HIV Clinician

DELTA REGION AIDS EDUCATION & TRAINING CENTER

Educating health care providers about HIV/AIDS

formerly FACULTY NOTES

Winter 2004 • Vol. 16, No. 1

Review of studies raises question: Is triple-nucleoside therapy a viable option?

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In the rapidly changing world of HIV care, a single study can often have a profound effect on the prescribing habits of HIV care professionals. A recent such study is the ACTG A5095 study.

The goal of HIV therapy is suppression of the replication of HIV, allowing the reconstitution of the infected individual's immune system. Of importance in choosing a regimen for treatment is the efficacy in initially suppressing the viral replication as evidenced by a decrease in viral load to <50 copies/ml, as well as the ability of the regimen to maintain suppression for a long duration of time. There are also many other factors to consider in the choice, including the adverse drug effect profile, the co-morbidities of the patient, possible baseline resistance or likely cross-resistance, future sequencing choices, drug-drug interactions, the "pill burden," as well as the frequency of administration of the medication regimen.

The initial naive patient trials of triple-nucleoside therapy included the use of zidovudine (AZT) + lamivudine (3TC) + abacavir (ABC) and compared this combination to AZT + 3TC + indinavir (IND). In the closed-label

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Inside

New version! Dr. Zachary's practical guidelines on the web

A major update of Dr. Jim Zachary's web-based, clinician-focused document entitled *Practical Guidelines for the Management of the Adult HIV-Infected Patient* is now available on the Delta Region AETC site at deltaaetc.org/arvintro.html.

The document is notable for its comprehensive yet user-friendly format. According to Dr. Zachary, his objectives are to familiarize the HIV provider with the standard principles and guidelines of antiretroviral therapy for persons with early HIV infection, the latest antiretroviral agents including their proper dosing, side effects and interactions, and other important aspects of HIV care.

The conveniently hyperlinked document includes:

- DHHS-based principles of therapy of HIV infection
- guidelines for prescribing, combining, managing, and monitoring highly active antiretroviral therapy: nucleoside reverse transcriptase inhibitors (NRTI), non-nucleoside reverse transcriptase inhibitors (NNRTI), protease inhibitors (PI), and fusion inhibitors
- information on other forms of therapy for HIV infection including investigational therapies
- information on adherence to therapy
- recommended vaccines for use in HIV+ patients
- recommended use of preventative antimicrobials against opportunistic infections in persons with AIDS or symptomatic HIV
- recommended laboratory testing for persons with HIV, including guidelines for interpretation of resistance testing
- recommendations for anti-tuberculous therapy in the setting of HIV and/or therapy for HIV
- recommendations for therapy of hepatitis B and/or hepatitis C in the setting of HIV infection
- principles of post-exposure prophylaxis for HIV exposure—possible or confirmed
- links to other informational websites
- antiretroviral rapid reference tables including NRTIs, NNRTIs, PIs, FBs, PI boosting, and PI combinations

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Medicine

Clinicians must weigh multiple factors in choosing a regimen

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blinded study (CNA3005) (n=562), the two arms at 48 weeks showed equal efficacy in viral suppression to less than 400 copies/ml (as treated 94 vs 86%) but found that the triple-nucleoside arm had a lower suppression rate to the goal of less than 50 copies/ml when the baseline viral load was greater than 100,000 copies/ml (45 vs. 31%).[1] When the study was re-done in an open-label fashion (CNA3014) (n=342), at 48 weeks, the triple-nucleoside arm, as treated, performed as well as the PI-containing arm at suppression to the goal of a viral load < 50 copies/ml (79 vs 81%) except again in the group with a baseline viral load of > 100,000 copies/ml (59 vs. 73%). Because of these initial studies, the use of triple-nucleoside therapy was mainly used in patients whose baseline viral load was less than 100,000 copies/ml.[2]

An additional study performed in France by Matheron et al (CNA3007) assessed the efficacy of this triple-nucleoside regimen (AZT + 3TC + ABC) as compared to a regimen of nelfinavir (given 750 mg TID) for 48 weeks of therapy (n=195). For intent-to-treat analysis with switch or missing equals failure, the amounts with full viral suppression to < 50 copies/ml were 57% vs 58% at 48 weeks with a rise in CD4 counts of 110 and 120 cells/mm^3, respectively.[3]

The CLASS study assessed the performance of a triple-nucleoside regimen of stavudine (d4T) when given with 3TC and ABC as compared to a regimen of efavirenz (EFV) or ritonavir-boosted amprenavir (AMP/r) with 3TC and ABC. At 48 weeks, the EFV-containing arm clearly showed improved efficacy over the d4T-containing or AMP/r-containing arms (viral load < 50 copies/ml in 76 vs 62 vs 59% by ITT analysis, 89 vs 71 vs 72% by AT analysis). As shown in the first two studies mentioned, this difference was even more marked in the group with a baseline viral load > 100,000 copies/ml (87 vs 60% in AT analysis).[4]

One study that has caused a major shift in providers' thinking is the ACTG A5095 study

A study in Denmark looking at the use of ABC with d4T and didanosine (ddI) as compared to 3TC + AZT with either nelfinavir + nevirapine (1250/200 mg bid) or ritonavir + saquinavir (400/400 mg bid) showed an increase in adverse drug effects in the triple-nucleoside arm (neuropathy 27%, hypersensitivity 12%, symptomatic lactatemia 8%) as well as a decrease in efficacy as compared to the other two arms with viral load at 48 weeks measuring less than 20 copies/ml of 43% vs 69% vs 62% respectively ($p<0.05$).[5]

Because of the questionable efficacy shown in the above trials, triple-nucleoside therapy has been also proposed as an option for simplification of therapy after full-viral suppression has been attained using a regimen containing either a PI or a NNRTI. A study by Clumeck et al in Belgium took 211 patients who had full viral suppression (< 50 copies/ml) after six months of a regimen consisting of a PI with two nRTIs and randomized them to either continue on their current regimen (n=106) or replace the PI with abacavir (n=105). At 48 weeks the results showed a significantly longer time to treatment failure in the triple-nucleoside arm as compared to the PI arm ($p=0.03$) with treatment failure occurring more commonly in the PI arm (12 vs 23% respectively, $p=0.03$). Also demonstrated was an improvement in both non-fasting triglyceride levels and cholesterol levels.[6] The TRIZAL study done at 47 centers in nine European countries (n=209) showed equal virologic suppression failure rates at 48 weeks when patients with full viral suppression on a PI or NNRTI or triple-nucleoside containing regimen were switched to Trizivir (AZT+3TC+ABC) as their therapy (22% failure in each arm) with the incidence of adverse events comparable in each arm.[7]

The ACTG (AIDS Clinical Trial Group) A5095 study is a randomized, placebo-controlled, double-blind study comparing AZT+3TC+ABC (Trizivir) vs

AZT+3TC (Combivir) + EFV vs Trizivir + EFV as initial therapy in naive patients. The definition of failure of a regimen was two consecutive viral loads > 200 copies/ml drawn after week 16 of therapy. The triple-nucleoside arm was discontinued early in 2003 due to findings on early analysis that there was a 21% failure rate in the triple-nucleoside arm as compared to a 10% failure rate in the two arms containing EFV. This occurred in both patients with baseline viral loads above 100,000 copies/ml and those below. The patients randomized to the three nRTI arm were offered the choice to change to one of the other two arms or to continue on the three nRTI arm. In the post-hoc analysis, it was also seen that even those who initially suppressed well on the triple-nucleoside regimen had a shorter time interval to viral failure. The study is ongoing for evaluation of the remaining two options.[8] Since the preliminary results of this study were revealed, there has been a major shift in many providers' minds regarding the appropriateness of triple-nucleoside therapy.

It has also been suggested that the use of tenofovir (TDF), a nucleotide reverse transcriptase inhibitor, may be given as part of a triple nRTI regimen for treatment of naive patients but three studies with results recently released dispute this hypothesis. The ESS30009 study sponsored by GlaxoSmithKline randomized patients to receive once daily dosages of ABC (600 mg) and 3TC (300 mg) given with either TDF (n=102) or EFV (n=92). The interim analysis showed that of those patients who had reached 48 weeks of therapy, nearly 100% on the EFV-containing arm had full viral suppression to less than 50 copies/ml whereas those on the TDF-containing arm had only 40% fully suppressed. Resistance data obtained on 34 patients at 12 weeks on the TDF arm revealed 32 of the isolates expressing an M184V resistance mutation and 21 also had a K65R/K or K65R mutation present.[9] An independent single arm study being done by Farthing et al (n=19) using this same regimen also found a 58% virologic non-response rate defined as either rebound after initial suppression or a drop of viral load < 2 $\log_{10}$ by week 8 of therapy.[10]

Official guidelines update: triple nucleoside/tide regimen is not appropriate for naive patients.

Another study with results given in September 2003 evaluated the use of ddI EC 250 mg + 3TC 300 mg + TDF 300 mg once daily in 24 treatment-naive patients. 91% of the patients on this regimen at week 12 had a decrease of less than 2 $\log_{10}$ in their viral loads. 95% of these patients demonstrated an M184I/V mutation and 50% also had a K65R mutation present at the time of failure.[11]

The DHHS guidelines have been recently updated in November 2003 to state that a TDF-containing triple-nucleoside/tide regimen is not an appropriate option for treatment of naive patients and that a triple-nucleoside regimen with ABC + 3TC as the backbone is an option although not a preferred regimen.[12] Due to the results of these studies, there is controversy as to the approach a clinician should take for those patients who are currently on a triple-nucleoside regimen. There are no clear guidelines for the appropriate response for these patients. The clinician should closely monitor the patient's immune status via CD4 and viral load measurements. Consideration of intensification with either a PI or an NNRTI should be given even if the patient currently is suppressed, although this approach is not mandated at this time. If the patient is already experiencing some viral rebound while on a triple-nucleoside regimen, the clinician should obtain resistance testing while the patient is still on medication and make the appropriate choice of regimen options based on results. Simplification due to "pill fatigue" or metabolic adverse drug effects with an ABC-containing regimen may be an option, although the efficacy and durability of this practice in experienced patients remains to be evaluated adequately.

Triple-nucleoside therapy seems a reasonable approach when given as 3TC + ABC + (AZT or d4T) although not an ideal approach for the best viral response. Some clinical

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Regimen may be useful in certain scenarios

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scenarios where it might be appropriate would be during treatment for a patient who has tuberculosis (no interaction with the rifampin), a pregnant patient whose baseline viral load is relatively low, an adolescent patient, or as simplification after initial viral load suppression with a more extensive regimen.❖

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See back cover for our training calendar

Pharmacy

Ritonavir increases levels of erectile dysfunction agent 49 fold

Tina Edmunds-Ogbuokiri, PharmD, FASCP

Within the past few weeks, there have been several requests from providers in our clinic and HIV-infected patients regarding the new drug being marketed as Levitra by Bayer Pharmaceuticals. Levitra (vardenafil) is a new selective inhibitor of cyclic guanosine monophosphate (cGMP)-specific phosphodiesterase type 5 recently FDA-approved for the treatment of erectile dysfunction in adult males over the age of 18 years. The increase in the prevalence of erectile dysfunction has been associated with increased awareness on the part of the public and providers, much like the increase in the prevalence of obesity, disorders of lipid and glucose metabolism, smoking, hypogonadism (especially when associated with HIV infection and AIDS) as well as depression. It is therefore not surprising that patients with HIV infection may experience different levels of difficulties with erectile dysfunction during different stages of their HIV disease trajectory. Though only available by prescription the internet availability of vardenafil makes it attractive for all patients including those with HIV infection.

While recent pharmacological advances have generated increased public interest and demand for clinical services regarding erectile dysfunction, epidemiological data on sexual dysfunction across social groups are scant for both men and women.

In reviewing the highlights of this new agent, it became necessary to address some of the issues of drug-drug interaction associated with its use in the setting of HIV disease.

DRUG INTERACTIONS OF CLINICAL SIGNIFICANCE WITH VARDENAFIL (LEVITRA)

Protease inhibitors

Vardenafil is eliminated primarily through hepatic metabolism, mainly CYP3A1 and to a lesser extent by CYP2C isoforms. Concurrent use of drugs that inhibit the CYP3A system, such as ritonavir, indinavir, ketoconazole, itraconazole, as well as drugs with moderate CYP3a activity such as erythromycin, result in significant increases in plasma levels of vardenafil. In the case of ritonavir, 600mg in a twice daily dosing regimen was reported to increase levels of vardenafil 49-fold with a 13-fold increase in C_{max} of Levitra. This drug interaction is a consequence of the blocking of the hepatic metabolism vardenafil by ritonavir, a highly potent CYP3A4 inhibitor which also inhibits CYP2C9. Ritonavir significantly increased the half-life of vardenafil to 26 hours. The clinical implications of this are not yet completely understood but such high levels may precipitate problems of priapism even more. Data on the effect of vardenafil on efavirenz and other non-nucleoside reverse transcriptase inhibitors are expected. It is of interest to note that no pharmacokinetic interactions were observed when vardenafil was used with the other drugs used to treat the co-morbidities often associated with HIV disease, such as glyburide, ranitidine, antacids such as Maalox, warfarin and digoxin.

Nitrates and nitric oxide producing drugs

The blood pressure lowering effects of oral nitrates (0.4mg) taken 1 and 4 hours after vardenafil and increases in heart rate were potentiated by a 20 mg dose of Levitra in healthy middle-aged adult subjects. These effects were not observed when Levitra was taken 24 hours before the nitroglycerin dose. Potentiation of the hypotensive effects of nitrates in patients with ischemic heart disease has not been evaluated in clinical studies and concomitant use of Levitra with such nitrates is contraindicated.

Alpha blockers

Levitra should not be used by patients on alpha blocker therapy either as part of their antihypertensive regimen or for the treatment of benign prostatic hypertrophy (BPH). This is because significant hypotension was observed to develop in a substantial number of subjects when given to healthy volunteers as 10mg or 20mg 6 hours after a 10mg dose of terazosin (Hytrin). Six of eight subjects experienced a standing systolic blood pressure of less than 85mm Hg.

Patients on antiretroviral agents, like the general public, are aware of the new developments in the management of erectile dysfunction and are fielding their questions to pharmacy and other providers. It is in recognition of these questions and issues that are being raised by clients and providers, that the above quick review of clinically-relevant drug-drug interactions is hereby offered.❖

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Examining the duty to warn in HIV psychotherapy cases

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After being diagnosed with HIV, individuals may require professional mental health intervention at some point to deal with mood disturbance, anxiety, depression, grief and loss, or all these feelings. Accordingly, unique legal and ethical questions arise when working with this special population and must be recognized and understood by mental health professionals (Stanard & Hazler, 1995). Above all is confidentiality. Confidentiality is an ethical standard of professional conduct that comes from the right to privacy and keeps professionals from divulging personal information without the client's written consent (Morrison, 1989). Such confidentiality is essential to the practice of psychotherapy and is covered in Principle 5 of the Ethical Principles of Psychologists and Code of Conduct adopted by the American Psychological Association, which obliges practitioners to minimize intrusions of clients' privacy and suggests that the obligation to maintain client confidentiality is superseded in cases where to do so would result in harm to the client or others (APA, 1992).

This principle highlights the ethical dilemma that practitioners face when their responsibility to maintain confidentiality is at odds with their duty to warn, especially when faced with these ethical constraints in their work with individuals with HIV. Although a thorough knowledge of professional ethics is crucial for automatic and intuitive decision-making by mental health professionals, complete reliance on these codes is not always possible in all cases (Costa & Altekruse, 1994).

The addition of concomitant psychiatric disorders, including psychoses, personality disorders, and dementias associated with poor judgment, disinhibition of impulses, and diminished capacity for self-monitoring, represent yet further challenges for clinicians (Searight & Pound, 1994). Because of its potentially life-threatening nature, a critical question becomes whether the counselor has a duty to warn individuals who are sexually intimate with a client with HIV infection (Stanard & Hazler, 1995). Depending on the state where mental health professionals practice, some are required to break client confidentiality and warn intended victims when clients pose threats to themselves or others. However, these laws are often vague and do not provide clear consensus for handling the myriad of scenarios that may arise in these complicated cases. The Tarasoff case is often cited when referring to confidentiality, duty-to-warn, and mandatory reporting requirements (Sizemore, 1995; Schlossberger & Hecker, 1996; Stanard & Hazler, 1995; Morrison, 1989; Koocher & Keith-Spiegel, 1998; McGuire et al, 1995). Although one generally does not have a duty to control another's conduct, the court determined in this landmark case that an exception exists when a therapist has a "special relationship" either to the client whose conduct needs to be controlled or to the "foreseeable victim" of that conduct (Sizemore, 1995). Louisiana, like many other states, follows the principles of Tarasoff in cases requiring mental health professionals to warn in cases where clients have communicated threats of physical violence toward clearly identified victims, but so far, not in the context of intentional exposure to HIV (Carney & Dugas, 2003). However, given that many of the recently proposed bills and measures across the United States have advocated duty to warn over the primacy of confidentiality, Beckerman and Gelman (2000) argue that it is just a matter of time until this shift in ideology and policy will likely be extended to cases involving HIV reporting.

Duty to warn situations place practitioners in a double

An ethical dilemma can result when confidentiality turns out to be at odds with the duty to warn.

bind. If professionals fail to warn intended victims, they are negligent. Conversely, if client threats are misjudged and warnings are delivered erroneously, therapists can be sued for invasion of privacy (Costa & Altekruse, 1994).

Therefore, what should mental health professionals do when faced with the dilemma of whether or not to break the confidentiality of their HIV positive clients? Stanard and Hazler (1995) argue that the determination of "clear and imminent" danger should be used as the guiding principle for practice with consideration for the specific issues presented. When dealing with patients with HIV who are engaging in high-risk sexual or needle sharing behaviors with identifiable partners and who refuse to inform them of their HIV status, mental health professionals may have a legal and ethical duty to warn (Searight & Pound, 1994). In these cases, factors such as patients' ability to comprehend the significance of their HIV status and consequences of their high-risk behaviors must be fully considered prior to breaking confidentiality. Even then, all reasonable alternatives should be examined prior to warning others and breaches of confidentiality should be undertaken only as a last resort (Zonana, 1989). When in doubt, seek consultation to make sure no other reasonable alternatives can be utilized and then release only information that is necessary, relevant, and verifiable (Stanard & Hazler, 1995). If a decision is made to breach confidentiality to protect a third party, whenever possible, the client should be informed first in order to minimize the harm to both the client and the therapeutic relationship (Morrison, 1989). Therapists should speak openly and directly with clients about "dangerous" behaviors. Often, those who are putting others at risk typically have emotional conflicts about their behavior and may be grateful for the therapist's attention to this matter (Koocher & Keith-Spiegel, 1998). If the client continues to resist informing partners or using safer sex practices, then clinical judgment is the key issue in the duty to protect. Once all options are exhausted, the client should be included in the decision to breach confidentiality to warn identified partners in hopes of gaining client cooperation with the notification process (Koocher & Keith-Spiegel, 1998).

Although it may be tempting to propose a specific course of action based directly on the broad application of the Tarasoff principles in HIV cases, such a course of action may be

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Table 1. **Guidelines for Providing Psychotherapy Services with HIV-positive Clients**

- Foster a strong therapeutic alliance/working relationship with the client.
- Collect a thorough history (e.g., past history of high risk sexual behavior, needle-sharing behavior, and psychiatric impairment) and identify situational variables (e.g., current alcohol and substance use).
- Determine the presence and extent of any significant psychiatric disorders (both Axis I and II), including how treatable the condition(s) is/are, how much the active conditions may reduce their behavioral control, and how likely treatment will result in substantial behavior change.
- Provide ongoing assessment of mental status and determine clients' ability to understand the consequences of their behavior.
- Educate client about HIV (as needed) and speak openly and knowledgeably about risks.
- Determine if client is disclosing HIV status to needle-sharing and sexual partners and carefully explore reasoning for non-disclosure.
- Support and prepare the client to make disclosures. If the client refuses, professional should notify partners (as a last resort) and inform client of intent to break confidentiality.
- When client is engaging in high-risk behaviors with partners that are not clearly identified, consider other mechanisms for supervising and monitoring the client and document actions.
- Review relevant state laws and determine if health department has been notified (if applicable).

Adapted from Searight and Pound (1994)

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premature, as of yet, in terms of the legal and ethical development of the counseling profession's handling of such cases (Stanard & Hazler, 1995). Many of the provocative questions proposed here are often answered by the courts and pose a tremendous challenge for mental health professionals. Therefore, until greater clarity results from specific case law or statutes, each case needs to be carefully examined individually and include therapists' own thoughtfulness and good judgment in order to make ethically responsible decisions (Morrison, 1989; Stanard & Hazler, 1995). Until then, clinical interventions that reduce HIV-related risk behaviors should be made a priority for mental health professionals (Satriano, 2000). Clearly, how practitioners work with clients will need to be modified as the traditional primacy of confidentiality yields to a "duty to warn" era (Beckerman & Gelman, 2000).❖

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Dentistry

How does tobacco consumption affect oral health in HIV?

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While U.S. death rates for heart disease (the nation's number one killer) have declined substantially in 50 years, the cancer death rate (the nation's number two killer) was 4% higher in 2000 as compared to 1950. Lung cancer remains the most common fatal cancer for men and women, but a reduction in lung cancer death rates since 1990 is attributed to a decrease in cigarette consumption. Adult cigarette consumption dropped between 1965 and 1990, from 50% to 28% of men and from 35% to 23% of women, and by 2000, 25.7% of US men and 21.0% of women were smokers. The prevalence of tobacco use among those with HIV disease is unknown, but recent increases in the number of anti-tobacco ads in gay and lesbian media demonstrate a heightened awareness of the consequences.

Tobacco use appears to reduce the ability of white blood cells to engulf and/or kill bacteria, and decreases serum level of protective immunoglobulins, except for IgE. Smoking may induce a compartmentalized immunosuppressive environment in the lungs of HIV-infected individuals. Possible consequences include an increased risk of infection and a loss of immune surveillance. In a population-based, case–control study conducted by Nuorti et al, approximately half of otherwise healthy adults with invasive pneumococcal disease were cigarette smokers. This study, however, did not control for the possibility of undiagnosed human immunodeficiency virus (HIV) infection. Wewers et al studied both HIV-infected smokers and nonsmokers and found an increase in the peripheral blood CD4+ cell counts among nonsmokers, and significant depression in both the percentage and absolute number of CD4+ and CD8+ cells in the bronchoalveolar lavage fluid (BALF) of smokers.

One study suggests a strong association between cigarette smoking and specific HIV-related OIs.

The impact of tobacco use on HIV-infectivity and/or progression of disease have been studied over the past 15 years, but cohort sizes vary and a meta-analysis has yet to be published. In 2001, the U.S. Surgeon General reported that smoking has been associated with HIV type 1 (HIV-1) infection among women, but it is unclear whether this association is due to an underlying relationship between smoking and high-risk sexual behavior, biological effects of smoking, or both. The Women's Interagency HIV Study (WIHS) reported that women who smoked were more likely ($p<0.01$) to self-report AIDS of 1397 women studied, and those who self-reported had greater immunodeficiency and higher viral loads. An investigation of the association between cigarette smoking and maternal-child HIV transmission, adjusting for illicit drug use, maternal clinical status, and delivery factors, was performed in New York State using vital-statistics birth data linked to the New York State Medicaid HIV/AIDS Research Database. HIV transmission occurred in 24.5 percent of the 901 maternal-child pairs, however, transmission rate for smokers was 31 percent versus 22 percent for nonsmokers.

The effect of cigarette smoking on CD4+ T lymphocytes was investigated in the San Francisco Men's Health Study cohort. Smoking showed an association with increased CD4+ cell counts in all men but the effect was attenuated in HIV-seropositive men (85 cells/microliter difference in median counts, non-smokers compared with smokers) compared with HIV-seronegative men (230 cells/microliter difference in median counts) suggesting that health providers who monitor CD4+ cell counts in HIV-infected individuals should also consider smoking status. Cigarette smoking as a risk factor in progression of HIV-1 disease among 2,499 homosexual males was investigated in the Multicenter AIDS Cohort Study. Adjusting for CD4-+ T-lymphocyte count and antiretroviral medication use, smoking did not appear to

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Dentistry

Clinicians should conduct oral exams to detect OIs, oral cancers

Tobacco consumption, from page 9

significantly affect progression to AIDS or development of *Pneuomocyctis carinii* pneumonia (PCP), but may have a role in the incidence of oral thrush. A study reported in 1991 of 230 HIV-infected military personnel showed that tobacco use was related to the increased occurrence of both oral mucosal lesions and periodontal diseases.

Others have attempted to link tobacco use with an increased risk for oral opportunistic infections and oral cancers in HIV disease. A cross-sectional study comparing CD4 cell count, smoking history, and oral examination findings from 1,058 HIV-infected male patients at the University of California, San Francisco, Oral AIDS Center Clinic, showed that six percent of subjects had normal oral examination findings, 47 percent had lesions of a single type, and 31 percent had a combination of two or more types of lesions. After adjusting for CD4 cell count, current smokers were significantly more likely to have oral thrush but less likely to have oral aphthous ulcers than were current nonsmokers. Results from this study suggest a strong association between cigarette smoking and the presence of specific HIV-related opportunistic infections. Oral hairy leukoplakia (OHL), an Epstein-Barr virus-related oral lesion, may be associated with cigarette smoking. The six-year incidence of OHL occurrence in the San Francisco Men's Health study was 32 percent among 291 HIV-infected men. The risk of developing OHL doubled with any 300-unit decrease in CD4 count, or if men smoked 20 or more cigarettes per day compared with nonsmokers. This study suggests that cigarette smoking may have some affect on the oral mucosa's local immune response.

Alcohol consumption and tobacco use are common etiologic agents for oral cancer in non-HIV-infected individuals. Oral cancer accounts for about three percent of all diagnosed cancers, and the American Cancer Society estimates that 28,900 Americans will be diagnosed with oral or pharyngeal cancer in 2003. Over 90 percent of oral cancer is squamous cell carcinoma, but Kaposi Sarcoma, lymphomas, and metastatic malignancies are found orally in HIV disease. Squamous cell carcinoma presents clinically as either a painless ulceration or an exophytic mass, and early recognition of precancerous mucosal changes, such as color changes, improves morbidity. Various alterations in mucosal health are associated with smoking, including pigmentary changes of the gingiva. Mucosal alterations in those who smoke include nicotine stomatitis (a palatal mucosal condition), changes to the surface of the tongue, and leukoplakia (a white lesion associated with increased tissue keratinization). The role of immunodeficiency in addition to tobacco use in the development of oral cancers is unclear. Frisch et al studied the relative risk (RR) for cancers among those with HIV-related immuno-deficiency from population-based and cancer registry data on 302,834 people in the U.S., and reported that the RR for cancer of the lip rose from 1.6 to 5.8 post AIDS. The RR for other oral cancers did not increase over time, offering little support to link immunodeficiency with oral cancer.

HIV-infected persons should be informed about the potential health risks associated with tobacco use.

Opportunistic viral infections are also believed to contribute to malignant oral cancers in immunodeficient individuals, including human herpesvirus 8 (HHV) in Kaposi Sarcoma, human papillomaviruses (HPV) in squamous cell carcinoma, and Epstein-Barr virus in oral lymphoma. Schwartz et al (1998) conducted a population-based, case-control study of 284 subjects and 477 controls in three counties in western Washington to determine whether the risk of oral squamous cell carcinoma (SCC) is related to HPV infection. Results showed that approximately 26 percent of the oral tumors in case subjects contained HPV DNA, with 16.5 percent of the tumors containing

HPV type 16 DNA, and cigarette smoking and HPV type 16 capsid seropositivity correlated strongly with oral SCC in this population.

Health professionals are encouraged to monitor tobacco consumption during the health history and perform oral examinations to identify opportunistic infection and detect oral cancers. Tobacco use affects the oral surface epithelium, resulting in changes in the appearance of the tissues, which may range from an increase in pigmentation to a thickening of the epithelium (white lesion). Tobacco use can also irritate the minor salivary glands on the hard palate causing dryness (xerostomia) and directly increase a person's risk for periodontal disease, as expressed by gingival bleeding and tooth mobility. Persons with HIV infection who use tobacco should be informed about the potential health risks associated with tobacco use, and encouraged to participate in tobacco cessation activities.❖

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Nursing

Low health literacy: a covert barrier to patient self-management

Jill Devereux, RN, BSN, ACRN

Numerous barriers to adherence and successful self-management have been explored in the HIV literature. Some of the barriers including scarce material resources, inadequate HIV knowledge, and limited self-efficacy may be closely related to patients' facility with language. This article explores the issue of low literacy in the care of HIV/AIDS patients.

Literacy, historically, has been understood as the ability to read and write. In the 19th century, an individual was deemed literate if he could read a simple sentence and write his name. By 1950, literacy was defined in terms of reading/grade level. The U. S. Census Bureau considered an individual literate if he read at a 5th grade level. The current understanding of literacy, however, focuses on functionality rather than school-based proficiencies. Literacy now is thought of as a continuum of language and numeracy skills which develop over the lifespan and allow an individual to respond to the changing demands of society. Since 1985, the definition of literacy which has guided federally-sponsored projects is: "Using printed and written information to function in society, to achieve one's goals, and to develop one's knowledge and potential."

Health Literacy, or Functional Health Literacy (FHL) as it is sometimes termed, refers to the ability to read, understand, and act on health-related information. Adequate health literacy is needed for making informed decisions, correctly decoding instructions, and successfully navigating the health care system. A number of studies, though, suggest that health literacy is usually lower than general literacy, and individuals with literacy skills sufficient for handling daily reading tasks may experience serious difficulties when encountering unfamiliar health-related materials.

Health literacy refers to the ability to read, understand, and act on health-related information.

Scope of the literacy problem

The findings of the National Adult Literacy Survey (NALS) of 1992 indicate that low literacy is a pervasive problem. In this study, more than 26,000 adults in 12 states were asked to perform a variety of common-place tasks to evaluate different aspects of reading and quantitative skills. Nationally, 46% of participants scored at the lowest literacy levels. Among incarcerated adults surveyed, 70% scored at the lowest literacy levels. These findings suggest that 90 million American adults of all ages, races, and socioeconomic classes have inadequate or marginal literacy skills.

In Louisiana, 60% of NALS participants scored at the lowest two literacy levels. Nearly half in this group were determined to be functionally illiterate or reading at or below the 5th grade level. Thirty-nine percent of adults in the New Orleans area scored at the lowest literacy level indicating that the city in the Delta Region with the highest prevalence of HIV also has some of the highest rates of functional illiteracy.

As a follow-up to NALS, the 2003 National Assessment of Adult Literacy (NAAL) is currently underway. The NAAL study is very similar in purpose and methodology to NALS. One difference, however, is the addition of 24 health-related questions embedded within the literacy test itself, as well as 10 health-related items in the background questionnaire. The NAAL data will offer health care professionals a greater understanding of patients' ability to understand health-related information, materials, and forms.

Impact of low literacy on health care delivery and patient outcomes

There is evidence that those patients in greatest need of the skills to self-manage health

problems are among those with the poorest literacy abilities. Among the participants in NALS who reported having a debilitating physical or mental health condition, 75% scored at the lowest literacy levels. In a study of more than 3200 Medicare enrollees in a national managed care organization, Gazmarian et al determined that 37% of patients having a chronic health condition such as DM, COPD, or CAD had poor health literacy. Williams et al in a study of 2,659 patients seen in acute care clinics at two public hospitals in Georgia and California found that 60% could not understand a standard consent form, 26% could not determine from an ordinary appointment card when they were to return to clinic, and 41% were unable to decode the meaning of the instruction: "Take medication on empty stomach."

Among HIV patients, health literacy has been associated with health knowledge, health status, and adherence. Kalichman and Rompa in a study of 339 HIV patients found that 25% had low health literacy skills. These patients had lower CD4 counts, higher viral loads, a greater number of hospitalizations, and more negative perceptions of their health status and health care experiences than did their higher health literacy counterparts. In a longitudinal study examining knowledge of HAART dosing regimens and adherence, Miller et al found that lower literacy was an independent predictor of deficits in medication knowledge. Inadequate medication knowledge is one factor associated with poor adherence.

A number of studies indicate that literacy ability trends downward with increasing age. NALS findings showed that more than half of the participants who scored at the lowest literacy level were 65 or older. In the study of 3260 Medicare enrollees, reading ability declined dramatically with age, and 58% of respondents over 85 years had inadequate health literacy. In the Williams, et al study more than 80% of patients older than 60 years had inadequate health literacy.

Addressing literacy problems can reduce costs, risk of harm to patients, and frustration levels for providers.

Assessing health literacy in the clinical setting

Assessing health literacy may seem burdensome, embarrassing, or impractical to providers working in busy HIV clinical settings. It is certainly beyond the duty and the skill of medical, nursing, and social service professionals to remedy the educational deficits with which many of their patients struggle. However, in the context of promoting patient self-management, strong arguments, as well as useful tools, exist for incorporating formalized literacy testing into practice. In addition to improving health outcomes for patients, addressing literacy problems has the potential to reduce medical costs, reduce risk of harm to patients and their children from poorly understood instructions, and reduce frustration levels for providers working with patients inaccurately labeled as 'noncompliant.'

Many nurses and other clinicians are accustomed to asking patients questions such as "What was the last grade you completed in school?" and "Do you have any difficulty reading or writing?" Evidence suggests, though, that these questions often fail to elicit useful information. Many patients with lower literacy are apparently unaware of their reading problem. Two-thirds of the participants in NALS who tested at the lowest literacy level reported to surveyors they read "well" or "very well." Many patients experience a great deal of shame due to poor literacy. Twenty percent of them had never told *anyone* they had difficulty reading. Grade level attainment also fails to provide an accurate measure of reading ability. It has been demonstrated that most adults read 4-5 grade levels below the last grade they completed in school.

Numerous standardized tests are available to assess a patient's reading ability, but most of these are quite time-consuming or expensive to administer. Two tests, however, have been used extensively in a variety of medical settings.

The first is the Rapid Estimate of Adult Literacy in Medicine (REALM). It consists of 66 health-related words divided

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Two literacy tests have been extensively used in medical settings

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into three columns. Patients are instructed to read aloud each of the words. On a separate sheet, the examiner tallies the total number of correctly read words to obtain a raw score which corresponds to an estimated grade level range. The REALM ordinarily takes 2-3 minutes to administer and score, and it may be used at no cost.

The second tool of interest is the Short Test of Functional Health Literacy in Adults (S-TOFHLA). The S-TOFHLA, using passages taken from forms and other materials found in the medical setting, tests both reading comprehension and numeracy skills. The S-TOFHLA usually takes about 12 minutes to administer, and large-print and Spanish-language versions are available.

Clinicians may wish to familiarize themselves with some of the signs of inadequate literacy that patients may display. Typically, patients who have difficulty reading forms and other materials will make excuses for not completing them. These excuses may include things such as "I forgot my glasses" or "I'm late for the bus" or these patients may bring their friends or relatives to assist them. They may frequently miss appointments or fail to respond to mailed items. These patients may ask their provider to explain something they've apparently just read. They may also fail to exhibit eye movements when 'reading' or they may be slow to right a piece of written material handed to them upside down.

Strategies for teaching patients who are poor readers

There are a number of strategies the clinician may employ when teaching patients who have lower literacy skills. First, focus on the key information which must be conveyed to the patient. Speak in the present tense, use the active voice and a conversational style, and explain to the patient the purpose or use of this new information and how it will fit into the context of his life. Use simple words and lay terms, when possible, and use the same words consistently throughout an exchange. Avoid using statistics or complex graphs and charts; emphasize pertinent skills and behaviors rather than inessential facts. Because patients with lower literacy may have difficulty framing questions, employ a "show me" approach, frequently asking the patient to demonstrate or describe what has just been shown or said to him. When possible, support verbal instructions with low literacy print materials and pictographs, audio or video tapes, and in-person or telephone follow-up.

Study: Lower literacy is a predictor of deficits in medication knowledge which is associated with poor adherence.

It has been estimated that less than 10% of adults who might benefit from a literacy program actually ever participate in one. The clinician might consider familiarizing himself with literacy resources available in the community, and referring patients to these as appropriate.❖

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Nutrition

A look at nutrition and the HIV-positive substance abuser

Ginger Bouvier, MEd, LDN, RD

Substance abuse has become a leading risk factor for acquiring HIV in the United States. The drugs of abuse most closely associated with HIV infection in the U.S. are heroin and cocaine. Substance abuse impacts HIV disease as well as the effectiveness of medical treatments and therapeutic interventions. Substance abusers and addicts often pose unique challenges to clinicians, including nutritionists.

Drug abusers are at high risk for protein-calorie malnutrition as a result of adverse consequences of the drug(s), combined with a disruption in social and familial ties, and often a lack of resources. [1] Drug users often have poor eating habits, and rarely eat more than once a day. It has been well established that the chronic use of cocaine/crack, heroin or alcohol is associated with anorexia and can lead to severe weight loss and malnutrition.

Cocaine/Crack

The main routes of cocaine administration are oral, intranasal, intravenous, and inhalation (including freebase and crack cocaine). Cocaine use causes a lack of appetite, and many chronic users will experience severe weight loss, often becoming emaciated. The appearance of a cocaine addict can be difficult to differentiate from that of a patient with AIDS Wasting Syndrome. Cocaine use can also impact nutrition as a result of various gastrointestinal complications, including gastric ulcerations, retroperitoneal fibrosis, visceral infarction, intestinal ischemia, and gastrointestinal tract perforation.[2, 3] The author of a referenced article has observed several crack cocaine addicts with burns to the lips and oral cavity from using a glass crack pipe.

Heroin

Heroin, a derivative of morphine, is typically snorted, smoked, or injected, with injection being the predominant method of administration. Heroin can cause nausea and vomiting, constipation, and loss of appetite. Chronic heroin users usually spend most of their time and energy on seeking, obtaining, and using heroin. As a result, personal hygiene, nutrition, and overall health are often neglected.

Alcohol

Alcohol abuse, like drug abuse, can result in protein-calorie malnutrition. Alcoholism is the most common cause of thiamin deficiency in the United States. Alcohol inhibits the breakdown and absorption of nutrients by damaging the cells that line the stomach and intestines. Some alcoholics consume as much as half of their total daily calories from alcohol, neglecting important foods. [5] Consumption of greater than one quart of hard liquor per day is associated with weight loss and malnutrition.

Several studies have examined the relationships between drug abuse, nutrition, body weight, and HIV. In a Spanish study, Varela et al performed anthropometric measurements and immune function assessments on HIV-negative and asymptomatic HIV-positive women undergoing detoxification from illicit intravaneous (IV) drugs. No significant differences in anthropometric measurements were noted between the two groups. The researchers concluded that HIV did not affect nutritional improvement or weight recovery, as all subjects gained similar amounts of weight, and had adequate recovery of nutritional status after six months of detoxification. [6]

Forrester et al examined weight, body composition, and self-reported dietary intake in HIV-infected patients who were current IV drug users, past IV drug users, non-IV drug users, or nonusers. The researchers found lower body weights and body fat in female IV drug users compared to non-users despite higher self-reported calorie intake. In the men, they found no differences in weight or body composition in the IV drug users compared to non-users, although the IV drug users and past IV drug users had higher self-reported calorie intakes than non-users. [7]

A study by Himmelgreen et al compared food security, nutritional status, and food preparation patterns of low-income Puerto Rican female drug users with that of low-income Puerto Rican women who reported no drug use. The results showed that the drug users were more likely to be food insecure, ate significantly more sweets and desserts, and generally maintained poorer nutritional status than non-users. [8]

Clinicians treating HIV-positive individuals in outpatient settings must recognize the impact of substance abuse on nutrition. In any patient with malnutrition, it is critical to first determine the cause(s) and contributing factors of the nutritional problems in order to determine appropriate interventions. In the HIV-positive substance user with malnutrition, traditional nutrition interventions are unlikely to provide sustainable improvement in nutritional status without abstinence from drugs and/or alcohol, which often requires treatment for the chemical dependency.❖

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