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HEPP Report: Infectious Diseases in Corrections, Vol. 7 No. 2

HIV & Hepatitis Education Prison Project

HEPP REPORT

HIV & HEPATITIS EDUCATION PRISON PROJECT

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INFECTIOUS DISEASES IN CORRECTIONS

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ABOUT HEPP

HEPP Report, a forum for correctional problem solving, targets correctional physicians, nurses, administrators, outreach workers, and case managers. Published monthly and distributed by email and fax, HEPP Report 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 the Brown University Office of Continuing Medical Education. HEPP Report is distributed to all members of the Society of Correctional Physicians (SCP) within the SCP publication, CorrDocs (www.corrdocs.org).

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TUBERCULOSIS UPDATE 2004

Renee Ridzon, MD*

TREATMENT OF TB

In the Spring of 2003, the American Thoracic Society (ATS), Infectious Diseases Society of America, and Centers for Disease Control and Prevention (CDC) issued updated guidelines for the treatment of tuberculosis (TB).[1] These guidelines are substantially longer and significantly more comprehensive than the prior ATS/CDC guidelines published in 1994.[2] The document is a guideline for the treatment of TB disease only and does not include management of latent TB infection (LTBI).

"The responsibility of successful treatment of TB rests with the provider rather than the patient."

There are some notable differences between the revised guideline and the 1994 treatment statement. The revised guideline strongly emphasizes that 1) the responsibility of successful treatment of TB rests with the provider rather than the patient and 2) case management should be patient-centered, with direct observation of therapy as the strongly preferred method of administration of medicines.

The document has a complete discussion of the drugs currently available to treat TB, including dosing, dose adjustments needed for renal or hepatic dysfunction, toxicities, management of common adverse effects and information about interactions between antituberculars and other drugs. Because rifamycins have the potential for drug-drug interactions with numerous agents, there is special attention to this class of drugs. It also discusses treatment issues in special groups, such as children and pregnant and breast-feeding women. According to the guidelines, treatment completion is now determined by the number of doses delivered, as well as the duration of therapy. Also included is an algorithm on how to manage treatment interruption, a problem that is not uncommon.

Among patients with TB caused by drug-susceptible organisms, those with cavitary pulmonary disease on the initial chest radiograph and/or a sputum specimen that is still culture positive for *Mycobacterium tuberculosis* at the completion of the initial two-month phase of treatment have been shown to be at increased risk of relapse. In patients with both of these risk factors, the rate of relapse disease is further increased. Accordingly, the guidelines recommend that the continuation phase of therapy be prolonged from four to seven months in patients with both risk factors. Patients having just one of these risks do not need to be treated with an extended continuation phase, but should be monitored closely for signs of a poor response to therapy and have treatment extended if there is not a prompt response to treatment. In order to identify patients at risk for relapse, culture of sputum specimens should be obtained in all patients with pulmonary disease at the completion of the initial two-month phase of therapy.

As a result of clinical trials examining the use of the long-acting rifamycin rifapentine for the treatment of TB, recommendations for its use are now included in the guideline. Because of the drug's extremely long half-life, it can be used once-weekly, making it an attractive option for supervised regimens. Once-weekly dosing of isoniazid and rifapentine is now included as a choice for the continuation phase of treatment in patients who meet the following criteria: 1) HIV-uninfected 2) non-cavitary, pulmonary TB, 3) *M. tuberculosis* that is drug-susceptible, and 4) sputum specimens are smear

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negative for acid-fast bacilli at the end of the initial phase of treatment. Patients with advanced TB disease or HIV infection have increased risk treatment failure and relapse when treated with highly intermittent regimens. Once-weekly treatment with rifabutin should never be used in these patients.

Treatment of TB in those with HIV infection is also addressed by the guidelines. Some patients with HIV infection are at risk for emergence of TB caused by organisms with rifamycin resistance when treated with intermittent regimens. Because of reports of disease caused by rifampin-resistant organisms in persons with advanced HIV infection, persons with CD4 counts less than 100 should not be treated with twice-weekly regimens and should receive medications daily or three times weekly. As stated above, no one with HIV infection should receive once-a-week treatment.

QuantiFERON®-TB Test

This year CDC issued guidelines for the use of QuantiFERON®-TB test.[3] The QuantiFERON®-TB (QFT) test was approved by the Food and Drug Administration in 2001. Like the tuberculin skin test (TST), this test is used to aid in the detection of LTBI. This test measures the production of interferon-gamma and is an *in vitro* cytokine-based assay to detect cell-mediated immune reactivity to *M. tuberculosis*. Unlike a TST, this assay requires phlebotomy, can be completed with only a single patient visit, can assess and distinguish between responses to both *M. tuberculosis* and environmental mycobacteria, and does not boost amnestic immune responses. It appears that interpretation of the whole-blood interferon gamma assay is less subjective than the TST and that it may be less affected than TST by prior BCG vaccination, reactivity to nontuberculous mycobacteria, and reader error.[4]

The characteristics of the test that make it appealing as a screening tool include the ability to distinguish between *M. tuberculosis* and other mycobacteria, need for a single patient visit and less interference from BCG vaccination. In its recommendations for QFT, CDC suggests that this test be considered for LTBI screening of persons at increased risk of having or acquiring LTBI, including residents and employees of correctional facilities, injection drug users, recent immigrants, and some health care workers.

There are, however, several significant limitations to the use of this test. For example, it should not be used in persons with symptoms of TB since TB disease is associated with suppressed interferon-gamma responses. It should also not be used in children, pregnant women, those with HIV infection or other clinical conditions that increase the risk of progressing from LTBI to TB disease, or in the context of contact investigations since the appropriate use of the test in these situations and populations has not been defined. It also should not be used within 12 months of the administration of a TST, as the injection of purified protein derivative can affect the results of QFT. These limitations will probably make the use of this tool difficult in some settings where frequent screening takes place, such as correctional facilities. Further data on appropriate use of the test is needed and will be helpful to determine the settings and populations where this test can be best used.

Revised Recommendations for the use of Rifampin and Pyrazinamide for the Treatment of LTBI

Following an earlier recommendation that two months of rifampin and pyrazinamide (RZ) could be used as an option for the treatment of LTBI[5], cases of severe liver injury were noted among patients who received this regimen. CDC issued cautions to providers and recommended enhanced monitoring for patients receiving RZ. From October 2000 through June 2003, 48 patients with severe liver injury were reported in the U.S. Eleven of these patients died.[6-8]

In a report published in August 2003, CDC reported the results of surveillance conducted on patients who received RZ from January 2000 through June 2002 to estimate the risk of severe liver injury associated with this regimen.[9] Of the 7,737 patients who received RZ, 204 discontinued treatment because of aspartate aminotransferase serum concentrations that exceeded five times the upper limit of normal, (26.4 per 1,000 treatment initiations, 95% CI 22.8-30.0). RZ use was stopped in 146 more patients due to symptoms of hepatitis (18.9 per 1,000 treatment initiations, 95% CI 17.4-20.4). There were 30 cases of severe liver injury in the cohort, defined as hospitalization or death of the patient. Seven of these patients died, giving estimated rates of hospitalization and death of 3.0 (95% CI 1.8-4.2) and 0.9 (95% CI 0.2-1.6), respectively, per 1,000 treatment initiations. These rates are significantly higher than seen in recent studies examining adverse events associated with isoniazid for the treatment of LTBI, where median hospitalization and death rates have been reported to be 0.15 and 0.04 per 1,000 treated, respectively.

Based on these high rates of adverse effects, hospitalization and death, ATS and CDC have changed the official recommendation for the use of RZ, and now state that this regimen generally should not be offered to patients, including patients with or without HIV infection. Isoniazid should be the first choice for treatment of LTBI. Rifampin alone should be used for patients suspected to be infected with *M. tuberculosis* resistant to isoniazid.

Use of Rifamycins for the Treatment of TB among HIV-Infected Patients Receiving PIs or NNRTIs

Protease inhibitors (PIs) and non-nucleoside reverse transcriptase inhibitors (NNRTIs) are metabolized by the hepatic enzyme CYP3A4. Because rifamycins induce the activity of this enzyme, there are substantial decreases in serum concentrations of these antiretroviral drugs when they are co-administered with rifamycins. The rifamycins differ in the degree to which CYP34 is induced; rifampin is the most potent followed by rifapentine and then rifabutin. Since PIs and NNRTIs, depending on the agent, can inhibit or induce this same enzyme, it is difficult to predict the drug-drug interactions that will occur when these agents are co-administered. With the addition of new antiretroviral agents or new combinations of antiretroviral agents (such as those used for pharmaco-enhancement) to the therapeutic armamentarium, and limited published studies on the pharmacokinetics of these drug-drug interactions, it is a therapeutic challenge knowing how to optimally administer these medications to patients with both HIV infection and TB.

Despite periodic updates of recommended dose adjustments for concurrent use of anti-TB and antiretroviral medicines,[10,11] there is a need to present updated information to providers as new data become available. The CDC now maintains a website www.cdc.gov/nchstp/tb/TB_HIV_Drugs/TOC.htm, where this information will be updated on a continuing basis. This contains text, tables with recommendations of which rifamycins can be used with PIs and NNRTIs and dose adjustments needed for drugs that can be used together.

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Letter from the Editor

"Those who cannot remember the past are condemned to repeat it."
George Santayana, philosopher and poet

Dear Colleagues:

Consider the following from the recent report to congress entitled "The Health Status Of Soon To Be Released Inmates":

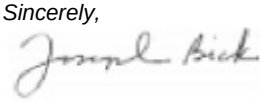
-The prevalence of latent tuberculosis infection (LTBI) among inmates is markedly increased compared to the general population.
-Nationwide, >500,000 inmates with LTBI are released each year.
-The rate of active tuberculosis in jails is fifteen times that seen in the general population.
-One-third of those with active tuberculosis in this country have been recently incarcerated.
-Approximately 15% of those with HIV in this country have been recently incarcerated.

Unfortunately, it has become all too easy in the U.S. to become complacent about tuberculosis. A marked decrease in new cases over the past 30 years has led to a situation in which many clinicians rarely, if ever, encounter a case of active disease. In the U.S. correctional setting, we treat a disproportionate number of individuals who are infected with HIV and/or MTB. Those coinfected with these two pathogens are at a significantly increased risk for progressing from LTBI to active contagious disease. Just one such individual in an overcrowded, underventilated congregate living environment can quickly lead to an outbreak situation among staff, inmates, and visitors. Those who are latently infected can be identified and treated while incarcerated, preventing the future development of active disease and transmission to others. It is unlikely that this nation will achieve its TB elimination goals without the efforts of all of us who work in correctional settings.

This month, Deputy Editor Renee Ridzon (currently with the Bill and Melinda Gates Foundation and formerly of the CDC TB control branch) provides an update of new information in the field of tuberculosis. This month's HIV 101 is an extremely useful table for clinicians detailing dosing interactions between rifamycins and antiretroviral agents, while our spotlight focuses on the use of electronic medical records in the correctional healthcare setting.

Next month, a trio of HEPP Report editors will bring you the latest in information from this year's conference on retroviruses and opportunistic infections, to be held in San Francisco February 8-11. Thank you for your ongoing readership of HEPP Report, and please let us know how we can better serve you in the future.

Sincerely,



Joseph Bick, MD

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SPOTLIGHT: Electronic Medical Records (EMRs) in Corrections

Joseph Bick, MD, Julia Noguchi**, MA*

It's Friday afternoon. The director of your Department of Corrections has been summoned to testify before the legislature on Monday morning concerning the correctional health care budget. You have been given one hour to provide her with the following information:
-complete outcome data for all patients evaluated and treated for hepatitis C in the past 18 months
-HIV-infected patients stratified by nadir and most recent T cell count, viral load, and current HAART regimes
-percentage of your diabetic patients who received urine protein screening, podiatric evaluation, and hemoglobin A1C monitoring within the past year
-total expenditures by drug for the twenty most costly medications on your formulary.
You:
a) freeze the gate, and put all available staff to work pouring over your paper medical records
b) decide to accept that early retirement you have been contemplating
c) query your EMR and obtain all the requested data (and more) within the time allotted.

The effective medical management of any chronic illness depends upon the ability to record and recall data. In addition, reimbursement and risk management often hinge upon the maintenance of an accurate, complete medical record. As treatments become more complex, it has become increasingly difficult to accomplish these tasks solely through the use of a paper record. In response to these growing demands, a wide variety of electronic medical record (EMR) systems have been created. EMRs are being used for charting, to remind clinicians when patients with chronic illnesses such as HIV, diabetes, or hypertension need routine testing, to schedule healthcare appointments, to prompt clinicians to order lab work and vaccinations, and to record data in a way that it can be accessed and manipulated by health care providers. EMRs can simplify the movement of data for patients who are seen by multiple clinicians at many different facilities. It has been estimated that between 10 and 20 percent of physicians in this country are currently using EMRs.

Although some clinicians have been slow to embrace these new technologies, the federal government may accelerate the use of EMRs by requiring them as a condition of participation in programs such as Medicare. In 2001, the Institute of Medicine (IOM) published a report outlining obstacles to the provision of quality healthcare. The IOM specifically recommended the use of information technology to address organizational deficiencies in the treatment of chronic conditions. The American Academy of Family Practice has announced a goal of having electronic medical records in place by 2006. The academy is evaluating a number of web-based systems, and believes that an EMR will reduce medical errors, improve safety, increase screening and preventive care, reduce complications including drug errors, and facilitate the introduction of evidence-based guidelines.

Although most of the commercially available EMR systems have been designed to comply with the Health Insurance Portability and Accountability Act, (HIPPA), security of web-based systems continues to be of paramount concern. For this reason, some health organizations have chosen to maintain all information on a local server. Some clinicians have not embraced EMRs because of the start-up cost involved or concerns about the need for ongoing logistical support. Furthermore, converting paper records to electronic format can be a daunting task. With recent technological improvements, it is now possible to scan electronically existing medical records, simplifying the conversion process to an EMR. Once an EMR is in place, clinicians can input medical information using a personal computer or a notepad-sized wireless personal digital assistant (PDA).

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*Disclosures: *Nothing to disclose.*

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SPOTLIGHT...*(continued from page 4)*

What follows are comments on some of the EMRs currently being used in correctional settings around the country. Rather than being an exhaustive review, this spotlight is intended to stimulate discussion and information sharing concerning information technologies among our correctional colleagues. We encourage feedback from readers about systems in use in jail or prison settings around the country.

Emerald

Dr. David Paar of the University of Texas Medical Branch utilizes an EMR that he describes as an "in house" custom designed program called Emerald. With Emerald, the ordering physician views a menu and enters a request for labs to be drawn. Once obtained, the results of these tests are then entered into the system and emailed to the ordering physician. Dr. Paar notes the convenience of an integrated electronic system whereby the physician simply clicks on a patient's chart and puts lab results into context. Dr. Paar suggested the need for a similar system for radiographs and other imaging studies. "We shouldn't limit our thinking to just laboratory values. This concept could be applied to other studies to manage all diagnostic tests and biopsies, such as chest x-rays, so all of these test results could come back in timely fashion."

Serapais®

Dr. Lou Tripoli of the Correctional Medical Institute uses Serapais®, an EMR that has been modified for the correctional setting. Serapais® allows the user to search a patient by name, inmate #, account #, DOB, and SSN. This system can capture detailed patient information including demographics, problem lists, health assessments, and test results. It provides alerts for identifying potentially chronically ill patients during the health screening process and sends out reminders for appointments, test preparations and test results. Moreover, Serapais® generates SOAP or "Subjective, Objective, Assessment and Plan" notes during patient encounters with the healthcare provider. Accordingly, this system not only offers the "four building blocks" required for an effective EMR, but also effectuates the final step whereby the progress notes are generated electronically.

Quest Diagnostics® TORO

Dr. Joseph Paris of the Georgia D.O.C. uses a system developed by Quest Diagnostics® called TORO. His correctional facility opted for a vendor with an extensive server that has the capacity to store medical information for tens of thousands of inmates. For a given correctional facility to reproduce these data is not only time-consuming, but expensive. TORO allows providers to access their own database that is housed on Quest's server by paying a very reasonable surcharge. According to Dr. Paris, the biggest advantage of this EMR is instant laboratory data retrieval. Although TORO does not presently have plotting capabilities that can graph specific results, Dr. Paris feels that this feature, which will be available in the near-future, will further improve upon what is already an excellent system.

Labtracker

Lab Tracker™ from Ground Zero Software (info@labtracker.com) is a full-purpose electronic medical record (EMR) with disease-specific programming for HIV and other infectious diseases, including hepatitis. The database platform was originally developed as a way to manage and graph laboratory results and medications specific to HIV, and has since become an all-inclusive EMR. The platform currently houses records for 10 percent of HIV patients in the U.S. through institutions such as Emory University and the University of Miami, and two-thirds of all hemophilia patient records in the U.S. through coordinated efforts of Baxter Bioscience and the CDC.

"Electronic Medical Records (EMRs) may reduce medical errors, improve safety, increase screening and preventive care, reduce complications including drug errors, and facilitate the introduction of evidence-based guidelines."

What follows are case examples of three representative installations: statewide (Louisiana), regional (Owen Clinic at the University of California at San Diego), and an individual facility (Cape Vincent Correctional Facility in New York).

State of Louisiana

The Health Care Services Division (HCSD) of Louisiana State University Health Sciences Center comprises eight state hospitals. A wide-area network (WAN) of shared servers connects the healthcare center in New Orleans to geographically dispersed hospitals.

New Orleans implemented a customized version of Lab Tracker for HIV-infected patients in May 2003. Currently, four hospitals use Lab Tracker to accommodate approximately 5,000 unique patient files. The Lab Tracker initiative is led by Newton E. Hyslop, Jr. MD, Clinical Lead of LSU HCSD's HIV Disease Management Initiative, and Nathan Daigrepont, Lab Tracker Project Coordinator.

Prior to Lab Tracker, providers had to retrieve information from several different systems and sources for a complete patient profile. Daigrepont says the criteria for the new EMR were ambitious in scope, and included a single database that integrated all SOAP notes, radiology, laboratories, clinics, and pharmacies.

Lab Tracker data integration and data mining capabilities were a key product differentiator, according to Daigrepont. At the patient level, Lab Tracker provides graph and trend analysis using linear plots and logarithmic scales to show how, for example, a given patient's CD4 counts or viral loads have responded by medication, dosage and other variables over time. The visual image can be used as an education tool to encourage patient adherence. At present, 300 laboratory tests have been validated for the system. Medication data is uploaded from a pharmacy database. Modifications are underway to automate medication entry, as well as simplify SOAP notes entry with optional voice recognition. When fully integrated, graph and trend analysis are expected to

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significantly reduce the amount of time needed to retrieve records, analyze patient health, and prepare for patient visits. Lab Tracker has recently added screens that will allow clinicians to more effectively track hepatitis data. These screens provide "at a glance" information to clinicians, which will be useful in avoiding unnecessary repetition of tests and procedures.

At a statewide level, the ability to bring together disparate patient files in a single uniform database will enable LSU HCSD to improve utilization management from a central location. It will be possible to conduct costs analyses budgetary forecasts and access patient data archives to assess needs for improvements for patients who are failing treatment or falling out of care.

Under the auspices of Special Projects of National Significance grant from the U.S. Department of Health and Human Services, LSU HCSD is conducting an analysis of the impact of introducing Lab Tracker as a medical record system to the LSU HCSD HIV Clinics.

Owen Clinic

The Owen Clinic at the University of California San Diego Health Center has been using Lab Tracker since 1997. Approximately 9,000 unique patient files dating back more than 10 years are housed in the EMR, of which 2,000 are active files.

Since 2000, the Liver Clinic has been using a version of Lab Tracker tailored to hepatitis and liver cancers for approximately 5,000 patient files. More recently, the Mother, Child & Adolescent HIV Clinic implemented a pediatric version of Lab Tracker in 2002 to help manage its 500 patient files. Presently, each clinic runs its own versions on separate servers with the option to share data as needed.

At the Owen Clinic, physicians have reduced preparation time using Lab Tracker to access patient histories and SOAP notes, and enhanced patient visitations with the visual snapshots of patient progress using graph and trend analysis. The clinic uses Lab Tracker's analytical capacity to compile internal reports on a variety of factors, including longitudinal studies based on CD4 counts or viral loads, and cross-sectional studies, such as the most recent Hepatitis C status.

Cape Vincent Correctional Facility

The Cape Vincent Correctional Facility in New York is an example of how Lab Tracker can benefit healthcare at smaller, individual sites. Attending physician Dr. Charles Moehs is a family physician who has worked in corrections for 10 years and is a member of the American Association of HIV Medicine. Of the total Cape Vincent population of 900 to 1,100 inmates, Moehs sees approximately 75 HIV and hepatitis C patients on a regular basis.

Prior to Lab Tracker, Moehs handled records by hand. Patient charts would be circulated among many places and difficult to locate. At times he went into patient visits without knowing whether the patient was adherent. In order to bring order to the process, he began entering patient data in Microsoft Excel. He sought an EMR that enabled him to sort and conduct population trends; the program had to be intuitive, simple to install and easy to use.

Moehs has used Lab Tracker since 1999. The EMR converted all existing Excel data, allowing him to begin entering additional data immediately and customizing the program to fit his needs. He estimates a new patient profile takes 15 minutes to create, and that his preparation and analysis time has been reduced to about five minutes per patient encounter.

According to Moehs, the biggest benefit of Lab Tracker has been its graph and trend analysis. It provides him an instant snapshot of CD4 counts, viral loads and other key indicators in relation to current and new medications. Moehs believes that the graphs have enhanced the patient-provider relationship. When a patient can see a graph of his progress, the level of trust in both the clinician and the treatment improves. As research by HEPP Report's Dr. Rick Altice has demonstrated, these are two of the main factors predicting patient adherence. Lastly, Lab Tracker has improved the patient discharge process. Moehs can provide a complete packet of pertinent patient information and medication records so that released inmates experience a more seamless transition in continuing treatment at an outpatient clinic.

Conclusions

Regardless of institutional size, correctional health care providers can benefit from an all-purpose EMR. At smaller facilities, an EMR can enhance the quality of provider service, improve levels of patient trust and adherence, and streamline the discharge process. At a regional level, an EMR can provide integrated records management that links hospitals, clinics, laboratories and pharmacies in one uniform database. In its clinical capacity, an EMR can save time in preparation and analysis, allowing doctors to offer equal level of care more effectively.

High-level outcome studies can enable administrators to manage chronic diseases by indicators. The statewide example of the Health Care Services Division at Louisiana State University indicates that a fully networked EMR can significantly improve utilization management from a central location. Once direct data entry by providers of critical information such as medications and immunizations is implemented, an EMR's potential ability to perform any number of outcomes studies will ease the burden of conducting cost analyses and budgetary forecasts.

Additional considerations for corrections facilities in particular are that improved records management can reduce the expenses associated with unnecessarily repeating studies on patients who have moved from one facility to another. Better archival and records management can also improve litigation management and correspondence with a state's Medical Board. Most importantly, an EMR enables healthcare providers to improve care, ease the transition of records to new providers, and reduce the human toll of outdated bureaucratic information flow.

DISCLOSURES:
**Nothing to disclose.*
***Nothing to disclose.*

HIV 101: Guidelines for the Use of Rifamycins for the Treatment of Tuberculosis in Patients Taking PIs or NNRTIs*

	RIFAMPIN			RIFABUTIN		
	PI/ NNRTI dose change	**Rifampin dose change**	**Comments**	**PI dose change**	**Rifabutin dose change**	**Comments**
SINGLE PROTEASE INHIBITORS (PIS)						
Ritonavir	None	None (600 mg/day)	Ritonavir AUC ↓ by 35%; no change in rifampin concentration.	None	↓ to 150 mg/day or 300 mg every other day or 150 mg 3x/week	Rifabutin AUC↑ by 430% no change in ritonavir concentration.
Amprenavir	Rifampin and amprenavir should not be used together.		Amprenavir AUC ↓ by 82%, Cmin ↓ by 92%.	None	↓ to 150 mg/day or 300 mg 3x/week	Rifabutin AUC ↑ by 193%; no change in amprenavir concentration.
Fos-Amprenavir	Rifampin and fos-amprenavir should not be used together.		See amprenavir	None	↓ to 150 mg/day or 300 mg 3x/week	Comparable to amprenavir.
Atazanavir	Rifampin and atazanavir should not be used together.		Interaction studies not performed, but marked decrease in atazanavir concentrations predicted.	None	↓ to 150 mg every other day or 150 mg 3x/week	Recommendation as per package insert. Rifabutin AUC ↑ by 250%.
Indinavir	Rifampin and indinavir should not be used together.		Indinavir AUC ↓ by 89%.	↑ to 1000 mg q8h	↓ to 150 mg/day or 300 mg 3x/week	Rifabutin AUC ↑ by 204%; indinavir AUC ↓ by 32%.
Nelfinavir	Rifampin and nelfinavir should not be used together.		Nelfinavir AUC ↓ 82%.	↑ to 1000 mg q8h	↓ to 150 mg/day or 300 mg 3x/week	Rifabutin AUC ↑ by 207%; nelfinavir AUC ↓ by 32%.
Saquinavir	Rifampin and saquinavir should not be used together.		Saquinavir AUC ↓ by 84%.	Rifabutin and non-boosted saquinavir should not be used together.		Saquinavir AUC ↓ by 43%.
DUAL PROTEASE-INHIBITOR COMBINATIONS						
Saquinavir / ritonavir	Saquinavir 400 mg + ritonavir 400 mg bid	None (600 mg/day)	Limited clinical experience			
Lopinavir / ritonavir (Kaletra®)	Rifampin and lopinavir/ ritonavir (Kaletra®) should not be used together.	None (600 mg/day)	Lopinavir AUC ↓ by 75% & Cmin ↓ by 99%. Limited clinical experience. Increased hepatotoxicity from ritonavir is likely.	None	↓ to 150 mg every other day or 150 mg 3x/week	Rifabutin AUC ↑ by 303%; 25-O-desacetyl rifabutin AUC ↑ 47.5-fold.
Ritonavir (any dose) with saquinavir, indinavir, amprenavir, fos-amprenavir, or atazanavir				None	↓ to 150 mg every other day or 150 mg 3x/week	
NON-NUCLEOSIDE REVERSE TRANSCRIPTASE INHIBITORS (NNRTIS)						
Efavirenz	↑ to 800 mg/day May ↓ to 600 mg/day if 800 mg dose not easily tolerated.	None (600 mg/day)	Efavirenz AUC ↓ by 22% no change in rifampin concentration.	None	↑ to 450 mg/day or 600 mg 3x/week	Rifabutin AUC ↓ by 38%. Effect of efavirenz + protease inhibitor(s) on rifabutin concentration has not been studied.
Nevirapine	200 mg twice-daily	None (600 mg/day)	Nevirapine AUC ↓ 37-58% and Cmin ↓ 68% with 200 mg 2x/day dose Limited, though favorable, data for 200 mg BID. Should only use if no other options exist and clinical and virologic monitoring possible.	None	300 mg/day or 300 mg 3x/week	Rifabutin and nevirapine AUC not significantly changed.
Delavirdine	Rifampin and delavirdine should not be used together.		Delavirdine AUC ↓ by 95%.	Rifabutin and delavirdine should not be used together.		Delavirdine AUC ↓ by 80%; rifabutin AUC ↑ by 100%.

**Updated January 20, 2004. Adapted from the Centers for Disease Control and Prevention: http://www.cdc.gov/nchstp/tb/tb_hiv_drugs/Table1.htm http://www.cdc.gov/nchstp/tb/tb_hiv_drugs/Table2.htm*

Save the Dates

The 11th Conference on Retroviruses and Opportunistic Infection
February 8-11, 2004
San Francisco, CA
Contact: Office of the Retrovirus Conference Secretariat
Call: 703.535.6862
Fax: 703.535.6899
Email: info@retroconference.org
Visit: www.retroconference.org

8th North American Region Conference of the International Union Against Tuberculosis and Lung Disease
February 26-28, 2003
Austin, TX
Themes will include Global Threats to Regional TB; Cross-Border TB Issues; Treatment Strategies and Disparities of TB Control in Low-Incident Countries; and Scientific Challenges for TB Control: Resistance, Drug Discovery, and Laboratory Methods.
Call: 312.243.2000
Fax: 312.243.3954
Email: TB@alamc.org
Visit: www.lungchicago.org or www.iuatld.org

Antiretroviral Update 2004
March 16, 2004
12:30 PM - 3:30 PM EST
Sponsored by Albany Medical College
CME and Nursing credits available
Call: 518.262.4674
Email: ybarraj@mail.amc.edu
Visit: www.amc.edu/Patient/hiv/hivconf/index.htm

National HIV/AIDS Update Conference
March 27-30, 200
Hyatt Regency, Miami, FL
Sponsored by amfAR
To register contact Jessica Bush
jessica@fa-events.com

NCCHC: Clinical Updates in Correctional Health Care
May 22-25, 2004
Hyatt Regency, Chicago, IL
The NCCHC and Academy of Correctional Health Professionals are calling for abstracts.
Call: 773.880.1460
Fax: 773.880.2424
Visit: www.ncchc.org

Inside News

Tipranavir: Phase II Study, 80-week Follow-up
A study presented at the 9th European AIDS Conference evaluated the durability of TPV-based therapy in PI-experienced patients. Patients were randomized to either low-dose or high-dose ritonavir-boosted (100mg) TPV, plus efavirenz and one new NRTI. After 16 weeks on therapy both dose groups achieved full viral suppression, which appears to be fully maintained in terms of log change in viral load at week 80: -2.43 log for high dose and -2.55 for low dose. Using on-treatment analysis, 90% on high dose and 43% on low dose had <50 copies/ml at week 80. In low-dose patients 90% had <50 copies/ml at week 48, but this fell to 43% at week 80. Using <400 copy test, 90% using high dose and 64% using low dose had undetectable VL. Median increases in CD4+ cell counts were +143 for high dose group and +175 for low dose group. Results indicate that TPV-based therapy can provide a durable response in the majority of PI-experienced patients.
Long-term 80-week follow-up of highly treatment-experienced (HTE) patients on tipranavir-based antiretroviral therapy. (BI 1182.2) Boehringer Ingleheim Pharmaceuticles, Inc. et al. 9th European AIDS Conference (EACS) October 2003.

Bristol-Myers-Squibb Announces $30 Million in Grants for Africa
BMS announced that it will allocate six new program grants totaling $30 million as part of the Secure the Future initiative to fight HIV/AIDS in Africa. The program focuses on funding programs at community and medical centers in Botswana, Nambia, Lesotho, Swaziland, and South Africa, the country most devastated by the HIV/AIDS epidemic. Secure the Future works to develop sustainable models in resource-limited settings for community-based initiatives, building internal resources and infrastructure and implementing modern science within a local context.
NATAP - www.natap.org

Trinity Biotech's Rapid HIV Test Gets U.S. Approval
Trinity Biotech has announced that Uni-Gold Recombigen, already in use in Africa, has been approved in the U.S. for the detection of antibodies to HIV in human serum, plasma or whole blood. The product requires only one step, produces a result within 10 minutes, and can be conducted in a doctor's office. Studies have shown that as many as 40% of those taking HIV tests do not return for their results. Rapid testing methods have the potential to increase the likelihood that those who are tested will receive their results.
NATAP - www.natap.org

Study: Oral Sex Not Linked to HIV Risk
In a ten-year couples study, a cohort of 135 HIV-negative (110 women and 25 men) Spanish heterosexuals in a sexual relationship with an HIV-positive partner were evaluated. Of the women, 96 had performed fellatio on their HIV-positive partner, giving an estimated total of 8,965 instances of unprotected fellatio, with ejaculation occurring in the mouth on an estimated 3,060 occasions (34%). Ninety-eight HIV-positive men carried out unprotected cunnilingus on their HIV-negative partner. Among the 25 HIV-negative men with a positive partner, 12 had unprotected cunnilingus, with an estimated 614 total number of episodes. Twenty-four of the 25 men had passive fellatio, with a total of 1,081 instances of fellatio without a condom performed by the HIV-positive partner. In this study, over 19,000 instances of unprotected oral sex did not lead to a single case of HIV transmission. This data adds to the growing number of studies that suggest a significantly lower risk of HIV transmission from oral sex as compared to anal or vaginal intercourse. It is speculated that certain factors may increase the risk of transmitting HIV via oral sex, such as the HIV-positive person having a high viral load, the HIV-infected person ejaculating into the mouth of their partner, the presence of another sexually transmitted disease, and poor oral health. Although the authors concluded that study results point to a very low probability of HIV transmission related to oral sex, other STDs such as syphilis and gonorrhea can be easily transmitted in this manner.
Romero J et al. Evaluating the risk of HIV transmission through unprotected orogenital sex. AIDS 16:9 1269-97, 2002.

Resources

Updated Guidelines for the Use of Rifamycins for the Treatment of Tuberculosis Among HIV-Infected Patients Taking Protease Inhibitors or Nonnucleoside Reverse Transcriptase Inhibitors
www.cdc.gov/nchstp/tb/TB_HIV_Drugs/TOC.htm

CDC Division of HIV/AIDS Prevention
www.cdc.gov/hiv/pubs/guidelines.htm

CDC National Center for Infectious Diseases: Hepatitis C
www.cdc.gov/ncidod/diseases/hepatitis/c/

Hepatitis C Informational Brochure
http://www.harmreduction.org
The 32-page informational brochure is geared toward drug users, and provides information about HCV infection risks, prevention, screening, and diagnosis. Copies are available as a free PDF file or for 35 cents per printed pamphlet. Call (212) 213-6376 x10 for more information.

Body Pro CME/CE
www.thebodypro.com/cme/
A new way to earn CME or CE credits online.

Self-Assessment Test for Continuing Medical Education Credit

Brown Medical School 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 August 31, 2004. The estimated time for completion of this activity is one hour and there is no fee for participation.

1. Among patients with TB caused by drug-susceptible organisms, the following characteristic has been found to be associated with an increased risk of relapse:
   a. Cavitary pulmonary disease on the initial chest radiograph
   b. Less than 21 years of age
   c. Hispanic ethnicity
   d. Female gender

2. For patients who have risk factors for the relapse for TB, the recommended duration of the continuation phase of therapy is:
   a. Four months
   b. Five months
   c. Seven months
   d. One year

3. In a supervised regimen for the treatment of TB, which of the following agents can be dosed once-weekly:
   a. Pyrazinamide
   b. Rifabutin
   c. Rifampin
   d. Rifapentine

4. Which of the following statements about the QuantiFERON®-TB test (QFT) is false?
   a. It requires phlebotomy
   b. It can distinguish between responses to both *M. tuberculosis* and environmental mycobacteria.
   c. It does not boost amnestic immune responses
   d. It requires multiple patient visits

5. The Centers for Disease Control and Prevention recommends that the combination of rifampin and pyrazinamide be used as first line treatment for latent tuberculosis infection.
   a. True
   b. False

6. Which of the following statements is false:
   a. Rifampin increases the metabolism of nelfinavir
   b. When used in patients who are receiving Kaletra, the dose of rifabutin should be increased to 450 mg q day
   c. Efavirenz can be safely used in patients who are being treated with rifampin
   d. Rifampin should not be given to patients who are receiving amprenavir or Kaletra

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	educational value	clarity
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2. Do you feel that HEPP Report helps you in your work? Why or why not?

3. What future topics should HEPP Report address?

4. How can HEPP Report be made more useful to you?

5. Do you have specific comments on this issue?

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