



**DELTA REGION
AIDS EDUCATION
& TRAINING CENTER**

*Educating
health care providers
about HIV/AIDS*

HIV Clinician

formerly FACULTY NOTES

Fall 2002 • Vol. 14, No. 4

Upcoming drugs that inhibit viral entry will be a new frontier for antiretroviral therapy

Mary J. Murphy, MD

Over the past several years, the impact of HAART on reducing morbidity and mortality from HIV in resource-rich countries has revolutionized HIV care. Unfortunately these gains are now being tempered by increasing resistance to the currently available antiretrovirals. New classes of anti-HIV drugs with novel mechanisms of action are needed.

Drugs that interfere with viral entry into CD4 cells represent a new category of anti-HIV drugs that promise to complement the existing drugs that inhibit viral replication (NRTIs and NNRTIs) and assembly (PIs). They also offer hope for effective salvage therapy for patients whose virus has developed resistance to many of the currently available drugs. Fortunately, one of these entry inhibitors, the peptide fusion inhibitor T-20, an injectable drug, is expected to be submitted for FDA approval by the end of the year with pre-approval expanded access available before then.

Entry of the HIV virus into CD4 lymphocytes is a multi-step process which offers several different potential targets for interruption. This process begins when the viral surface glycoprotein gp120 attaches to CD4 receptors on the surface of the cell. This causes a conformational change in gp120 allowing it to further bind to one of two coreceptors, CXCR4 or CCR5, also found on the surface of CD4 cells. Syncytium-inducing (SI) virus uses the CXCR4 coreceptor and demonstrates low affinity

binding while non-SI virus binds to the CCR5 coreceptor with high affinity.

Coreceptor binding induces a further conformational change that affects a second viral envelope glycoprotein gp41, permitting it to insert itself into the CD4 cell membrane and fold in such a way that the viral and cell membranes are brought into close apposition. The insertion process involves one region or end of gp41 known as HR1 (heptad region 1). The

See Inhibition of viral entry, next page

Inside

3 HIV Conferences

7 Psychosocial

8 Dentistry

9 New website

10 Mental Health

11 Consultation

12 Journal Articles

12 CE Programs

Legal

Legal implications for HIV-infected clinicians

Stacey LaFleur-Spaw, JD

Are you an HIV-positive individual practicing medicine? An HIV-positive practicing nurse? Or are you a dentist who is HIV positive? If so, there are several things you should know that may affect your job.

HIV-positive physicians

In October 1991, the 102nd Congress passed a law requiring states to establish guidelines to apply to HIV-positive health care professionals. The Louisiana State Board of Medical Examiners and the Arkansas State Medical Board have essentially adopted the language of the Congressional legislation into their rules regulating HIV-positive physicians. The rules for both states are as follows: Once the Board learns that a physician is HIV-positive, it will make contact with the physician and set up a process

See HIV-infected clinicians, page 4



Medicine

This new category of drugs will complement current regimens

Inhibition of viral entry, from page 1

folding or coiling process involves another portion of gp41 designated HR2. The folding of HR2 brings it into close contact with HR1, a process also known as gp41 zipping, and draws the two membranes together. This is followed by fusion of the viral and host cell membranes, allowing entry of the viral particle into the cell and hence infection.

T-20, now called enfuvirtide, is a 36-amino-acid peptide that corresponds to the HR2 region of gp41 and inhibits the fusion process by interfering with the HR2 mediated folding step. Enfuvirtide has undergone extensive investigation with results now available from two large phase III trials TORO 1 and 2. TORO 1 was conducted in North America and Brazil, TORO 2 in Australia and Europe.

The TORO trials compared the efficacy of salvage therapy using an optimized regimen guided by genotypic and phenotypic resistance testing compared to an optimized regimen plus T-20. In both trials, the patients were highly treatment experienced with exposure to all three classes of antiretrovirals. The median baseline HIV RNA was $> 5 \log_{10}$ copies. The individualized optimized regimens contained three to five drugs and the participants were randomized two to one to the T-20 arm. The primary endpoint of the trials was reduction in HIV viral load and 24 week data is available for

both trials. T-20 was given at a dose of 90 mg subcutaneously twice daily.

The TORO 1 trial found a median HIV viral load decrease of 1.70 log₁₀ copies/mL in the T-20 arm compared to a 0.76 log drop in the control group. The addition of T-20 was associated with a further viral load decrease of 0.94 log and was statistically significant ($P < .0001$). In addition, twice as many patients in the T-20 arm had viral loads in the undetectable range. The

New drugs also offer hope for salvage therapy for patients whose virus has developed resistance.

TORO 2 trial showed a median 1.43 log drop in viral load in the T-20 group vs a 0.65 log reduction in the control arm. The difference was 0.78 log favoring the T-20 containing regimens.

CD4 count response was also found to be superior in the T-20 arm. In TORO 1, the CD4 count increased by a mean of 76 cells/mm³ in those on T-20 compared to 32 cells/mm³ in controls. In TORO 2 the CD4 increase was 65 cells/mm³ and 38 cells/mm³ respectively.

Adverse events occurred at the same rate in both groups

and the analysis did not suggest excess laboratory or clinical toxicity associated with T-20. However, T-20 was associated with injection site reactions in most patients. Still, only 3% discontinued the study as a result of this. Non-tender subcutaneous nodules were the most common reaction.

Similar to existing antiretrovirals, resistance to T-20 is expected to occur. In vitro resistance to T-20 has already been demonstrated. Virologic's Phenosense assay has been expanded to include T-20 for use in trials and for future clinical use. Differences in clinical response to T-20 and other fusion inhibitors may become more apparent as experience with the drug increases. This is thought to be related to the percentage of virus exhibiting high affinity binding because the accelerated binding process would offer less time for exposure of the T-20 target, the HR2 region of gp41.

T-1249 is a second peptide fusion inhibitor. It is currently only in phase II trials and therefore two to three years away from clinical availability. It is also administered subcutaneously. T-1249 also targets the HR2 region of gp41 but at a distinct site and has a different amino-acid sequence. It has a longer plasma half life than T-20 and has been shown to be active against T-20 resistant virus, suggesting the potential for salvage of T-20 failures in the future.



Coreceptor inhibitors are another group of entry inhibitors in varying stages of development. At least one of these is in phase II trials. These drugs block either the CXCR4 or CCR5 receptor on the surface of CD4 cells. CXCR4 binding inhibitors have been developed but none are presently in clinical trials. One of these, AMD-3100, was associated with abnormal cardiac activity at higher doses and poor anti-HIV activity at lower doses, so that further clinical studies have been halted.

At least three CCR5 inhibitors have been developed. The most promising of these at this time is the SCH-C compound which has shown potent in vitro activity against HIV. In phase I trials, QTc interval prolongation was seen at higher doses of the drug. Currently it is in phase II trials at lower doses, which appears to reduce cardiac toxicity, and it is hoped this will maintain acceptable CCR5 inhibition. Oral bioavailability of this drug has been demonstrated. A second compound, SCH-D, is also in early clinical trials. Because coreceptor inhibition slows the fusion process there is potential for synergy between these drugs and the fusion inhibitors.

Finally, Bristol-Myers Squibb has identified a compound, BMS 806, that is in preclinical development. This drug blocks the attachment of gp120 to the CD4 receptor and has shown oral availability in some animals.

Entry inhibitors are an exciting group of drugs that will certainly be the next new class of drugs in the anti-HIV arsenal. Though some of these have the drawback of parenteral administration, others may

prove suitable for oral use. The potential for synergy between these drugs is also of great interest. While initially their use will probably be in salvage therapy, in the future they promise to enable clinicians to substantially extend the durability of HIV suppression. ❖

BIBLIOGRAPHY

Moyle G. Time for T. *The AIDS Reader*. 2002;12(6):240-254.

Hunter E. Viral binding and fusion - the next targets in antiretroviral therapy. *Topics in HIV Medicine*. 2002;10(3):4-7.

Henry K. T-20, prototype of a new class of AIDS drugs shows promise. *Peer View Press. Reports from AIDS 2002*. Barcelona, Spain, July 7-12, 2002.

Allen B, Currier J, Kuritskes D, Squires K, Tapper M. Changing Concepts in the Management of HIV Disease. Update 22. The 14th International AIDS Conference, Barcelona. UAB School of Medicine. August, 2002.

Mary Murphy is Assistant Professor of Clinical Medicine, Section of Infectious Diseases, LSU Health Sciences Center, New Orleans, and Adult Medical Director, HIV Outpatient Program (HOP) Clinic, Medical Center of Louisiana

For the
latest in
official
HIV/AIDS
treatment
guidelines:

www.hivatis.org

Plan ahead to attend HIV conferences...

▲ November 15-17, 2002
The 1st National Asian and Pacific Islander Summit on HIV/AIDS Research
Oakland, California
E-mail: brobin@s-3.com

▲ November 17-21, 2002
6th International Congress on Drug Therapy in HIV Infection
Glasgow, UK
E-mail: HIV6@gardiner-caldwell.com

▲ December 1-3, 2002
Second International Conference on Substance Abuse and HIV
Mumbai, India
yusufmerchant@sanskritiindia.com

▲ December 15-19, 2002
HIV DART 2002: Frontiers in Drug Development for Antiretroviral Therapies
Naples, Florida
E-mail: info@informedhorizons.com

▲ March 27-30, 2003
2003 National HIV Prevention Conference
Atlanta, Georgia
Sponsor: Centers for Disease Control and Prevention (CDC)

▲ April 19-21, 2003
5th International Conference on Nutrition and HIV Infection
Cannes, France
E-mail: hivcannes@wanadoo.fr

▲ April 28-30, 2003
7th International Conference on Malignancies in AIDS and Other Immunodeficiencies: Basic, Epidemiologic and Clinical Research
Bethesda, MD
E-mail: jquinn@mail.nih.gov

▲ July 13-17, 2003
The 2nd IAS Conference on HIV Pathogenesis and Treatment
Paris, France
E-mail: ias2003@jcdconseil.com

▲ September 14-17, 2003
43rd Interscience Conference on Antimicrobial Agents and Chemotherapy
Chicago, Illinois

▲ December 2-5, 2003
8th World STI/AIDS Congress
Punta del Este, Uruguay
E-mail: congreg@congreg.se



Legal

Inconsistencies surround infected physicians, nurses, dentists

HIV-infected clinicians, from page 1

of monitoring his/her practice. A physician who is HIV-positive, "or who otherwise knows or should know that he or she carries and is capable of transmitting . . . HIV, shall not thereafter perform or participate directly in an exposure-prone procedure" except when the following four conditions have been met:

- 1) The physician has advised the patient, or the patient's lawfully authorized representative, that the practitioner is HIV-positive.
- 2) The patient, or the patient's lawfully authorized representative, has been advised of the risk of the physician's transmission of HIV to the patient during an exposure-prone procedure. The physician shall personally communicate such information to the patient or the patient's representative.
- 3) The patient, or the patient's lawfully authorized representative, has subscribed a written instrument setting forth:
 - a) Identification of the exposure-prone procedure to be performed by the physician.
 - b) An acknowledgement that the advice required above has been given to and understood by the patient or the patient's representative; and
 - c) The patient or the lawfully authorized representative gives consent to the performance of or participation in the designated procedure by the HIV-positive physician.
 - d) The physician's HIV-positive status has been disclosed to each physician or other health-care personnel who participates or assists in the exposure-prone procedure.¹

Mississippi has taken a different approach. The Mississippi State Board of Medical Licensure recommends that physicians submit to HIV, hepatitis B (HBV), and hepatitis C (HCV) tests on an annual basis so that they may be kept up to date as to their status. A physician must give written notice to the Board within thirty (30) days of testing positive. A panel will then be established to monitor the physician's practice. All information regarding HIV-

positive physicians is to be kept confidential. Note that under the Mississippi Board of Licensure's rules, HIV-positive physicians who perform exposure-prone procedures can be found guilty of unprofessional conduct.²

HIV-positive nurses

Under the Arkansas State Board of Nursing Rules and Regulations, nurses may be charged with unprofessional conduct if they fail "to conform to the Universal Precautions for preventing the transmission of [HIV] and HBV to patients during exposure-prone invasive procedures."³ There is no other reference to HIV in the Board of Nursing's regulations.

The Louisiana State Board of Nursing has specific rules for those nurses who are HIV-positive. Registered nurses and registered nurse applicants who are HIV-positive and "who perform or participate in exposure-prone procedures shall report their status to the Board of Nursing within 30 days from the date of the performance of the diagnostic test."⁴ Furthermore, HIV-positive registered nurses and registered nurse applicants "shall not perform exposure-prone procedures unless they have sought periodic counsel from an expert review panel . . . and have been advised under what circumstances, if any, they may continue to perform these procedures."⁵ If the HIV-positive nurse is approved to participate in exposure-prone invasive procedures, their patients shall be notified of their seropositivity before the procedure is undergone and an informed consent shall be obtained from the patient or his/her lawfully authorized representative.⁶

The Mississippi Board of Nursing has not adopted rules regarding nurses or nurse applicants who are HIV-positive.

HIV-positive dentists

The Arkansas State Board of Dental Examiners has promulgated rules for HIV-positive dentists that are similar to those for HIV-positive doctors, but are more far-reaching in that they include the staff of a dental practitioner as well. Under the Arkansas Board's rules, an HIV-positive practitioner licensee,

dentist, dental hygienist, employee or associate who assists in the practice of dentistry, shall disclose HIV-positive status to the Board and shall refrain from participating in an invasive procedure. A review panel will be appointed which will make recommendations as to whether the practitioner may proceed with an exposure-prone procedure. In addition, "all reports and information furnished to and by the Board relative to the HIV . . . infectivity of a practitioner shall not be deemed to constitute a public record but shall be deemed and maintained by the Board as confidential and privileged as medical records."⁷

In Louisiana, if an HIV-positive dental practitioner will at any time in the course of his/her practice undertake to perform or participate in an exposure-prone procedure, he/she must give notice of positive status to the board.⁸ Those individuals who are applicants for licensure as dental health care providers are also required to report their HIV status to the board in their applications.⁹ Dental health care providers who are HIV-positive shall not perform or participate directly in an exposure-prone procedure unless:

- they have provided proper notice,
- submitted to periodic physical and psychological evaluations by a board-appointed expert review panel, and
- have received authorization to practice and perform procedures as determined by the panel.¹⁰

The Mississippi State Board of Dental Examiners does not have any specific rules or regulations regarding HIV-positive dental practitioners. To "protect the public" from transmission of HIV in the practice of dentistry "all professionals licensed by the [Board] must meet or exceed the current *Recommended Infection-Control Practices for Dentistry* as published by the Centers for Disease Control and Prevention."¹¹ Under this rule dentists must ensure that their staff "who may be exposed to blood and other body fluids" also comply with the Centers for Disease Control (CDC) recommendations.¹²



Universal Precautions

The CDC has promulgated guidelines for the use of handling blood or other bodily fluid, such as semen, which may transmit the HIV virus.¹³ These guidelines, or universal precautions, state that “all health-care workers should routinely use appropriate barrier precautions” such as gloves, masks, protective eyewear, face shields, and gowns “to prevent skin and mucous-membrane exposure when contact with blood or body fluids of any patient is anticipated.”¹⁴ A good many of the regulating boards for doctors, nurses, and dentists have adopted the CDC guidelines.

The rules for physicians in Arkansas, Louisiana, and Mississippi are virtually identical in that they require physicians who participate in an invasive procedure to adhere to “general infection control practices and universal blood and body-fluid precautions” as recommended by the CDC.¹⁵

As for the state nursing boards, nurses in Arkansas can be charged with unprofessional conduct if they fail to follow universal precautions.¹⁶ In Louisiana, nurses and registered nurse applicants must adhere to standard precautions for prevention of transmission of infectious disease as recommended by the CDC.¹⁷ An HIV-positive registered nurse or registered nurse applicant in Louisiana who performs “invasive procedures not identified as exposure prone” is to “practice standard surgical or dental technique and comply with standard precautions and current standards for sterilization/disinfection.”¹⁸ Again, Mississippi does not appear to have regulations concerning the use of universal precautions for nurses.

According to the CDC, the “blood, saliva, and gingival fluid from ALL dental patients should be considered infective,” (emphasis in the original) and dental practitioners must protect themselves from these particular transmission agents.¹⁹ Therefore, in addition to wearing protective barriers, dental practitioners should also sterilize handpieces after each use; clean blood and saliva from material that has been used in the mouth; and wrap dental equipment and surfaces that are difficult to disinfect in removable paper, aluminum foil, or clear plastic wrap.²⁰ The state dental boards of Arkansas, Louisiana, and Mississippi have adopted these

universal precautions for all dental practitioners who perform invasive procedures.²¹

Employment Discrimination against HIV-positive physicians, nurses, and dental practitioners: The Americans with Disabilities Act and the Rehabilitation Act.

Section 504 Rehabilitation Act of 1973 prohibits a qualified handicapped individual from being discriminated against “solely by reason of his handicap,” under any program or activity receiving federal financial assistance.²² Under Section 504 a handicapped individual is defined as any person who “i) has a physical or mental impairment which substantially limits one or more of such person’s major life activities, ii) has a record of such impairment, or iii) is regarded as having such an impairment.”²³

Rules regarding HIV-infected clinicians can vary widely by state...and also by discipline.

To establish a violation under Section 504, handicapped persons must not only show that they are handicapped, but they must also show that they are “otherwise qualified” for the employment. A qualified handicapped person is one who “with reasonable accommodation, can perform the essential functions of the job in question.”²⁴ The Supreme Court has ruled that an individual with an infectious disease is not otherwise qualified under Section 504 if they pose “a significant risk of communicating an infectious disease to others” and reasonable accommodations will not eliminate that risk.²⁵ To determine whether an individual poses a “significant risk” to the health and safety of others, the Supreme Court in *School Board of Nassau County v. Arline*, devised a four-part test that evaluates: a) the nature of the risk (how the disease is transmitted), b) the

duration of the risk (how long is the carrier infectious), c) the severity of the risk (what is the potential harm to third parties) and d) the probabilities the disease will be transmitted and will cause varying degrees of harm.²⁶

The Americans with Disabilities Act (ADA) prohibits discrimination against individuals with disabilities in employment and places of public accommodation. Specifically, no employer “may discriminate against a qualified individual with a disability in the terms and conditions of employment.”²⁷ The ADA’s definition of a person with a disability is the same as its predecessor, the Rehabilitation Act.²⁸ The Supreme Court has ruled that HIV is a disability under the ADA, even if an HIV-positive individual is asymptomatic.²⁹

As with the Rehabilitation Act, under the ADA an individual must not only be disabled, but must also be qualified for the position in question. The definition of a “qualified individual with a disability” under the ADA is the same as under the Rehabilitation Act.³⁰ Also, to be covered under the ADA, an HIV-positive individual must not pose a “direct threat to the health or safety of other individuals in the workplace.”³¹ The ADA standard for determining whether an employee or potential employee poses a direct threat is almost identical to the factors articulated in *Arline* for the Rehabilitation Act. To determine whether an employee poses a direct threat the employer should analyze 1) the duration of the risk; 2) the nature and severity of the potential harm; 3) the likelihood that the potential harm will occur; and 4) the imminence of the potential harm.³²

Two courts have held that an HIV-positive physician is not an otherwise “qualified individual” with a disability because he/she poses a significant risk or direct threat to the health and safety of their patients.³³ In *Doe v. University of Maryland Medical System Corp.*, the plaintiff was a neurosurgical resident who had tested positive for HIV. Upon learning of Dr. Doe’s HIV status, UMMSC administrators permanently suspended him from surgical practice, but offered him alternative residencies in non-surgical fields, which he rejected.³⁴ The Fourth Circuit agreed with UMMSC that Dr. Doe posed a significant risk and that “the risk of injury from needles and other sharp instruments cannot be eliminated

See HIV-infected clinicians, next page



Legal

Courts: invasive procedures pose significant risk to patients

HIV-infected clinicians, from page 5

through reasonable accommodation.”³⁵ Similarly, the plaintiff in *Scoles v. Mercy Health Corp. of Southeastern Pennsylvania* was an HIV-positive orthopedic surgeon who had his “clinical privileges to perform diagnostic or therapeutic invasive procedures” suspended after he disclosed his status to the hospital administration.³⁶ According to the hospital administration, the only way Dr. Scoles could perform an invasive procedure would be to submit “documentation that the patient had consented to the procedure being aware of Dr. Scoles’s HIV status,” similar to what the Arkansas and Louisiana medical boards require.³⁷

Although there are no cases on record regarding the termination of HIV-positive nurses, there are two cases involving a surgical technician and a surgical assistant. In the first, *Bradley v. University of Texas M.D. Anderson Cancer Center*, when a surgical assistant’s positive HIV status was revealed in a *Houston Chronicle* article, his employer reassigned him to the purchasing department as a procurement assistant.³⁸ The Fifth Circuit, which covers Texas, Louisiana, and Mississippi, determined that the hospital could not make any reasonable accommodations “to eliminate the risks connected with the ‘essential functions’” of the surgical assistant position, particularly the essential function of being in the operative field.³⁹ Similarly, in *Mauro v. Borgess Medical Center*, an HIV-positive operating room technician had his status disclosed to the Human Resources department by an undisclosed source.⁴⁰ A new full-time position of case cart/instrument coordinator was created for Mauro, which he declined.⁴¹ A task force was created to “determine whether an HIV-positive employee could safely perform the job responsibilities of a surgical technician.”⁴² Because the technician position required an individual to place his/her hands into a patient’s body cavity in the presence of sharp instrumentation, the task force determined that an HIV-positive worker would represent “a direct threat to patient care and safety.”⁴³

There are two cases of note regarding HIV-positive individuals practicing in the field of dentistry. The first case, *Doe v. Washington University*, involved a third-year dental student who was HIV-positive.⁴⁴ The Washington University Medical Center Communicable Diseases Council met to discuss the student’s case and recommended that “given the risk of transmission of HIV from an HIV-infected dental student to a patient during the performance of invasive procedures, the dental student should not be allowed to engage in any invasive dental procedures.”⁴⁵ After much deliberation it was determined that the student could not satisfy the graduation requirements of the program without participating in invasive procedures.⁴⁶ The court sided with Washington University stating that given this fact, the student “failed to establish that he was ‘otherwise qualified’ for participation in the program.”⁴⁷

In a more recent ABA/Rehabilitation Act case, an HIV-positive dental hygienist named Spencer Waddell was terminated from his job after he refused a clerical position that was offered following the discovery of his HIV status.⁴⁸ The Eleventh Circuit evaluated several factors including: “the use of sharp instruments by dental hygienists; routine patient bleeding during dental work; the risk that hygienists will be stuck or pricked while using an instrument; . . . and the possibility of an inadvertent bite or other accident during a dental cleaning,” and determined that Waddell posed a significant risk to others in the workplace.⁴⁹ These factors were also evidence that Waddell was “a direct threat to his workplace, and therefore not a qualified individual under the ADA.”⁵⁰

Conclusion

The laws in Arkansas, Louisiana, and Mississippi require all health care workers to use universal precautions in their practice. They also require doctors and dentists to disclose their HIV status according to CDC guidelines. Although Arkansas and Louisiana have adopted similar rules for nurses, Mississippi appears not to have done so.

Health care practitioners who are HIV-positive and who perform or assist in performing invasive procedures are unlikely to succeed in obtaining reasonable accommodations under either the Rehabilitation Act or the ADA. The courts have held that such individuals pose a significant risk to their patients and have permitted employers to remove HIV-infected practitioners from positions that require them to perform invasive procedures. ❖

REFERENCES

- ¹ See Arkansas State Medical Board Regulation No. 16 and Louisiana State Board of Medical Examiners Regulations §6707, §6709, §6711, and §6713.
- ² Mississippi State Board of Medical Licensure §1XVD-F.
- ³ Arkansas State Board of Nursing Rules and Regulations Chapter 7 §XV A.6.n.
- ⁴ Louisiana State Board of Nursing, Chapter 40 §4005B.
- ⁵ Louisiana State Board of Nursing, Chapter 40 §4007C.
- ⁶ Louisiana State Board of Nursing, Chapter 40 §4007E.
- ⁷ Arkansas State Board of Dental Examiners Rules and Regulations, Article XV §C4.
- ⁸ LA. ADMIN. CODE tit. 46, Part XXXIII, §1207A (2000).
- ⁹ LA. ADMIN. CODE tit. 46, Part XXXIII, §1207D (2000).
- ¹⁰ LA. ADMIN. CODE tit. 46, Part XXXIII, §1205A, and §1210A.
- ¹¹ Board Regulation Number 39.
- ¹² *Id.*
- ¹³ Centers for Disease Control. Recommendations for prevention of HIV transmission in health-care settings. MMWR 1987;36 (suppl no. 2S) pp.4-6.
- ¹⁴ *Id.*, p. 4.
- ¹⁵ Arkansas Regulation 16, §10; LA Admin. Code §6705; and MS State Bd of Medical Licensure §1 XV C.1.
- ¹⁶ Arkansas State Board of Nursing Rules and Regulations Chapter 7 §XV A.6.n.
- ¹⁷ LSBN Chapter 40 §4003A.
- ¹⁸ LSBN Chapter 40 §4003D.
- ¹⁹ Centers for Disease Control. Recommendations for prevention of HIV transmission in health-care settings. MMWR 1987;36 (suppl no. 2S) p. 6.
- ²⁰ *Id.*
- ²¹ See Ark State Bd. of Dental Examiners, Art. XV B. 1. and C.1.; LA Admin. Code Title 46, PartXXXIII, Chapter 12, §1203A.; and MS State Bd. of Dental Examiners Regulation No. 39.
- ²² 29 U.S.C.A. §794(a) (2002).
- ²³ 45 CFR 84.3(j) (2002).
- ²⁴ 45 CFR 84.3(k) (2002).
- ²⁵ *School Board of Nassau County v. Arline*, 480 U.S. 273, 287 n.16, 94 L. Ed. 2d 307, 107 S.Ct. 1123 (1987).
- ²⁶ *Arline*, 480 U.S. at 288.
- ²⁷ 42 USCS §12112(a).
- ²⁸ 42 USCS §12102 (2002).
- ²⁹ *Bragdon v. Abbott*, 524 U.S. 624, 118 S. Ct. 2196, 141 L. Ed. 2d 540 (1998).
- ³⁰ 42 USCS §12111(8) (2002).
- ³¹ 42 USCS §12113(b) (2002).
- ³² 29 C.F.R. §1630.2(r) (2002).
- ³³ See *John Doe v. University of Maryland Medical System Corporation*, 50 F. 3d 1261, 1266 (4th Cir.

See HIV-infected clinicians next page



Psychosocial

HIV and substance use: the biggest challenge for many clinicians

Danny Sansovich, LCSW

The HIV outpatient clinic where I work divides adult male and female patients into teams as part of a primary care management tool. The adult females are on the “Yellow” team and the adult males are divided into the “Purple” and “Green” teams.

Each team has a multi-disciplinary meeting (primary care providers, nurses,

nutritionist, social workers, health educators, case managers) each month to discuss patients whose care has reached such a level of complexity that it requires input from all team members.

**We invite your
email questions,
comments and cases
for discussion.**

The substance-abusing HIV patient is certainly not a new topic, nor is it a novel idea to suggest that substance use contributes to the spread of HIV. However, the substance-abusing patient is the single most challenging patient in our clinic. The primary care team members often struggle in their attempts to develop an effective plan of care that addresses both HIV and substance use, and there is not always universal agreement as to the best plan.

Three primary topics will be presented in our series:

- Harm reduction
- Pain management and HIV/AIDS
- Drug use and the immune system

Additionally, I will be contacting other HIV primary care clinics around the country to discover strategies that they use for dealing with this population and I will share those strategies here.

I would also like to strongly encourage readers to e-mail me (dsanso@lsuhsc.edu) with general or specific questions—or cases related to this topic—and I will address them in this column. ❖

Danny Sansovich is Clinical Social Worker, Mental Health Services, HIV Outpatient Program (HOP) Clinic of the Medical Center of Louisiana at New Orleans.

HIV-infected clinicians, from page 6

1995) and *Scoles v. Mercy Health Corp. of Southeastern Pennsylvania*, 887 F.Supp.765,772 (E.D. Pa. 1994).

³⁴ *UMMSC*, 50 F.3d at 1262-1263.

³⁵ 50 F. 3d at 1265.

³⁶ *Scoles*, 887 F.Supp. at 767.

³⁷ *Id.*

³⁸ *Bradley v. University of Texas M.D. Anderson Cancer Center*, 3 F.3d 922, 923 (5th Cir. 1993).

³⁹ *Bradley*, 3 F.3d at 925.

⁴⁰ *Mauro v. Borgess Medical Center*, 137 F.3d 398, 400 (6th Cir. 1998).

⁴¹ *Id.*

⁴² *Id.*

⁴³ *Id.*

⁴⁴ *Doe v. Washington University*, 780 F. Supp. 628 (E.D.Mo. 1991).

⁴⁵ *Washington University*, 780 F. Supp. at 629-630.

⁴⁶ 780 F. Supp. at 630.

⁴⁷ *Id.* at 635.

⁴⁸ *Waddell v. Valley Forge Dental Associates, Inc.*, 276 F. 3d 1275, 1278 (11th Cir. 2001).

⁴⁹ 276 F. 3d at 1284.

⁵⁰ *Id.*

Stacey LaFleur-Spawn is an attorney with AIDS Law of Louisiana. The author wishes to acknowledge the research assistance of law clerks Duke Alden, Jeff Brinkman and V. Denise Rose.

Other general information, such as changes in case management, is also presented at these meetings but most of the discussion is focused on complex patients.

A review of the team meeting notes for the past six months indicates that approximately 60% of the patients on the discussion list are there because of issues related to substance use/abuse.

This article will be the first in a series to examine some core topics related to HIV and substance use disorders. The intent will be to educate, to raise some challenging questions, and to present topics that will stimulate thought-provoking discussion.



Dentistry

New HRSA program will give options to rural HIV-infected

Janet Leigh, BDS, DMD

The dental branch of the US Department of Health and Human Services has searched for several years for ways to increase the number of HIV-positive individuals accessing dental care.

The Ryan White Dental Reimbursement plan provides financial support to dental schools and hospital-based post-graduate dental programs throughout the country that provide oral health care to such patients. However, most of these programs are situated in urban areas, leaving those individuals living in rural areas few options as far as dental health is concerned.

On April 19, 2002, the Health Resources and Services Administration (HRSA) announced the initiation of a new and exciting funding opportunity "to support oral health care training and the provision of oral health care to individuals with HIV in unserved areas." The intent of this grant was twofold: first, to increase the number of dental health care professionals being educated in the care and management of HIV-positive individuals and secondly, to increase the number of HIV-positive individuals accessing dental care. HRSA had the funding to support twenty institutions for up to three years.

The significant barriers to access to dental care identified in Louisiana through the State-Wide Coordinated Statement of Need document and consumer

surveys were 1) lack of funding for dental care for low income or indigent HIV-positive patients and 2) transportation to and from dental facilities. This funding proposal offered us the opportunity to address these issues.

The emphasis of this grant was that proposals must be collaborative with other Ryan White CARE Act-funded programs in the area. Partnerships with at least one community-based organization (local public health department, social service and support agencies, private dental practices and AIDS service organizations) were also encouraged. HRSA was looking for innovative ideas that could be transformed into practical reality.

LSU School of Dentistry, as a recipient of Ryan White CARE Act Dental Reimbursement Program funds, was eligible to apply. A nationwide pre-application conference call was set for May 15, following which it was decided that this funding was exactly what was needed to provide dental services in the rural areas of Louisiana. Louisiana Office of Public Health Region VI (Alexandria region) was identified as a potential site for two reasons: need and potential resources.

The eight rural parishes of Region VI (Avoyelles, Catahoula, Concordia, Grant, LaSalle, Rapides, Vernon and Winn), according to the 2000 US Census, have a population of 301,390. In 2001, Region VI ranked third among the nine

regions in Louisiana in rates of newly detected HIV/AIDS cases (21 per 100,000), behind the Baton Rouge (46 per 100,000) and the New Orleans (40 per 100,000) Public Health Regions. Therefore it was clear that this region had a strong need for HIV services

HPL Medical Center (HPLMC), the only LSUHSC public hospital in Region VI, is the major provider of inpatient and ambulatory medical services to persons with HIV in the area. The vast majority of persons living with HIV/AIDS (PLWH) in the region receive HIV care at the HPLMC CD4 clinic, therefore, the need for dental services at HPLMC was evident. A satellite dental clinic situated in HPLMC was created in 1998 by LSU School of Dentistry in response to the need for quality oral health care in this region, as well as to expose dental students and residents to the possibility of working and living in rural areas of the state of Louisiana.

AEGD (Advanced Education In General Dentistry) residents, dental students and dental hygiene students rotate through this clinic during their educational career. This established dental clinic meant that there were resources that could possibly be expanded and utilized for this proposal.

Therefore with a fast approaching deadline of June 14, it was decided that LSU School of Dentistry would submit a proposal to increase dental care to HIV-positive individuals living in Region VI



and to increase the education of dental health care professionals in the provision of oral health care to HIV-positive individuals. The model to be utilized was the dental clinic created by the Dental School in 1994 at the MCLNO HIV Outpatient Clinic.

A team was formed comprised of the following individuals: Dr. Janet E. Leigh and Dr. Kishore Shetty as the representatives from the Dental

LSUHSC School of Dentistry is one of twelve to be awarded partnership funds

School; Beth Scalco, Administrative Director for the HIV/AIDS Program of the Louisiana Office of Public Health (OPH); Deann Gruber, a consultant from OPH; the Title III awardees at HPLMC; the Central Louisiana Support Service (CLASS); and the Health Enterprise Network.

The proposal addressed three main issues. The provision of dental services at HPL dental clinic by General Practice residents, dental students and dental hygiene students was developed by expanding an already successful program at this site. Difficulties in patient transportation were approached in two ways, one by the provision of "gas vouchers" for those individuals with private transportation and secondly by the use of transportation facilities developed by the Health

Enterprise Network. Finally, the educational component was addressed through the goal that all LSU School of Dentistry residents and students rotating through this facility will have "hands-on" training in the diagnosis and management of HIV-positive dental patients and also the creation of quarterly videoconferences in Alexandria and New Orleans where clinical cases will be discussed before members of the dental and medical communities.

Forty-two institutions submitted letters of intent to apply for this funding proposal, nineteen institutions submitted grant applications and twelve were funded. That LSU School of Dentistry was one of the successful applicants is a testament to the dedication and collaboration of all those individuals who contributed to the development of this grant. The annual budget of \$310,000 for a three-year period was approved. An additional \$75,000 has been contributed to the project by the Ryan White Title II funds in support of expanded dental efforts in rural areas.

Collaborations have been established between LSU School of Dentistry and Ryan White CARE Act funded Titles II and III, Delta Region AIDS Education and Training Center (AETC), CLASS, the Health Enterprise Network and a private dentist in the Alexandria area. This was seen as one of the strengths of this proposal and affords us the exciting opportunity to expand dental care in an area of great unmet needs.

Why is this dental funding for HIV-positive individuals important? Oral health plays a vital role in both physiological

and psychological health of medically compromised patients. Increasing numbers of individuals infected with HIV, coupled with the increased numbers of HIV-positive individuals who are living longer, will surely call for greater need for oral health care services in the coming years.

It is the intention of LSUHSC School of Dentistry that the goals of treating these patients and educating the dental health care professionals in the state of Louisiana can be accomplished. Funding such as that created by the Ryan White CARE Act Community Based Dental Partnership will help us to achieve these goals in the years to come.❖

Janet Leigh is Director of the HIV Dental Clinic of the Medical Center of Louisiana at New Orleans and Dental Director of the Delta Region AETC.

Our web address has changed!

Please make a note of our new web address:
www.deltaaetc.org

It looks very similar to our old address, but please note that it now has two "a's" in it. Once you go to the site, please put it in your favorites and check back often for updated materials!



Mental Health

Obtaining informed consent in an HIV setting can be difficult

Penelope Wasson Dralle, PhD

In the Fall 2001 issue of *HIV Clinician*, ethical and legal issues related to informed consent in an HIV infected population were reviewed. The need for extra care in obtaining informed consent in this population was related to certain risk factors that either impair patients' ability to understand, process, and apply information to themselves and/or to problems in communication with the health care team resulting from cultural, language, or relational issues. In addition, problems related to determination of surrogate decision makers in this population were also noted. The focus of this column is on the application of principles and methods of obtaining informed consent in an HIV health care setting.

In HIV-infected populations, as in general health care settings, the assumption is that patients have the right to self-determination and are able to make their own decisions regarding health care options. However, when conditions suggest that there is a need for a more thorough examination of a patient's capacity (see Fall 2001 column), it is important to focus the evaluation on the specific decision at hand. Marc Tunzi, M.D. (*Can the Patient Decide? Evaluating Patient Capacity in Practice*, July 15, 2001, American Family Physician) suggests that questions address the ability of patients to

1) understand about treatment and the options that are available;

2) apply the information to their particular situation;

3) think through choices in line with realistic assessments of their situation and with their values; and

4) communicate their choices to their health care team.

He reviews two formal assessment tools that have standardized questions and scoring systems, which provide more systematic and objective assessments of capacity. One tool, the MacArthur Competence Assessment Tool (Mac CAT), is designed for complex cases including those with psychiatric or neurological impairments (Grisso, T., Appelbaum, PS, *Assessing competence to consent to treatment: a guide for physicians and other health professionals*. New York: Oxford University Press; 1998.) A shorter instrument, the Aid to Capacity Evaluation (ACE), is more easily administered and quicker to score (A copy of the ACE is included in Tunzi's article).

Generally, the primary care physician decides who has capacity and documents the evidence of obtaining informed consent in the patient's chart. The primary care physician often has the benefit of an ongoing relationship with the patient and is knowledgeable of the patient's medical and behavioral history. However, in certain situations it is necessary to seek consultation with others such as surrogate decision makers, consultants,

and other clinicians. In some settings, hospital policy requires consultation in situations of refusal of life-sustaining therapies. Psychiatrists may be consulted in cases where patients have a history of severe mental illness. A study reported in the *Journal of General Internal Medicine* (Etchells, E, Darzins, P, Silberfeld, M, Singer, PA, McKwnny, J, Naglie, G, Katz, M, Guyatt, G, Molloy, D, Strang, D, in "Assessment of patient capacity to consent to treatment, *J Gen Inter Med.* 14(1):27-34, 1999 Jan) compared treating clinicians determination of capacity using an ACE and a Standardized Mini-Mental Status with two identified expert assessors. They found close agreement between the two groups.

It is important to know the laws and policies that determine appropriate procedures for obtaining consent in your setting. At the Medical Center of Louisiana, the Policy and Procedures for Informed Consent is Policy # 5016. The required steps for obtaining consent and copies of appropriate forms are contained in this policy, as well as procedures for exceptions such as emergency situations and dealing with special populations such as minors, prisoners, mentally ill patients, and those with communication difficulties. For example, the priority order of persons authorized to give informed consent for patients in Louisiana is defined as follows: 1) Any adult, for himself/herself; 2) The judicially appointed tutor or



curator of the patient, if one has been appointed; 3) An agent acting pursuant to a valid mandate; 4) The patient's spouse not judicially separated; 5) Any parent, whether adult or minor, for his/her minor child; 6) The patient's sibling; 7) The patient's other ascendants or descendants; 8) Any person temporarily standing loco parentis, whether formally serving or not. In certain complex cases, the specific situation may need to be evaluated and discussed with consultation from the Ethics Committee, Social Services, Legal Group, and/or Medical Director.

The case of a young woman with AIDS, nephropathy and renal failure requiring dialysis is presented and analyzed with reference to relevant statutes and cases in the article, "An AIDS Patient's Right to Refuse Life-Sustaining Treatment" (Majette, GR. American Family Physician, Dec, 1998). In this case, the patient did not state the wish to die but by her actions (refusing dialysis) appeared to be on a life-threatening course. She was evaluated by a psychiatrist who found her depressed but not incapacitated by her depression. Although her physician and her family (husband and mother) opposed her choice, the author points out that courts generally will uphold a competent adult's decision to forgo medical treatments even if doing so is life-threatening unless there is compelling state's interest such as protection of innocent third parties. The author notes that "Her behavior and verbal statements are consistent with a person who wants to live, but who is unwilling to live if her existence means that she must

undergo certain types of treatment to which she objects." The author also points out that the definitions and determinations of "capacity" and "competency" depend upon the context and are defined in the applicable statutes of the state. In addition, guidelines are often provided by institutional policies. Risk management and hospital attorneys are likely to be very helpful and knowledgeable about current legal issues related to problematic cases. Another resource for HIV clinicians involved in difficult cases is access to a Medical Ethics Committee of the institution.

Over the course of the last year, our Ethics Committee Acute Response Team has been contacted to review and consult on several cases involving questions of the patient's capability to consent. Often there are other issues precipitated by what appear to be incompetent patient choices. It is difficult for professionals who are committed to preserving life to see patients make choices that appear incongruent with that commitment. The November 7, 2002, educational workshop sponsored by the LSUHSC/MCLNO Ethics Committee will address ethical and legal issues related to informed consent in a health care setting. If you are interested in attending the workshop, contact the author at pdrall@lsuhsc.edu for more information.❖

Penelope Dralle is Associate Professor, Department of Psychiatry, LSU Health Sciences Center, New Orleans, and a faculty member of Delta Region AIDS Education and Training Center.

Health professionals earn continuing education credits at the Delta AETC's clinical HIV preceptorship programs

See back cover for our training calendar

Clinical Consultation for Health Care Providers

Delta Region health care providers can consult with HIV experts at university medical centers:

- Louisiana 504-903-0788
- Mississippi 601-984-6105
- Arkansas 870-535-3062

National Consultation Lines:

- National Warmline 800-933-3413
- National PEpline 888-448-4911



Stay current with the latest HIV/AIDS journal articles

▲ Interventions to Reduce Unintended Pregnancies Among Adolescents: Systematic Review of Randomized Controlled Trials [DiCenso A et al. *BMJ* 2002;324:1426]

▲ Antiretroviral Treatment for Adult HIV Infection in 2002 [Yeni PG et al. *JAMA* 2002;288:222]

▲ Dual vs. Single Protease Inhibitor Therapy Following Antiretroviral Treatment Failure: A Randomized Trial [Hammer SM et al. *JAMA* 2002;288:169]

▲ Time Trends in Primary HIV-1 Drug Resistance Among Recently Infected Persons [Grant RM et al. *JAMA* 2002;288:181]

▲ Hepatitis C and Progression of HIV Disease [Sulkowski MS et al. *JAMA* 2002;288:199]

▲ High Prevalence of Osteonecrosis of the Femoral Head in HIV-Infected Adults [Miller KD et al. *Ann Intern Med* 2002;137:17]

▲ Long-term Metabolic Consequences of Switching From Protease Inhibitors to Efavirenz in Therapy for Human Immunodeficiency Virus-Infected Patients with Lipodystrophy [Estrada V et al. *Clin Infect Dis* 2002;35:69]

▲ Cost-Effectiveness of HIV/AIDS Interventions in Africa: A Systematic Review of the Evidence [Creese A et al. *Lancet* 2002;359:1635]

▲ Impact of Active Drug Use on Antiretroviral Therapy Adherence and Viral Suppression in HIV-

Infected Drug Users [Arnsten JH et al. *J Gen Intern Med* 2002;17:377]

▲ Human Immunodeficiency Virus (HIV) Type 1 Reverse Transcriptase Resistance Mutations in Hepatitis B Virus (HBV)-HIV-Coinfected Patients Treated for HBV Chronic Infection Once Daily with 10 Milligrams of Adefovir Dipivoxil Combined with Lamivudine [DeLaugerre C et al. *Antimicrob Agents Chemother* 2002;46:1586]

▲ SENC (Spanish Efavirenz vs. Nevirapine Comparison) Trial: A Randomized, Open-Label Study in HIV-Infected Naive Individuals [Nunez M et al. *HIV Clin Trials* 2002;3:186]

▲ Randomized, Open-Label, Comparative Trial to Evaluate the Efficacy and Safety of Three Antiretroviral Drug Combinations Including Two Nucleoside Analogues and Nevirapine for Previously Untreated HIV-1 Infection: The OzCombo 2 Study [French M et al. *HIV Clin Trials* 2002;3:177]

▲ Association of a Pool of HIV-1 with Erythrocytes In Vivo: A Cohort Study [Hess C et al. *Lancet* 2002;359:2230]

▲ Genotypic and Phenotypic Analyses of HIV-1 in Antiretroviral-Experienced Patients Treated with Tenofovir DF [Margot NA et al. *AIDS* 2002;16:1227]

▲ Tenofovir DF in Antiretroviral-Experienced Patients: Results from a 48-Week, Randomized, Double-Blind Study [Schooley RT et al. *AIDS* 2002;16:1257]

Source of listings: AETC National Resource Center

Delta ETC CONTINUING EDUCATION PROGRAMS

NEW ORLEANS, LOUISIANA

A clinical preceptorship for dentists: Oral Health Management of the Patient with HIV Disease—November 4-5, 2002. 7 hrs CDEs. Contact: Danielle Pierce-Smith, 504-903-0788 or dpierce@lsuhsc.edu

NEW ORLEANS, LOUISIANA

A clinical preceptorship for physicians: Care and Management of the Patient with HIV Disease—November 4-5, 2002. 13 CMEs from AAFP. Contact: Danielle Pierce-Smith, 504-903-0788 or dpierce@lsuhsc.edu

NEW ORLEANS, LOUISIANA

A multidisciplinary preceptorship for APRNs, PAs, RNs: Comprehensive Management of the Patient with HIV Disease—December 2-4, 2002. 21 contact hours. Contact: Danielle Pierce-Smith, 504-903-0788 or dpierce@lsuhsc.edu

JACKSON, MISSISSIPPI

A multidisciplinary preceptorship for primary care providers: Comprehensive Management of HIV Disease—January 30-31, 2003. Discipline-specific CEs. Contact Jessie Lindsay at 601-984-5542 or jlindsay@medicine.umsm.edu

PINE BLUFF AND LITTLE ROCK, ARKANSAS

Clinical preceptorships for primary care providers—ongoing. To arrange, contact: Derrick Newby, 870-535-3062 or dnewby700@aol.com

HIV Clinician

LSU—Delta Region AIDS Education & Training Center
1542 Tulane Avenue
New Orleans, LA 70112

Return Service Requested

Non-Profit Org.
U.S. Postage
PAID
New Orleans, LA
Permit No. 1017

HIV Clinician is published four times a year by the Delta Region AIDS Education and Training Center (AETC), 136 S. Roman St., New Orleans, LA 70112. Phone 504-903-0788, Fax 504-903-7893

Executive Editor
Jane E. Martin, MA, RN, C-FNP

Editor
Toni Newton

Non-commercial reproduction of this newsletter is encouraged. The opinions expressed are those of the authors and are not necessarily those of the Delta ETC. The Delta ETC is funded through the Ryan White Care Act by HRSA Grant 1H4AHA00002-01.



NOTE!

our web address has changed: www.deltaaetc.org