

AIDS ALERT®

The most comprehensive source of HIV/AIDS information since 1986

THOMSON
AMERICAN HEALTH
CONSULTANTS

IN THIS ISSUE

- Clinicians find PATH in treating HIV patients who are mentally ill 111
- Intervention has pharmacists calling patients between visits 113
- HIV patients without Internet access face 'digital divide' 115
- HPV and anal dysplasia screening and treatment improving 116

Statement of Financial Disclosure:

Editor Melinda Young, Managing Editor Leslie Hamlin, and Editorial Group Head Lee Landenberger report no relationships with companies related to this field of study. Physician Reviewer Morris Harper, MD, reports consulting work with Agouron Pharmaceuticals, Gilead Sciences, Abbott Pharmaceuticals, GlaxoSmithKline, and Bristol-Myers Squibb. Nurse Planner Kay Ball is a consultant and stockholder with Steris Corp. and is on the speaker's bureau for the Association of periOperative Registered Nurses.

OCTOBER 2006

VOL. 21, NO. 10 • (pages 109-120)

Mentally ill patients with HIV often have the worst problems

Researchers design intense intervention for group

Research shows that people with severe mental illness are at greater risk of becoming infected with HIV, their care is more costly when they are infected, and their health outcomes are worse than populations without mental illness.^{1,2,3,4}

While health care providers need to pay closer attention to people with severe mental illness in order to provide specialized HIV prevention interventions, HIV screening among this population could be improved.⁵

Also, Medicaid recipients with mental illness often die younger and have a higher rate of HIV infection than Medicaid recipients who are not mentally ill, says **Michael B. Blank**, PhD, assistant professor of psychiatry, assistant professor in the School of Nursing, and senior fellow at the Leonard Davis Institute for Health Economics all at the University of Pennsylvania in Philadelphia. Blank also is assistant professor of nursing at the University of Virginia in Charlottesville, VA, and he's on the executive committee of the national Social and Behavioral Sciences Research Network.

"Severely mentally ill people are more likely to be HIV positive and less likely to adhere to their pharmacologic regimen," Blank says.

"We have data showing that people with severe mental illnesses are at much higher risk — over five times the risk — of becoming HIV infected as the general population," Blank says. "Other data show that people who are HIV positive and have a comorbid mental illness have much higher rates of opportunistic infections than the general HIV positive population."

Recent national reports highlight the health care issues impacting Americans with mental illness and outline the fragmentation of the health care system, which serves an estimated 33 million Americans who use health care services for mental health problems. These reports note the problems with having a health care system that provides piecemeal services to the mentally ill, rather than closing gaps, improving access, and making screening, assessment, and referrals the best practice model.⁶

NOW AVAILABLE ON-LINE: www.ahcpub.com/online.html

For more information, contact (800) 688-2421.

Mentally ill people are stigmatized and marginalized in society, says **Nancy P. Hanrahan**, PhD, RN, assistant professor for the Center for Health Outcomes and Policy Research at the University of Pennsylvania School of Nursing in Philadelphia.

"They have a lot of difficulty accessing very well documented, evidence-based treatment that helps people get better," Hanrahan says.

For example, people with mental illness are

less likely to receive primary care, which leads to more serious health conditions later, she says.

"The people we care for are very sad stories," Hanrahan says. "The people are generally very poor and they've been in the [Medicaid] system a long time."

Often, the patients have a cognitive or mood disturbance that negatively impacts their quality of life, she adds.

With appropriate care and treatment, mentally ill people can live a fairly normal life, Hanrahan notes.

"One study showed that 65 percent of people with schizophrenia could live a normal life with minimal symptoms," she says.

While evidence-based treatment is available, too few are receiving it, Hanrahan says.

"One reason we're looking at this vulnerable HIV population is because if people don't take their HIV medications at least 80 percent of the time, they can develop mutant strains of the virus," Hanrahan says. "This is a very serious public health problem because mutant strains of the virus result in greater research costs to develop new antiretroviral medications."

Blank began to look into the HIV epidemic among mentally ill populations after a colleague's investigation found elevated AIDS deaths among a Medicaid population in Massachusetts.

"Bruce Dembling used Massachusetts Medicaid claims data," Blank says. "He found 14 years of lost life associated with a mental health diagnosis in the Medicaid system."

While an exam of the causes of death revealed that suicides were the leading cause, Dembling found that deaths from HIV/AIDS were elevated, Blank says.

Blank, who is a co-director of the Behavioral and Social Sciences Core of the Penn Center for AIDS Research (CFAR) in Philadelphia, was funded by the Penn CFAR to conduct a pilot study of Medicaid claims. He looked for both HIV and severe mental illness, and found that about 7 percent of mentally ill people were also HIV positive.

"We looked at the Medicaid claims and found a much higher seroprevalence among people with mental illnesses than we would have expected," Blank says.

Further research included a prevention study, funded by the National Institute on Drug Abuse in Bethesda, MD, for severely mentally ill people who used substances and who were HIV negative.

AIDS Alert® (ISSN 0887-0292), including **AIDS Guide for Health Care Workers**®, **AIDS Alert International**®, and **Common Sense About AIDS**®, is published monthly by Thomson American Health Consultants, 3525 Piedmont Road, Building Six, Suite 400, Atlanta, GA 30305. Telephone: (404) 262-7436. Periodicals postage paid at Atlanta, GA 30304. POSTMASTER: Send address changes to **AIDS Alert**®, P.O. Box 740059, Atlanta, GA 30374.

Thomson American Health Consultants is accredited as a provider of continuing nursing education by the American Nurses Credentialing Center's Commission on Accreditation.

AHC also is approved by the California Board of Registered Nursing, provider number CEP10864. This activity is approved for 18 nursing contact hours. This continuing education program does not fulfill State of Florida requirements for AIDS education.

Thomson American Health Consultants is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

Thomson American Health Consultants designates this educational activity for a maximum of 18 AMA PRA Category 1 Credits™. Physicians should only claim credit commensurate with the extent of their participation in the activity.

This activity is intended for HIV/AIDS physicians and nurses. It is effective for 36 months from the date of publication.

Because of the importance of investigational research relating to HIV/AIDS treatment, *AIDS Alert* sometimes discusses therapies and treatment modalities that have not been approved by the U.S. Food and Drug Administration.

Opinions expressed are not necessarily those of this publication. Mention of products or services does not constitute endorsement. Clinical, legal, tax, and other comments are offered for general guidance only; professional counsel should be sought for specific situations.

Subscriber Information

Customer Service: (800) 688-2421. **Fax:** (800) 284-3291. **Hours of operation:** 8:30 a.m.-6 p.m. M-Th, 8:30-4:30 F EST. **E-mail:** ahc.customerservice@thomson.com. **Web site:** www.ahcpub.com.

Subscription rates: U.S.A., one year (12 issues), \$499. Approximately 18 nursing contact hours or Category 1 CME credits, \$549. Outside U.S., add \$30 per year, total prepaid in U.S. funds. Discounts are available for multiple subscriptions. For pricing information, call Steve Vance at (404) 262-5511. Missing issues will be fulfilled by customer service free of charge when contacted within one month of the missing issue date. **Back issues,** when available, are \$83 each. (GST registration number R128870672.)

Photocopying: No part of this newsletter may be reproduced in any form or incorporated into any information retrieval system without the written permission of the copyright owner. For reprint permission, please contact Thomson American Health Consultants. Address: P.O. Box 740056, Atlanta, GA 30374. Telephone: (800) 688-2421.

Editor: **Melinda Young**, (864) 241-4449.

Vice President/Group Publisher: **Brenda Mooney**, (404) 262-5403, (brenda.mooney@thomson.com).

Editorial Group Head: **Lee Landenberger**, (404) 262-5483, (lee.landenberger@thomson.com).

Managing Editor: **Leslie Hamlin**, (404) 262-5416, (leslie.hamlin@ahcmedia.com).

Copyright © 2006 by Thomson American Health Consultants. **AIDS Alert**®, **AIDS Guide for Health Care Workers**®, and **Common Sense About AIDS**® are registered trademarks of Thomson American Health Consultants. The trademark **AIDS Alert**® is used herein under license. All rights reserved.

THOMSON
AMERICAN HEALTH
CONSULTANTS

Editorial Questions?

Call **Alison Allen**
at (404) 262-5431.

"The idea was to use a case manager to deliver individually oriented HIV prevention messages," Blank explains. "They have knowledge about their clients' cognitive and emotional deficits and were particularly well suited to deliver these programs."

While the social network model for HIV prevention works well for many populations, it is not suited for serving mentally ill people, Blank notes.

"These are people who have difficulty in social situations and who need the messages reinforced over time," he says. "The message needs to be titrated to their constellation of risk factors."

This population's excess risk for infection is due to both their mental illness, substance use, and their risky sexual behavior, Blank notes.

"Because these folks are community dwelling and vulnerable, they're easily exploited, and they tend to trade sex for food, money, drugs, and a place to stay," Blank explains.

For the approximate 7 percent of mentally ill patients who already are HIV positive, investigators developed a program, funded by the National Institute of Nursing Research (NINR) of Bethesda, called Preventing AIDS Through Health (PATH) Plus.

The PATH intervention includes the use of advanced practice nurses who serve as liaisons between physical health and mental health providers, Blank says. (*See the story about PATH, at right.*)

The intervention is intensive, resulting in an average of 22.9 contacts per participant, including face-to-face interventions with the nurse nearly half of the time.¹

Despite its cost, it will save money by preventing AIDS cases and new HIV infections, Blank says.

Since this population's risk behaviors result in further HIV exposures, the intervention can prevent new infections through keeping clients on highly active antiretroviral therapy (HAART), which lowers their viral loads and their risk of transmitting the virus to other people, he says.

"We think preventing even a single case of HIV will save a huge amount of costs," Blank says.

The PATH research, which received National Institutes of Health (NIH) funding, shows that the public health community has grown more aware of the problems facing mentally ill people with HIV infection, Hanrahan says.

"I think the HIV community has begun to open their eyes about this," Hanrahan says. "The funding of our study was very significant — a five-year, funded study at a time when NIH funding is dropping."

NIH's National Institute of Nursing Research, which provided the funding, had the foresight to see this as a multidimensional problem, Hanrahan says.

"Also, it's a significant niche for nurses because of the mental health and physical health needs of this population," Hanrahan says. "They're generally people who are hard to keep track of, and so we go out to their homes or meet them wherever we can find them." ■

References:

1. Blank M, et al. A Community Health Nursing Approach to HIV Treatment Adherence Among Persons with Comorbid Mental Illnesses. Presented at the XVI International AIDS Conference, held Aug. 13-18, 2006, in Toronto, Canada. Available at www.iasociety.org/abstract/.
2. Blank MB, et al. Co-occurrence of HIV and Serious Mental Illness Among Medicaid Recipients. *Psychiatr Serv.* 2002;53:868-873.
3. Rothbard AB, et al. Cost of Care for Medicaid Recipients with Serious Mental Illness and HIV Infection or AIDS. *Psychiatr Serv.* 2003;54:1240-1246.
4. Bogart LM, et al. Patterns of HIV Care for Patients with Serious Mental Illness. *AIDS Pat Care STDS.* 2006; 20:175-182.
5. Johnson-Masotti AP, et al. Efficacy and Cost-Effectiveness of the First Generation of HIV Prevention Interventions for People with Severe and Persistent Mental Illness. *J Ment Health Policy Econ.* 2003;6:23-35.
6. Improving the Quality of Health Care for Mental and Substance-Use Conditions. Committee on Crossing the Quality Chasm: Adaptation to Mental Health and Addictive Disorders. National Academies Press. 2006. Executive summary Available at www.nap.edu.

How PATH works for mentally ill patients with HIV

Nurses provide comprehensive, hands-on help

An intervention called Preventing AIDS Through Health (PATH) is designed to keep mentally ill people infected with HIV from progressing to AIDS.

Still under investigation, the intervention uses a cascade that includes adaptive treatment applied to prevention interventions, says **Michael B. Blank**, PhD, assistant professor of psychiatry, assistant professor in the School of Nursing, and senior fellow at the Leonard Davis Institute for Health Economics at the University of Pennsylvania in Philadelphia.

The advanced practice nurses also assist patients by helping them with housing and other psychosocial problems, Blank says.

The nurses educate and provide outreach to patients' families, says **Nancy P. Hanrahan**, PhD, RN, assistant professor for the Center for Health Outcomes and Policy Research at the University of Pennsylvania School of Nursing in Philadelphia.

"The other part of this that is really important is that providers of people with mental illness often do not know their patients have HIV infection," Hanrahan says. "So the nurses do a lot of education among case managers, mental health workers, and providers about the incidence of HIV and what to look for."

The nurses raise the mental health provider community's awareness about the need for HIV testing among any patient who is at risk, Hanrahan adds.

"Nurses bridge the gap between primary care providers and the client," she says. "A lot of their clients are in and out of the hospital, and there is poor communication between the treatment of mental illness and the treatment of health care."

So, the PATH nurses help patients with admission to health care services, they write up reports, talk with providers, and attend clinic visits with patients, Hanrahan says.

"They call providers and, when the patient is discharged, they help them transition into their home environment," Hanrahan adds. "They provide a big link that's helpful in the process."

For mentally ill patients who are HIV positive, the program provides cascading levels of service, including the first cascade of a basic intervention. This consists of a nurse teaching them about their illness, HAART, psychotropic treatment, and the importance of adherence, Blank says.

They are given a watch that can be programmed to beep or vibrate, depending on their preference, at the time they are supposed to take their medications.

They were also given a pill box, and have scheduled nurse visits each week, Blank says.

"So, the intervention provides a psychoeducational program about adherence, as well as a memory aid in the form of the watch and dosing assistance in the form of the pill box," he adds.

Nurses monitor patients' adherence at the weekly visits. They checked the pill box to count pills, elicited a self-report of adherence, and obtained pharmacy reports about the prescriptions being filled, Blank says.

If any of these indicators fell below 80 percent adherence, then the patient was moved to the next cascade level where a social network was engaged, Blank says.

"We ask family members, friends, and signifi-

cant others to help remind them to take their medications when they should and as they should," Blank says. "The nurse does this by providing the same kind of psychoeducation to family members that is provided to patients themselves."

If the patient remains nonadherent after the second cascade step, then they are given a beeper for the third cascade of the intervention, Blank says.

The beeper is programmed, through a Boston company's service called E-Pill, to go off when the patient is scheduled to take his or her medication, and an alphanumeric display on its screen will say, for example, "Take the blue pill with food," Blank explains.

The fourth cascade is activated for those patients for whom even the beeper does not work. This intervention involves giving patients a cell phone, and the patient's own family members or other social network members are trained by the nurse to call the patient at the time the patient is scheduled to take medication, Blank says.

"They talk them through taking their medications in real time," he says.

For the patients who still remain less than 80 percent adherent, the fifth and final cascade intervention is having the nurse set up a schedule for directly-observed therapy, Blank says.

The study, which will continue to enroll participants for two more years, has shown in early data some potential for success.

Of 125 patients enrolled, 72.9 percent maintained 80 percent adherence using the basic intervention only.¹

Another 12.4 percent were able to maintain 80 percent adherence with the addition of the second cascade, while 3.7 percent needed the beepers, and 4.3 percent needed the cell phones.¹

Only 1.9 percent needed the directly observed therapy.¹

The patients' adherence is continuously monitored, and once they are above 80 percent, they are moved back to the previous cascade intervention, Blank says.

The intervention and its cascades were designed to be used with a particularly difficult population of HIV patients, he notes.

"That comes from my conviction that most prevention programs are one size fits all and represent a departure from what we do in the rest of clinical medicine, where if something doesn't work, you go a little bit farther," Blank says. "This tailors the intervention to the needs of the individual patients."

The program, if it proves successful in the

outcome measures of behavioral risk and biological indicators, including risky sexual behavior and substance use, as well as CD4 cell counts and viral loads, could serve as a model for other clinics, he says.

"We think this could serve as a model for how to provide comprehensive adherence intervention for not only this population, but for others that have trouble following treatment regimens," Blank says. ■

Reference:

1. Blank M, et al. A Community Health Nursing Approach to HIV Treatment Adherence Among Persons with Comorbid Mental Illnesses. Presented at the XVI International AIDS Conference, held Aug. 13-18, 2006, in Toronto, Canada. Available at www.iasociety.org/abstract/.

ADHERENCE STRATEGIES

Telephone follow-ups improve virologic outcomes

Program could be worked into regular budget

A study shows that telephone interventions led by pharmacists result in improved viral load suppression over usual care.

Investigators worked with an indigent population at a Southeastern clinic that was well-known for adherence issues, says **Heather L. Cox**, PharmD, BCPS, pharmacy clinical specialist in infectious diseases at the University of Virginia Health System, department medical center - pharmacy in Charlottesville, VA.

They designed a simple intervention that would have pharmacists call patients to discuss their HIV medication adherence and side effects.

"By the six-month clinic visit, 53 percent of the phone call group and 26 percent of the standard-of-care group had achieved undetectable viral loads," Cox says.

The population was at risk for adherence problems because of socioeconomic issues. Investigators screened 123 patients for the study, but excluded 62, including 34 percent because they declined to participate and 32 percent because of lacking a telephone.¹

The study was designed to be an intervention that would work in any HIV clinic, using existing resources, says **Aimee Wilkin**, MD, MPH, AAHIVS, assistant professor in the section on infectious diseases, Wake Forest University Health Sciences (WFUHS) of Winston-Salem, NC.

"We did this without any funding, and worked it into our clinic's programs," Wilkin says. "What motivated us from our clinical perspective was to come up with a simple intervention to improve adherence in a busy, Title III Ryan White-funded clinic."

The Infectious Diseases Specialty Clinic, operated by WFUHS, has a population that is 75 percent African American, 36 percent female, 40 percent uninsured, and 35 percent Medicaid, Wilkin says.

The clinic typically has at least five people starting medications in a week, with maybe a caseload of 20 to 30 at any given time, Wilkin says.

"The key is there are some lovely adherence interventions you can read about, and they have multidisciplinary groups and beepers and those sorts of things," Wilkin says. "But without funding, it's very difficult to implement those — so this was an effort to find something that fits into existing clinic work flow."

The intervention had pharmacists call patients once a month between the monthly clinic visits, although the first calls took place within two or three days of the first clinic visit, Cox says.

The second call was at the two-week mark when it was assumed the patient had picked up his or her medications and could now talk intelligently about how he or she was doing, Cox says.

The end point was when the patient's viral load became undetectable, or at the six-month visit.

"Most of those who declined didn't want us calling them at work," Cox says.

Lack of access to a telephone remained a barrier throughout the study, she adds.

"Obviously, it would be nice to figure out how to expand the intervention to patients who don't have phones readily available, but we haven't figured out that one yet," Wilkin says.

In the study's informed consent, researchers asked participants to identify who the pharmacists could call and talk to and what they could say in answer to questions, Cox notes.

"Our primary end points included adherence, change in CD4 count, and virologic outcomes, as defined by a log change in viral load and proportion of patients who achieved undetectable viral load at follow-up," Cox says.

“One thing we found that was no big surprise is that adherence is extraordinarily difficult to measure.”

Also, investigators found that participants had difficulty adhering to clinic visits, as well as to their medication regimens, Cox says.

“People didn’t show up for appointments, and that opens the door to people falling out of care,” Cox says.

One of the intervention’s limitations was that it relied on three pharmacists who were trained in infectious diseases and who were not exclusively employed by the HIV clinic, Cox notes.

“We all rotated between that clinic,” Cox says. “I think this intervention is best applied by a clinic that has a dedicated pharmacist because it takes a lot of time out of your day.”

For example, the pharmacists had difficulty getting participants on the telephone, and they couldn’t leave messages. So they made repeated calls, she says.

Also, they frequently encountered canceled cell phone services and changed numbers, Cox adds.

While having an assistant initiate the calls and track down clients might work, it would have problems of its own, such as confidentiality, privacy issues and staffing conflicts, Cox notes.

However, the intervention is being modified to use phone triage nurses, who could work the phone calls into their routine of handling patient calls and issues, Wilkin says.

The clinic currently has one triage nurse, and another one will be hired, she adds.

“One of our practical limitations once the project was done is reworking things so we have the personnel time to implement the intervention on a large scale,” Wilkin says.

“In our particular situation, we used pharmacists who were available part time in the clinic,” Wilkin says. “I think it could be done with nurses or other available clinic staff, and each setting would have an array of people who would be available for it.”

Here are the questions the pharmacists would ask:

- How are you taking your medications?
- How many times a day do you take the blue one? Cox says the questions have to be posed in terms of the pill’s color because the patients often didn’t know the names of their medications.
- How many times do you take the big orange one?
- Where do you store your pills? When

patients had difficulty answering these first questions, it was a signal to the pharmacist that the patient was not taking the medications as prescribed, Cox notes.

- How many doses do you think you had to miss last week?

- How many doses did you lose? Questions about doses were asked in a way that would help the patient feel more at ease in admitting missed doses, Cox says.

Pharmacists also would inquire about adverse events, and provide interventions and referrals when necessary.

For example, one patient was taking Abacavir and had a hypersensitivity reaction that was potentially life threatening. The pharmacist told the patient to stop taking the medication, and had the patient return to the clinic for an evaluation and new prescription, Cox says.

“One patient was on an opportunistic infection (OI) prophylaxis, and we felt it was time to reverse that,” Cox says. “Another was not taking an OI and needed it.”

For patients who were doing well, the pharmacist call might last five minutes. For others, it could last 40 minutes, Cox says.

“This wasn’t a cheap intervention because of the trouble getting hold of patients,” Cox notes.

However, the intervention was designed to work in a real world setting with patients who typically have difficulty with adherence, Cox says.

“There were certainly patients we called on the phone where we made important interventions,” Cox says. “Whether another center would find the same results remains to be seen, but I would imagine it would only prove helpful.”

When the intervention is modified using triage nurses, it would include back-up by physicians or clinicians. Also, the triage nurses are trained in handling adverse events and other medication problems, Wilkin says.

“Pharmacists would still be involved, doing the initial counseling for patients when they start new regimens,” Wilkin says. “They do usually see people at follow-up visits, and they would be available also to provide back-up for the triage nurses.” ■

Reference:

1. Cox HL, et al. Clinician-Initiated Telephone Follow-Up Improves Virologic Outcomes in an HIV Outpatient Clinic. Presented at the XVI International AIDS Conference, held Aug. 13-18, 2006, in Toronto, Canada. Available at www.iasociety.org/abstract/.

Study empowers HIV patients to use Internet

Depression, consumer skills improved

Researchers say there's a digital divide among HIV patients, and it has consequences in medical care and quality of life.

People with HIV who use the Internet seem to be doing better than those not using the Internet, and those left behind in the digital divide tend to be low-income African Americans, says **Seth Kalichman**, PhD, professor of psychology at the University of Connecticut in Storrs, CT.

"We clearly, in our data, demonstrated an individual divide," Kalichman says. "What we're excited about in this study is how it clearly addresses a health discrepancy in that people who are African American and low income in Atlanta have a health disadvantage when it comes to accessing information about cutting-edge treatment and clinical trials for HIV."

HIV patients who do not have access to the Internet are being left out of the benefits of information technology, including learning more about their disease, he says.

"It's not like they don't know about it," Kalichman says. "They say, 'It's a www dot thing, and I don't have access to it, but I know there's good stuff there.'"

The study found that people who received training in how to use the Internet demonstrated increased information-seeking coping and significant increases in social support that were sustained over nine months. They also had less depression at a six-month follow-up.¹

The intervention group, compared with the control group, was more critical about information found online after the intervention, Kalichman says.

"The intervention group also demonstrated improvement with mental health outcomes like depression, a sense of well being, and practicing health-related behaviors like fitness," he says. "They were more likely to have accessed information that they would take to their doctor."

Kalichman and colleagues screened 835 HIV-positive clients from community settings in Atlanta, GA, for the study. The Atlanta area accounts for 62 percent of the AIDS cases in Georgia.

People who had used the Internet no more than two or three times in the past month were

recruited, and 448 people were randomized for the study. Most study participants were African American and had annual incomes below \$10,000.¹

"The people recruited were not Internet users and didn't have email accounts," Kalichman notes. "We clearly saw in our demography in the recruitment for the study that white, gay men in Atlanta were more likely to be using the Internet than African-American women."

Calling this a digital divide, investigators set out to study a way of teaching HIV-infected people how to find information and seek support over the Internet.

"We developed this intervention to get them online and teach them about the Internet and how to use it," he adds. "Once people knew how to use the Internet and do a search online, we taught them critical thinking skills for how to shift through useless information on the Internet."

The HIV clients who were randomized to the control group received standard support group services.

The intervention was divided into eight two-hour sessions. Sessions were offered twice a week.

The eight sessions focused strictly on learning how to use the Internet, Kalichman says.

"Near the end of the intervention, we talked about meeting people online and applying those same critical thinking skills when you meet people online," Kalichman says. "We encouraged them to get into social support groups on line, doing chat lines, and emailing their doctors."

Since social interactions via the Internet pose unique hazards, investigators also taught participants how to protect themselves from people who might mean to harm them, he adds.

"We're applying for funds to do a follow-up regarding sexual risk reduction for HIV-positive people who might meet sex partners on line," Kalichman notes.

The control group were given limited exposure to the Internet, and received two-hour informational support group sessions that covered a lot of the same territory as the intervention group, but which were not held online, he says.

They could bring in information to share with each other, and were offered information about stress reduction and medication adherence. It was a general health information support group, Kalichman says.

"The important thing about the study is that everyone had equal access to the Internet

because it was run by the AIDS Survival Project in Atlanta, which has a technology center that provided online access to everyone who visits the center," Kalichman says.

Participants receiving the intervention would get online as part of a group, and there would be a PowerPoint presentation to instruct and assist them in their Internet use and searches, he says.

"The control group had nothing like that," he adds. "We made the control group like a standard informational support group in the community."

Participants in the intervention were taught how to use the Internet in a way that most interested them. For example, they were asked about their hobbies and shown how to access Internet information about those special interests, Kalichman says.

"In the pilot group I did, one guy said, 'I believe in UFOs and abduction and want to know more about it,'" Kalichman recalls.

"Another person had a sister who had diabetes, and wanted to know more about that disease."

Yet another person was interested in horseback riding and wanted to know whether there were any places to ride horses in the Atlanta area, he adds.

"What hooked their interest was rarely a new treatment for AIDS," Kalichman explains. "So we helped them find whatever they were interested in."

The first three sessions focused on how to use a mouse and keyboard, Google, and other search engines. They also received email accounts on Yahoo.

"Once they were familiar with searches and understood the difference between searching for information and email, we said, 'Let's focus on how you can use this tool and sift through the good and bad stuff.'"

Then investigators talked about HIV disease and treatment.

Called Connect, investigators are offering the intervention material for free to any AIDS service organization or other group that would like to use it for their own HIV population, or for other groups, Kalichman says.

"Other researchers and health professionals might grab onto it and change it for other vulnerable populations," Kalichman says. "Anyone who has a chronic, life-threatening disease is vulnerable to fraud over the Internet because people will search for any cure that might make them better."

The intervention's instruction in critical thinking skills will help patients steer away from fraudulent Internet Web sites and access useful information, he says.

"We clearly believe this is useful for people

with HIV because it affects so many young people who are disparate in health care access," Kalichman says. "We find younger people who don't have education or access to the Internet or technology, and they're the ones who are the target population for Connect." ■

[Editor's note: For more information about Connect and the educational course about accessing the Internet, contact Seth Kalichman, PhD, at seth.k@uconn.edu or call him at 860-486-8978.]

Reference:

1. Kalichman SC, et al. Internet-Based Health Information Consumer Skills Intervention for People Living with HIV/AIDS. *J Consult & Clin Psych.* 2006;74:545-554.

Recognizing the need for anal HPV screening

Vaccine study results in MSM population needed

HIV-positive men who have sex with men (MSM) today more commonly develop cancer of the anus than women developed cervical cancer prior to Pap screening, an expert says.

However, this disease is largely overlooked among the HIV-positive MSM population because of the serious nature of their HIV disease, as well as the prevalence of hepatitis C infection in this population, says **Timothy Wilkin, MD, MPH**, assistant professor of medicine at Weill Cornell Medical College of Cornell University in New York, NY.

"When you talk about the risk of dying from AIDS or HCV, these have a much higher risk than anal cancer, so people don't feel it's the same pressing issue," Wilkin says.

Researchers still seek answers to questions about how human papillomavirus (HPV) infection is affected by HIV and HIV treatment, Wilkin says.

"Does treating HIV make it less likely that patients are going to have pre-cancerous conditions related to HPV?" he says. "It does seem patients are less likely to develop these precancerous conditions if their HIV is well-controlled, but we're not using that in our decision-making process about whether or not to start HIV therapy."

Among women infected with HIV and HPV, research shows they do not respond as well to treatments for cervical dysplasia, even if they are

on antiretroviral medications, Wilkin says.

"HIV-infected women are more likely to have persistent or recurrent disease than women without HIV infection," Wilkin says. "So despite antiretroviral therapy, we need to keep a close watch on these HPV-related conditions."

Thanks to a generation of public health practice and education, cervical screening for dysplasia is commonplace. The same cannot be said for anal screening, although that is changing.

Anal pap tests are a valid cancer screening target, and the screening has gained ground in recent years, Wilkin says.

"When I started this about seven years ago, there really was almost no one doing the test," Wilkin recalls. "Now it's becoming much more widespread and, recently, the New York State AIDS Institute has recommended the screening as part of routine care for people with HIV."

As a result, more physicians and clinics are showing an interest in screening, Wilkin says.

"So we need a lot more people trained in how to diagnose and manage these conditions," he adds.

While anal screening is simple, and clinicians could learn how to do it by reading a brief article on the topic, treating anal dysplasia and cancer is more difficult, Wilkin notes.

While select medical centers are making anal screening routine among HIV-infected MSM, there is some reluctance among clinicians to screen for HPV because there aren't enough clinicians who are trained in the techniques of treating and diagnosing pre-cancer conditions, Wilkin says.

"Anyone with an abnormal pap smear needs to have a high resolution anoscopy," Wilkin says. "You put a speculum in the anus with vinegar and a topic anesthetic, and then take small biopsies of the white areas that are pre-cancerous."

The point is to find high-grade anal intraepithelial, which are the areas that can turn into cancer if left untreated, Wilkin explains.

While screening for anal dysplasia is easier than a cervical pap smear and it's read the same way as a cervical pap smear, performing the high resolution anoscopy is challenging, Wilkin says.

"It doesn't fall into anyone's clinical practice," Wilkin says. "Gynecologists aren't performing this procedure, and surgeons don't really perform this procedure."

So mid-level and general practitioners have to be trained to do the procedure by the American Society for Colposcopy and Cervical Pathology.

"What's really great is they've recently started offering training for anal anoscopy," Wilkin says.

The next step is infrared coagulation, in which infrared light causes abnormal tissue to shrink, allowing normal skin to grow, Wilkin says.

"Once you find high-grade dysplasia, then you have to treat it," Wilkin says.

Another new area of HPV prevention and treatment is the newly approved HPV vaccine.

While there is some hope that the newly approved HPV vaccine will provide some protection to MSM in the future, at present, there is not enough data about it being used in this population, Wilkin says.

"There are no published data on its ability to prevent anal HPV infection and anal dysplasia," Wilkin says. "There is an ongoing study sponsored by Merck that is enrolling thousands of young women to see if the vaccine will prevent penile infection with HPV and prevent genital warts."

This study has a subset of young gay men who will be monitored by researchers to see if the vaccine prevents anal dysplasia and HPV infection, but those results are a couple of years away, he adds.

Even if studies show that the vaccine will help prevent anal HPV infection among MSM, the public health system may continue to have problems reaching young MSM for vaccination and screening, Wilkin says.

"I think it's hard to reach young men; they're not really engaged in the health care system," Wilkin explains. "Women go to see their gynecologist regularly for pap smears, but there's not the same access for young men, so it will be challenging to try to administer the vaccine to them."

For women, public health recommendations call for vaccinating them against HPV infection from ages 11 to 26, Wilkin says.

"The vaccine is going to be most effective as a preventive vaccine, and it's going to be most useful prior to any infection with any of the four vaccine types," Wilkin says. "HPV infection occurs quite commonly after a few sexual partners, so I think people should err on the side of vaccinating earlier rather than later."

A Scandinavian study is investigating the vaccine's durability, following young women who were vaccinated a few years ago to see how long the antibody persists, he adds.

There is no information about the HPV vaccine in HIV infected populations, but studies are planned, Wilkin says.

"The main thing about HIV is that patients have difficulty clearing the HPV infection, which is the norm in patients without HIV," Wilkin says. ■

FDA Notifications

FDA's meeting of Antiviral Drugs Advisory Committee

The FDA will hold a public meeting of its Antiviral Drugs Advisory Committee on Oct. 19 and 20, 2006, to discuss design issues in the development of products for treatment of chronic hepatitis C, including co-infection with HIV.

The meeting will be held on Oct. 19, 2006, from 8 a.m. to 4 p.m. and on Oct. 20, 2006, from 8 a.m. to 4 p.m. at the Hilton Washington DC/Silver Spring, 8727 Colesville Road, Silver Spring, MD, 20910 in The Ballrooms. Please note that meeting will be closed to the public on Oct. 20 from 1 p.m. to 4 p.m., to permit discussion and review of trade secret and/or confidential information.

On both days, the committee will discuss clinical trial design issues in the development of products for the treatment of chronic hepatitis C infection. This meeting is being convened in response to the growing number of products in development for this indication. The primary objectives for committee deliberations are to discuss issues related to the identification of appropriate control arms, populations for study, end points, and long-term follow-up. As noted above, on Oct. 20, 2006, the meeting will be open to the public from 8 a.m. to 12 noon, unless public participation does not last that long, and closed to the public from 1 - 4 p.m.

Background material will become available no later than 1 business day before the meeting and will be posted on FDA's Web site at <http://frwebgate.access.gpo.gov/cgi-bin/leaving.cgi?from=leavingFR.html&log=linklog&to=http://www.fda.gov/ohrms/dockets/ac/acmenu.htm>. (Click on the year "2006" and scroll down to the Antiviral Drugs Advisory Committee meeting.)

Interested parties may submit comments electronically on line at:

<http://frwebgate.access.gpo.gov/cgi-bin/leaving.cgi?from=leavingFR.html&log=linklog&to=>

<http://www.fda.gov/dockets/ecomments>. Select "2006N-0219--Clinical Trial" and follow the prompts to submit your statement.

Written comments may be submitted to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, by close of business on Oct. 5, 2006.

All comments received will be posted without change, including any personal information provided. Comments received on or before Oct. 5, 2006, will be provided to committee members before the meeting.

Oral presentations from the public (the open public hearing section of the meeting) will be scheduled between approximately 1 p.m. and 2 p.m. on Oct. 19, 2006. Time allotted for each presentation may be limited depending on the number of requests to speak. Those desiring to make formal oral presentations should notify the contact person (below) on or before Oct. 5, 2006, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the name(s) and contact information of the proposed speaker(s), and an indication of the approximate time requested to make their presentation.

Contact Person: Cicely Reese, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane, (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301-827-7001, FAX: 301-827-6776, e-mail: cicely.reese@fda.hhs.gov

For up-to-date information about the meeting, please use the FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), and enter code no. 3014512531.

No registration is necessary

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Cicely Reese at least 7 days in advance of the meeting.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets. If you need hotel accommodations or directions, please contact the hotel directly at 301-589-5200.

FDA grants tentative approval for stavudine capsules under PEPFAR

On Aug. 28, 2006, the FDA granted tentative approval for stavudine capsules, 30 mg and 40 mg, manufactured by Strides Arcolab Ltd., Bangalore, India, under the expedited review provisions created for the President's Emergency Plan for AIDS Relief (PEPFAR).

The FDA's tentative approval means that although the product meets all of the safety, efficacy, and manufacturing quality standards required for marketing in the U.S., existing patents and/or exclusivity currently prevent marketing of this product in the United States. Tentative approval, however, qualifies the product for consideration for purchase under the PEPFAR program.

As with all generic applications, the FDA conducts an on-site inspection of each manufacturing facility and of the facilities performing the bioequivalence studies prior to granting approval or tentative approval to these applications to evaluate the ability of the manufacturer to produce a quality product and to assess the quality of the bioequivalence data supporting the application.

This product is a generic version of Zerit Capsules, 30 mg and 40 mg, a nucleoside reverse transcriptase inhibitor used in combination with other antiretroviral agents for the treatment of HIV-1 infection, manufactured by Bristol-Myers Squibb.

FDA approves generic formulation of nevirapine

The FDA granted tentative approval on Aug. 11, 2006, for Nevirapine tablets, 200 mg, manufactured by Strides Arcolab Ltd., Bangalore, India. This action represents the first product manufactured by Strides Arcolab to receive tentative approval for a generic formulation of a therapy for HIV/AIDS from the FDA. It is, however, the fourth generic formulation of Nevirapine to receive tentative approval from

FDA under the expedited review provisions created for PEPFAR.

The FDA's tentative approval means that although existing patents and/or exclusivity prevent marketing of this product in the United States, the product meets all of the safety, efficacy, and manufacturing quality standards required for marketing in the U.S., and can be considered for purchase under PEPFAR.

As with all generic applications, FDA conducts an on-site inspection of each manufacturing facility and of the facilities performing the bioequivalence studies prior to granting approval or tentative approval to these applications to evaluate the ability of the manufacturer to produce a quality product and to assess the quality of the bioequivalence data supporting the application.

This product is a generic version of Viramune tablets manufactured by Boehringer Ingelheim, a non-nucleoside reverse transcriptase inhibitor used in combination with other antiretroviral agents for the treatment of HIV-1 infection.

The use of single dose of nevirapine for the prevention of mother-to-child transmission of HIV is permitted under PEPFAR.

FDA grants tentative approval to lamivudine/zidovudine fixed dose tablet

The FDA, on Sept. 13, 2006, granted tentative approval for a fixed dose tablet containing lamivudine/zidovudine 150 mg/300 mg, manufactured by Cipla Limited of Mumbai, India. The tablets are indicated for use in combination with other antiretroviral agents for the treatment of HIV-1 infection in adults.

Tentative approval means that the FDA has concluded that a drug product has met all of the required quality, safety and efficacy standards, though it may not be marketed in the U.S. due to existing patents and/or exclusivity rights. However, tentative approval makes the product eligible to be considered for purchase under the PEPFAR program. ■

COMING IN FUTURE MONTHS

■ ART medication errors: program reduces problems, works on adherence

■ HIV dementia key: research shows viral genetic differences as possible answer

■ Routine HIV testing: new guidelines, studies provide model for standard HIV screening

■ ADAP update: waiting list grows to 300-plus and some states have 18 month long waits

EDITORIAL ADVISORY BOARD

Morris Harper, MD, AAHIVS
Vice President,
Chief Medical Officer
HIV/AIDS & Hepatitis
Associates
Waynesburg, PA

Kay Ball
RN, MSA, CNOR, FAAN
Perioperative
Consultant/Educator
K & D Medical
Lewis Center, OH

John G. Bartlett, MD
Chief
Division of Infectious
Diseases
The Johns Hopkins
University
School of Medicine
Baltimore

Aaron Glatt, MD
Chief Medical Officer
New Island Hospital
Bethpage, NY
Professor of Clinical
Medicine
New York Medical College
Valhalla, NY

Lawrence O. Gostin, JD
Professor of Law
Georgetown Center for Law
and Public Policy
Georgetown University
Washington, DC

Jeanne Kalinoski, RN, MA
Director of Nursing
Rivington House
New York City

Douglas Richman, MD
Professor of Pathology
and Medicine
University of California
San Diego
La Jolla

Michael L. Tapper, MD
Director
Division of Infectious
Diseases
Lenox Hill Hospital
New York City

Melanie Thompson, MD
Principal Investigator
AIDS Research
Consortium of Atlanta

CE/CME questions

13. Which of the following is true about people who are mentally ill?
 - A. They are at greater risk of becoming infected with HIV
 - B. If they are HIV positive and on Medicaid, they are at risk of dying younger than the general Medicaid population
 - C. If they are HIV positive their health outcomes are worse than for HIV populations without a comorbid mental illness
 - D. All of the above
14. A study involving a simple, pharmacist-led, telephone intervention that was not funded except through an HIV clinic's available resources found that the phone calls to indigent, HIV patients resulted in what?
 - A. Better HIV antiretroviral drug adherence
 - B. Improved quality of life and decreased depression
 - C. Improved viral load suppression
 - D. Improved CD4 cell count and decreased HIV drug resistance
15. New research shows that low income HIV patients who are trained to use the Internet and receive free access to it are more likely to receive which positive benefit?
 - A. Improved outlook on life, decreased depression, better critical thinking skills, and competence in using Internet search engines
 - B. Higher quality of life, better adherence to ARTs, improved opinions of HIV providers
 - C. Both A and B
 - D. None of the above
16. HPV and anal cancer are a prevalent problem among HIV-infected men who have sex with men (MSM). What do clinicians need to do if they screen for anal HPV infection and find an abnormal pap smear?
 - A. Perform a colonoscopy
 - B. Refer patient to a colon and rectal surgeon
 - C. Perform a high resolution anoscopy
 - D. All of the above

Answers: 13. (d); 14. (a); 15. (c); 16. (c)

CE/CME objectives

The CE/CME objectives for *AIDS Alert*, are to help physicians and nurses be able to:

- Identify the particular clinical, legal, or scientific issues related to AIDS patient care;
- Describe how those issues affect nurses, physicians, hospitals, and clinics;
- Cite practical solutions to the problems associated with those issues.

Physicians and nurses participate in this medical education program by reading the issue, using the provided references for further research, and studying the questions at the end of the issue.

Participants should select what they believe to be the correct answers, then refer to the list of correct answers to test their knowledge. To clarify confusion surrounding any question answered incorrectly, please consult the source material.

After completing this activity at the end of each semester, you must complete the evaluation form provided and return it in the reply envelope provided to receive a letter of credit. When your evaluation is received, a letter of credit will be mailed to you.