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HIV Education Prison Project

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Managing HIV Care in a Large State System - Texas

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Division of Infectious Diseases
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The University of Texas Medical Branch at Galveston
Speaker's Bureau: Roche Pharmaceuticals, Grant & Research Support:
Merck, Roche, Pfizer, Glaxo Wellcome, Immune Response Corp.

With an area of 267,277 square miles and a population of 18.7 million inhabitants, Texas is the second largest and second most populous state in the U.S. The combination of multiple, large cities with attendant inner city conditions predisposed to high rates of HIV infection (socioeconomic impoverishment, low educational levels, illicit drug use) and a racially and ethnically diverse population disproportionately affected by the U.S. HIV epidemic, account for a large HIV positive population in Texas jails and prisons. It follows that Texas prisoner populations have the fourth highest AIDS prevalence rate in the nation (1876 HIV or AIDS cases reported in 1996)(1).

HIV in TDCJ
The Texas Department of Criminal Justice (TDCJ) is responsible for correctional custody of "offenders", the preferred designation for Texas state inmates. Texas has the second largest incarcerated population in the U.S. (an estimated 135,407 offenders in TDCJ facilities and an additional 15,000 - 16,000 offenders who are housed in private correctional facilities)(2). Texas offenders diagnosed with chronic medical conditions are assigned to TDCJ facilities rather than to private correctional facilities, so that chronic care can be provided by a managed health care system.

Several independent managed healthcare contracts provide pharmacy services and medical care. Under these contracts each TDCJ facility has its own primary care health care delivery system which may be staffed by physicians, dentists, optometrists, mid-level practitioners (physician assistants, clinical pharmacists, nurse practitioners), Certified Medication Aids (CMAs), nurses, laboratory personnel, and other ancillary health care personnel. In contrast, outpatient specialty health care as well as inpatient hospitalization occurs at facilities located on Texas Tech and UTMB Galveston campuses.

With regard to Medical Care, the state is divided into eastern and western halves that are approximately equal in area, but unequal in terms of TDCJ offender population. University of Texas Medical Branch Galveston is responsible for the eastern half of the state, which houses approximately 104,264 offenders in TDCJ units. Virtually all HIV positive offenders are assigned to units in the eastern half of the state, which means UTMB provides CJ units. Virtually all HIV positive offenders are assigned to units in the eastern half of the state, which means UTMB provides nearly all of the HIV health care for TDCJ. Given the number of offenders in TDCJ, medical health care and pharmacy budgets are enormous. Delivery of services must be efficient in order to derive maximum benefit from these health care dollars (see Table 1 on page 2).

HIV Care Management
The HIV-Specific Infection Control Policy, developed and periodically updated by the TDCJ Office of Preventive Medicine in Huntsville, Texas, serves as a guideline for HIV health care and is reflective of local standards of HIV health care. The policy is comprehensive and covers a variety of HIV-related issues including the method of HIV testing offered, referral of HIV positive offenders for specialty care, baseline and follow-up clinical and laboratory evaluations, schedule of vaccine administration and periodic HIV-related health screening (PPD, pelvic examinations, retinal exams, etc.), initiation of prophylactic therapies to reduce the incidence of opportunistic infections, and initiation of antiretroviral therapy.

Testing
As of May 1998, TDCJ has offered "routine HIV testing" to offenders. Routine testing means that an HIV test is conducted, unless the offender...
Managing HIV Care in a Large State System - Texas

Continued from page 1

refuses, for offenders:

*who report a past history of HIV infection, hemophilia, or a history of high risk behaviors for acquiring HIV infection;
*for whom live virus immunization is planned;
*who have psychiatric disorders or display symptoms possibly consistent with AIDS-related dementia; and
*who have certain indicator conditions (TB infection or disease, any sexually transmitted disease, cervical dysplasia, Hepatitis B and C infections).

Routine testing is performed at entry into the TDCJ and yearly thereafter. Verbal consent is required before HIV testing is performed and all tested offenders receive pre- and post-test counseling. Prior to May 1998, HIV testing was offered on a voluntary basis (see Tables 2 and 3 below).

The Treatment System

The Infection Control Policy specifies that TDCJ offenders with HIV infection must be evaluated and treated by a physician with expertise in HIV health care. As a result of recent endeavors to unify UTMB Galveston HIV Health Care and Unit-Based HIV Health Care, clinic visits at the two locations are linked so that offenders do not have to be transported as frequently as in the past, when Specialty Health Care and Unit-Based Health Care were isolated from one another. The current Infection Control Policy also specifies CID nurse visits every 60 days for HIV positive offenders.

The Infection Control Policy for vaccine administration, HIV-related periodic health screening, and initiation of prophylactic therapies are based on nationally published guidelines (1999 USPHS/IDSA Guidelines for the Prevention of Opportunistic Infections in Persons Infected with Human Immunodeficiency Virus available at: http://aepo-xdv-www.epc.cdc.gov/wonder/PrevGuid/m0048226/m0048226.htm. Similarly, initiation of antiretroviral therapy is based on nationally published guidelines (Report of the NIH Panel to Define Principles of Therapy for HIV Infection and Guidelines for the Use of Antiretroviral Agents in HIV-Infected Adults and Adolescents available at: http://text.nlm.nih.gov/ rindex/dbaccess/ddgge/p4/). Antiretroviral therapy is individualized and based on informed decisions made by the treating physician and the patient. In other words, there are no set CD4 numbers or virus load values that automatically trigger or preclude antiretroviral therapy.

Administering and Monitoring HAART

The TDCJ Pharmacy and Therapeutics (P & T) Committee have developed policies regarding the administration and continuation of antiretroviral drugs. In recent years, the director of the AIDS Care and Clinical Research Program has been appointed to this committee which has allowed the input of treating physicians to shape policy. Several P & T policies affect the use of antiretroviral medication administration. The policies are as follows:

1. All antiretroviral agents are included on the TDCJ Formulary; new agents are usually approved for addition to the formulary within a month of receiving FDA approval.
2. Combination therapy that includes a protease inhibitor or nonnucleoside reverse transcriptase inhibitor is considered standard and is distributed by directly administered therapy (DAT) multiple times per day at pill windows. Monthly pharmacy computer reports are monitored and if an offender is found to be on suboptimal therapy (dual or single nucleosides), the pharmacy notifies a unit-based provider, who is asked to correct or justify the suboptimal therapy.
3. A 10-day supply of medication is dispensed at release from prison and Texas AIDS Drug Assistance Program (ADAP) papers are completed and submitted by pharmacy personnel at release. The offender is given the responsibility of obtaining the medications by calling the ADAP program toll-free number and designating a pharmacy for dispensing of drugs.
4. Finally, an antiretroviral medication discontinuation policy has been implemented in which 80% of the scheduled doses of each antiretroviral medication must be taken in order for the offender to continue treatment.

Adherence

Adherence is documented by Certified Medication Aids (CMAs) who enter this data on the pharmacy computer system as they distribute medications to offenders at “pill windows” at the correctional units. Pharmacy personnel review adherence data every month. When an offender’s adherence on any antiretroviral medication falls below 80%, a unit-based provider is notified and asked to perform adherence counseling. During counseling, the offender is assessed for conditions that impair adherence: medication side effects, unreasonable medication combinations, and the occurrence of other activities (work, meals, school) scheduled simultaneously with pill window times. The medication discontinuation policy is also reviewed with the offender. Necessary adjustments are made to the antiretroviral regimen or related medications in order to minimize non-adherence due to drug side effects. When possible, daily routines are altered or medication passes are given so that non-adherence due to conflicting events is minimal. After 30 days, adherence is reassessed. If adherence remains below 80%, antiretroviral therapy is discontinued. The offender has the opportunity to resume antiretroviral therapy after a 90-day hiatus.

Upon initial review, the antiretroviral medication discontinuation policy seems unduly harsh and/or paternalistic. However, if one considers that poor adherence not only leads to drug-resistant virus which impairs treatment response for the individual, but may also lead to transmission of drug-resistant virus within and outside of the prison, this policy is beneficial to the individual who may accept effective therapy in the future and beneficial to the public health by reducing the incidence of treatment-resistant HIV infection.

Challenges and Solutions

Initially, our HIV clinic was at UTMB at Galveston, which made it difficult to provide optimal HIV care due to distance, staffing, and separation of care from the offender’s home unit. Therefore, a Center for Excellence in HIV Care was established at the maximum security Stiles Unit in Beaumont, Texas is approximately 85 miles from Galveston. Currently, 1,200 HIV positive men of various security designations are housed there. Security regulations were modified at this unit so that offenders with different security designations can be housed together in specified quarters that are centered around health care delivery areas where clinic and pill windows are located. The trip to UTMB takes a

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<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td># of Offenders Tested</td>
<td>7192</td>
<td>7395</td>
<td>9310</td>
<td>16,634</td>
<td>16,241</td>
<td>21,549</td>
<td>25,721</td>
<td>29,024</td>
<td>48,114</td>
<td>37,807</td>
</tr>
<tr>
<td># of Positive Tests</td>
<td>415</td>
<td>485</td>
<td>459</td>
<td>615</td>
<td>616</td>
<td>702</td>
<td>549</td>
<td>691</td>
<td>971</td>
<td>606</td>
</tr>
<tr>
<td>% Positive</td>
<td>5.7</td>
<td>6.6</td>
<td>4.9</td>
<td>3.7</td>
<td>3.8</td>
<td>3.3</td>
<td>2.1</td>
<td>2.4</td>
<td>2.0</td>
<td>1.6</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CDC Classification</th>
<th>Men</th>
<th>Women</th>
<th>Total (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>A1, A2 (asymptomatic)</td>
<td>1072</td>
<td>200</td>
<td>1272 (80.2)</td>
</tr>
<tr>
<td>B1, B2 (symptomatic)</td>
<td>237</td>
<td>22</td>
<td>259 (10.2)</td>
</tr>
<tr>
<td>A3, B3, C1-3 (AIDS)</td>
<td>932</td>
<td>70</td>
<td>1002 (38.9)</td>
</tr>
<tr>
<td>Total (%)</td>
<td>2241 (88.5)</td>
<td>292 (11.5)</td>
<td>2533 (100)</td>
</tr>
</tbody>
</table>

(Continued on page 5)
LETTER FROM THE EDITOR

Dear Colleagues,

October, a busy time for all, was exceptionally busy for HEPP, the HIV Education Prison Project at Brown University, due to preparations for our conference on Clinical Trials in Correctional Settings. Most of you probably thought we dropped off the face of the earth! Please accept our apology for two late issues in a row. We pledge to get the Newsletter back on track (faxed during the second week of the month) by the December issue. In this issue of HEPP News, we are pleased to bring you reports on HIV care in four major correctional facilities across the nation. The main article, by Dr. David Paar, describes in detail how the Texas Criminal Justice Department, a very large state system, provides HIV care. We also include another succinct update from ICAAC by Dr. Joe Bick, of the California DOC. This month’s HIV 101 provides a list of routine vaccinations for HIV infected persons. After reading this issue, clinicians should be able to identify which vaccines to administer to HIV infected patients and to understand current debates about discontinuing prophylaxis for opportunistic infections.

And now for a quick report on our Clinical Trials meeting. Correctional medical experts, legal experts, ethicists, and prisoner advocates gathered in Providence on October 13, 14, and 15 to review the history, legal and ethical aspects, and medical conduct of clinical trials in correctional settings and to propose expanded guidelines which may enable inmates and their medical providers to have access to experimental therapies, while protecting inmates from potential abuses of clinical research.

HEPP editor Dr. Rick Allicte (Yale HIV/Prison Project), Dr. Al Novick (Yale Center for Interdisciplinary Studies on AIDS), and Dr. David Thomas (Florida DOC) helped HEPP and the Brown AIDS Program (BRUNAP) organize the conference. Additional organizers included Drs. David Wohl and Becky Stevenson of U. North Carolina (and the NC DOC), Dr. David Paar of Texas UTMB and DOC, Dr. Joe Bick of California DOC, Betty Ryder of the NC DOC, Ned Heltzer of PHS, Dr. Lou Tripoli of CMS (central office) and Dr. Ken Mayer of Brown University.

During the course of the conference, participants learned that inmates currently do participate in clinical trials in a number of correctional institutions. In Texas, for example, the close association between the University of Texas medical programs and corrections has enabled inmate participation in a wide range of trials of anti-retroviral agents. In Florida, clinical studies have been carried out at the Central Florida Receiving Facility South Unit under the direction of the University of Miami AIDS Clinical Trials Group (ACTG). In North Carolina, clinical research studies have also been conducted, however that research is currently limited to studies unique to the prison setting, such as the efficacy of Directly Observed Therapy (DOT) versus Self-Care Therapy (SCT).

Conference participants heard nationally recognized ethicist Nancy Dubler and a federal delegate from the Office for Protection from Research Risk, Jeffrey Cohen, expound on the participation of prisoners in research trials. Highlights of the conference also included presentations by Dr. Margaret Fisch (U. Miami) and Dr. Rich Pollard (U. Texas Medical Branch at Galveston). The latter half of the conference was devoted to discussions by “working groups” that included former inmates, prisoner advocates, ethicists, lawyers, correctional representatives, and correctional physicians. These groups conducted open discussions on four topics: who should conduct trials, what type of correctional setting would be appropriate for trials, what type of research should be allowed in correctional settings, and whether coercion and undue influence were factors influencing prisoner participation in research. Following these discussions, a small group of 16 experts and 20 observers met in a closed session to report on issues raised by the working groups and to begin the process of formulating more detailed guidelines for the conduct of clinical trials in correctional settings.

In general, participants at the conference and members of the closed panel appeared to agree that prisoners should not be denied access to clinical trials in correctional settings. Due to concerns about prisoner vulnerability to coercion and undue influence, however, it was also agreed that the setting for the trial should conform to certain standards and that the conditions at the site should be monitored on a regular basis. Participants who were in favor of allowing prisoners access to clinical trials, were also in favor of restricting trials to locations where “good clinical practice” was in place or where good clinical care would be independently introduced before a clinical trial would begin, so that prisoners would not be restricted to participating in a clinical trial in order to obtain decent medical care. One interesting proposal was that a clinical trials review committee specifically formed for correctional trials should be established at the national level (similar to existing groups that accredit prisons, or prison hospitals). The committee would be responsible for carefully reviewing each trial proposed for a correctional setting and monitoring the trial site for compliance with the criteria to be set forth in the guidelines.

Overall, conference participants reported feeling that they were present at a momentous event, which was one of the first national meetings on the topic of clinical trials in correctional settings to be convened in greater than 20 years. Many different perspectives were voiced during the course of the meeting, and additional perspectives will be gathered before the proposed guidelines are published. Conference organizers hope that this meeting will eventually lead to the development of guidelines that will protect prisoners from research abuses while preserving their access to clinical trials. A full report on the closed panel discussions and a set of expanded guidelines for clinical trials in correctional settings will be published in two to three months - and you can be sure, as a HEPP subscriber, that you’ll hear about the guidelines first!

Lastly, I want to mention that I enjoyed meeting many of you at the National Conference on Correctional Health Care in Fort Lauderdale this month. I appreciated the positive feedback you gave me on HEPP News, and I encourage you to continue to send us your comments and suggestions. Don’t forget to check out the website at http://www.HIVCorrections.org.

Sincerely,

Anne S. DeGroot, MD
Spotlight: California, Florida, and New Jersey Correctional HIV Care

For this spotlight on correctional HIV care, HEPP staff asked physicians from the departments of corrections from California, Florida and New Jersey to outline the HIV care programs at their institutions. We asked them to include what they consider the best aspects of their programs, as well as what they might change. Their reports are summarized in the table below, followed by their own words.

<table>
<thead>
<tr>
<th>Type of Care</th>
<th>California Medical Facility (CMF), Vacaville CA (Men's)</th>
<th>Florida Department of Corrections</th>
<th>New Jersey</th>
<th>Texas Department of Criminal Justice</th>
</tr>
</thead>
<tbody>
<tr>
<td>Testing</td>
<td>Volunteer</td>
<td>Volunteer</td>
<td>Volunteer</td>
<td>Volunteer</td>
</tr>
<tr>
<td>Seroprevalence (HIV+)</td>
<td>2.5% (4500) Men ≤ 500</td>
<td>3.2% (1929) Men 6.8% (223) Women</td>
<td>3.4% (900) Men 10% (100) Women</td>
<td>1.3% (1845) Men 2.3% (231) Women</td>
</tr>
<tr>
<td>Medication Distribution</td>
<td>DOT, except if &gt;15 days or those with special food</td>
<td>DOT</td>
<td>Varies from site to site: DOT or KOP</td>
<td>DOT</td>
</tr>
<tr>
<td>Peer Education Programs</td>
<td>Yes (Vacaville)</td>
<td>Yes (Central Florida Receiving Center)</td>
<td>Yes, depending on hospital</td>
<td>Outside prevention education group and KOP</td>
</tr>
<tr>
<td>Discharge Planning</td>
<td>Social worker is assigned to each patient. Patient is linked to transitional programs and providers.</td>
<td>Patient directly linked to a treatment facility in the community in which the patient will be discharged</td>
<td>Given 2 weeks of medication, encouraged to seek assistance at PH clinics</td>
<td>Given 10 days of medication, encouraged to call the AIDS Drug Assistance Program (ADAP)</td>
</tr>
</tbody>
</table>

This is the N(number) of HIV seroprevalence in the entire California Department of Corrections

Patient Access to Care
California Medical Facility (CMF), Vacaville CA
Joe Bick, MD
Chief Medical Officer, HIV Treatment, California Medical Facility, Vacaville, CA, Speaker’s Bureau: Agouron, Bristol-Myers Squibb

California Medical Facility (CMF) has the largest HIV treatment program in the California Department of Corrections (CDoC), providing comprehensive care to 500 men. Each physician in the outpatient setting has responsibility for approximately 160 HIV infected patients. An additional physician is responsible for the hospice and supported living units, and three provide care in the hospital. Fundamental to the success of this program is an organizational structure that allows one individual to supervise all aspects of the HIV treatment unit. In the ever-changing and unpredictable environment of corrections, this type of authority is crucial if a program is to rapidly adapt to obstacles (lockdowns, correctional policy changes, etc.). Patients initiate a clinic visit by submitting a request for services. These requests are triaged by the nursing staff, who then schedule patients to be seen. There is a physician on site 24 hours a day seven days a week to handle emergencies. For routine requests, patients may wait 1 to 14 days to be seen. Patients can self refer to mental health, dentistry, optometry, and podiatry. All other consultations are physician generated. Patients are seen on average once a month. Although patients can refuse medical care, an effort is made to ensure that all patients are seen at least once every three months.

Provider and Peer Education
Florida Department of Corrections
Bert Hurwitz, MD

There are two important components to the HIV Care program at the Florida Department of Corrections: our peer education program, and our provider education program. The programs begin once we have found an inmate is seropositive. Treatment of newly diagnosed inmates and those who self identify as HIV infected is dependent upon the stage of the disease, prior treatment, past history of opportunistic infections, co-morbidities, and especially the desires of the inmate. We take the patients’ own readiness into account, since we cannot mandate HIV therapy, and we recognize that we obtain maximal adherence when we have the full commitment of the patient. To facilitate and encourage adherence, we have established inmate to inmate (peer) education groups and a health care team to provide additional HIV education. Because we have found it difficult to provide all of these services at every institution, we have elected to re-structure our facilities so that treatment for HIV/AIDS will occur at selected sites. By the time we finish restructing, HIV infected inmates who are on treatment will be located in selected institutions, representing less than a third of our over sixty institutions. Two institutions will provide the highest level of care and the remainder of the institutions will provide the type of care that is usually provided in outpatient HIV clinics in the community. All of the practitioners at the HIV facilities will be “experts” in the care of this infection.

To educate and update the practitioners, we have developed a unique educational program. Similar to the program in Texas, we have been operating a “mini-HIV residency” at the HIV specialty institutions over the past two years. The program is a one-week total immersion course concerning HIV/AIDS and closely associated subjects, such as tuberculosis, hepatitis, and special women’s concerns. This course is both didactic and clinical. The “students” have direct hands-on experience. They review case histories and examine patients who have many of the conditions discussed during the course. The faculty consists of experts from both inside and outside of the Florida DOC. In addition to the mini-residency, we present updates on HIV/AIDS treatments at our monthly staff meetings. Last year we devoted eight hours of our yearly staff workshop to lectures on HIV and AIDS.

Finally, we have offered inmates the opportunity to volunteer for investigational treatment programs through collaboration with the University of Miami. These programs give our staff opportunities to be part of “state of the art” treatment protocols and they offer our patients access to the newest treatment modalities.

HIV Care in New Jersey State Prisons
Sheree Starrett, MD
Speaker’s Bureau: Roxane, Merck, Bristol-Myers Squibb, Glaxo Wellcome

The current goal of the HIV program in NJ is to try to provide the best possible services at our local sites. To accomplish this goal, a statewide HIV advisory panel was created to include the NJ correctional physicians most skilled in HIV care. This group of eight physicians meets quarterly to discuss various HIV issues. Four outside HIV physician experts also attend these meetings, providing us with even more knowledge on how best to care for HIV infected inmates.

By court order, we are not allowed to segregate HIV patients for any reason, and therefore are unable to follow the Florida model of creating “centers of excellence.” Some of our sites may have as few as 3 or 4 patients, while larger sites will have 100 + inmates. We have seen a dramatic decline in all HIV morbidity and mortality, presumably relating to the use of effective antiviral therapy. As previously stated, we try to provide all care at the local sites. All patients are managed by members of the HIV advisory panel or by health care providers (physicians or NPs) under their immediate supervision. Many sites have Infection Control Nurses, who are also very active in patient care. Patients are generally treated according to the DHHS and IAS guidelines. Patients are seen at least quarterly and more frequently at the discretion of the caregiver. Lab work, including CD4 count and unsensitieal viral loads are done every 3 months and whenever therapy changes require repeat testing. All FDA approved antivirals are available to inmates. Medications are provided in monthly quantities from a wholesale pharmacy. Monitoring of patient adherence is problematic. Withdrawal of therapy from persistently nonadherent patients is at the discretion of the provider. Patients are not charged any co-pay for HIV services, except for medications. This fee is $1.00 for every 90-day prescription, (i.e. 90 days of nelfinavir for $1.00). No patient is denied care based on inability to pay.

Patient outcomes have improved tremendously throughout the state in recent years. The number of AIDS related deaths in NJ declined from 74 in 1996 to 17 in 1999. Hospital admissions and lengths of stay have shown the same trends. The key to our success has been the major effort devoted to staff education and with that, the widespread usage of highly active antiviral therapy. Despite all our successes, we need to improve our patient education and discharge planning programs. Because of a high rate of nursing and medical staff turnover, we have to continually work on developing the skill levels of new staff members. We also need to work on educating the general prison population as well as the custody staff. Many prisoners must not only deal with the issues of having a difficult disease, but also with all the stigmas related to this disease. Improving the knowledge of all the inmates and custody personnel might help alleviate this problem. Lastly, we need to try to develop more effective discharge planning and linkages with the outside community. I feel that without this essential last step, many of our efforts are lost upon prison release.
Managing HIV Care in a Large State System - Texas

Continued from page 2

couple of hours and offenders return to Stiles the same day as their UTMB appointment. One of the Galveston ACCRP Physicians travels to the Stiles Unit one day every other week to see patients and to consult with unit-based physician assistants who have reviewed medical and antiretroviral history on patients who are failing therapy and need to have medications changed. Similarly, the minimum security Texas City Women’s Sheltered Housing Unit, only 15 miles from UTMB Galveston, houses minimum security female offenders with HIV infection. Another ACCRP AIDS specialist travels to Texas City every other week to see the offenders housed there and to see HIV positive female offenders who are transported to Texas City from other units of assignment.

Minifellowships for Better Providers

In order to provide HIV care training to Unit-Based Providers as well as to foster a mutually respectful relationship between the Galveston Specialists and the Unit-Based Providers, a three day “HIV Minifellowship for Correctional Care Providers” (18 category 1 CME hours) was developed and is conducted three times per year for 10 - 15 Unit-Based Providers per session. We need to establish a working relationship with 61 physicians, 73 mid-level providers, and 71 Chronic Infectious Diseases (CID) nurses in the TDCJ units in the Eastern Region. Although the course is intensive and consumes three eight hour days, having Galveston HIV Specialists serve as faculty as well as participate in evening recreational activities with the Unit-Based Providers has facilitated an appreciation for each others’ roles and has definitely enhanced communication regarding HIV care of offenders between the units and Galveston.

Teleconsults

Unit providers who have completed the minifellowship and Galveston Specialists consult with one another regularly by telephone or by means of telemedicine video equipment - thus a system of communication and care delivery called “teleconsults” is evolving. Patient cases are summarized on data sheets and faxed to the Galveston HIV Specialist prior to the teleconsult session. During the session, the patient’s course is discussed and revised treatment plans are developed. Twice weekly telemedicine clinics were developed and are being refined so that a Galveston specialist can use state of the art electronic equipment to evaluate inmates at remote sites across the state. To make telemedicine work, unit level laboratory capabilities had to be expanded so that viral loads and other tests could be performed there instead of UTMB Galveston.

Summary

The large geographic expanse of Texas and the sheer number of HIV positive offenders within the TDCJ are primary forces that made it necessary to change from a centralized HIV Health Care System based at UTMB Galveston to a cooperative system in which HIV Health Care responsibilities are shared by providers at the units. A uniform HIV-Specific Infection Control Policy, along with several Pharmacy and Therapeutics Committee Policies regarding antiretroviral medications, provided a foundation for this shared health care, but was not enough, by itself, to facilitate the transition. A three day “HIV Minifellowship for Correctional Care Providers” not only prepares unit-based providers to assume additional responsibility for HIV Health Care, but also facilitates a cordial working relationship between the Galveston HIV specialists and Unit-Based Providers. Telemedicine clinics have permitted UTMB Galveston HIV Specialists to evaluate offenders while they remain at remote sites throughout Texas, and a budding “teleconsult” clinic have enhanced efficiency without impeding quality of care. Finally, unit-based laboratory capabilities, in particular, the ability to collect and process viral load specimens were expanded in order to meet the needs of unit-based, specialty-driven, HIV care. The role of the CID nurse is being evaluated and hopefully, will be modified to become a crucial link between the units and UTMB Galveston. It has been useful to recognize that the analysis and revision of our HIV care delivery programs in a geographically large and populous institution like TDCJ is a process that moves slowly, but ultimately leads to more efficient delivery of quality health care.

References:

2. Personal communication, Alan Sapp, Assistant Director for Administrative Services, Texas Correctional Managed Health Care Committee. 1999.

Table from the Texas Department of Criminal Justice Health Services Division Inter-Office Communication from Scott L. Samford, PHT-III, HIV Program Coordinator; August 31, 1999
ICAAC Highlights Part II: Opportunistic Infections
by Joe Bick, MD
Speaker’s Bureau: Bristol-Myers Squibb, Consultant: Agouron, BMS

The 39th annual Interscience Conference on Antimicrobial Agents in Chemotherapy (ICAAC) was held in San Francisco in September. Last month, HEPP News provided a review of HAART trial reports and HIV resistance testing. This month’s report will discuss discontinuation of prophylaxis for opportunistic infections (OIs).

As increasing numbers of patients experience dramatic increases in their CD4 counts due to highly active antiretroviral therapy (HAART), the question is raised as to if and when OI prophylaxis can be discontinued. Specifically, if an individual at one time had a CD4 count low enough to put them at risk for a particular OI but subsequently had an increase in CD4 to a level above the risk threshold, can preventative therapies be discontinued? Does the increase in CD4 count necessarily represent immune reconstitution? If so, has the individual’s immune system retained the ability to recognize the OI in question? Several abstracts were presented that attempt to answer these questions for Pneumocystis carinii (PCP), and Mycobacterium avium (MAC).

PCP: Abstract 1165 was an Italian study of 600 patients receiving PCP prophylaxis because of a past CD4 count <200 who subsequently had a CD4 rise to >200. PCP prophylaxis was discontinued in all patients. During a median follow-up of 6.2 months, there were no cases of PCP. A second study involving PCP prophylaxis was late breaker #24 from Spain. In this study of 488 patients, half were randomized to continue prophylaxis and half to discontinue it. After 11.3 months of follow-up, no cases of PCP developed in either group.

MAC: Late breaker abstract #23 examined 643 patients who were on MAC prophylaxis because of previous CD4 counts of <50 who now had CD4 counts >100. These patients were randomized to receive either weekly azithromycin or no MAC prophylaxis. In all, there were only two cases of MAC, both in the untreated group. Further supporting the discontinuation of prophylaxis was abstract #1164, which demonstrated that within six weeks of beginning a macrolide for MAC prophylaxis, the respiratory flora is all resistant to macrolides. This could potentially make treatment of subsequent respiratory illnesses more problematic. It should be noted that the above abstracts address discontinuation of primary MAC prophylaxis, which is not the same as stopping therapy in those with past documented MAC disease.

The above data adds to the growing consensus that it may be appropriate to discontinue primary prophylaxis for MAC and PCP in those who have experienced a reconstitution of their immune systems as manifest by a rise in CD4 count to >200 for PCP and >100 for MAC. The data is not clear concerning those with prior PCP, nor is it clear that treatment for MAC can be stopped in those with rising CD4 counts.

In spite of this encouraging information, I believe that in the correctional setting the decision to discontinue primary prophylaxis for PCP should not be made lightly. Many incarcerated patients fail to follow-up medically following their parole. If a patient is not likely to obtain regular CD4 counts, the risk associated with continuing PCP prophylaxis is less than that of experiencing immune deterioration and subsequently developing PCP. Depending upon the patient, it might be most prudent to encourage continuation of prophylaxis regardless of CD4 count. Keep in mind that bactrim may also help prevent otitis, sinusitus, and other respiratory illnesses.
News Flashes

Anti-HIV Treatment Improves Immune System and Fights CMV

A new combination of HAART appears to prevent the progression of cytomegalovirus (CMV) retinitis. Researchers at the NIH found that all 14 patients with CMV retinitis enrolled in the study who took HAART were able to cease their standard anti-CMV medications safely and without progression of CMV. Although the study focused on CMV retinitis, the results may be a "gateway" for researchers in treating other opportunistic infections, such as Mycobacterium avium complex (MAC), which also can be controlled by HAART alone, according to preliminary results from NIAID-supported trials. (NIH News Release, 11/2/99. JAMA 1999; 282(17):1633-1637.)

Vaccine Combination for HIV

Two experimental vaccines taken together are safe and have induced anti-HIV immune responses in the majority of volunteers enrolled in Phase II clinical trials sponsored by the National Institute of Allergy and Infectious Diseases. The trial, called AVEG 202/HIVNET 014, was designed to test ALVAC-HIV vCP205, which stimulates cellular immunity and ramps up T-cell activity, and SF-2 rgp120, which stimulates the production of HIV neutralizing antibodies. These preliminary data do not prove that the vaccine is effective against HIV infection, since the trial was neither large enough nor long enough to draw conclusions (NIAID press release, 7/13). For more information, see the HIVNET website: http://www.niaid.nih.gov/d aids/hivnet.htm

HIV Rebounds after Cessation of Therapy

In a recent Nature article, Anthony Fauci, MD, and Tae-Wook Chun, PhD et al published findings that the viral load in two of their patients rebounded after HAART and interleukin-2 (IL-2) were stopped. The two patients were treated with HAART for 33 and 30 months. Both patients also had received intermittent intravenous infusions of IL-2 for 42 and 50 months. HIV plasma levels were below 50 copies/mL before treatment was stopped. The replenishing of the virus seen in these two patients may be due to viral reservoirs that hide from even the most potent HAART regimens. This data supports the findings of recent reports that suggest eradicating HIV from the body with currently available HIV treatments is unlikely because the virus remain undetected in sanctuaries that drugs cannot access, and can exist in latent forms on which the drugs have no effect. (NIH News Release, 10/27/99. More info. available at http://www.niaid.nih.gov.

Subscribe to HIV Inside

A new quarterly newsletter addressing HIV-management issues specific to correctional care. If you are interested in receiving this free publication, please fill out the form below. In addition to receiving HIV Inside, this contact information will be entered into an HIV-management database, allowing additional education materials to be forwarded.

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HIV 101

Routine Vaccinations for HIV-Infected Adults

The following vaccines are recommended for HIV-Infected persons. Inactivated or subunit vaccines pose no additional risk of adverse events and should be considered part of routine health maintenance for these individuals. In some cases, viral load may increase slightly after an immunization. Such increases, however, appear to be transient, and their clinical significance is unknown.


Inactive or Subunit Vaccines

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Indication</th>
<th>Regimen</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pneumococcal vaccine</td>
<td>All HIV patients, once every ten years</td>
<td>0.5 mL IM</td>
<td>Risk of S. pneumoiae infection is increased 100-fold. Efficacy of vaccine is best when CD4 count is &gt;200. Revaccinate if CD4 was &lt;200 before HAART and is &gt;200 6 months after the first vaccine.</td>
</tr>
<tr>
<td>Influenza vaccine</td>
<td>All HIV patients yearly in Oct-Dec, during the flu season</td>
<td>0.5 mL IM</td>
<td>Risk of influenza is not clearly increased, but prevention may avoid expensive and complicated diagnostic evaluation of flu-like complaints, and may reduce transmission of flu in correctional settings. Vaccination may increase HIV viral burden, but natural flu infection may increase it more.</td>
</tr>
<tr>
<td>Haemophilus influenza B vaccine</td>
<td>Not recommended</td>
<td>0.5 mg IM x1</td>
<td>Not recommended because most infections with H. influenzae in HIV-infected persons involve non-typeable strains that are not included in the vaccine (JAMA 1992;268:3350).</td>
</tr>
<tr>
<td>Hepatitis B vaccine</td>
<td>See Comments</td>
<td>3 IM doses at 0, 1, and 6 mo. Alternate dose timing: 0, 2, 4 mo; or 0, 1, 4 mo. Recombivax: 10 µg Energix: 20 µg</td>
<td>CDC Indications: Members of high risk groups*, inmates of long term correctional facilities, seronegative IDU, sexually active gay men, heterosexual men and women with STD or &gt;1 sex partner in past 6 mo and household or sex contacts of HBsAg carriers. Screening test is anti-HBC. Risk of becoming HBsAg carrier is increased with HIV infection. CDC recommends measurement of antibody response in HIV infected patients at 1-6 months after 3rd dose; non-responders should receive 1-3 boosters. Note that funds for immunizing patients &lt;18 years may be available from local Health Departments.</td>
</tr>
<tr>
<td>Inactivated polio vaccine (eIPV)</td>
<td>Those without prior immunization, one time only adult booster.</td>
<td>0.5 mL subcutaneously</td>
<td>Preferred for HIV-infected persons and close contacts. Polio has been eliminated from the Western hemisphere.</td>
</tr>
<tr>
<td>Hepatitis A vaccine</td>
<td>Men who have sex with men, illicit drug users, people with chronic liver disease, especially HCV</td>
<td>1 mL adult formulation intramuscularly x1 ≥14</td>
<td>Havrix was FDA approved in 1995 and may be used in place of immune globulin. Serologic tests show 30% of adults are protected by prior infection.</td>
</tr>
<tr>
<td>Tetanus-diptheria (Td)</td>
<td>All adults—booster q10 yrs</td>
<td>0.5 mg IM</td>
<td>HIV infection is not a contraindication.</td>
</tr>
</tbody>
</table>

Live Attenuated Vaccines

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Indications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bacille Calmette-Guérin (BCG) vaccine</td>
<td>Contraindicated</td>
</tr>
<tr>
<td>Oral poliomyelitis vaccine</td>
<td>Contraindicated (eIPV preferred)</td>
</tr>
<tr>
<td>Varicella-zoster vaccine</td>
<td>Contraindicated (if HIV-infected person is seronegative—avoid contact with chicken pox and zoster and vaccinate susceptible close contacts).</td>
</tr>
<tr>
<td>Measles, mumps, rubella (MMR) vaccine</td>
<td>Contraindicated</td>
</tr>
</tbody>
</table>

* High Risk groups include: household contacts and sex partners of HBsAg-positive persons; users of illicit injectable drugs; heterosexuals with more than one sex partner in 6 months; men who have sex with men; people with recently diagnosed STDs; patients in hemodialysis units and patients with renal disease that may result in dialysis; recipients of certain blood products; health care workers and public safety workers who are exposed to blood; clients and staff of institutions for the developmentally disabled, and certain international travelers.
Self-Assessment Test for Continuing Medical Education Credit

Brown University School of Medicine designates this educational activity for 1 hour in category 1 credit toward the AMA Physician's Recognition Award. To be eligible for CME credit, answer the questions below by circling the letter next to the correct answer to each of the questions. A minimum of 70% of the questions must be answered correctly. This activity is eligible for CME credit through December 31, 1999. The estimated time for completion of this activity is one hour and there is no fee for participation in this activity.

1. Which of the following vaccines are recommended for HIV-infected inmates? (more than one may be correct).
   a) Haemophilus influenza B vaccine
   b) Hepatitis B vaccine
   c) BCG vaccine
   d) Oral poliomyelitis
   e) MMR vaccine

2. At intake, an HIV infected inmate has revealed a history of illicit drug use and reports that one of the children in his household just had chickenpox. He also has not had his TD shot in 12 years. Which vaccine or vaccines would you recommend? (more than one may be correct)
   a) Hepatitis B vaccine
   b) Tetanus-diptheria
   c) Varicella-zoster vaccine
   d) Measles, mumps, rubella (MMR) vaccine
   e) HBV

3. Which of the following statements is false?
   a) Vaccination may increase HIV viral burden, but natural flu infection may increase it more.
   b) Haemophilus influenza B vaccine is not recommended because most infections with H. Influenzae in HIV-infected persons involve non-typeable strains that are not included in the vaccine.
   c) Pneumococcal vaccines should not be given again even if CD4 was <200 before HAART and is >200 6 months after the first vaccine.
   d) Risk of becoming HBsAg carrier is increased with HIV infection.
   e) HIV infection is not a contraindication for tetanus diptheria vaccine.

4. In which of the following states are HIV/AIDS investigators currently conducting clinical trials?
   a) Texas and Georgia
   b) Massachusetts and California
   c) New York State and North Carolina
   d) Florida and Texas
   e) Maryland and New York

5. Clinicians are now considering it possible to discontinue Mycobacterium Avium prophylaxis when the patient is responding to HAART and their CD4 T cell count has been
   a) over 50 for two months
   b) over 200 for two months
   c) over 100 for six months
   d) over 200 for six months
   e) over 500 for two months

6. Which of the following statements is false?
   a) Recent studies have shown that discontinuing PCP prophylaxis does not increase chances of developing PCP within 6 months after stopping treatment.
   b) Recent studies on PCP have shown that discontinuing PCP prophylaxis is recommended even if the patient has a prior history of PCP infection.
   c) Risk of becoming HBsAg carrier is increased with HIV infection.
   d) Researchers have found that 14 patients with CMV retinitis who were taking HAART were able to cease standard anti-CMV medication without progression of CMV.

HEPP News Evaluation

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