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# HIV Clinician

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## Prezista® offers potent new combo when used with Fuzeon® in ritonavir-boosted regimen

*Tina Edmunds-Ogbuokiri, PharmD, FASCP*

**D**arunavir (Prezista<sup>®</sup>), like Tipranavir (Aptivus<sup>®</sup>), is another non-peptidic protease inhibitor (PI) recently granted accelerated approval by the FDA in June of 2006, for use in patients who are highly treatment-experienced or have HIV-1 strains resistant to multiple PIs based on their demonstrated activity against PI-resistant viruses. Darunavir has a molecular structure that differs from those of earlier PIs, conferring activity against HIV protease in the presence of major mutations. Because of its low oral bioavailability, darunavir must be coadministered with ritonavir.

In 2005-2006, the guidelines established maximal suppression of HIV as the goal of therapy in this patient population and recommended the use of an entry inhibitor (such as Fuzeon<sup>®</sup>) with an active ritonavir-boosted PI (such as darunavir) as a strategy for achieving that goal. This is in contrast to the recommendations two years earlier when the same guidelines addressed the treatment of patients with extensive prior exposure to antiretrovirals by commenting that “viral suppression is often difficult or impossible to achieve” and emphasized the preservation of immune function and prevention of disease progression as the primary goals of therapy in these patients.

With the relatively low barrier of resistance of NNRTIs, therapies for treatment-experienced patients with multi-class resistance have continued to rely

heavily on PIs. Where the development of several PIs, such as lopinavir/ritonavir (LPV/r), darunavir (DRV), atazanavir (ATV) and fosamprenavir (FPV) have provided a resource for therapy after initial PI failure because of their non-overlapping resistance and potential ability to be used in novel dual-boosted regimens, the role of these PIs in highly treatment-experienced patients with high-level class resistance remains to be fully established. Because of the overlapping resistance profiles of peptidomimetic PIs, even with pharmacoenhancement of boosted PIs, the need for agents with activity against HIV isolates with high level protease resistance has led to the search for nonpeptidic PIs with broader antiretroviral activity. Darunavir and tipranavir represent two agents in this newer group of PIs.

The clinical data that supported the approval of darunavir, also referred to as TMC-114, were derived from the pooled results of two 24-week studies, TMC114-C213 (POWER 1) and TMC114-C202 (POWER 2) which looked at the risks and benefits of this drug in 497 triple-class experienced patients. These studies compared darunavir/ritonavir (DRV/RTV) at four different doses with an investigator-selected comparator PI (CPI). In comparison to 10% of those in the CPI arm, 47% of those receiving DRV/RTV at the recommended dose of 600/100mg BID (n=99) achieved HIV RNA levels of < 50 copies/ml. The patients taking darunavir also had larger increases in their CD4 cell counts (92 versus 17 cells/

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## Pharmacy

# Second-generation PI approval adds option for salvage therapy

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mm<sup>3</sup>). The efficacy benefits of DRV/RTV over CPI in subgroup analysis occurred independent of baseline resistance or treatment-emergent mutations. As was the case with both the TORO and RESIST studies respectively, a greater proportion of patients receiving lopinavir/ritonavir (LPV/RTV), tipranavir/ritonavir (TPV/RTV) and DRV/RTV with enfuvirtide (ENF) achieved virologic response, compared with those who received RTV-boosted PIs without ENF, thereby once again emphasizing the need for combining more than one active agent in an optimized background regimen. Darunavir did not show antagonism when studied in combination with the protease inhibitors amprenavir, atazanavir, indinavir, lopinavir, nelfinavir, ritonavir, saquinavir or tipranavir, the nucleotide tenofovir, all of the nucleoside and non-nucleoside reverse transcriptase inhibitors, and the sole fusion inhibitor, enfuvirtide. Darunavir contains a sulfonamide moiety and should be used with caution in patients with sulfa allergy.

Population pharmacokinetics of darunavir showed mean higher exposure (16.8%) in HIV-infected females compared to males. The difference is deemed not to be clinically significant. Population kinetics shows that race has apparently no apparent effect on darunavir exposure.

The most treatment-emergent adverse events with darunavir (>10%) reported in the

de novo subjects, regardless of causality or frequency (although not all known yet), include diarrhea, nausea, headache and cold-like symptoms, including running nose or sore throat. Patients should tell their health care providers if they have any of these side effects. Around 7% of patients in these studies also had skin rashes which were serious in a few cases. Laboratory abnormalities included hyperlipidemia and increases in amylase and hepatic transaminases. It is important to assess patient

**Drug interactions of clinical significance between darunavir and other PIs are well established.**

motivation and discuss adverse drug reactions and strategies for their management before initiating treatment with darunavir.

Like most of the older PIs, new onset diabetes mellitus, exacerbation of existing diabetes mellitus, and hyperglycemia have been reported during post marketing surveillance in HIV-infected patients receiving protease inhibitor therapy. Some patients required either initiation or dosage adjustments of insulin and oral hypoglycemic agents for treatment of these events. Because most of these events have been reported voluntarily during

clinical practice as opposed to being specifically studied, causal relationships between PI therapy and these events have not been established and estimates of frequency cannot be made.

Resistance to darunavir is associated in the selection of one or more of several resistance mutations. HIV-1 isolates with a decreased susceptibility to darunavir have been selected in cell culture and also obtained from subjects treated with darunavir boosted with ritonavir. Darunavir-resistant virus derived in cell culture from wild-type HIV had 6-21-fold decreased susceptibility to darunavir and harbored three to six of the following amino acid substitutions: S37N/D, R41E/S/T, K55Q, K70E, A71T, T74S, V77I or 185 in the protease.

Drug interactions of clinical significance between darunavir and other PIs are well established and mostly occur with drugs that are either CYP3A substrates, inhibitors or enhancers. Drugs that should not be co-administered with boosted darunavir include anticonvulsants such as carbamazepine, phenobarbital and phenytoin, antihistamines such as astemizole, terfenadine, antimycobacterials such as rifampin, ergot derivatives such as dihydroergotamine and methylergonovine, gastrointestinal agents such as cisapride, HMG-COA reductase inhibitors such as lovastatin and simvastatin, neuroleptics such as pimozide, and sedative-hypnotics such as midazolam and triazolam. Herbal products such



as St. Johns wort should not be administered with darunavir. It is important that patients report all prescription and over-the-counter medications to their health care providers.

In addition to the above non-antiretroviral medications, there are also potentially significant drug interactions between darunavir and other PIs. When coadministered with LPV/RTV and saquinavir (SQV), the AUC of darunavir was decreased by 53% and 26% respectively. It is therefore not recommended that LPR/RTV or SQV be coadministered with DRV/RTV. Data suggest that atazanavir (300mg daily) can be administered with no dosage adjustment since there were no significant changes in ATV drug levels. Levels of indinavir (IND) 800mg b.i.d were increased when coadministered with DRV/RTV 400/100mg b.i.d.

When DRV/RTV was co-administered with other antiretroviral agents, both tenofovir (TDF) 300mg q.d. and nevirapine (NVP) 200mg b.i.d. had their levels increased while co-administration of DRV/RTV with EFV decreased the AUC of darunavir by 13% and increased the AUC of efavirenz by 21%. Since the clinical significance of this interaction is not known, the combination of DRV/RTV with EFV should be used with caution while closer monitoring of patients for TDF and NVP toxicity is suggested.

The recommended dose for darunavir is 600mg (two tablets) twice a day and each dose must be taken in combination with ritonavir 100mg, and with food, in order to achieve effective plasma concentrations. Darunavir is produced in orange tablets containing 300mg of the active drug.

Darunavir is not yet approved for use in children or in antiretroviral-naïve patients. No dosage adjustments are needed in renal impairment. Like most drugs granted accelerated approval, more studies are presently being carried out in order to delineate issues such as interactions with other drugs and use in hepatic impairment. Darunavir is not yet well studied in pregnancy and is classified as FDA Pregnancy Category B. Approval of darunavir in the European Union is expected later this year.❖

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## Medicine

# Telemedicine improves access to care for HIV-infected prisoners

C. Lynn Besch, MD

With advances in communications technology, it has become possible to interact with others across long distances by both voice and video. Over the past several years, this technology has been adapted to the needs of health care systems so that a discipline of telemedicine has resulted. The term *telemedicine*, or sometimes *tele-health*, is used to mean either videoconferencing between a patient and health care provider (with or without the ability to perform limited examinations), or the ability to perform procedures from a distance using robotic mechanisms and video capabilities. In the context of this report, telemedicine describes videoconferencing between the Medical Center of Louisiana at New Orleans and currently four correctional, psychiatric and/or long-term care facilities.

Telemedicine has been successfully used by a large number of Internal Medicine subspecialties, such as endocrinology, cardiology, rheumatology, as well as neurology, ophthalmology, otolaryngology, pediatrics, psychiatry, and radiology. These programs have either been for traditional patient-doctor visits, or for patient self-management programs such as for diabetes and heart failure. Limited physical examinations are possible with the use of specially-designed attachments, including hand-held otoscopes, stethoscopes and a high-intensity light used for skin examinations.

Robotic technology allows surgical procedures to be performed by specialists on patients at a site thousands of miles away.

The benefits of telemedicine include improved access to medical information for patients and clinicians, improved access to care, increased care delivery to larger numbers of individuals, improved access to professional education, and in some cases, lower costs for both medical institutions and patients (less travel time and less missed work, especially for those in rural areas). Drawbacks have included breakdowns in relationships between patient and provider or between health care professionals, issues with quality of health information, need for and maintenance of specialized equipment, and organizational or bureaucratic barriers.

In 2002, LSU's Health Care Services Division (HCS) assisted the Louisiana Department of Corrections (DOC) to increase access to care for the DOC's HIV-infected population by establishing a telemedicine program. Two clinicians (a physician and a nurse practitioner) from the HIV Outpatient Program (HOP) clinic met with administrators and medical personnel of the targeted institutions and set goals, developed criteria for inclusion, established guidelines for division of duties regarding patient management, and created schedules for the telemedicine clinics.

The HOP-DOC telemedicine HIV initial clinic design and schedule were as follows: HOP clinicians met twice a month

with inmates and prison medical staff over a video link. Inmates were interviewed, laboratory tests results were reviewed, and recommendations regarding monitoring and treatment were given. Discharge planning also took place. Occasionally, consultation was given regarding non-HIV medical issues. There was limited physical examination capability (without specialized tools), primarily examination of the skin, extremities, face and oropharynx.

The prison telemedicine team's initial guidelines were as follows:

- a) The inmate had to have been seen at least twice at the HOP Clinic, ensuring that baseline laboratory tests and physical examinations were available for reference;
- b) Inmates had to be reasonably immunologically competent, (i.e., CD4 cell counts > 200);
- c) The HOP HIV team would not be responsible for all medical problems (i.e., severe diabetes, COPD, etc.);
- d) Recent laboratory tests (usually done on-site at the prison) were to be available for each telemedicine visit;
- e) A dedicated nurse and/or physician from each correctional institution was requested to attend the clinic sessions to ensure continuity of care, and to educate the HOP team about prison-related issues that might impact the plan of care, such as available formulary, laboratory capabilities, dietary interventions and institutional rules about medication dispensing.



It was never intended that HIV care via telemedicine would replace the need for inmates to come to the HOP Clinic, but there was a clear intent that telemedicine would significantly decrease the number of these clinic visits in New Orleans. The program was successful and was expanded to four institutions by August 2005. Three of the four programs had enough patients for a monthly telemedicine clinic. Department of Corrections medical staff attending these clinics included two physicians (one regularly attended, the other as needed), a nurse practitioner and an RN.

**My experience serving as the physician in the telemedicine program has been very positive.**

The disruption caused by the 2005 hurricanes intensified the need for telemedicine services because of increased patient load (displacement of Orleans Parish Prison inmates to other correctional institutions) and the inability to get appointments in the overcrowded remaining HCSD HIV clinics. During the fall and winter of 2005-2006, the HOP telemedicine team (which had evacuated to the Baton Rouge and Lafayette areas) provided on-site clinics at two of the state prison facilities.

By February 2006, telemedicine capabilities were re-established and the HIV "tele-clinic" was again being held with three

of the four previous institutions. The HOP physician is now the sole provider of telemedicine HIV care.

Since re-opening, over 100 individual patients have been seen using this modality, and individual sessions average five patients (range 2-9). Over 95% are men and the majority are African-American. Over half have co-morbid conditions such as hepatitis C, diabetes, lung disease, or renal insufficiency or failure. The vast majority are on antiretroviral therapy and have undetectable HIV RNA levels. Two of the institutions have dedicated nurses (RN and nurse practitioner) and two have physicians, as well as nurses, participating in the telemedicine visits.

Original program guidelines that required modification were the requirement that new HIV-infected inmates be initially seen at HOP and that the HIV team would limit their recommendations to HIV care. Because the few open MCLNO clinics are unable to accept inmates as patients and the other HCSD hospitals were (and remain) greatly overcrowded, the HOP physician now sees both new and established inmate patients via telemedicine, and also assists the medical staff at the correctional facilities with non-HIV medical issues as requested.

As the physician in the described telemedicine program, my experience has been very positive. The delivery of health care in the correctional institutions is extremely well-organized and comprehensive. The health care professionals participating in this clinic are knowledgeable and are interested in learning more. Health maintenance is efficiently managed. Laboratory

capabilities, including access to HIV genotyping, equals that of MCLNO. The Department of Corrections formulary is sufficient and there is a non-formulary request process.

For those considering developing telemedicine clinic capabilities, I recommend clinic program guidelines similar to what is listed above. A dedicated block of time for a clinic is probably more efficient than mixing regular clinic patients with those from telemedicine, at least in a correctional setting where meal, medication and work times are rigidly fixed. ♦

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## Legal

# State laws v. CDC: The future of HIV testing and informed consent

By Linton Carney, JD,  
and Barbara Siefken

At the end of 2003, an estimated 1.0-1.2 million people were living with HIV/AIDS in the United States, and of this population, an estimated 25 percent were undiagnosed and unaware of their infection.<sup>1</sup> In the same year, the Centers for Disease Control and Prevention (CDC) introduced the initiative "Advancing HIV Prevention: New Strategies for a Changing Epidemic," which proposed that HIV testing become a routine part of medical care on the same basis as other diagnostic and screening tests.<sup>2</sup> The CDC, which has studied the development of the AIDS epidemic in the United States since the 1980s, has suggested that state law requirements of obtaining written or oral informed consent for HIV testing and providing prevention counseling in conjunction with testing have hindered earlier detection and diagnosis. In September, 2006, after several years engaging in dialogue and review panels with health-care providers, public health agencies, community organizations and persons living with HIV,<sup>3</sup> the CDC released new recommendations for HIV testing of persons 13 to 64 years old and pregnant women in all private and public health care settings.

The CDC recognizes that these new recommendations differ in some significant ways

from the procedures currently in place in health care settings throughout the 50 states. The key differences between the recommendations and the current procedures followed by many states have created confusion, controversy, and opposition to the 2006 CDC recommendations. For example, the recommended routine, voluntary HIV screening for patients ages 13 to 64 would be performed unless the patient declines to be tested, after being given basic information about the HIV test, HIV infection, and the meaning of the test results (opt-out screening). The CDC recommends against the process of obtaining separate written informed consent, and favors an incorporation of HIV screening into the general consent for medical care.<sup>4</sup> The CDC also asserts that prevention counseling should not be required in conjunction with HIV screening in health care settings. Each of these recommendations promotes a streamlined approach to HIV screening that eliminates certain communications between the patient and health care provider, but also removes some barriers to increasing HIV detection.

### **Informed consent**

The legal concept of informed consent significantly overlaps with the ethical duties of health care practitioners. Physicians and other practitioners abide

by an ethical obligation to give patients sufficient information about the nature, risks and benefits of proposed treatment in order for the patient to have the ultimate decision-making power regarding his/her own body and health care.

As a legal standard, the doctrine of informed consent is defined in all 50 states as a consent to treatment obtained after adequate disclosure, and each state has specific legislation to govern how informed consent must be obtained in a health care setting. In general, written and/or verbal informed consent is obtained only after telling the patient the nature of proposed treatment, name and description of procedure, risks associated with that treatment, alternatives and associated risks, and the risk of no treatment.<sup>5</sup> This communications process of disclosure and discussion with the patient allows the patient to make an informed decision to proceed or to refuse a particular course of treatment.

But is an HIV test a routine test? The risks and benefits of an HIV test involve significant physical, emotional, social, and legal consequences for a patient, particularly in the event of a positive test result. Therefore, many states require pre-test and post-test counseling to address the broad impact that HIV infection can have on a person's life and medical care. In addition, the majority of states require

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some form of specific informed consent (with some exceptions in Delta states to be discussed below) to perform an HIV test on a patient. Consequently, practitioners still should look to the legal requirements and application of the relevant state statute before proceeding to obtain consent and perform testing.

#### Look to state law

Although the CDC may hold persuasive authority with physicians and other health care providers, the CDC recommendations on HIV testing are only suggested guidelines. HIV testing is regulated by state law, and therefore, state legislatures would need to conform legisla-

HIV-related illness, as well as information about behavior known to pose risks for transmission and contraction of HIV infection.<sup>7</sup> The process of pre-test counseling and written informed consent ensures that the individual being tested receives practical information, even a basic education, about the disease. Regardless of the test result, an individual receiving an HIV test in Louisiana is to be informed about prevention, transmission, symptoms, treatment, and HIV-related services.

In contrast to Louisiana's informed consent procedure, public health statutes in Mississippi and Arkansas do not uniformly mandate specific informed consent for HIV-related testing. Neither Mississippi nor Arkansas has a statute that explains the procedure to be used for HIV-related testing or the means by which consent is to be obtained.<sup>8</sup> Both statutes address only the exceptions to informed consent, and thus the general rule that practitioners are normally required to obtain specific informed consent for HIV testing is given only by implication.

The relevant Mississippi statute reads in part, "A hospital or physician...may conduct an AIDS/HIV antibody test...without specific consent...if the hospital or physician determines that the test is necessary for diagnostic purposes to provide appropriate care or treatment to the person to be tested...The person who is to be tested shall be informed of the nature of the test which is to be conducted."<sup>9</sup> This statute does not contain provisions for pre-test counseling, it does not explain what information will be provided to the patient, and it

does not contain an opt-out provision for the HIV-related testing. Thus an argument could be made that the language contained in the Mississippi statute already allows the hospital or physician enough flexibility to follow some of the CDC recommendations within the bounds of the current Mississippi law.

The same question applies to the Arkansas "HIV Shield Law," which is the only relevant Arkansas statute regarding informed consent to HIV-related testing. The statute reads in part, "Informed consent, information, and counseling are not required for the performance of an HIV test when, in the judgment of the physician, such testing is medically indicated to provide an appropriate diagnosis and treatment to the subject of the test provided that the subject of the test has otherwise provided his or her consent to such physician for medical treatment."<sup>10</sup> The language of this provision does not specify the standards which a health care provider must follow before performing an HIV test for medical diagnosis or treatment. Again the question arises whether the Arkansas statute already permits HIV-related testing to be included within a general medical consent to treatment.

Despite the explicit requirement of specific informed consent for HIV-related testing in

See *States v. CDC*, next page

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CDC's new recommendations differ significantly from procedures in place in some states.

tion to these recommendations before the new guidelines can be followed.

In Louisiana, the statute governing HIV-related testing requires health care providers to obtain written informed consent, or verbal informed consent contemporaneously documented in the medical record, from the subject of an HIV-related test.<sup>6</sup> Prior to obtaining such consent and performing the test, the health care provider must provide an oral or written explanation of the nature of AIDS and



## Legal

# Is it possible for a patient's decision to ever be too informed?

### [States v. CDC, from previous page](#)

Louisiana's statute, the same statute contains an exception to informed consent in a similarly vague, and potentially broad, manner. "When, in the medical opinion of the physician requesting the HIV-related test, the request for informed consent to perform such test would be medically contraindicated."<sup>11</sup>

The exceptions to informed consent found in these state statutes have generally been interpreted by medical professionals as necessary for public health and medical emergencies. The physician, and hospitals in Mississippi, will necessarily be faced with a decision to weigh the best interests of the community, or of a patient in an emergency life-threatening situation, against the patient's autonomy to make an informed decision regarding his/her own body and health. The influence of the CDC recommendations, however, could lead to these exceptions being used more frequently, particularly the Arkansas law which arguably permits unauthorized HIV testing as part of routine treatment. Note that the present exceptions are limited to physicians (and Mississippi hospitals) and do not apply to other practitioners.

### **Dismantling crucial communications/counseling**

According to the CDC, the rationale for the new recommendations, advocating routine HIV screening in all public and

private healthcare facilities as a "normal part of medical practice,"<sup>12</sup> centers on the need to increase diagnosis of HIV infection. The CDC also argues that routine HIV testing, detached from a pre-test assessment of risk behaviors and a detailed discussion of the nature and transmission of HIV, reduces the stigma associated with the testing process.<sup>13</sup> But many civil liberties advocates and AIDS organizations argue that the opposite will result if the CDC recommendations are implemented.

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**ACLU has responded with concern for the health and privacy of those diagnosed under new recommendations.**

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The American Civil Liberties Union (ACLU) has publicly responded to the new recommendations with concern for the health and privacy of individuals who would be diagnosed in the recommended manner. An attorney with the ACLU AIDS Project commented, "In addition to having to learn to live with a life-threatening disease, people with HIV deal with the continuing stigma that comes with having HIV. Without pre- and post-test counseling requirements, we risk losing a critical opportu-

nity to educate people about HIV and how to prevent the spread of it."<sup>14</sup> The ACLU supports broader testing, but only with full counseling and documented informed consent, because that communications process is intended to encourage patients to feel secure in agreeing to be tested.

According to a 2003 survey of HIV service providers conducted by the ACLU, HIV-related discrimination in employment, housing, and health care is still persistent throughout the United States.<sup>15</sup> In 2001, the CDC published "Revised Guidelines for HIV Counseling, Testing, and Referral," in which the CDC recognized the need to protect newly diagnosed HIV patients from prevalent discrimination. "Clients who test positive should be referred to legal services as soon as possible after learning their test result for counseling on how to prevent discrimination in employment, housing, and public accommodation by only disclosing their status to those who have a legal need to know."<sup>16</sup> The AIDS Coordinating Council of the American Bar Association has opposed the new CDC recommendations for omitting the legal services referral and for proposing that all pre-test counseling be replaced with general medical consent to care.<sup>17</sup>

Organizations opposing the new recommendations worry that trimming or eliminating pre-test counseling and informed consent could mislead or coerce a patient to consent, and then many newly diagnosed individu-



als would not seek or stay in medical treatment and other services. An ACLU attorney stated, "Studies have shown that patients who are tested without consent are less likely to get the follow-up care that is critical to maintaining good health."<sup>18</sup> One physician, who works with homeless teenage boys at risk for AIDS and knows the importance of establishing a dialogue with patients and securing their trust, has stated that even trimming pre-test counseling would increase the likelihood that patients will not get into proper treatment. "You have to make them comfortable or when you give them the result that they're positive, you'll never see them again."<sup>19</sup>

### Conclusion

Practitioners will always need to follow state law governing HIV-related testing regardless of CDC recommendations. A wholesale adoption of CDC recommendations could significantly change practices in Louisiana, particularly for pre- and post-test counseling. Practice would change less, at least on paper, in Arkansas and Mississippi if the state legislatures decided to adopt the recommendations.

The CDC states that the HIV testing still must be voluntary and the patient must not be tested without his/her knowledge. But as a matter of practice, the practitioner may want to consider the impact on patients from being tested without detailed pre-test information about the nature of HIV, means of transmission and prevention, and the meaning of the test results. A lack of communication

from the practitioner could cause the patient to be misinformed, anxious, or distrustful. Will new patients stay in treatment? Will they know where to turn for support?

As a matter of ethics, practitioners may want to question the CDC's premise that increased patient knowledge feeds stigma and deters testing. Even if true, should patient autonomy take second place to earlier diagnosis? Can a patient's decision ever be too informed?❖

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## Nursing

# In clinic, every team member counts when it comes to adherence

Pat Gootee, NP

25 years ago, HIV came along and changed the way primary care is delivered in the United States. In the best of outpatient settings, ten minutes was the allotted time for provider/patient encounters, where one or perhaps two immediate problems were addressed and other problems saved for the next ten minute visit.

Then along came a disease that would involve every organ as well as every system, including social, psychological and financial systems. Now all of these issues needed to be addressed at once. Primary care visits for HIV-infected patients had to be longer than ten or fifteen minutes. The team approach evolved and was funded, at least in part, by federal and state funding sources.

When HAART became available mid-1990, the death rate from AIDS dramatically declined. No one had to tell someone dying of HIV midway into the epidemic that taking their medications was the only chance they had to hang around until a cure or a vaccine was developed. But that was then. HIV wears different faces today, as women make up one out of three newly infected persons, and minority populations account for 75% of newly diagnosed cases in the South. The hierarchy of needs for many of our patients today is very different than when the epidemic was new.<sup>1</sup>

As one example, HIV in Louisiana is becoming commonplace in rural communities,<sup>2</sup> challeng-

ing the notion that HIV only happens in places like "The Big Easy." Transportation to regional care centers would be an overwhelming problem if it weren't for AIDS Service Organizations (ASOs) whose primary job (after counseling and testing) is assisting patients in getting to clinic appointments, obtaining medications, and helping with financial emergencies, etc. Access to care is greatly enhanced by these organizations.

With available antiretroviral medications, patients can live longer, feel better, and avoid opportunistic infections and hospital stays. So why is it that people with HIV don't always take the medications that can save their lives, return them to work, allow for a better quality of life? The answers are complicated and different for every community infected and affected by the HIV epidemic.

Adherence to medications for chronic diseases has always perplexed the medical community and remains a prominent research topic. In 2005, researchers at Stanford University, reported that adherence rates were higher among patients with acute conditions as compared with those with chronic conditions, especially after six months. The study also reported that the "ability of physicians to recognize non-adherence was poor."<sup>3</sup>

Perhaps the burden for convincing patients to take their medications lies on the shoulders of the many team members who help patients navigate life with HIV/AIDS.<sup>4</sup> The team (pharma-

cists, physicians, nurse practitioners, physician assistants, nurses, social workers, dentists, mental health counselors, administrative and ancillary staff) has another consideration to address when patients take their medications improperly, sporadically or partially: resistant virus.

Resistant virus emerged only after medications were available to treat HIV/AIDS. Partial adherence complicates treatment options not only for current patients, but for those who will acquire a resistant virus in the future.

Another consequence of poor adherence is cost. Poor adherence to medications accounts for 33-69% of medication-related hospital admissions in the U.S. and about \$100 billion a year.<sup>5</sup> So why don't patients take their antiretroviral medications as prescribed? Some experts offer that persons in an impoverished community or a minority community have concerns more pressing than a virus they cannot see, or that the fastest growing population, newly infected young women of color, may be struggling with abuse and blame from the very men who infected them and not want their secret to be discovered. Hiding to take medications just doesn't seem feasible in these situations.<sup>6</sup>

Mentally and emotionally challenged persons are even more at risk for being infected and less able to follow the prescribed regimens for treating HIV or even their mental health conditions. For persons with mental illness, such as bipolar disorder,



schizophrenia, and chemical dependency, they can be distracted from health concerns or lack the essential self-worth necessary to have health promoting behavior in general.<sup>7</sup>

Simple depression is common among patients with chronic diseases and is an important consideration in the reasons many HIV-infected patients don't take their medications.<sup>8</sup> Knowing this should help the team plan for addressing the underlying causes of depression. Sadly, affordable preventative mental health care (i.e., counseling/medication) can be a scarce resource in many communities, as is acute mental health care. Thus primary care providers have to address the mental health issues as well as the specific diseases for which they are highly trained.

The first team member to encounter patients during an outpatient visit (usually the nurse) may ask them what medications they take. But that question doesn't assess adherence. Additional questions that might illuminate the issue could be:

- Did you bring your medications with you today?
- When was the last time you picked them up from the pharmacy?
- Where do you get your medications?
- Tell me how you take your medications?
- This week how many doses did you miss?
- How many of the yellow pills do you take, etc?

If the patient has vague answers to any of these questions, there is probably an adherence problem. Resistance testing is expensive but useful in many instances. Finding out that there

is no resistant virus is also useful, but that information might be obtained by asking the right questions.

Pharmacy records show rates of refilling prescriptions which have been shown to be accurate measures for adherence. Most pharmacists will gladly share that information over the phone. Prescribing mistakes can be caught, as well as lost prescriptions, that end in unintentional sub-optimal therapy. Drug resistance is inevitable eventually but it can be postponed if details are attended to by team members. Having this information available when the provider sees the patient allows that provider to address the underlying cause for the inadherence, such as depression, side effects and regimen complexity.

There is also the trust factor in patient adherence: the patient-provider relationship. Seeing different providers with varying skill levels may sometimes be the only way to obtain primary care. Yet in this atmosphere of changing providers, a therapeutic relationship can be more difficult with any patient, especially one with complex needs. A patient may want to make a good impression on a new provider and not be honest about adherence to medications.

The constant in most clinics is the nursing staff who often develop rapport with the patients and can glean important information in a non-judgmental, non-threatening manner better than a provider who is meeting the patient for the first and last time.

Training medical providers is important for the future of health care and can be perceived at times as an inconvenience by

the nursing staff. But it's also an opportunity to do what they do best: develop a therapeutic relationship with their patients in order to help them obtain optimal health by attention to the details of adherence. Every team member counts!❖

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## HIV CONFERENCE IN ARKANSAS

Mark your calendars for this year's regional HIV/AIDS conference *Expanding the Circle of Compassion* to be held in Little Rock on February 1-2. The conference is designed for community-based and service organizations, health care providers, and people who are living with or are affected by HIV/AIDS. Complete information, as well as registration and scholarship applications, are available at the conference website at <http://jccsi.org/>.



## Dentistry

# Periodontal disease is more aggressive in HIV-infected patients

Alicia Rose Hathorn, DMD

I believe it holds great significance for patients to know and understand the etiology of all oral infections (i.e., caries, periodontal disease, fungal and bacterial infections). Dental education is a high priority in the clinic where I work. As patients begin to understand how these infections affect their overall health, they become more interested in maintaining their oral health and being a “team member.”

Comparing my practice now to that of residency and the public health sector, the percentage of patients presenting with some stage of periodontal disease is about the same, around forty to sixty percent. One difference is that the periodontal disease I see associated with HIV patients is more aggressive and thus makes it more difficult to achieve a maintenance level.

Periodontitis is a bacterially induced chronic inflammatory disease. The development depends on the oral microbes that reside in the oral tissues found in plaque and the host's response. This association ultimately leads to a breakdown of gingival tissue and bone loss.

Many studies have looked at periodontal disease in the HIV population and some have concluded that the prevalence of disease in both HIV and non-HIV populations is the same. However, studies also showed that periodontal disease progression associated with HIV

is usually more aggressive and severe. Suggestions have been made that HIV infection may lead to an overgrowth of periodontal pathogens due to host suppression contributing to the rapid destruction of the disease.

One study looked at mast cells as a contributor to periodontal disease and concluded that the enzymes secreted by mast cells (matrix metalloproteinase -1, -2, and -8) are key to the degradation of periodontal tissue. A higher number of mast cells were formed in patients with HIV who had chronic inflamed gingival tissue.

The initial colonizing of bacteria that causes gingivitis and periodontitis is what leads to the clinical signs of disease. One study suggests that a chlorhexidine rinse is a good antiseptic agent able to suppress colonization and that systemic antibiotics could help reduce plaque scores and improve gingival conditions.

Three main oral bacterial infections are associated with HIV. They are: linear gingival erythema (LGE), necrotizing ulcerative gingivitis (NUG), and necrotizing ulcerative periodontitis (NUP). Conditions as severe as NUG and NUP are usually seen with lower CD4 counts and elevated viral loads.

Linear gingival erythema presents as a 2-3mm red band along the marginal gingival tissue. Bleeding may occur with brushing and flossing, and mild pain can be associated although most patients are asymptomatic. LGE can be present without

gingival plaque. No bone loss is identified on radiographs. Patients are encouraged to seek a dental professional for routing, dental scaling and curettage, and to continue excellent oral hygiene at home with adjunct use of a chlorhexidine rinse.

Necrotizing ulcerative gingivitis presents with necrotic destruction of dental papillae. Bleeding is seen with easy irritation (pressure or brushing). No bone loss occurs. NUG is also treated with rigorous scaling and curettage and use of chlorhexidine rinse. Some systemic antibiotics have been used successfully to combat gram negative bacteria present in the gingival tissue.

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**Patient education  
can be a big factor  
in the fight against  
periodontal disease  
and tooth loss.**

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Necrotizing ulcerative periodontitis is characterized by rapidly progressing loss of periodontal attachment and bone. Pain is present at times when the loss of tissue exposes interdental bone. Bleeding is spontaneous and the gingival tissue is edematous and erythematous. If treatment is *not* started, more than 6mm of gingival tissue and bone can be lost in less than six months. High amounts of gram



negative bacteria are present. If NUP is suspected, the patient must consult a dental professional as soon as possible and begin periodontal therapy.

As these conditions are identified, patients should be encouraged to seek out an oral health professional for treatment. Definitive treatment will be more successful with the patients taking an active role in preserving their oral structures.

### Case presentation

A 46-year-old African American male presented to the dental clinic wanting an exam and cleaning. He stated he had not seen a dentist in years. His latest CD4 count was 282 with a viral load of <50. Patient said he brushed twice a day but his gums bled when he brushed and he complained of bad breath. He also said that some of his teeth felt loose and that he was afraid of losing his teeth. Medical history review yielded HIV infection, HTN, CHF diagnosed in 1997, and potential kidney failure.

On clinical exam, several root tips were noted along with caries and generalized heavy calculus. The lower anterior incisors were mobile with advanced tissue and bone loss. General debridement was completed at initial appointment which also included periodontal education and treatment plan. Patient was given chlorhexidine rinse and instructed to rinse one-half capful a day. At the next appointment, anesthesia was given and quadrant scaling begun. Patient had developed more calculus since his last appointment. His root tips were extracted and patient was

re-appointed to begin a weekly evaluation of gingival tissues. Calculus remained heavy at each appointment regardless of the scaling that was being done. The lack of improvement, including a continuous accumulation of calculus and tissue necrosis, suggested a diagnosis of NUP. Patient was given metronidazole 500mg to take BID and return in 14 days while continuing home care. At the following appointment there was less redness, though tissue was still spongy and calculus present. Patient continued with antibiotic therapy along with routine dental appointments for quadrant scaling and restorative procedures. Patient's outlook became more positive as time passed, his gingival tissue became more firm, and less calculus was seen between appointments. At his most recent appointment, calculus was minimal with a moderate plaque level. Bleeding was present but gingival tissue was firmer and had begun to develop a slightly scalloped appearance. Mandibular incisors had lessened in their mobility. Patient now feels great about his increased oral health. He is continuing his home therapy and presents to the dental clinic every other month.

### Conclusion

It is very important to ask patients about their dental status at each physical exam. A general dental exam can be done with a tongue depressor and gauze. A look at the hard and soft tissues, including the tongue, can indicate whether the patient needs to contact a dentist. The health care profes-

sional may also ask if the patient has had any pain from a tooth or gingival tissue. Patients are usually quite aware of any changes in their mouth and need to feel comfortable voicing concerns to their provider. Periodontal disease is a diagnosis that needs treatment as early as possible to achieve a maintainable level of disease without loss of tooth. ❖

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## Nutrition

# How can patients protect themselves against foodborne illness?

Ginger Bouvier, MEd, LDN, RD

Recent foodborne illness outbreaks remind us that our source of nourishment, food, can also be a source of serious illness when that food becomes contaminated. People at greater risk of developing serious and sometimes fatal foodborne illnesses include pregnant women, infants, the elderly, and the immunocompromised.

According to the U.S. Food and Drug Administration, an outbreak of *E. coli* 0157:H7 associated with the consumption of raw spinach in September 2006 sickened 204 people and resulted in the death of a two-year-old child and two elderly women.<sup>1</sup> Coming on the heels of the *E. coli* 0157:H7 outbreak caused by tainted spinach was an outbreak of *Salmonella typhimurium* associated with contaminated fresh tomatoes. Although there were no reports of deaths in the *Salmonella typhimurium* outbreak, at least 183 people were sickened, according to the Centers for Disease Control and Prevention.<sup>2</sup>

Reducing foodborne illness requires not only ensuring food safety on the farm and during processing, but also educating consumers, particularly high-risk populations such as HIV-positive individuals. In the United States, most patients turn to their health care providers for health-related information. In a study by Wong, et al., researchers found that those physicians who perceived foodborne disease to be a serious

problem, felt comfortable in making food-safety recommendations, believed that food-safety education was their role, or believed that patients perceived them as a valuable source of food-safety information were more likely to provide food-safety information to patients.<sup>3</sup>

In April 2004, Morbidity and Mortality Weekly Report published *Diagnosis and Management of Foodborne Illness, A Primer for Physicians and Other Health Care Professionals*.<sup>4</sup> This guide and teaching tool was produced collaboratively by the American Medical Association, the American Nurses Association, the Centers for Disease Control and Prevention, the Center for Food Safety and Applied Nutrition, the Food and Drug Administration, the Food Safety and Inspection Service, and the US Department of Agriculture. This detailed document can be accessed at <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5304a1.htm>.

In light of the recent outbreaks of produce-related foodborne illnesses, the Food and Drug Administration has issued the following consumer advice to reduce the risk of foodborne illness from fresh produce.<sup>5</sup>

### Purchasing

- Purchase produce that is not bruised or damaged.
- When selecting pre-cut produce, choose only those items that are refrigerated or surrounded by ice.
- Bag fresh produce separately

from meat, poultry and seafood products when packing them to bring home.

### Storage

- Maintain certain perishable fresh produce in a clean refrigerator at a temperature of 40° F or below.
- All produce that is purchased pre-cut or peeled should be refrigerated within two hours to maintain quality and safety
- Keep your refrigerator at 40° F or below. Use a refrigerator thermometer to check.

### Preparation

- As an extra measure of caution, wash pre-washed bagged produce just before you use it.
- Pre-cut and pre-washed produce stored in open bags should always be washed before using.
- Cut away damaged or bruised areas on fresh produce before preparing or eating.
- Produce that looks rotten should be discarded.
- All unpackaged fruits and vegetables should be washed before eating.
- Even if you plan to peel the produce, wash it just before peeling.
- Scrub firm produce such as melons and cucumbers with a clean produce brush.
- Drying with a paper towel may further reduce bacteria that may be present.

### Separate

- Keep fruits and vegetables that will be eaten raw away from other foods such as raw meat,



poultry and seafood and from utensils used to cut those products.

- Wash cutting boards, dishes, utensils with hot water and soap between the preparation of raw meat, poultry and seafood products and the preparation of produce that will not be cooked.
- For added protection, periodically sanitize food surface areas such as countertops and cutting boards with one teaspoon of chlorine bleach to one quart of water.
- If you use plastic or other non-porous cutting boards, run them through a dishwasher after each use.

Physicians and other health care providers serving patients with HIV are in a position to educate them about food-safety practices and the prevention of foodborne illness. As with other preventable infections, it is important to teach your patients how they can lower their risk of foodborne illness. ❖

**Additional Resources:**

- [www.cfsan.fda.gov/~dms/prodsafe.html](http://www.cfsan.fda.gov/~dms/prodsafe.html)
- [www.fsis.usda.gov/Fact\\_Sheets/Food\\_Safety\\_for\\_Persons\\_with\\_AIDS/index.asp](http://www.fsis.usda.gov/Fact_Sheets/Food_Safety_for_Persons_with_AIDS/index.asp)
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