AIDS ALERT®

The most comprehensive source of HIV/AIDS information since 1986

THOMSON
AMERICAN HEALTH CONSULTANTS

July 2005 • Volume 20, Number 7 • Pages 73-84

IN THIS ISSUE

Editor's note: AIDS Alert *is providing in this and the August issue stories based on topics discussed at the 2005 HIV Prevention Conference, sponsored by the CDC and held in Atlanta June 13-17. This issue focuses on the trend for evidence-based interventions. In the August issue, there will be stories on the problems of adaptation and a closer look at the trials and tribulations of investigators working on adapting two different evidence-based interventions, Mpowerment and Street Smart.*

HIV prevention researchers and CBOs say there are many problems with adapting approved HIV interventions

State and federal funding already was tight, and now it has become tighter for prevention work since most funding sources are requiring HIV organizations to follow strict guidelines regarding the use of evidence-based HIV prevention interventions. So far, the CDC has a list of 12 evidence-based interventions that include training materials for sites that desire to replicate them, but this limited list does not meet all of the target population needs. So behavior scientists say the interventions often need extensive adaptation, which is both expensive and difficult. . . . . cover

DEBI list is growing slowly, but many are being adapted

Community-based organizations and others that are looking for evidence-based HIV prevention interventions to use might be discouraged by how few are included on the DEBI list, but they should know that help is on the way 78

Statement of Financial Disclosure:
To reveal any potential bias in this publication, and in accordance with the Accreditation Council for Continuing Medical Education guidelines, we report that Melinda Young (Editor), Lee Landenberger (Editorial Group Head), and Alison Allen (Managing Editor) report no relationships with companies related to this field of study. Morris Harper, MD (physician reviewer) reports consulting work with Agouron Pharmaceuticals, Gilead Sciences, Abbott Pharmaceuticals, GlaxoSmithKline, and Bristol-Myers Squibb. Kay Ball (nurse planner) is a consultant and stockholder with Steris Corp. and is on the speaker's bureau for the Association of periOperative Registered Nurses.

In This Issue **continued on next page**

AIDS Alert **Update: 21st Century Prevention Work**

Adapting CDC DEBI list for target audiences is a major issue among CBOs

Translation changes can affect funding

The most recent HIV data show that about 1 million Americans are living with HIV, and the epidemic is becoming more firmly entrenched in the African American community, who now account for 47% of people estimated to be living with HIV.[1]

Also, about 45% of the people infected with HIV nationwide are men who have sex with men (MSM), while 27% were infected through heterosexual contact, and 22% through injection drug use, according to data presented at the 2005 HIV Prevention Conference, held June 12-15, 2005, in Atlanta. The CDC presented data gathered through 2003.

While the epidemic has moved to the high water point of 1 million people infected, the major ways prevention work is funded and provided has been undergoing major changes.

States are continuing to tighten HIV prevention funding and some are requiring strictly enforced guidelines regarding the use of evidence-based interventions, causing distress among many community-based organizations (CBOs) and concern among HIV prevention researchers.

(Continued on page 75)

In This Issue **continued from cover page**

Public health officials study the various ways methamphetamine use affects HIV epidemic

The use of crystal methamphetamines doubles a person's risk for HIV infections, and there has been increasing awareness among public health officials that methamphetamine use is driving new HIV infections, especially among men who have sex with men, an expert says 79

Adherence Strategies:

Depression is common among HIV patients, and antidepressant treatment may improve adherence

While surveying long-term data of HIV-infected people, an investigator was struck by how commonly HIV patients were diagnosed with depression. This observation led to a study of depression and medication adherence among HIV-infected patients seen in urban health settings between 1997 and 2001 80

New York City determines true HIV prevalence

Name-based reporting of HIV infection has been successful in New York City since it was begun in June 2000, but there still remain holes in the surveillance system in which thousands of HIV-infected individuals are lost, according to recent research 81

FDA Notifications 82

COMING IN FUTURE ISSUES

- Adapting prevention program for Latino MSM
- Rural providers often do better job in prevention counseling
- HIV center improves adherence by focusing on couples support
- More people are being tested, and it's more often for routine purposes
- The lowdown on men on the 'down low'

BINDERS AVAILABLE

AIDS ALERT has sturdy plastic binders available if you would like to store back issues of the newsletters. To request a binder, please e-mail **ahc.binders@thomson.com**. Please be sure to include the name of the newsletter, subscriber number, and your full address.

If you need copies of past issues or prefer on-line, searchable access to past issues, you may get that at **www.ahcpub.com/online.html.**

If you have questions or a problem, please call a customer service representative at **(800) 688-2421**.

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.

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.)

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 CEP 10864. 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 designates this education activity for a maximum of 18 hours in Category 1 credit toward the AMA Physicians' Recognition Award. Each physician should claim only those hours of credit that he/she actually spent in the activity.

Thomson American Health Consultants is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians. This CME activity was planned and produced in accordance with the ACCME Essentials.

This CME program is intended for HIV/AIDS physicians. 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.

Statement of Financial Disclosure:

To reveal any potential bias in this publication, and in accordance with the Accreditation Council for Continuing Medical Education guidelines, we disclose that Advisory Board Members Kay Ball is a consultant and stockholder with the Steris Corp. and is on the speaker's bureau for the Association of periOperative Registered Nurses; John G. Bartlett is a consultant for Abbott Laboratories and Bristol-Myers Squibb; Lawrence Gostin is a consultant for Merck and Aventis; Morris Harper reports consulting work with Agouron Pharmaceuticals, Gilead Sciences, Abbott Pharmaceuticals, GlaxoSmithKline, and Bristol-Myers Squibb. Douglas Richman reports consultant work for Bristol-Myers Squibb, Gilead Sciences, GlaxoSmithKline, Merck & Co, Pfizer Inc., Roche, Boehringer Ingelheim, and Virologic, Inc. Michael L. Tapper is a consultant for Abbott, GlaxoSmithKlein, Amgen, Boehringer Ingelheim, Serono, Merck, Roche, and Ortho Biotech; is a stockholder in Merck; and is on the speakers bureau at Bristol Myers-Squibb, Ortho Biotech, and Boehringer Ingelheim. Melanie Thompson reports research connections with Abbott, Bristol Myers Squibb, Chiron, DuPont, GlaxoSmithKlein, Roche, Triangle, Boehringer Ingelheim, Amgen, Gilead, Serono, VaxGEN, and Oxo Chemie. Board members Aaron Glatt and Jeanne Kalinoski report no relationships with companies related to this field of study. This CME activity receives no commercial support.

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.

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: **Alison Allen**, (404) 262-5431, (alison.allen@thomson.com).
Senior Production Editor: **Nancy McCreary**.

THOMSON™
AMERICAN HEALTH CONSULTANTS

Editorial Questions

For questions or comments, call **Melinda Young** at (864) 241-4449.

Researchers and CBO officials across the nation have been scrambling in the past year to find ways to adapt for a wide variety of uses a very narrow list of evidence-based interventions promoted by the CDC.

Commonly called the DEBI list, after the program's title of Diffusion of Effective Behavioral Interventions, the interventions include 12 HIV prevention projects that were selected from a list of more than 30 prevention programs on a CDC compendium of effective behavioral interventions.

From theory to community

While the federal government and other agencies have invested a great deal in scientifically sound intervention programs for AIDS, there are concerns that the translation of these programs is complicated, says **Bart Aoki**, PhD, associate director of the Universitywide AIDS Research Program, University of California, Office of the President in Oakland. Aoki spoke about community interventions and translation issues at the CDC's prevention conference.

"It's a social and behavioral issue that brings more complexity to the translation of scientifically developed interventions into communities than say would a biomedical device," he says.

"It raises the issue of how are resources that are being invested in research and developed ultimately benefiting the community in general," Aoki says.

Other researchers and CBO officials raise similar questions about the CDC's DEBI list and how states are including these in prevention funding plans.

For example, in North Carolina, one CBO lost its prevention funding for a DEBI adaptation in the second year because of changes it made to the intervention to make a better fit with the CBO's target Latino population, says **Scott Rhodes**, PhD, an assistant professor in the department of public health sciences at Wake Forest University School of Medicine in Winston Salem, NC.

"The CBO is doing amazing outreach with Latinos living with HIV, and they're leaders in North Carolina in working with the Latino community," he says. "Because they've been so successful with outreach they've begun to take on some primary prevention responsibilities."

The organization was adapting a DEBI intervention that involves primary care prevention case management, but the CBO's adaptation fell outside the state's list of criteria, and so funding was withdrawn, Rhodes explains.

Very few states require CBOs to use only the 12 interventions on the DEBI list, says **Charles Collins**, PhD, supervisor health scientist and science application team leader for the CDC. **(See story on how the CDC compiled DEBI list, p. 78.)**

States frequently have one of three requirements for indirectly funded CBOs, and the most common one is for the state to say they should use evidence-based interventions, Collins says.

While the CDC's intervention compendium list is limited, and the DEBI list is even smaller, there are dozens of HIV prevention interventions that were studied, published, and found significant behavior changes, Collins says.

"Some states go further and say, 'We suggest you look at the compendium of effective interventions,'" Collins adds. "And some states take it one more step and say, 'Not only do we want evidence-based interventions, but we also want you to look in the DEBI because prevention materials are available."

DEBI interventions offer users a step-by-step detailed protocol for implementing the intervention, and there are models provided and technical assistance guides, Collins says.

However, CBOs and researchers say the DEBI list is too small to be of use to many at-risk populations without extensive and often expensive adaptations, and few states are providing enough funds for the adaptation process.

For instance, Connecticut changed its HIV prevention funding criteria, strongly encouraging CBOs to use one of the DEBIs.

"Many agencies have relied heavily on the funds from the Connecticut Department of Health, and if an agency didn't feel they had the resources available to replicate a DEBI, then that would put the agency in a really difficult position," says **Ann O'Connell**, EDD, an associate professor at the University of Connecticut in Storrs. The University of Connecticut held a conference titled, "Capacity Building for Translation of Effective HIV Prevention Interventions" on May 22-24 in Storrs.

Even when CBOs received funding to use and adapt a DEBI, it often isn't enough, says **Mark Bond-Webster**, an outreach worker with Perception Programs in Willimantic, CT. Perception Programs, which was founded in 1970 to provide substance abuse interventions and treatment, established an AIDS/HIV prevention program in 1988, and in the 1990s opened a residential home for people living with HIV/AIDS.

The core list of DEBIs and their target populations

The Diffusion of Effective Behavioral Interventions (DEBI) list of 12 HIV prevention programs includes the following evidence-based interventions (www.effectiveinterventions.org), selected by the CDC:

- **Healthy Relationships:** This five-session, small-group intervention is for men and women living with HIV/AIDS, and is based on Social Cognitive Theory, focusing on developing skills and building self-efficacy and positive expectations about new behaviors through modeling and practicing skills. Staff include group peer facilitators, program coordinators, mental health professional, and program manager, and sites would need video/DVD/TV equipment, as well as incentives and refreshments for participants. Also, sites will need to form a community advisory group, obtain community buy-in, develop a logic model and preliminary implementation plan, and train staff to facilitate the program.
- **HHRP:** The Holistic Health Recovery Program (HHRP) contains 12 sessions, manual-guided, group-level intervention for HIV-positive and HIV-negative injection drug users. Based on the Information-Motivation-Behavioral Skills model of HIV prevention behavioral change, HHRP takes a harm reduction approach to behavior change in which abstinence from drug use or sexual risk-taking behavior is one goal along a continuum of risk-reduction strategies.
- **Many Men, Many Voices:** Also called 3MV, the intervention has six or seven sessions and is a group level HIV/sexually transmitted disease (STD) prevention intervention for gay men who have sex with men (MSM), including men on the "down low," meaning they do not identify themselves as gay or bisexual but have sex with men. Some factors specific to this population addressed in the intervention include cultural/ societal norms, sexual relationship dynamics, and social influences of racism and homophobia.
- **Mpowerment:** Originally designed for young MSM, including acculturated Latino men, this intervention uses informal and formal outreach, discussion groups, creation of safe spaces, social opportunities, and social marketing to reach its target population with HIV prevention, safer sex, and risk reduction messages.
- **Popular Opinion Leader:** A community-level intervention, POL involves identifying, enlisting, and training key opinion leaders to encourage safer sexual norms and behaviors within their social networks. It has been adapted for use with a variety of at-risk populations, including inner-city black women and black MSM, and the CDC have promoted it for use with any population.
- **PROMISE:** Titled, Peers Reaching Out and Modeling Intervention Strategies, PROMISE is a community-level intervention based on several behavior change theories. Training sites were established in four regions nationwide. PROMISE has been tested with African American, white, and Latino communities, including IDUs and their sex partners, MSM, high-risk youth, female sex workers, and high-risk heterosexuals. The program requires recruitment and training of peer advocates from the target population, and it has role model stories written from interviews with the target population and then distributed to target audiences to help people move toward safer sex or risk reduction.
- **RAPP:** A community mobilization program, the Real AIDS Prevention Project is based on the transtheoretical model of behavior change and was designed to reduce HIV risk and unintended pregnancy among women in high-risk communities, chiefly through increasing condom use. This intervention uses peer-led activities, including outreach, one-on-one conversations, brochures, referrals, and condom distribution, along with some small group safer sex discussions and presentations. Community business leaders also may participate in media campaigns.
- **Safety Counts:** This HIV prevention intervention is for active IDU and crack cocaine users, and its goal is to reduce both high-risk drug use and sexual behaviors. It has seven sessions, including structured and unstructured psycho-educational activities in group and individual settings, and it works well with the CDC's Advancing HIV Prevention initiative by strongly encouraging HIV testing. Both HIV-positive and HIV-negative, at-risk populations are addressed.
- **SISTA:** Five peer-led group sessions are conducted among sexually-active African American women. The goal is to increase condom use, and the sessions focus on ethnic and gender pride, HIV knowledge, and skills training for sexual risk reduction behaviors and decision making. The intervention is based on the Social Learning theory and the theory of Gender and Power.
- **Street Smart:** This multisession, skills-building program originally was designed for use with runaway and homeless youth, ages 11 to 18, populations. It addresses improving their social skills, assertiveness and coping skills, and reducing substance use and harmful behaviors. Individual counseling and trips to community health providers also are provided.
- **TLC:** Teens Linked to Care targets youth, ages 13 to 29, living with HIV. The intervention is delivered in small groups, using cognitive-behavioral strategies to change behavior. Participants meet regularly to learn new skills, provide social support, and to socialize. The goal is to help young people identify ways to improve their lives by setting new habits and daily social routines, and it's based on the Social Action Theory. Low-cost, regional training sessions for TLC will begin in 2006.
- **VOICES/VOCES:** Titled, Video Opportunities for Innovative Condom Education & Safer Sex, this group-level, single-session, video-based intervention was designed to increase condom use among heterosexual African American and Latino men and women who visit STD clinics. Staff training is necessary, and the video sessions include either an English or Spanish video on HIV risk behaviors and condom use, followed by a facilitated discussion. ■

"What we were told when we applied for funding was that although we didn't absolutely have to use a DEBI, the proposals that would be smiled on most favorably were those that based themselves on DEBIs," he says.

Perception Programs fared very well during the latest funding round, receiving $130,000 in funds to implement two different DEBIs, the Mpowerment intervention and the Community Promise intervention. **(See list and description of DEBIs, p. 76.)**

And while the CBO's bottom line looks a great deal better than its brethren CBOs, some of whom saw significant funding cuts, the reality is that $130,000 isn't enough money to do these interventions well, Bond-Webster says.

The CBO had requested $95,000 per DEBI in funding, and essentially has received enough money to pay for 1.5 DEBIs, which are directed toward different populations, he adds.

"When you read the DEBIs, they give minimum staffing requirements, and we cannot afford, even with the increased funding, to employ the people necessary for the DEBIs," Bond-Webster says.

And that's not even counting how much it might cost to adapt the DEBIs to the CBO's target populations. For example, the Mpowerment intervention was designed for young men who have sex with men, and Bond-Webster says he hopes to adapt it for use with both young and older men.

Creativity leads to funding cuts?

Both the lack of flexibility in state's funding decisions and the lack of adequate funds itself are huge problems, says **George Ayala**, PhD, director of the Institute for Gay Men's Health at the David Geffen Center in Los Angeles.

"Health departments end up being very rigid in interpretation of evidence-based interventions, so there's an expectation that organizations follow manualized interventions verbatim and allow no room for creativity or real-life decisions, adjustments, and changes to the intervention, Ayala says.

Policy-makers want to keep the recipe the same, so they recommend strict modeling of the DEBIs when what's needed are translational sciences, says **Blair T. Johnson**, PhD, a professor of psychology and member of the executive committee of the Center for Health/HIV Intervention and Prevention at the University of Connecticut in Storrs.

Instead of making CBOs focus on a dozen DEBIs, the CDC should come up with guidelines based on what has worked among 300 studies, he suggests.

"Something like this blended with a more qualitative strategy of the CDC models may well lead to greater prevention," Johnson says.

Collins says he used to believe this approach was best, but became disillusioned after seeing how the CDC spent years teaching CBOs the four ways to increase self-efficacies and finding out that the models were too complex and needed to be turned into something concrete before the organizations could adapt them.

For instance, the SISTA intervention, which is on the DEBI list targeting African American women, provides information on how to increase the female partner's assertive sexual negotiation skills by decreasing feelings of threat in a male partner, Collins explains.

"We could teach CBOs the difference between assertive and aggressive, but why have them work out all of the thousands of details of how to turn this into an intervention, when they could come to a SISTA intervention and see the process," he says.

"Frankly, I think the biggest problem is funding," says **Susan Kegeles**, PhD, a professor at the University of California-San Francisco.

"It's difficult for organizations, even with the 12 interventions to use, when they don't have enough money to do the interventions," she says. "And they're told to focus on testing, focus on prevention for positives, and there's just not enough money."

The bottom line is the federal government, which has cut or flat-funded CDC prevention funding in recent years, should not be pulling back funding from HIV prevention programs, Kegeles says.

Collins says the use of evidence-based interventions, once it becomes widespread will result in lower HIV infection rates even if funding remains the same.

"Several years ago, there were several researchers and surveys that came out and indicated approximately 70% of HIV prevention efforts in this country were street outreach where an individual on his first day of work, first hour of work, would know the intervention because all they had to do is walk down a street and try to put a condom in people's hands," he recalls.

"We had strong notions that even though 30% may have been involved in fairly creative interventions, the vast majority were doing a simple intervention with dubious effects," Collins says. "And so the other issue is that the number of new

infections in this country has hovered at the 40,000 range for five years, and we have got to increase the prevention and science-based prevention so we can stop new infections."

Now that the CDC recommends that states and cities fund evidence-based interventions instead of unscientific street outreach, there should be improvements, even if funding levels remain the same, he adds.

However, implementing evidence-based interventions costs a great deal more than community outreach prevention, researchers say.

Cost effectiveness studies show that even for the DEBI programs that are not very expensive, the cost of implementing them exceeds the typical prevention funding budget for many CBOs, says **Robin Lin Miller**, PhD, an associate professor at Michigan State University in East Lansing.

Many CBOs are expected to serve all different at-risk populations within a geographic region, but if they implement a DEBI, they only may have enough money to serve one segment of the population they intend to reach, she adds.

So an organization may shift its relationships to the one population, and there is no research to indicate whether this is beneficial or harmful and how CBOs could manage this change, Miller notes.

Reference

1. Estimated HIV prevalence in the United States at the end of 2003. Presented at the 2005 HIV Prevention Conference. Atlanta; June 2005. Abstract presentation: T1-B1101. ■

***AIDS Alert* Update: 21st Century Prevention Work**

DEBI list grows slowly as CBOs adapt models

CDC official explains process

The Diffusion of Effective Behavioral Interventions (DEBI) list of HIV prevention programs that are evidence-based was compiled by the CDC for the purpose of giving states and community organizations detailed models for providing prevention services.

Researchers applaud the focus on evidence-based interventions, but note that it may be difficult for communities to find an ideal model since the list contains only 12 DEBIs, accompanied by more than 30 additional interventions included in a compendium of effective behavioral interventions, also compiled by the CDC.

For instance, there are not any good interventions on the list addressing the HIV prevention needs of new and poor arrivals in the Latino community, says **Scott Rhodes**, PhD, an assistant professor in the department of public health sciences at Wake Forest University School of Medicine in Winston Salem, NC.

"We don't have enough for African American men," he explains. "It's difficult to do prevention research, and it's difficult to get it funded, so we have huge holes in what we know about HIV prevention."

Although the evidence-based list is limited, help is on the way, says **Charles Collins**, PhD, supervisor health scientist and science application team leader at the CDC.

One reason it is a slow process is because the evidence-based interventions on the DEBI list are ones for which there are materials available for duplication. Many behavioral interventions had great published results, but no one created materials that could be used by people who wished to replicate the programs, he adds.

"We're working with 20 behavioral interventions, but they're in various stages," Collins says. "Some we have diffused for almost two years, and some are still in the materials development stage."

Also, some states, including California, are funding translation projects, targeting different populations, for some of the interventions on the DEBI list.

Although HIV behavioral researchers routinely use the term "translation" in referring to the process of taking a DEBI project and adapting it to be used in a setting and for a population that are different from its original use, the CDC prefers not to use the same term, Collins says.

"We use the terms adaptation and tailoring," he says. "Adaptation and tailoring may involve a language translation, but we believe these interventions have to be adapted for various different target populations and settings and venues."

The DEBI list was started in 2003 following a year of start-up work, Collins says.

It takes some time to add an intervention to the list because each DEBI must first meet criteria to be placed on the CDC compendium, he explains. The criteria include:

- The intervention studied must have had a comparison or control group.
- There has to be statistically significant differences in risk behavior for the intervention group compared with the comparison group.

• There has to have been a behavior change that was sustained for at least 120 days after the intervention ended.

• At least 70% of the people who go through the intervention must be retained for the follow-up.

Once interventions are included in the compendium, they may be selected for the DEBI list based on their relevance for target at-risk populations and their readiness for diffusion, meaning there are materials and guidelines established that could be used by a community-based organization or health department that desires to use and/or adapt the same intervention, Collins notes.

"We look to see if the intervention is culturally competent," he says.

The first compendium was published in November 1999 with 25 interventions, and that list was updated in 2003 with 30 interventions.

"The DEBI interventions have instrumental utility and conceptual utility," Collins says. "Instrumental utility means you learn how to do the intervention as it was designed, but conceptual utility is you learn how important it is to give health messages through multiple channels."

To make an intervention ready for diffusion, it requires meeting with researchers to discuss their vision and beginning a dialogue about how to get their intervention diffused across the country, including what materials would need to be developed, he notes.

While there are perhaps hundreds of evidence-based interventions with published results, even some that meet the compendium criteria are not included on the list because of other issues, including relevance, Collins says. For example, an intervention designed for men who have sex with men (MSM) in 1989 might not be relevant to the population of at-risk MSM in 2005, he explains.

Also, there's a financial constraint, so the CDC has had to prioritize which interventions to move to the next levels, Collins notes. "There's a wonderful intervention by Don Des Jarlais, PhD, called Sniffer," he says. "It works with heroin sniffers who have been sniffing for less than 90 days, and it supports them in continuing to sniff heroin rather than to switch to injecting heroin, which protects the person from HIV and hepatitis C."

The reason the CDC has not put this intervention on the list of DEBIs is because there's a greater need for interventions addressing African American MSM, Collins says. "We don't have enough money to fund every one of those interventions, so we need to choose those interventions that best fit the HIV epidemic." ■

***AIDS Alert* Update: HIV Prevention Conference**

Meth's impact on HIV epidemic being studied

Drug's use is growing problem among MSMs

The use of crystal methamphetamines doubles a person's risk for HIV infections, and there has been increasing awareness among public health officials that methamphetamine use is driving new HIV infections, especially among men who have sex with men (MSM), an expert says.

"Methamphetamines are used in conjunction with sexual activity, and when we look at risk activity among methamphetamine users, they're much riskier than when they don't use the drug," says **Grant Colfax**, MD, co-director of HIV/AIDS statistics, epidemiology, and intervention research section of the San Francisco Department of Public Health. Colfax spoke about the HIV epidemic and methamphetamine use at the 2005 HIV Prevention Conference in Atlanta, held June 12-15, and sponsored by the CDC.

"Even when we control for behavioral factors, methamphetamine use appears to put people at risk for HIV infection," he says.

Researchers speculate that this finding could be due to any number of other factors, including the possibility that investigators haven't collected data on all of the behavioral factors that may contribute to HIV infection when someone is using methamphetamines, Colfax says.

For instance, it might be that people are having more traumatic sexual activity, causing mucosal breaks that increase transmission risk, he notes.

"Or is it some people are so high when having sex that even if they try to use a condom, it's not used correctly and it breaks and people don't recognize that," Colfax explains.

There also are questions about whether methamphetamine use may increase HIV infection, independent of its impact on behavior, he notes.

Research hasn't been done on whether the drug could be acting as an immune suppressant or whether it increases blood flow in the rectal area, he says.

"It's very speculative, but are there somehow some immune or vascular effects of methamphetamine that puts people at higher risk for infection, aside from behavior?" Colfax asks.

The big challenge for HIV clinicians and public health officials is how to reduce methamphetamine

use, which in turn fuels the HIV epidemic, he points out.

Some research is looking into the possibility of a pharmaceutical intervention, in which some medication might reduce a person's desire for methamphetamine, Colfax notes. But in the short term there need to be effective prevention strategies to convince people to reduce sexual risk and methamphetamine use, he says.

"People who get into substance use programs will reduce their risk behavior, but they are a select group of people who have bottomed out," he says.

Ideally, prevention services would be made more widely available for methamphetamine users, and there would be collaborative efforts to increase the awareness of the problem within the gay community, Colfax says.

Some behavioral scientists currently are studying whether incentive programs work with methamphetamine users, including those that offer meth users a voucher as an incentive when their urine tests negative for methamphetamine use, he reports.

Other interventions being studied include a behavioral counseling program, called Project Mix, consisting of six group sessions in which participants talk about their substance use and the goal is to de-link sexual behavior from substance use, Colfax says.

"The goal is for people to develop strategies to be safer and to reduce or stop using substances," Colfax explains. "It's a risk-reduction strategy where we're not telling people to stop using any substances, although we say that's an option for them, but if they choose to use, here are some ways to reduce their HIV risk."

Project Mix, which is funded through the CDC, is enrolling about 1,200 participants in San Francisco, Los Angeles, New York City, and Chicago should have data available in 2007, says Colfax, who is one of the study's principal investigators.

What remains clear to HIV scientists and public health officials is that methamphetamine use is closely tied to risky sexual behaviors, particularly among MSM who use the Internet to find sexual partners, Colfax notes.

"We know the methamphetamine epidemic is integrated into the whole 'party and play' Internet world," Colfax says. "'Party and play' means I do drugs and engage in sexual activity, and the partying involves a lot of methamphetamine use."

MSM will go on line to find other men who use methamphetamines and then link up with them, have sex, and typically engage in high levels of risky behaviors, Colfax adds.

"We need to have more people access substance use treatment and have that more available for methamphetamine users," Colfax says. "There is just not enough availability of substance use treatment anywhere at this point, so one public health need is to get more people into treatment."

The second public health challenge is to get the word out about the link between methamphetamine use and HIV infection to the populations most at risk, he says.

"Gay and bisexual men are much more likely to use methamphetamines compared to heterosexual men," Colfax says. "We found that 13% in San Francisco have used methamphetamine in the last six or 12 months, but most are not heavier users."

Although only 2% are using methamphetamine weekly, the men who are using it intermittently often will engage in high-risk behavior during when they are using meth, and that's when HIV infection risk occurs, he adds. ■

ADHERENCE STRATEGIES

Antidepressant treatment may improve adherence

Routine depression screening recommended

While surveying long-term data of HIV-infected people, an investigator was struck by how commonly HIV patients were diagnosed with depression.

This observation led to a study of depression and medication adherence among HIV-infected patients seen in urban health settings between 1997 and 2001, says **Lourdes Yun**, MD, MSPH, epidemiologist with the Denver Health TB Clinic.

"Adherence of antiretroviral drugs is a big issue because of the big regimens with their side effects," she says. "We started to think about if depression had anything to do with adherence to antiretroviral therapy."

Investigators measured data already collected from 1,713 HIV-infected patients, and found that 57% were depressed. Of those diagnosed as depressed, 46% received antidepressant medication, and 52% received antiretroviral treatment.[1]

The observational study found that people who have HIV and who are receiving antidepressant treatment for depression have a higher adherence to their antiretroviral drugs than do those who are diagnosed as depressed, but who do not receive antidepressant treatment, Yun says.

"So we recommend more routine screening of depression among HIV patients, and among those found to have depression, we recommend antidepressant therapy," she explains. "We need to be really aware that depression is a common diagnosis among HIV patients, and when they're found to be depressed, antidepressants can improve adherence to antiretroviral therapy."

A prospective study would be a good way to confirm these findings, Yun notes.

"It'd be nice to follow those patients and see if prospectively patients found to be depressed and if put on antidepressant therapy will improve therapy," she says.

In defining depression for the purposes of the study, investigators relied on several pieces of information, including whether the primary physician diagnosed a patient with depression and used the appropriate ICD-9 code. In other instances, physicians referred patients to a psychiatrist where a diagnosis was made, or the physician failed to make the diagnosis of depression, but prescribed the patient antidepressant medication, Yun explains.

"Anyone prescribed an antidepressant medication was described as depressed," she says.

Although using pharmacy prescription refill data is not an ideal way to measure adherence, this was the best method available to investigators, Yun notes.

"There is some validity in using this method," she says. "We took all the patients on antiretroviral therapy, and we measured when was the first time the patient picked up an antidepressant drug and when was the last time the patient ever picked up a prescription, and that was our numerator."

The denominator was how many times the patient had the prescription filled, so if someone was 100% adherent, they would in a period of 12 months pick up the prescription 12 times, Yun adds.

An important take-home message from the study is that it's very important to screen HIV patients for depression because it such a common diagnosis in this population, she points out.

"We should look more carefully at every single HIV patient and assess depression," Yun says. "Our recommendation is we should look at outpatients and specifically those who are not adherent and go back to see if some psychiatric issue is affecting their antiretroviral adherence."

In clinics where this is possible, HIV patients should be referred to a psychiatrist, perhaps on the second visit, she adds.

While not all patients who are depressed will need antidepressant medication, this prescription appears to be of benefit to many and appears to benefit antiretroviral adherence, Yun concludes.

Reference

1. Yun LW, Maravi M, Kobayashi JS, et al. Antidepressant treatment improves adherence to antiretroviral therapy among depressed HIV-infected patients. *J Acquir Immune Defic Syndr* 2005; 38(4):432-438. ■

NYC study determines true HIV prevalence

Study puts number to untested, unreported

Name-based reporting of HIV infection has been successful in New York City since it was begun in June 2000, but holes still remain in the surveillance system in which thousands of HIV-infected individuals are lost, according to recent research.

"Name-based reporting has worked pretty well, but there are a lot of people who are not tested to begin with, and without their getting tested there's no way surveillance will pick them up," says **Yussef Bennani**, MPH, research scientist with the New York City Department of Health and Mental Hygiene.

Another gap in the HIV reporting system involves people who had been tested before 2000 but who have fallen out of medical care, he says.

"They may have no provider, and their viral load may be sufficiently suppressed that they don't have any reportable events, like a diagnostic antibody test or CD4 cell counts below 500," Bennani says.

"The law does not require HIV doctors to list all HIV patients," Bennani notes. "From this analysis, it seems the majority of folks who are not part of the 90,000."

He participated in a study that analyzed data to arrive at a more accurate number of HIV-infected individuals in New York City. The study reports a total of 88,479 people diagnosed with HIV or AIDS as of Dec. 31, 2003, with an estimate range

of 11,336-45,914 people who have HIV/AIDS but who are not diagnosed. Also, between 5,151-8,216 people have been diagnosed but are not reportable, the study states.[1]

Based on this analysis, the prevalence of HIV in New York City is 22% to 44% greater than what the surveillance system has measured.[1]

Few cities have gone through this extensive of an analysis to obtain a better estimate of undiagnosed, unreported HIV cases than by using the CDC's estimate that 25% of people infected with HIV are undiagnosed, says **Judith Sackoff**, PhD, director of HIV/AIDS surveillance at the New York City Department of Health and Mental Hygiene.

"We've had a lot of special studies in high-risk populations that have allowed us to make those kinds of estimates," Sackoff notes.

Investigators calculated the number of unreported persons with HIV infection by dividing the city's population into subpopulations by risk and demographic characteristics and estimating the untested population and multiplying that number by a high- and low-prevalence estimate.

New York sends the CDC its new diagnoses for HIV and AIDS each month, Sackoff says.

"We're quite confident about the quality and accuracy of the data," she reports.

Although there were some concerns raised about the impact name-based reporting would have on voluntary HIV testing in New York City prior to its implementation in 2000, subsequent surveys have shown that the HIV reporting law has not had an impact on testing, Sackoff says.

Nonetheless, New York City has about 4,000 new HIV diagnoses each year, and it takes time for a new surveillance system to mature, so the new diagnoses data cannot be used to determine new infections, she explains.

Also, it's too soon to say whether the data show any trends, such as an increase in HIV diagnoses, in the past few years, Sackoff says.

The new analysis of suspected undiagnosed and unreported HIV infection prevalence shows how it's important for governments to continue promoting HIV testing, Bennani notes.

"I don't know if the analysis had any surprises," he says. "But it strengthens our thoughts about the problem of undiagnosed HIV in New York City."

For this reason, the city's health department has begun a new campaign, called Take Care New York," which stresses the importance of people knowing their HIV status, Bennani says.

"The campaign is fairly visible throughout the city to anyone who takes the subway," he says.

"The analysis does reinforce the importance of HIV testing because undiagnosed people can be unwittingly spreading HIV over the course of many years as well as missing out on the opportunity to get care for themselves that would improve the quality of their lives," Sackoff says.

Reference

1. Torian LV, Bennani Y, Frieden T. What is the true prevalence of HIV in New York City? Estimating the number of undiagnosed and unreported persons living with HIV and AIDS, 2003. Poster presented at the 12th Conference on Retroviruses and Opportunistic Infections. Abstract 970. Boston; Feb. 22-25, 2005. ■

FDA Notifications

FDA approves generic foscarnet sodium injection

The FDA issued an approval on May 31 for a generic formulation of foscarnet sodium injection, 24 mg/mL, 250 mL, and 500 mL single-dose containers, manufactured by Pharmaforce Inc. of Columbus, OH. The product is indicated for the treatment of CMV retinitis in patients with AIDS, making a generic alternative formulation available in the United States.

The product is a generic version of Foscavir (foscarnet sodium injection) 24 mg/mL, 250 mL and 500 mL single-dose containers, manufactured by AstraZeneca, originally approved in 1991.

Tentative approval of generic lamivudine

The FDA granted a tentative approval for a generic formulation of lamivudine tablets, 150 mg, manufactured by Ranbaxy Laboratories Limited (India), for use in combination with other antiretroviral agents in the treatment of HIV-1 infection in adults. The tentative approval was issued May 27.

A tentative approval means that FDA has concluded that a drug product has met all of the required quality, safety and efficacy standards, even though it may not yet be marketed in the U.S. due to existing patents and/or exclusivity. It does, however, make the product eligible for use under the President's Emergency Plan for AIDS Relief (PEPFAR) program outside the United States.

The lamivudine tablets are a generic version of Epivir (lamivudine) Tablets, 150 mg, manufactured by Glaxo Smith Kline.

Pediatric HIV Infection Guidelines updated

The Guidelines for the Use of Antiretroviral Agents in Pediatric HIV Infection were updated March 24, 2005. Please note that the Appendix, Characteristics of Available Antiretroviral Drugs, has been extensively modified to include up-to-date drug information, including updated information about pediatric dosing and new drug formulations. The updated Appendix also includes a matrix based on Table 18 in the Adult Guidelines (adverse drug reactions) and three matrices based on Tables 19-21 in the Adult Guidelines (drug interactions between antiretrovirals and other drugs).

The Pediatric Guidelines are developed by the Working Group on Antiretroviral Therapy and Medical Management of HIV-Infected Children, which reviews new data on an ongoing basis and provides regular updates to the guidelines.

The updated guidelines document is available in the Pediatric Guidelines section of the Guidelines page on the AIDSinfo web site.

The AIDSinfo web site (AIDSinfo.nih.gov) also is a valuable source of other information related to HIV/AIDS, including other treatment and prevention guidelines, downloadable databases for PDAs (Personal Digital Assistants), and HIV/AIDS-related clinical trials information.

Entecavir is approved for chronic hepatitis B infection in adults

On March 29, FDA approved entecavir (Baraclude) for the treatment of chronic hepatitis B virus infection in adults with evidence of active viral replication, and either evidence of persistent elevations in serum aminotransferases (ALT or AST), or histologically active disease.

This indication is based on histologic, virologic, biochemical, and serologic responses after one year of treatment in nucleoside-treatment-naive and lamivudine-resistant adult patients with HbeAg (hepatitis B e antigen)-positive, or HBeAg-negative chronic HBV infection with compensated liver disease, and on more limited data in adult patients with HIV/HBV coinfection who have received prior lamivudine therapy.

Limited data about entecavir in patients with HIV/HBV coinfection who received prior lamivudine therapy are presented in the label. Please refer to the attached label and the Special Population section under Description of Clinical Studies for information on HIV/HBV coinfected patients.

In summary, Study AI463038 was a randomized, double-blind, placebo-controlled study of

CE/CME *questions*

1. In 2003, the CDC formed the DEBI list for communities to use as models of effective HIV prevention programs. Which of the following is not among the criteria for a program to be put on that list?
   A. The intervention studied must have had a comparison or control group
   B. There has to be statistically significant differences in risk behavior for the intervention group compared with the comparison group.
   C. There has to have been a behavior change that was sustained for at least 120 days after the intervention ended.
   D. At least 80% of the people who go through the intervention must be retained for the follow-up.

2. The use of crystal methamphetamines increases a person's risk for HIV infections by how much, according to recent research?
   A. Doubles
   B. 2.8 times
   C. Triples
   D. 3.6 times

3. Investigators collecting data from 1,713 HIV-infected patients found that which percentage was depressed?
   A. 29%
   B. 35%
   C. 42%
   D. 57%

4. A New York study analyzing the city's surveillance system and HIV prevalence estimates that the prevalence of HIV in New York City is greater by what range than what the surveillance system has measured?
   A. 11% to 30%
   B. 22% to 44%
   C. 25% to 48%
   D. 33% to 50%

CE/CME *directions*

To complete the post-test for *AIDS Alert*, study the questions and determine the appropriate answers. After you have completed the exam, check the answers **on p. 84**. If any of your answers are incorrect, re-read the article to verify the correct answer. At the end of each six-month semester, you will receive an evaluation form to complete and return to receive your credits.

entecavir versus placebo in 68 patients coinfected with HIV and HBV who experienced recurrence of HBV viremia while receiving a lamivudine-containing highly active antiretroviral therapy (HAART) regimen. Patients continued their lamivudine-containing HAART regimen (lamivudine dose 300 mg/day) and were assigned to add either entecavir 1 mg once daily (51 patients) or placebo (17 patients) for 24 weeks followed by an open-label (nonblinded) phase for an additional 24 weeks where all patients received entecavir.

At baseline, patients had a mean serum HBV DNA level by PCR of 9.13 log10 copies/mL. Ninety-nine percent of patients were HBeAg-positive at baseline, with a mean baseline ALT level of 71.5 U/L. Median HIV RNA level remained stable at approximately 2 log10 copies/mL through 24 weeks of blinded therapy.

The proportion of HIV/HBV coinfected patients with HBV DNA < 300 copies/mL was 6% for the entecavir 1 mg group vs. 0% for the placebo group. The mean change from baseline for HBV DNA was -3.65 log10 copies/mL for the Baraclude 1 mg group vs. +0.11 log10 copies/mL for the placebo group. Thirty-four percent of patients in the entecavir 1 mg group had ALT normalization (< 1 x ULN) compared to 8% of patients in the placebo group. There are no data for patients with HIV/HBV coinfection who have not received prior lamivudine therapy.

Roche issues letter about saquinavir

Roche Pharmaceuticals of Nutley, NJ, has issued a "Dear Health Care Provider" letter to inform the clinical community that commercial distribution of Fortovase, the 200-mg softgel formulation of saquinavir, will be discontinued by Feb. 15, 2006.

The letter cites decreased demand for Fortovase as the reason for the product's discontinuation.

Roche suggests that physicians refrain from starting Fortovase treatment in their HIV-positive patients at this time, and encourages prescribing health care providers to discuss appropriate alternative treatment regimens with patients currently receiving Fortovase.

Invirase, another formulation of saquinavir manufactured by Roche Pharmaceuticals, will continue to be available in 200-mg and 500-mg formulations.

The complete Dear Health Care Provider letter is available at www.invirase.com/pdf/FTVDearDoctorFINAL.pdf. ■

CE/CME objectives

After reading this issue of *AIDS Alert*, CE participants should be able to:

- **identify** the particular clinical, legal, or scientific issues related to AIDS patient care;
- **describe** how those issues affect nurses, physicians, hospitals, clinics, or the health care industry in general;
- **cite** practical solutions to the problems associated with those issues, based on overall expert guidelines from the Centers for Disease Control and Prevention or other authorities and/or based on independent recommendations from specific clinicians at individual institutions. ■

CE/CME *answers*

Here are the correct answers to this month's CME/CE questions.

1. D 2. A 3. D 4. B