/3TC group compared to a gain in limb fat in the TDF/FTC subjects.

Resistance testing revealed that in both arms, mutations to efavirenz was most common among those with virologic failure, followed by resistance to FTC and 3TC. Thus far, the K65R mutation, which confers broad NRTI resistance and has been associated with tenofovir, was not seen with either study treatment.

Simplifying Therapy
Interest in simplifying combination HIV therapy has existed almost as long as there has been a three-drug antiretroviral cocktail. Early forays into induction-maintenance strategies produced inconsistent results but with the advent of potent ritonavir-boosted PIs, there have been renewed efforts to distill HAART to a simple regimens - including single drug treatment. Several presentations at the conference examined use of lopinavir/ritonavir as single agent therapy. In one study, lopinavir/ritonavir along with ZDV/3TC was administered to 104 treatment-naïve patients and those who achieved a viral load less than 50 copies/mL by three months then had the NRTIs removed.[4] Compared to a control arm receiving ZDV/3TC plus efavirenz, there was no significant difference in virologic suppression below 50 copies/mL at week 96 between the strategies and, interestingly, low level viremia was more commonly seen with lopinavir/ritonavir. In another study, 200 patients with suppressed HIV viremia on HAART were randomly assigned to lopinavir/ritonavir monotherapy or lopinavir/ritonavir plus ZDV/3TC.[5] Again, at 48 weeks there was no difference in the proportion of subjects in each arm with a viral load less than 50 copies/mL. Lastly, upping the monotherapy ante, French investigators assigned treatment-naïve patients to lopinavir/ritonavir alone or lopinavir/ritonavir plus ZDV/3TC. [6] In the intent-to-treat analysis the study arms produced rates of viral suppression below 50 copies/mL that were not significantly different. However, an on-treatment analyses demonstrated higher rates of low level viremia in the monotherapy arm. In all three studies, PI resistance during monotherapy was observed in a proportion of those with virologic failure in whom genotype testing was performed strongly suggesting that there is a small but important risk of resistance with this minimalist approach.

Monotherapy with a boosted PI holds many attractions but there are risks, as these studies demonstrate, namely increased rates of low level viremia and the possibility of PI resistance. Investigation of boosted PI monotherapy continues, and studies of other agents are ongoing (see News and Reviews). These will help define the role of boosted PI monotherapy. Until then, this is an approach that must be considered investigational.

The Treatment-Experienced Patient

For patients harboring a drug resistant virus, drugs able to suppress such viral strains are often desperately needed. The recent approval of agents active against drug resistant HIV, particularly tipranavir (Aptivus) and darunavir (Prezista), are important developments in the management of HIV disease and hold out hope for treatment-experienced patients. Updated 48 week data from two large trials of darunavir, POWER 1 and 2 were presented at the IAC.[7] Both POWER 1 and 2 studied patients with triple ARV class experience (mean number of PI mutations was three), at least one PI mutation and an HIV RNA level >1,000 copies/mL. The aim of both studies is to determine the optimal dose of the darunavir and its efficacy compared to an investigator selected ritonavir-boosted PI when both were included with optimized ARV regimens using existing drugs informed by resistance testing. In an analysis combining subjects from these two similar studies which compared responses among 131 subjects receiving 600 mg/100 mg of darunavir/ritonavir BID twice daily (the US FDA approved dose) and 124 on an optimized regimen alone, 46% of those assigned darunavir/ritonavir and 10% of the controls achieved a viral load of less than 50 copies/mL at 48 week (p = 0.001). The mean CD4 cell count increase was 102/mm^3 versus 19/mm^3 for the darunavir/ritonavir and control arms, respectively (P < 0.005). Darunavir/ritonavir was well tolerated without excess toxicity relative to the control arm.

Data were also presented on many of the new agents coming down the pike or already

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Management of HIV Infection...
(continued from page 6)

pulling into the driveway. Results demonstrating the antiviral activity of TMC-125, an NNRTI with activity against NNRTI-resistant HIV strains[8]; MK-0518, the first integrase inhibitor that will likely come to market[9]; the CCR5 inhibitors vicriviroc and maraviroc [10,11] and the maturation inhibitor TNX-355[12] were presented and justify an optimistic perspective on the future of HIV therapy.

Conclusions

The IAC is like no other conference. It is big, boisterous, political and a great opportunity to spot celebrities. While the conference has shifted away from therapeutics, the few clinical trial data presented this year did advance our understanding of the abilities of existing drugs and introduced us to hopeful newer agents. These results had a tough time competing for attention with the speeches by notables and the coverage of the more sensational aspects of the conference, but are of great importance to the enhancement of our care of HIV-infected persons in our correctional facilities.

References:

1. *U.S. Department of Health and Human Services, Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents - May 4, 2006 - www.aidsinfo.nih.gov - accessed September 14, 2006*
2. *Riddler S, et al. IAC 2006. Abstract THLB0204*
3. *Gallant J, et al. IAC 2006. Abstract TUPE0064*
4. *Cameron W, et al. IAC 2006. THLB0201*
5. *Arribas J, et al. IAC 2006. THLB0203*
6. *Delfraissy J-F, et al. IAC 2006. THLB0202*
7. *Lazzarin A, et al. IAC 2006. Abstract TUAB0104*
8. *Cohen C, et al. IAC 2006. Abstract TUPE0061*
9. *Markowitz M, et al. IAC 2006. Abstract THLB0214*
10. *Gulick R, et al. IAC 2006. Abstract THLB0217*
11. *Mayer H, et al. IAC 2006. Abstract THLB0215*
12. *Norris D, et al. IAC 2006. Abstract THLB0218*

Spotlight - Health Through Walls, Sustainable Prison Healthcare in Developing Countries: An Interview with John May, MD

Elizabeth Closson
IDCR Managing Editor

Disclosure:
EC - Nothing to disclose. JM - Speaker's Bureau: Abbott Laboratories, Boehringer Ingelheim, Bristol-Myers Squibb, Gilead Sciences.

Elizabeth Closson (EC): What is your current job?

Dr. John May (JM): I am Chief Medical Officer for Armor Correctional Health Services, based in Coconut Creek, Florida. We provide comprehensive health care services at several jails in Florida and a few prisons in Virginia. I am also an Associate Clinical Professor at NOVA Southeastern College of Medicine. In 2005, I founded Health through Walls, a non-profit organization of U.S.-based correctional health care professionals providing volunteer consultation and assistance to prison health care programs in developing countries.

EC: How would you describe your volunteer activities overseas with correctional institutions?

JM: Nearly every two months since 2001, we have provided patient care, resources, staff training, or consultations inside the Caribbean prisons of Haiti, Dominican Republic, or Jamaica. In addition we work in the African countries of South Africa, Tanzania, and Ghana. U.S. doctors, nurses, and others with correctional experience donate their time, travel at their own expenses, and collect and deliver needed materials to the prison programs. Our primary focus is the screening, prevention, and treatment of infectious disease, particularly HIV and tuberculosis. Our role is to guide and be in solidarity with prison health staff, build sustainable alliances within the community, and advocate for our patients.

EC: How did you get involved in providing help to overseas correctional institutions?

JM: I think it's natural for many correctional health care professionals to extend themselves to the underserved and disenfranchised and also to recognize that managing prison health and infectious disease is essential to public health. Health through Walls began as a personal quest to do just that, and has grown as countries learn of our work and request our services.

EC: What do you think the most pressing needs are in the countries you visit?

JM: It begins with a political and cultural commitment to recognize the humanity and dignity of incarcerated persons. This includes a commitment to the rights of the individual, including health, and the allotment of adequate resources for the population. In the countries in which we operate, some prisons struggle and fail to provide adequate nutrition and clean water. Many are so overcrowded that infectious diseases flourish. All need improved access to diagnostic services and medications, particularly antiretrovirals. Prisoners are dying because they cannot access treatment.

EC: How could other providers get more involved?

JM: The American Correctional Association has a project to deliver donations to prison systems of developing countries. They can facilitate contributions of equipment and supplies. Health through Walls needs clinicians, evaluators, diagnostic equipment, technical support, and unexpired medications especially antiretrovirals. Providers can contact me if they have something to contribute by email atjmay@armorcorrectional.com.

EC: What lessons have you learned through your volunteer activities that have applied to your domestic work?

JM: I never let a supply or medication go to waste or be used unnecessarily. I've gained admiration for the diagnostic skills and clinical judgment of clinicians practicing in settings of limited resources. And I've been inspired by the stronger emphasis in many countries on rehabilitation, openness to harm reduction measures, and keeping the prisoner more closely connected to family and community. Not surprisingly, they don't have the same high level of recidivism as we do.

Resources

XVI International AIDS Conference 2006
http://www.aids2006.org/

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

2006 United Nations Office of Drugs and Crimes' HIV/AIDS Prevention, Care, Treatment and Support in Prison Settings: A Framework for an Effective National Response
http://www.unodc.org/unodc/en/drug_demand_hiv_aids_policy.html

Health Through Walls: Sustainable Prison Healthcare in Developing Countries
http://www.healththroughwalls.org/

Institute of Medicine' 2006 Ethical Considerations for Research Involving Prisoners
http://www.iom.edu/CMS/3740/24594/35792.aspx

2003 Department of Health and Human Services Office for Human Research Protections Guidelines on the Involvement of Prisoners in Research
http://www.hhs.gov/ohrp/humansubjects/guidance/prisoner.htm

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

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www.virologycme.com

HIV 101 Results at 96 Weeks of A5142 - A Randomized Study of Initial HIV Therapy with Efavirenz or Lopinavir/Ritonavir Along with Two NRTIs or the Combination of the Two Alone.

	LPV/r (n=253)	EFV (n=250)	LPV/r+EFV (n=250	P Value LPV/r vs. EFV
% <50 HIV copies/mL (ITT)	77 %	89 %	83 %	0.003
% <200 HIV copies/mL (ITT)	86 %	93 %	92 %	0.041
% Without virologic failure*	67 %	76 %	73 %	0.006
% Without regimen completion due to virologic failure or toxicity**	54 %	60 %	61 %	0.02
CD4+ cell count change from baseline (/mm^3)	+285	+241	+268 %	0.01
Genotypic resistance mutations detected [# subjects (% genotypes in that arm)]:				
NRTI	8 (15%)	11 (33%)	4 (10%)	Not Reported
M184V	7	8	1	
K65R	0	3	0	
NNRTI	2 (4%)	16 (48%)	27 (69%)	
K103N	0	9	21	
Major PI (IAS guidelines)	0	0	2	
% Fasting triglycerides >750 mg/dL	6%	3 %	14 %	Not Reported

Modified from: Riddler S, et al. IAC 2006. Abstract THLB0204

LPV/r = Lopinavir/ritonavir, EFV = Efavirenz, ITT = intent-to-treat analysis with missing considered a failure, NRTI = nucleoside reverse transcriptase inhibitor, NNRTI = non-nucleoside reverse transcriptase inhibitor, PI = protease inhibitor. IAS = International AIDS Society
**Virologic failure defined as a) lack of 1 log10 drop in viral load or rebound before week 32 or b) failure to suppress to <200 copies/mL or rebound after week 32. Threshold for statistical significance p <0.016.*
***Regimen completion defined as virologic failure or toxicity related discontinuation of any regimen component. Threshold for statistical significance p <0.016.*

Special Report

In June of 2006 the Institute of Medicine (IOM) issued a report entitled Ethical Considerations for Research Involving Prisoners. The report documents the recommendations of an IOM committee commissioned by the Office of Human Research Protections (OHRP) of the Department of Health and Human Services (DHHS), to review the ethical considerations in research involving prisoners. The report will serve as the guideline for the updated prisoner protection regulations set forth by the DHHS. The committee contends that while the OHRP's jurisdiction is inherently limited, its enforcement of codified oversight should be strengthened. The recommendations found in the report should therefore be imposed on all governmental and privately funded research. See IDCR-O-GRAM for a summary of the IOM's Ethical Considerations for Research Involving Prisoners report.

IDCR-O-GRAM - Summary of the IOM's Ethical Considerations for Research Involving Prisoners report.

Recommendations	Details
Expanded Definition of "Prisoner"	In the OHRP (Office of Human Research Protections) regulations, the term "prisoner" will include inidividuals on parole and probation.
Consistent Ethical Protection	All publicly and privately funded research will be subject to the same ethical regulations. A national, publicly accessible registry of all research involving prisoners should be created.
Risk-Benefit Approach	All research proposals require a risk-benefit assesment. The potential benefits to prisoners must out number the risks for the research to be considered permissible. In biomedical research only personal benefits will be taken into consideration given the inherent risk of the research. Prisoners cannot make up more than 50% of the subject population in any given biomedical research project.
Collaborative Responsibility	Research should be tailored to fit the specific needs of the correctional setting, facilitating greater collaboration between researchers and the correctional facility.
Increased Systematic Oversight	Unbiased prison research subject advocates should monitor all research activity. The greater the research's risk and the more confined the correctional setting, the stricter the ethical guidelines.

Ethical Considerations for Research Involving Prisoners.
Institute of Medicine. 2006. Available at http://www.iom.edu/CMS/3740/24594/35792.aspx

Save the Dates

44th Annual Infectious Diseases Society of America (IDSA) Conference
October 12-15th, 2006
Toronto, Ontario, Canada
Visit: www.idsociety.org

"Managing Addiction in the HIV-infected Patient"
Live Satellite Video Conference
Part of Management of HIV/AIDS in the Correctional & Community Setting
October 18, 2006
Albany Medical College 12:30-2:30
CME & CNE credits available
Visit: www.amc.edu/HIVConference
E-mail: ybarraj@mail.amc.edu
Phone: 518.262.4674

Infectious Disease in Corrections Report (IDCR) Symposium
"Managing Infectious Disease: An Expert Panel"
Pre-conference before the NCCHC Conference
Saturday Afternoon, October 28, 2006
CME credits available
Hyatt Regency Hotel Atlanta, GA
Visit:http://www.ncchc.org/education/national2006/atlanta.html

57th Annual Meeting of the American Association for the Study of Liver Diseases
October 27-31, 2006
John B. Hynes Convention Center
Boston, MA
Visit: https://www.aasld.org/eweb/DynamicPage.aspx?webcode=06_Livermeeting

National Commission on Correctional Health Care (NCCHC) Conference
October 28- November 1, 2006
Hyatt Regency Hotel Atlanta, GA
Visit:http://www.ncchc.org/education/national2006/atlanta.html

134th Annual American Public Health Association (APHA) Meeting and Exposition
November 4-8, 2006
Boston, MA
Visit: http://www.apha.org/meetings/

6th National Harm Reduction Conference
November 8-12, 2006
Oakland, CA
Visit:
http://www.harmreduction.org/6national/

University of Texas Medical Branch (UTMB) HIV Mini-Fellowship
November 13-15, 2006
Moody Gardens Hotel and Convention Center
Galveston, TX
$50.00 Registration Fee
CME and CNE credits available
Contact: Victoria Korschgen
E-mail: vikorsch@utmb.edu
Phone: (409)747-2768

News and Literature Reviews

CDC Releases Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings

The Center for Disease Control and Prevention (CDC) released Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings in the September 22 issue of Morbidity and Mortality Week Report (MMWR). The new recommendations are intended to integrate voluntary HIV testing into routine medical care and to increase early HIV diagnosis among the estimated one of four persons with HIV infection in the U.S. who are not aware of their HIV-positive status.

The recommendations include voluntary HIV screening for all persons between the ages of 13 and 64 years as a standard practice of medical care. The recommendations also include an opt-out provision, allowing for patients to refuse testing after they have received basic information regarding HIV testing and treatment. To simplify HIV screening the CDC recommendations no longer require pre-test counseling and written consent, although the authors emphasize the importance of offering HIV-positive individuals post-test prevention counseling and access to care. Finally, the CDC contends that pregnant women at high risk for HIV or in areas with high HIV prevalence should be routinely tested for HIV in their third trimester. The report also recommends that rapid HIV tests be used for all women with unknown HIV status during labor. In early 2007, the CDC will issue further guidelines for providers, including practical tools and model approaches for implanting these recommendations.
CDC. Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings. Morb Mortal Wkly Rep.2006;55(RR14);1-17. Available at: http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5514a1.htm

Prison Research Group Honored by CDC

The Prison HIV Seroincidence Group of the CDC Division of HIV/AIDS Prevention (DHAP), received the National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP) Director's Recognition Award for September. From September 2004 to April 2006, the Prison HIV Seroincidence Group conducted the first large-scale investigation into HIV transmission in a prison system in the U.S. (see IDCR May 2006). The Group worked collaboratively with prisons and health department personnel, interviewed 226 prisoners and 8 correctional officers in 31 Georgia prisons, and conducted focus groups with ex-inmates. In addition, they obtained blood samples from the inmates, reviewed inmate medical charts, conducted HIV testing, HIV phylogenetic testing, and HIV antiretroviral resistance testing. The Group collected data on illegal and stigmatizing sex and drug behaviors in prison and the contexts and dynamics that place inmates at risk for HIV infection, and made recommendations for HIV prevention in corrections.

The Group's investigations identified and confirmed 88 cases of HIV transmission that occurred among inmates during incarceration and identified factors associated with HIV seroconversion. They also demonstrated the existence of several clusters of ongoing HIV transmission as evidenced by seroconverters sharing common HIV strains.

House Bill Would Require Federal Prisons to Provide HIV Testing for Inmates

Early this month, California Representative Maxine Waters (D) introduced a bill to the House that would require HIV testing for all federal prison inmates upon entry. The bill also includes an opt-out choice for inmates who do not wish to be tested. The opt-out provision acknowledges the complex issues of stigma and confidentiality often connected to HIV-positive status. Additionally, to foster a continuum of care from prison to the community, Waters' bill would require the Bureau of Prisons to contact former HIV-infected inmates and direct them to treatment and counseling in the community. Although the Bureau of Prisons' policies already emphasis the importance of testing inmates, Waters contends that under her bill more inmates will be tested and have greater access to care upon release. Skeptics question the effectiveness of a bill that includes an opt-out provision since there is no way to tell just how many inmates would refuse HIV testing.
Waters seeks to sway AIDS groups on prisoner testing. Young J. The Hill. September 12, 2006. Available at www.thehill.com.

HIV/AIDS, Sexually Transmitted Diseases (STDs) and Incarceration Among Women

This large-scale retrospective study utilized secondary data from federal and state corrections agencies to examine the relationship between incarceration and HIV and STD trends - focusing on black women living in poverty in the rural south. Across the U.S., Hammett and colleagues observed that an increasing proportion of inmates are women, with disproportionate representation of black and Latino women. Of all regions, incarceration rates were highest in the South (790 per 100,000), but unlike other areas, the South displayed similar rates of incarceration between urban and rural residents. The national prevalence of HIV and STDs was higher in female inmates (for HIV 3%) than in incarcerated males (for HIV 2%), and women releasees from the South suffer from one of the highest regional burdens of HIV with 15% of all Southern women released from a correctional facility living with HIV.

These data indicate that the overlapping of the epidemics of HIV/STDs and incarceration is greatest in the Southern U.S. Yet, despite the high prevalence of HIV among women involved in the criminal justice system in the South, it appears that only a small percentage (0.6-0.7%) of reported AIDS cases among women are diagnosed in prisons and jails. In response to this situation, the authors highlight the importance of deploying programs to prevent, diagnose, and treat individuals both within correctional facilities and rural community post release.
Hammett T, Drachman-Jones A. Sexually Transmitted Diseases. 2006;33(7):S17-22

Predictors of Post-Release Primary Care Utilization Among HIV-positive Prison Inmates: A Pilot Study

Recognizing the importance of the post-release period to the continuity of care in HIV positive inmates, researchers in Texas set out to examine (1) the proportion of HIV positive inmates utilizing primary care after release and (2) the variables associated with the utilization of primary care in the immediate post-release period. This pilot study of sixty inmates, both male and

Continued on page 11

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 1.5 AMA PRA Category 1 Credit(s)™. 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 learner will be able to describe major findings from the International AIDS Conference including results of clinical trials of HIV therapies
- The learner will become familiar with data presented at the International AIDS Conference regarding HIV transmission prevention in correc tional settings
- The learner will be able to cite new recommendations made by the U.S. Centers for Disease Control and Prevention on HIV testing in the U.S.

1. According to the World Health Organization (WHO), all the following regarding research on the provision of condoms in prisons are true EXCEPT:
   - A. Available data suggest that providing condoms in prison is feasible.
   - B. There is no direct evidence that providing condoms in prisons reduces HIV transmission.
   - C. Security problems including use of condoms as weapons and to smuggle contraband has been widely reported in facilities providing inmates access to condoms.
   - D. None of the above.

2. In the AIDS Clinical Trials Group (ACTG) study A5142 of treatment naïve patients, at 96 weeks:
   - A. A greater proportion of those assigned efavirenz plus two nucleosides achieved an HIV viral load <50 copies/mL than those assigned to lopinavir/ritonavir and two nucleo sides.
   - B. Lopinavir/ritonavir plus two nucleosides led to greater.
   - C. A and B.
   - D. Neither A or B.

3. The Centers for Disease Control and Prevention (CDC) now recommends that HIV testing?
   - A. Be offered to all persons in the U.S. aged 13 to 64 years.
   - B. Be performed without the need for a separate signed consent or lengthy pre-test counseling.
   - C. Patients should be notified verbally that HIV testing is being ordered and given an opportunity to opt out of testing.
   - D. All the above.

4. According to data presented at the International AIDS Conference, monotherapy of HIV infection with a ritonavir-boosted protease inhibitor:
   - A. Provided superior rates of virologic suppression as HAART regimens containing a combination of antiretrovirals.
   - B. Was associated with risk of protease inhibitor resistance.
   - C. Is highly successful and should become widely adopted as a strategy for the treatment of HIV infection.
   - D. All the above.

5. The recent Institute of Medicine report on ethics of research in prison settings concluded that research investigations in correctional setting should not be permitted (TRUE or FALSE)?

   TRUE or FALSE

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.

Instructions:

- Applications for Credit will be accepted until September 30, 2007.
- Late applications will not be accepted.
- Please anticipate 6-8 weeks to recieve your certificate.

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Please Check which credit you are requesting ___ ACCME or ___ Non Physicians

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Number of Hours (max. 1.5): _____

Signature: _____

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News and Literature Reviews *(continued from page 8)*

female, utilized qualitative and quantitative measures, obtained during interviews conducted three months prior to release and seven to twenty one days after release. They found that only 60% of the participants not lost to follow-up (n=30) utilized a primary care facility within the twenty one day post-release period. Variables positively associated with primary care usage included: receiving anti-HIV medications at the time of release, no alcohol usage since release, living in the same location as prior to incarceration, and a rating of housing situation as "comfortable" or "very comfortable." A logistical regression model comprised of these four variables correctly classified 80% of the cases in care overall. The generalizability of the findings is limited by the small sample size, an issue that the researchers plan to address in future studies.

Harzke A, Ross M, Scott D. AIDS Care. 2006;18(4):290-301

Therapy After Sustained Virologic Suppression

Multiple studies have attempted to simplify multi-drug antiretroviral therapies in order to reduce long-term adverse effects, expense, and difficulty of regimen adherence (See Main Article). The AIDS Clinical Trials Group (ACTG), A5201 Study Team, selected a ritonavir-boosted atazanavir (Reyataz) approach to explore this possibility. They proposed that the low-pill burden, once-daily dosing, safety, and unique resistance profile of atazanavir/ritonavir would make it a strong candidate for simplified maintenance therapy. In this multi-center pilot study 34 HIV-positive participants with persistent HIV RNA levels below 50 copies/mL while receiving their first protease inhibitor antiretroviral regimen. All had their protease inhibitor switched to atazanavir/ritonavir at study entry and the nucleosides discontinued at six weeks. Over the 24 week study period, the investigators observed an absence of virologic failure - defined as two consecutive HIV-1 RNA measurements of ?200 copies/mL - in 91% (31 of 34) of the subjects. Additionally, there were no treatment discontinuations for adverse events following simplification, no significant changes in CD4+ cell counts or plasma lipid levels, and no detectable HIV-1 RNA in seminal plasma from the eight participants providing semen. Resistance testing in the three participants exhibiting virologic failure did not identify protease inhibitor resistance mutations, while 2 of the 3 participants experiencing failure exhibited plasma atazanavir concentrations low or below detection - suggesting potential suboptimal adherence to the study regimen. These results suggest that ritonavir boosted atazanavir may be efficacious in for simplified maintenance therapy in selected patients with HIV infection and, at the least, is worthy of further investigation.

Swindells A, DiRienzo G, Wilkin T, et al. the AIDS Clinical Trials Group 5201 Study Team. JAMA. 2006;296:806-14.

Course Evaluation

I. Please evaluate this educational activity by checking the appropriate box:

Activity Evaluation					
	Excellent	***Very Good***	***Good***	***Fair***	***Poor***
Faculty					
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 learner will be able to describe major findings from the International AIDS Conference including results of clinical trials of HIV therapies **YES NO SOMEWHAT**
- The learner will become familiar with data presented at the International AIDS Conference regarding HIV transmission prevention in correctional settings **YES NO SOMEWHAT**
- The learner will be able to cite new recommendations made by the U.S. Centers for Disease Control and Prevention on HIV testing in the U.S. **YES NO SOMEWHAT**

III. Additional Questions

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

b. Additional Comments