



HEPP NEWS

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HIV & HEPATITIS
EDUCATION
PRISON
PROJECT

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ABOUT HEPP

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ANTIRETROVIRAL UPDATE: NEW DRUGS ON THE BLOCK

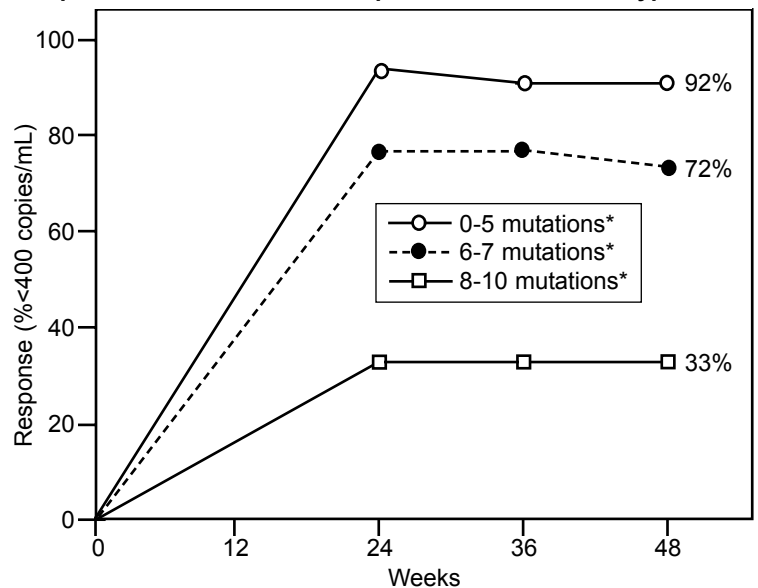
David Alain Wohl, M.D.*, Co-Director, Central Prison Infectious Disease Service, University of North Carolina Central Prison Hospital

Following a virtual renaissance in HIV therapeutics in the mid 1990's, the later part of the decade witnessed a sputtering of the HIV treatment pipeline. Since 1998 only three new antiretroviral agents have come to market, amprenavir (Agenerase), lopinavir-ritonavir (Kaletra) and tenofovir (Viread). In addition, re-formulations of existing drugs have been approved including the fixed dose combination of ZDV, 3TC and abacavir (Trizavir) and enteric coated ddI (Videx EC), bringing the current tally of approved antiretroviral agents to 19. This article will review aspects of these newer drugs and discuss their role in HAART of treatment naïve and experienced patients. A complete listing of available antiretroviral agents, doses, and common side effects is provided in HIV 101 of this issue.

LOPINAVIR/RITONAVIR (KALETRA)

One of the most exciting new antiretroviral agents in some time is the fixed combination of lopinavir and ritonavir (LPV/RTV). This combination exploits the ability of RTV to greatly enhance levels of another protease inhibitor (PI), in this case LPV. Each capsule of the drug contains 133 mg of LPV and 33 mg of RTV. As three (3) capsules of the combination are taken twice a day, each dose contains 400 mg of LPV and 100 mg of RTV. LPV/RTV has been studied in treatment naïve and antiretroviral experienced subjects in combination with other agents. Results of a pivotal study comparing d4T and 3TC in combination with either LPV/RTV versus nelfinavir, involving over 650 antiretroviral naïve subjects, were recently reported.¹ After 60 weeks, 64% of the subjects in the LPV/RTV arm had an HIV viral load below 50 copies/mL compared to 52% in the nelfinavir arm (p=0.001). Virologic failure was reported in only 1% of the LPV/RTV subjects versus 9% of the nelfinavir-assigned subjects.² Strangely, none of the 40 subjects failing LPV/RTV had genotypic or phenotypic resistance to protease inhibitors while 37% of the 84 nelfinavir assigned subjects with virologic failure did have mutations associated with decreased susceptibility to PIs. Even more unexpected was the virtual absence of the 3TC resistance-associated mutation at codon 184 in the LPV/RTV arm compared to the nelfinavir arm. Clearly, this is not a business-as-usual PI.

Figure 1: Phase II Multiple ARV-Experienced Patients: Virologic Response to LPV/TRV with Respect to Baseline Genotype



*Selected from 11 mutations associated with reduced susceptibility to LPV (protease amino acid positions 10, 20, 24, 46, 53, 54, 63, 71, 82, 84 & 90)

In PI- and NRTI- experienced but NNRTI-naïve subjects, LPV/RTV has been studied in combination with an NNRTI. In this context, the combina-

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ANTIRETROVIRAL UPDATE... (continued from page 1)

tion of LPV/RTV and the NNRTI was very effective at reducing viral load below detectable limits. However, the effect of adding an agent from a new class (i.e. NNRTI) makes pinning all this success on LPV/RTV difficult. Characterization of the resistance profile of LPV/RTV, as discussed above, has been hampered by the small numbers of subjects failing the drug and a lack of resistance mutations detected in those who have. Failure to respond to LPV/RTV in patients with pre-existing resistance mutations has been described and response to the drug is dependent on the number of mutations present at baseline. These data indicate that multiple mutations are required to reduce susceptibility to LPV/RTV (see figure 1).

The attraction of LPV/RTV as a component of a salvage regimen is obvious. Here is a drug that appears to be slowed down only by multiple mutations, is active against virus with protease inhibitors resistance mutations and can be given as 3 pills twice a day. 'Voilà!' the Abbott scientists must have proclaimed when they realized what they created. This strength, though, has turned out to be the drug's weakness. Some clinicians view LPV/RTV as a drug to reserve for salvage – a sort of ace in the hole. However, there is a compelling argument to use the agent earlier. The ease of administration, potency and probable high threshold for resistance accumulation position the agent as an attractive element of initial therapy. A major concern regarding this approach is the lack of understanding of the consequences of LPV/RTV failure and the implication for future treatment response. At this time, clinicians have to judge for themselves where to place this agent until more data are available to address the outstanding questions.

Drug-drug interactions of LPV/RTV are what would be expected of a ritonavir (RTV) -containing regimen. Additionally, data suggest a decrease in plasma levels when the agent is combined with an NNRTI. Therefore, the dose of LPV/RTV should, in most cases, be 4 capsules BID when efavirenz or nevirapine are also used. The drug is best absorbed with food.

Adverse effects include mostly gastrointestinal problems. There have been reports of lower extremity edema with LPV/RTV not due to deep vein thrombosis or right-sided heart failure. LPV/RTV does lead to perturbations of lipids, and therefore it would be surprising if it did not produce those body shape changes associated with the protease inhibitors class.

As in the case with RTV, there are storage issues relevant to correctional facilities,

especially those located in regions where it can get very hot. Unlike RTV, LPV/RTV does not need to be refrigerated if used within 2 months and can be stored at temperatures up to 77° F (up to room temperature). However, if the temperature is higher, as is the case in most of the cell blocks in North Carolina in July and August, the product breaks down quickly. If refrigerated, both LPV and RTV remain stable until the expiration date on the manufacturer's label. These storage requirements can pose challenges for systems where drugs are provided 'keep on person' (KOP) and where it gets hot as Georgia asphalt in the summer.

TENOFOVIR (VIREAD)

This newest addition to the antiretroviral war chest is a little pill that is taken once a day. Tenofovir is a nucleotide analogue, which means the agent is already in the nucleotide form that nucleoside analogues are converted to in the body. The drug has been approved for initial and salvage treatment of HIV infection despite the fact that there are few data regarding use of the drug as initial therapy. The manufacturers have conducted trials in HIV-therapy experienced patients and have demonstrated moderate potency of the drug. In one study 189 subjects, who were receiving antiretroviral therapy for a minimum of 8 weeks but continued to have detectable HIV viral loads, were randomized to receive intensification with three different doses of tenofovir or placebo. At 48 weeks, subjects assigned to receive the 300 mg dose of tenofovir had a modest, but meaningful, reduction in viral load (80% or 0.62 log).³ A larger study involving over 550 subjects compared the addition of 300 mg dose of tenofovir versus placebo, again in treatment-experienced patients with detectable HIV viremia. At 24 weeks, when all patients rolled over to active drug, 19% of the 368 tenofovir-assigned subjects had a viral load below 50 copies/mL compared to 1% of the 182 subjects randomized to placebo.⁴ These results are to be formally presented at the Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC) in December.

An international trial of 600 naïve subjects in which tenofovir, as part of a combination including efavirenz and 3TC, is being compared to a regimen of d4T, efavirenz, and 3TC, is ongoing.

Tenofovir susceptibility is reduced in the presence of multiple nucleoside analogue-associated mutations, particularly when the M41L and L210W mutations are present. Multiple thymidine analogue mutations or TAMs (M41L, L210W D67N, K70R, T215Y/F among others) is associated with decreased efficacy of tenofovir. The K65R mutation and multi-drug resistance mutations such as the T69S confer resistance to the drug.

The side effect profile of the drug, to date, appears favorable. Unlike related drugs such as adefovir and cidofovir, tenofovir does not seem to cause renal insufficiency to any great extent. Nausea, vomiting and diarrhea have been reported with use of the drug; however, it remains unclear if tenofovir contributes to metabolic complications of therapy such as fat redistribution or hyperlactatemia. In animal studies there have been problems with bone mineralization prompting the inclusion of bone density evaluations in Gilead sponsored studies of tenofovir in humans. Post-marketing surveillance of side effects will be required to fully characterize the adverse effect profile of this drug. To date, there are no data indicating that bone density is a problem in people. High fat meals increase the bioavailability of the drug, therefore, it is recommended tenofovir be taken with a meal.

Where tenofovir will fit in the grand scheme of treatment is not clear at present. This easy to take agent may become a "cherry on top" drug, added to regimens that are commonly perceived to need a bit of a boost, such as in the use of triple nucleosides in patients with high viral loads, in salvage regimens in multi-drug experienced patients and for intensification of a newly failing regimen. The drug may also become part of a once a day regimen along with other existent and forthcoming once a day therapies - provided meal requirements do not conflict.

AMPRENAVIR (AGENERASE)

Originally dismissed as a 'me-too' protease inhibitor, amprenavir does stand a little (and I mean a little) apart from the pack. Studies of antiretroviral naïve and experienced patients demonstrate that amprenavir is effective as a component of a three or more drug regimen and, by virtue of a somewhat disparate pattern of resistance development, may have some unique applications. For example, one of the biggest selling points for this hefty protease inhibitors (weighing in at 16 pills per day) is that it has a novel pattern of resistance which would indicate relatively limited cross resistance to other PIs. The initial mutation seen in patients failing amprenavir is at codon 50, which is relatively unique. Subsequently generated mutations, however, do overlap with other PIs (for a constantly updated list of HIV resistance mutations go to www.iasusa.org and click on 'Drug Resistance Mutations': see Resources and Websites). Likewise, this overlap of mutations, such as the I84V mutation in particular, would predict that virus resistant to indinavir and ritonavir would be less susceptible to amprenavir.

However, in a pivotal trial of nucleoside reverse transcriptase inhibitor (NRTI) experienced but protease inhibitor (PI) naïve sub-

LETTER FROM THE EDITOR

Dear HEPP News Readers,

As this issue of HEPP News went to press, we were busy at the 25th Conference on Correctional Health Care (NCCHC) in Albuquerque, New Mexico. We started the conference on a great note with the annual HEPP preconference symposium. This year's symposium was entitled: "Bridging the Gap: Getting High Risk Patients into Treatment," a topic that went with the theme of our Aug./Sept. 2001 HEPP News. We had fabulous presentations by many well-known correctional doctors, including our own Chief Editor, Anne De Groot, who gave presentations on TB in corrections and on the issues facing women inmates with HIV. Deputy Editor Joe Bick also reported on issues facing transgendered patients and their HIV treatment and prevention: Dr. Michael Wong gave a presentation on Hepatitis C in corrections; Joe Paris, another HEPP Editor, spoke about the outbreak of Hepatitis B in the Georgia DOC earlier this year; Rob Lyerla, from the CDC, discussed the state of Hepatitis B in corrections nationwide; and Dr. Eric Avery, spoke on mental health treatment in HIV-positive patients in corrections. We appreciate the time and effort our presenters gave to make the symposium a success.

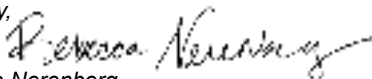
Many other HEPP "celebrities" were seen at the conference, including Dr. David Thomas, Dr. Dean Rieger, Dr. Ted Hammett and a great dancer, HEPP advisor Ned Heltzer. We all attended important presentations on health care in prison, especially as it relates to HIV and Hepatitis. Next month's issue will include a "Rapid Report" section with conference updates. We will focus on the presentations on women, Hepatitis B and C, and HIV as they relate to corrections.

In this issue, Associate Editor David Wohl provides a comprehensive drug update, looking at the three newest drugs that have become part of HAART: amprenavir, lopinavir/ritonavir, and the latest FDA approved drug, tenofovir. HIV101 complements the main article, providing an updated table describing all of the antiretroviral medications now available. This month's spotlight was written by The Corrections Connection's, Michelle Gaseau, who interviewed Robyn Gershon from Columbia University's school of public health. Gershon spearheaded a study on postexposure prophylaxis (PEP) in corrections, the first study of its kind. The HEPPigram supplements the interview by providing updated PEP recommendations for various types of exposures to HIV.

After reading this issue, health care providers should understand the basics of the new antiretroviral medications, including dosing and drug interactions; readers should also understand what an occupational exposure to HIV is, which drug regimens to use in the case of an occupational exposure to HIV, and what documentation is recommended.

Next month's issue will focus on opportunistic infections and recommendations for treating those infections presented by Dr. Joe Bick. We encourage our readers to submit summaries from any NCCHC presentation or any other topics!

Sincerely,



Rebecca Nerenberg,
Managing Editor, HEPP News

Published monthly and distributed by fax, HEPP News provides up-to-the-moment information on HIV and hepatitis treatment, efficient approaches to administering treatment in the correctional environment, national and international news related to HIV and hepatitis in prisons and jails, and changes in correctional care that impact HIV and hepatitis treatment.

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ANTIRETROVIRAL UPDATE... (continued from page 2)

jects pitting a triple drug therapy of two NRTIs and amprenavir against two NRTIs coupled with indinavir, there appeared to be no clear difference between these protease inhibitors in reducing viral load. At 24 weeks 43% of the amprenavir assigned patients had HIV viral loads below 400 copies/mL compared to 53% of the indinavir assigned subjects.⁵ This trend favoring indinavir was not statistically significant. Adverse events, however, were more common in the amprenavir arm and were related to gastrointestinal intolerance and rash.

Furthermore, in the most rigorous studies of amprenavir in NNRTI- and PI- experienced subjects, the role of the drug was obfuscated by an unforeseen drug-drug interaction with efavirenz, which was included as part of the experimental salvage regimens. After a dismal showing for amprenavir (only a quarter of subjects receiving amprenavir, efavirenz and abacavir had viral load below 400 copies/mL) it became apparent that efavirenz substantially lowers amprenavir levels in the blood.

Amprenavir appears more likely to produce rash than other drugs of this class and this can cause confusion when combined with a NNRTI or abacavir. Stevens-Johnson Syndrome is reported in as many as 1% of patients taking this drug. Gastrointestinal adverse effects are common as is circumoral paresthesia (tingling around the mouth). A suggestion that this is a protease inhibitor that is less likely to cause dyslipidemia and body shape changes has become somewhat less relevant as the drug has been coupled with lower dose RTV in an effort to reduce the pill burden of amprenavir. RTV at higher doses has been demonstrated to increase triglycerides and cholesterol and has been linked to truncal fat accumulation. Whether these effects are dose dependent remains unclear. Each 150 mg amprenavir pill contains 109 IU of vitamin E. Therefore, supplemental vitamin E should be avoided.

When used without RTV, the dose of amprenavir is 1200 mg BID. The drug can be taken with or without food but not with a high fat meal. With RTV the dose can be reduced as RTV acts to increase plasma levels of the drug. Several dose regimens have been examined including amprenavir-600 mg plus RTV-100 mg both BID, amprenavir-600 mg

plus RTV-200 mg both BID and amprenavir-1200 mg plus RTV-200 mg QD. While these regimens are not on the package insert, they are commonly used in clinics. Special attention must be paid to drug interactions. As mentioned, when the drug is coupled with efavirenz a reduction in plasma levels of amprenavir occurs. Some clinicians recommend that when efavirenz or nevirapine is added to amprenavir that 200 mg of RTV and 600 mg of amprenavir be used.

Capitalizing on a somewhat disparate sequence of resistance evolution to amprenavir, the manufacturers have tried to position the drug as a first PI-failure option. This application of the drug has not caught on in many places. It is likely that this has much to do with the extraordinary pill burden and the availability of other options. Hope, however, may be on the horizon. The manufacturers of amprenavir have developed a pro-drug formulation, GW433908, affectionately referred to as '908'. This drug will likely require 2 pills twice a day. Clinical study of this agent is underway but approval is likely to be one year away.

NEW FORMULATIONS OF OLDER AGENTS

By now most clinicians have become familiar with the fixed dose combination of ZDV, 3TC and abacavir (Trizavir). This one pill BID regimen has the efficacy and tolerability that would be expected with exposure to these compounds. In addition, an enteric-coated formulation of ddI has been approved. The original formulation of ddI contained an antacid to buffer against degradation of the drug in the acid or the stomach. The new formulation uses a protective coating instead. The result is a normal sized capsule that can be swallowed instead of chewed, less gastrointestinal disturbance caused by the buffer and reduced drug interactions with agents requiring stomach acidity for absorption. The drug still needs to be taken on an empty stomach. The toxicity is expected to mirror that of the older formulation, but with better palatability, one wonders whether we will see more people actually taking the drug as recommended and, therefore, more of the toxicity we associate with ddI.

NEW REGIMENS

The array of available agents for treatment of HIV infection has led clinicians to develop diverse therapeutic strategies. For instance, patients initiating antiretroviral therapy can

now be treated with a PI-based, PI-sparing, NNRTI-based or triple NRTI regimen, among others. Reassuringly, it appears there are no major differences in antiretroviral effectiveness across popular treatment strategies. John A. Bartlett from Duke University recently published an analysis of the results of 23 HIV treatment trials in which antiretroviral naïve subjects received dual NRTIs and either a PI, an NNRTI, or a third NRTI, and found that these three approaches were not significantly different in their ability to drive HIV viral load levels below 50 copies/mL.⁶

With generally similar efficacy expected with these treatment strategies, consideration of regimen composition now focuses on tailoring therapy to patient-specific issues of adherence and tolerability. Pill count, frequency of dosing, drug-drug interactions and side effect tolerance can now be considered when devising a regimen - recasting associations of HAART with handfuls of multicolored pills that make people sick.

Salvage therapy has also evolved and frequently involves inventive, and sometimes ragtag, collections of agents - often inspired as much by results of resistance testing and pharmacologic boosting as by wishful thinking. Yet, salvage therapy continues to provide diminishing returns with high long-term failure rates seen in most every study. As persons with HIV infection live longer and cycle through antiretrovirals, there is a need for new agents that are effective against viruses that have accumulated multiple resistance mutations.

CONCLUSION

More drugs, more choices. The question remains, though, 'How, short of a cure, can new drugs continue to be developed to meet the needs of an increasingly treatment experienced and socially complex HIV positive population?' With the rate of new HIV infections continuing to be on the order of 40,000+ per year and HAART failure rates high, there remains, unfortunately, a market for new antiretrovirals. Industry's most recent responses to this challenge were described in this article. While none of these agents offer what most would consider a major advance in the treatment of HIV, they do complement the palette of available drugs and provide an opportunity for creative options in initial and salvage treatment.

*Speaker's Bureaus: GSK, Gilead, Merck, BI, Roche

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HEPPIGRAM: Recommendations for HIV Postexposure Prophylaxis (PEP)

Accidental exposure to HIV exists in the health care setting and provides a possible avenue for HIV transmission. Like sexual exposure, this mode of exposure is often preventable,¹ but if it does occur, initiating post-exposure prophylaxis soon (within 1-2 hours optimally) after exposure provides the best defense against HIV transmission.² The overall HIV transmission rate for cases of occupational exposure is estimated at approximately 0.3%.³ Exposure to blood and body fluids or tissues contaminated with blood carry a risk of transmission as do genital secretions. The risk of transmission for nonbloody body fluids (e.g. cerebrospinal, pericardial, amniotic) is undetermined. Exposure to nonbloody tears, sweat, saliva, urine, vomit, or feces is not considered to pose a significant risk of HIV transmission.²

The rationale behind PEP is that it appears to stop cellular HIV infection before the virus becomes established in cells. In order for PEP to be effective, then, it must be initiated before there is detectable viremia.³ The following two tables provide guidelines for provided PEP in an occupational setting. Most often, the basic two-drug PEP regimen is the combination of zidovudine plus lamivudine, although other combinations may be considered.² The expanded three-drug PEP recommendation adds a PI (lopinavir), an NRTI (abacavir), or an NNRTI (efavirenz) to the basic regimen.² An occupational exposure report should also accompany each incident (Table 2).

Table 1: HIV PEP for Percutaneous Injuries²

Exposure Type	Infection Status of Source				
	HIV+ Class 1 ¹	HIV+ Class 2 ¹	Source of Unknown HIV Status ²	Unknown Source ³	HIV Negative
Less Severe ⁴	Recommend Basic 2 Drug PEP	Recommend Expanded 3 Drug PEP	Generally, no PEP warranted, however, consider basic 2 drug PEP ⁵ for source with HIV risk factors ⁶	Generally, no PEP warranted, however, consider basic 2 drug PEP ⁵ in settings where exposure to HIV-infected persons is likely	No PEP warranted
More Severe ⁷	Recommend Expanded 3 Drug PEP	Recommend Expanded 3 Drug PEP	Generally, no PEP warranted, however, consider basic 2 drug PEP ⁵ for source with HIV risk factors ⁶	Generally, no PEP warranted, however, consider basic 2 drug PEP ⁵ in settings where exposure to HIV-infected persons is likely	No PEP warranted

1. HIV-Positive, Class 1 -- asymptomatic HIV infection or known low viral load (e.g. <1,500 RNA copies/mL). HIV-positive, Class 2 --symptomatic HIV infection, AIDS, acute seroconversion, or known high viral load. If drug resistance is a concern, obtain expert consultation, initiation of postexposure prophylaxis (PEP) should not be delayed pending expert consultation, and, because expert consultation alone cannot substitute for face-to-face counseling, resources should be available to provide immediate evaluation and follow-up care for all exposures.

2. Source of unknown HIV status (e.g., deceased source person with no sample available for HIV testing).

3. Unknown source (e.g., a needle from a sharps disposal container).

4. Less severe (e.g., solid needle or superficial injury).

5. The designation "consider PEP" indicates PEP is optional and should be based on an individualized decision between the exposed person and the treating clinician.

6. If PEP is offered and taken and the source is later determined to be HIV-negative, PEP should be discontinued.

7. More severe (e.g., large-bore needle, deep puncture, visible blood on device, or needle used in patient's artery or vein).

For information on mucous membrane and non-impact skin exposures see the CDC Guidelines.

Note: Some State Departments of Health, including New York, recommend 3 drug PEP whenever PEP is indicated.

Table 2: Information for Occupational Exposure Report²

<ul style="list-style-type: none"> ■ date and time of exposure ■ details of where and how exposure occurred, including the procedure being performed at time of exposure ■ details of severity of exposure (amount, type of exposure, depth of injury, etc.) 	<ul style="list-style-type: none"> ■ details of exposure source ■ details of exposed person (i.e. HBV vaccination status) ■ details of PEP, counseling, and follow-up: counseling and follow up should always be offered to address psychological effects of occupational exposure.
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Table 3: Situations Requiring Expert* Consultation for PEP²

<ul style="list-style-type: none"> ■ Delayed (more than 24-36 hours) exposure report ■ Unknown source ■ Pregnancy (known or suspected) in exposed person 	<ul style="list-style-type: none"> ■ Antiretroviral resistance of source virus ■ Toxicity of initial PEP regimen
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*Expert: Local expert or the National Clinician's PEP Hotline (PEpline: 1.888.448.4911)

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SPOTLIGHT: Correctional Health Care Exposure to Infectious Disease

By Michelle Gaseau*, Managing Editor, *The Corrections Connection*

Exposure prevention and postexposure prophylaxis (PEP) can improve safety for correctional health care workers in a high-risk work environment. However, a new study by researchers at Columbia University's Mailman School of Public Health reveals that correctional health care workers are being exposed to infectious disease and may not be doing all they can to prevent that exposure.

The study, the first to focus on the practices of correctional health care workers, was funded by the National Institute for Occupational Safety and Health (NIOSH). It surveyed correctional health care workers in Rhode Island, Maryland and Texas – representing low, medium and high risk for exposure from inmate patients.

"We found 7 percent reporting an exposure in the last six months. This corresponds with our hospital data [for health care worker exposures.] We wouldn't have thought they would have had as much of a risk because they are not doing as many procedures [as hospitals]," said Robyn Gershon, Dr.PH, MHS of the Mailman School of Public Health at Columbia University.

Gershon said the research team entered the prisons in the three states with a questionnaire for health care workers to complete with inquiries regarding accidental exposures and Hepatitis B vaccines status, among others.

A tube of blood was drawn from consenting health care workers and tested for Hepatitis B antibody and antigen, and for markers of Hepatitis C virus (HCV) infection. In addition, a skin test was performed for the presence of TB. Gershon said the researchers received information from over 400 participants.

"[The inmate population] is getting older and [there are] more acutely ill inmates. They are pretty sickly and our health care workers are doing a lot of intervention with them and are [therefore] getting exposed [to infectious diseases]," said Gershon.

EXPOSURES ARE HAPPENING

The survey results revealed that 4 percent of participants were carriers of the Hepatitis B virus yet none of those knew their infected status. "It is almost a public health implication," said Gershon. Additionally, 3 percent of participants said they were aware of a previous positive HCV test, and in fact three percent were HCV infected.

In terms of types of exposure, 7 percent of respondents said they had experienced at least one needle stick, 4 percent had experi-

enced at least one splash to the eyes and 2 percent had been cut with sharps. Also, according to the study, 32 percent of those surveyed never reported an accidental exposure.

Why were they not reporting? The reason many respondents gave is that they did not know to whom to give the information, Gershon reported.

But Gershon also believes that many health care workers, who shared their feelings privately, perceive they would be penalized in some way if they reported an accidental exposure. "They know [what they should do] but a lot of them are in denial," she said. Moreover, for workers in facilities located in a remote spot from a local hospital, seeing a doctor may feel like too much of a burden.

Gershon explained that this under-reporting poses a problem for prevention in correctional health care settings. "How can you prevent it if you don't have the data," she said.

COMPLIANCE A PROBLEM

According to Gershon, one of the reasons for the relatively high number of exposures is lack of compliance with prevention measures. "There are some bad behaviors here - this is why they are getting exposed," Gershon said.

Despite improved safety measures including requirements to use safe needles that do not need to be recapped, some safety issues remain. The study results reveal the following lack of protection: 42 percent of respondents lack protective clothing, 46 percent lack eye protection, and 27 percent participate in improper sharps disposal. Beyond that, Gershon said that in some systems safer devices might be chosen for a whole agency without the consultation of those who work on the "front lines." "My understanding is safety committees don't always have representation from front line workers," she said.

Other issues mentioned by health care workers included no place for a proper break, where staff can eat and drink in a separate area. "They don't have stuff like that and have to go to the cafeteria and they don't want to do that. They eat and drink where they have clinic," Gershon said.

Other problems occur when these workers do not follow up with preventative vaccines. In the study, 55 percent of participants who said they had received Hepatitis B vaccine also had an observable titer. "It could mean if [the remainder] had an exposure they would not have a response. It is a heads up to let them know they might want to follow up.

They are advised to consult their own practitioner to get another shot," said Gershon. For TB risk, the researchers found that only 37 percent used a mask with HEPA filter, 25 percent used surgical masks and 22 percent used none at all.

On the positive side, Gershon said that 50 percent of respondents had had training on TB prevention in the last year and 97 percent had been tested at work. However, 16 percent of respondents tested positive for TB when in the last year they had tested negative.

So what should be done to reduce this risk for correctional health care workers? Gershon has some ideas.

RECOMMENDATIONS

A safe working environment is an important predictor for compliance with preventative measures. Availability of proper resources, including small details such as making sure workers have gloves that fit properly, can mean the difference between compliance or non-compliance. Agencies should be paying attention to these details to help prevent unnecessary exposures among employees, said Gershon.

Additionally, Gershon suggests that officials conduct a periodic review of employee risk. The data might show across institutions a pattern of exposures or a pattern of safety.

"It has to be a combination of public health and correctional agencies doing [the review]. I think [corrections] would be wise to do it themselves in their accreditation agencies and create a standardized reporting program," Gershon said. "Some facilities have marvelous state of the art programs but some need more direction. It would be nice if there were more uniformity. There's certainly room for improvement."

For more information about the study, contact Gershon via email at rg405@columbia.edu

Note: OSHA mandates HEPA respirator use and while new standards may not be necessary, compliance with existing standards is. The newly revised OSHA bloodborne pathogen control standard requires annual risk assessment and annual input from front line staff. Also, the existing OSHA 2000 log should record all needlestick injuries, and employee training is required to include what to do after an exposure incident. An employer can be fined if this process is not followed correctly. This study has revealed the need for the implementation of an increased compliance with the existing OSHA standards within corrections. Visit www.osha.gov.

**Nothing to disclose.*

HIV 101 Summary of Antiretroviral Agents Dosing and Administration Recommendations

by HEPP News Staff

Adapted from Bartlett JG and Gallant JE. 2001-2002 Medical Management of HIV Infection. Johns Hopkins University, Baltimore, MD. 2001. Additional information from http://www.gilead.com/prod_pdf/viread_pi.pdf.

NUCLEOSIDE REVERSE TRANSCRIPTASE INHIBITORS (NRTIs)

	Zidovudine (AZT, ZDV, <i>Retovir</i>)	Didanosine (ddl, <i>Videx</i> , <i>Videx EC</i>)	Zalcitabine (ddC, <i>Hivid</i>)	Stavudine (d4T, <i>Zerit</i>)	Lamivudine (3TC, <i>Epivir</i>)	Abacavir (ABC, <i>Ziagen</i>)	Tenofovir (<i>Viread</i>)
Recommended Dose	300mg bid (or with 3TC as Combivir 1 tab bid)	Tablets or oral solution >60kg: 400mg qd (EC) or 200mg bid (tabs) or 250mg bid (powder) <60kg: 250mg qd or 125mg bid (tabs) or 167mg bid (powder)	0.75mg tid	>60kg: 40mg bid <60kg: 30mg bid	150mg bid or with AZT as Combivir (1 tab bid) <50kg: 2mg/kg bid)	300mg bid	(nucleotide analog) 300mg once daily
Food Effect	None	Levels ↓55% Take 1 hr before or 1 hr after meal	None	None	None	None Alcohol ↑ ABC levels 41%	Should be taken with a meal
Major Toxicity Class Toxicity	<ul style="list-style-type: none"> ■ Bone Marrow suppression: anemia and/or neutropenia ■ subjective complaints: GI intolerance, headache, insomnia, asthenia 	<ul style="list-style-type: none"> ■ Pancreatitis ■ Peripheral neuropathy ■ GI intolerance, nausea, diarrhea 	<ul style="list-style-type: none"> ■ Peripheral neuropathy ■ Stomatitis 	Peripheral neuropathy	(minimal toxicity)	Hypersensitivity (2-5%), fever, nausea, vomiting, anorexia, cough, dyspnea, malaise, morbilliform rash. May be life-threatening with rechallenge.	<ul style="list-style-type: none"> ■ Bone (in animals) ■ Renal (in animals) ■ Mild to moderate gastrointestinal: nausea, vomiting, diarrhea, flatulence
Drug Interaction	Ribavirin may reduce AZT activity	Methadone ↓ ddl levels 41%, consider ddl dose increase	Methadone ↓ ddl levels 27%. No dose adjustment	None	None	None	take two hours before or one hour after didanosine (if applicable)

NON-NUCLEOSIDE REVERSE TRANSCRIPTASE INHIBITORS (NNRTIs)

	Nevirapine (<i>Viramune</i>)	Delavirdine (<i>Rescriptor</i>)	Efavirenz (<i>Sustiva</i>)
Recommended Dose	200mg po qd x 14 days, then 200mg po bid	400mg po tid	600mg po qd at hs
Food Effect	None	None	-50% with high fat meal; avoid after high fat meal
Drug Interaction	<ul style="list-style-type: none"> ■ Induces cytochrome P450 enzymes ■ PI interactions see Table 4-16 in Bartlett Guide* 	<ul style="list-style-type: none"> ■ Methadone AUC decreased 60% titrate methadone dose ■ Not recommended: Ketoconazole and rifampin ■ Caution: anticonvulsant 	<ul style="list-style-type: none"> ■ Inhibits and induces cytochrome P450 3A4 enzymes ■ Contraindicated drugs: astemizole, midazolam, triazolam, cisapride, ergot alkaloids, tergenadine ■ PI interactions: generally ↑ dose when given with PIs (like Kaletra) and see Table 4-16 in Bartlett Guide* ■ Possibly important drug interactions: see Chapter 4 in Bartlett Guide* ■ Methadone AUC decreased 60% titrate methadone dose
Major Toxicity Class Toxicity	<ul style="list-style-type: none"> ■ Rash (15-30%) may require hospitalization; rare cases of Stevens-Johnson syndrome; hepatitis 	<ul style="list-style-type: none"> ■ Rash; headaches ■ Increased transaminase levels 	<ul style="list-style-type: none"> ■ Dizziness, "disconnectedness," somnolence, insomnia, bad dreams, confusion, amnesia, agitation, hallucinations, poor concentration ■ 40% usually resolves after 2 weeks ■ take hs. ■ Rash- severe in 5%; rare reports of Stevens-Johnson syndrome: ■ Teratogenic in cynomolgus monkeys ■ Avoid in pregnancy, and women and men should use adequate contraception methods. ■ False positive drug screening test for cannabinoids (marijuana)

SUMMARY OF ANTIRETROVIRAL AGENTS... (continued from page 7)**PROTEASE INHIBITORS (PIs)**

	Indinavir** (Crixivan)	Ritonavir (Norvir)	Saquinavir** (Invirase) (Fortovase)		Amprenavir (Agenerase)	Nelfinavir (Viracept)	Lopinavir + Ritonavir (Kaletra)
Recommended Dose	800mg q 8h Separated ddl dose by 1 hr	600mg bid Separate ddl dose by 2 hr	Not recommended as single PI 400mg bid with RTV	1200mg tid	1200mg bid (caps) 1400mg bid (oral solution)	1250mg bid or 750mg tid	3 caps or 0.5mL twice daily 4 caps bid when used with efavirenz or nevirapine
Food Effect	↓77%; take 1 hr before or 2 hours after meals; may take with low fat snack or skim milk	↑15%; take with food if possible to improve tolerability	No food effect when taken with RTV	↑6x; take with large meal unless taken with RTV	high fat meal decreases AUC 20%; can be taken with or without food, but high fat meal should be avoided.	↑2-3x; take with meal or snack	Fat increases AUC 50% to 80%; should be taken with food
Side Effects*	GI intolerance (10-15%); nephrolithiasis or nephrotoxicity (10-15%); headache; asthenia; dizziness; rash; metallic taste; ITP; alopecia; lab: increase in indirect bilirubinemia (inconsequential) Class side effects*	GI intolerance (20-40%); paresthesias-circumoral and extremities (10%); taste perversion (10%); lab: triglycerides increase in 60% and transaminase increase in 10-15%, CPK and uric acid increase Class side effects*	GI intolerance (10-20%); increase Class side effects*	GI intolerance (20-30%); headache; hypoglycemia; transaminase increase (10%); Class side effects*	GI intolerance (10-30%); rash (20-25% - usually at 1-10 wks), Stevens-Johnson syndrome (1%); paresthesias (10-30% - perioral or peripheral) Increase in liver function tests. Class side effects*	Diarrhea (10-30%) Class side effects*	GI intolerance: nausea, vomiting, diarrhea Elevated Lipids Asthenia Class side effects*

*For full information on toxicity and drug interactions for PIs and class side effects, see Chapter 4 of Bartlett JG and Gallant JE. 2001-2002 Medical Management of HIV Infection. Johns Hopkins University, Baltimore, MD. 2001. For information on Tenofovir, see http://www.gilead.com/prod_pdf/viread_pi.pdf.

**These two drugs usually used in combination with ritonavir (see HEPP News, February 2001).

RESOURCES & WEBSITES**POSTEXPOSURE PROPHYLAXIS RESOURCES:****National Clinicians' Postexposure Prophylaxis Hotline (PEpline)**

This hotline is run by the University of San Francisco/San Francisco General Hospital staff and is supported by the CDC and other government health organizations.

Phone: 1.888.448.4911

Web: <http://www.ucsf.edu/hivcntr>

Needlestick!

Website to help manage and document occupation exposure to blood and other bodily fluids. Maintained by the University of California Los Angeles (UCLA) Emergency Medicine Center, UCLA School of Medicine.

<http://www.needlestick.mednet.ucla.edu>

CDC PEP Guidelines for HIV, HBV, and HCV MMWR 2001; 50 (No. RR-11) on the web at

<http://www.cdc.gov/mmwr/PDF/RR/RR5011.pdf>

DRUG UPDATE INFORMATION**Listing of Drug-induced HIV Genome Mutations**

http://www.iasusa.org/resistance_mutations/index.html

Complete Information on Kaletra

<http://www.fda.gov/cder/foi/label/2000/21226bl.pdf>

Complete Information on Viread

http://www.gilead.com/prod_pdf/viread_pi.pdf

HIV TREATMENT WEBSITES**AMFAR HIV/AIDS Treatment Directory, Summer 2001 Edition**

For free copies, contact Barbara Good at barbara.good@amfar.org or fax a request to 212.806.1601

Updated Adult and Adolescent HIV Treatment guidelines

http://www.hivatis.org/guidelines/adult/Aug13_01/pdf/AAAUG13S.PDF

Hopkins AIDS Service: Medical Management of HIV Infection

http://hopkins-aids.edu/publications/book/book_toc.html

SAVE THE DATES

3rd International Hepatitis C Update for the New Millennium

November 30-December 1, 2001
Houston, Texas

Fee: Physicians- \$165; Other Health Care Professionals- \$135

Visit: www.uth.tmc.edu/cme

Email: Kristen.K.Brockman@uth.tmc.edu

Call: 713.500.5127

CME and CEU credit available

41st Interscience Conference on Antimicrobial Agents and Chemotherapy

December 16-19, 2001

Chicago, Illinois

Sponsored by American Society for

Microbiology (ASM)

Visit: www.icaac.org

9th Conference on Retroviruses and Opportunistic Infections

February 24-28, 2002

Seattle, Washington

Registration: Dec. 10, 2001-

Jan. 23, 2002

Call: 703.535.6899

Visit: www.retroconference.org

2002 National STD Prevention Conference

March 4-7, 2002

San Diego, California

Fee: before Feb. 8: \$140;

after Feb. 8: \$165

Visit: <http://www.stdconference.org/>

Call: Glenda Vaughn,

404.639.8260

Email: ghv1@cdc.gov

14th National HIV/AIDS Update Conference (NAUC)

March 19-22, 2002

San Francisco, California

Sponsored by (amfAr) American

Foundation for AIDS Research

Abstract Deadline: Nov. 15, 2001

Fee: Before Dec. 15: \$275;

Dec 15-March 1: \$325;

After March 1: \$375

(special rates available)

Visit: [http://www.amfar.org/cgi-](http://www.amfar.org/cgi-bin/iowa/nauc/index.html)

[bin/iowa/nauc/index.html](http://www.amfar.org/cgi-bin/iowa/nauc/index.html)

CME credit available

International Conference on Emerging Infectious Diseases (ICEID)

March 24-27, 2002

Atlanta, Georgia

Visit: <http://www.cdc.gov/iceid/>

Email: cas1@cdc.gov

NEWS FLASHES

HIV

FDA Approves Tenofovir for all HIV Patients

Associated Press, 10/28/01

Tenofovir (Viread, produced by Gilead), a new antiretroviral medication, lowered the viral load of patients who had developed drug resistant virus (see Newsflashes, Aug/Sept HEPP News). The FDA has now approved the medication for use in all HIV-positive patients (10/26/01). Tenofovir has been shown to reduce the viral load by as much as 75% when used in combination with other medications. Experts caution against prescribing tenofovir for drug-naïve patients until study results on the use of the drug in newly diagnosed patients are released. Tenofovir is a once-a-day pill that will cost about \$4,135 for a year's supply.

Genetic Test Available to Show Drug-Resistance

Associated Press, 9/27/01

The FDA recently approved gene-based test, Visible Genetic Inc.'s Trugene, that analyzes an HIV patient's viral mutations in terms of drug resistance. This test will aid physicians in prescribing the best medications for each patient depending on his/her viral genotype. Trugene uses a blood sample to identify all known genetic mutations in the virus. It then compares the individual's genetic mutations to over 70 mutations known to be linked to resistance to specific drugs. The turnaround time is three days and will cost \$300-\$500 per patient (see Paar D, Altice F, HEPP News September 2000). This is the first genotyping test to receive FDA approval. Other genotyping tests are available from many commercial suppliers including the Phenosense test from Virologic.

Specialists More Likely to Recommend Appropriate Therapies

2001 July. The AIDS Reader 11(7): 348-353.

A survey of physicians in California, Florida, Massachusetts, and New York found that those with less experience caring for HIV/AIDS patients need expert advice in the process of treating patients. The study presented physicians with two hypothetical HIV/AIDS patients and asked the physicians how they would treat those patients. Infectious disease specialists were more likely to recommend treatments consistent with those of the HHS and the International AIDS society than were general internal medicine physicians. The general internists, however, were often aware of gaps in their knowledge and said they would refer the patient to a specialist.

No Mandatory HIV Testing of State Prisoners in Indiana

Indianapolis Star, 10/24/01

Indiana DOC officials estimate that approximately 1% of state inmates are HIV positive but do not know the exact number because Indiana does not have a mandatory testing law for inmates. Although a bill was passed by the state legisla-

ture last year that would require mandatory HIV and HCV testing for all inmates, it was vetoed by the governor for budgetary reasons. This testing is estimated to cost \$173,285 per year. HIV testing is available to inmates upon request. Experts recommend educating and counseling prisoners to be voluntarily tested for HIV and HCV.

HEPATITIS

HCV Costs the U.S. \$5 Billion in 1997

Arch Int Med 2001; 161 (18): 2231-2237.

A study reports that in 1997, hepatitis C cost the U.S. approximately \$5.46 billion in medical costs, lost wages, and lost home production. Hepatitis C is the most common blood-borne infection in the U.S. These costs are on par with the cost of asthma in US for the same year (\$5.8 billion). There are estimates that HCV-related mortality could triple within the next twenty years, indicating that increased prevention, treatment, screening, and research are necessary.

MA Canceling Hepatitis C Programs

Boston Herald, 10/5/01

The Massachusetts state legislature plans to cut a program that teaches physicians and others at risk for hepatitis C about the disease due to a budget impasse. Although the Massachusetts state senate set aside \$3.9 million for the program for fiscal year 2002 (which began on July 1, 2001) the House did not allocate any funding. According to a policy issued by the governor's office, agencies are to operate on a lower budget. The program provided counseling and education for those at risk for contracting hepatitis C and raised awareness of people who were unaware they were infected with HCV. The cuts will affect education programs but will have no effect on treatment funding. Approximately 110,000 people in Massachusetts are estimated to be infected with HCV.

OTHER

Syphilis on the Internet

San Francisco Chronicle, 10/26/01

Syphilis is on the rise among gay and bisexual men. This spike in syphilis cases has been recorded in San Francisco, San Diego, Florida, Boston, and Chicago according to the San Francisco Department of Public Health. The number of syphilis cases in San Francisco nearly doubled from 42 in 1999 to 77 in 2000 with a similar increase expected this year. Officials there say 16 syphilis cases in San Francisco this year have been linked to an internet chat room for gay and bisexual men. Although the internet service provider has been reluctant to post syphilis warnings, it has given the Health Department access to the chat room to post prevention messages, an offer that has been rejected as "ineffective". Health officials view the rise in syphilis cases as a decline in safe sex practices and a "complacency" about HIV. Syphilis sores (like other STDs) leave a person more vulnerable to HIV infection.

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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 May 31, 2002. The estimated time for completion of this activity is one hour and there is no fee for participation.

CME IS NOW AVAILABLE ONLINE AT WWW.HIVCORRECTIONS.ORG

1. What is the correct dosing for lopinavir+ritonavir (Kaletra) if NOT using in combination with an NNRTI?
 - (a) 3 caps or 3mL bid
 - (b) 3 caps or 5mL qod
 - (c) 5 caps or 3mL bid
 - (d) 3 caps or 5mL bid
 - (e) 5 caps or 5 mL qod
2. In addition to Trizivir (AZT, 3TC, Abacavir), Combivir (AZT, 3TC), and ddl EC (Enteric Coated), how many ART drugs are there?
 - (a) 6 NRTIs, 3 NNRTIs, 6 PIs
 - (b) 3 NRTIs, 6 NNRTIs, 3 PIs
 - (c) 4 NRTIs, 4 NNRTIs, 6 PIs
 - (d) 6 NRTIs, 6 NNRTIs, 3 PIs
 - (e) 3 NRTIs, 3 NNRTIs, 6 PIs
3. The basic two-drug PEP regimen most often consists of:
 - (a) one NRTI + one PI
 - (b) one NRTI + one NNRTI
 - (c) two NNRTIs
 - (d) two NRTIs
 - (e) one NNRTI + one PI
4. The expanded three-drug PEP regimen is recommend in the following circumstances (according to CDC guidelines):
 - (a) a less severe exposure to HIV-positive class 2 fluids
 - (b) a more severe exposure to HIV-positive class 1 fluids
 - (c) a less severe exposure to HIV-positive class 1 fluids
 - (d) a more severe exposure to HIV-positive class 2 fluids
 - (e) a, b, and d
5. In which of the following situations of occupational exposure should expert consultation be sought to determine the appropriate PEP regimen?
 - (a) initial PEP regimen is toxic
 - (b) exposure report occurs more than 36 hours after exposure
 - (c) source virus is resistant to antiretroviral medication
 - (d) the exposed person is pregnant
 - (e) all of the above
6. Exposure to which of the following fluids is NOT considered to pose a significant threat for HIV infection?
 - (a) blood
 - (b) nonbloody saliva
 - (c) vaginal fluids
 - (d) semen
 - (e) bloody cerebrospinal fluid

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