

# AIDS ALERT.

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### Studies predict possible increase in AIDS cases, deaths

Centers for Disease Control and Prevention officials presented numerous studies at the 2nd National HIV Prevention Conference in August showing an upswing in HIV risk behaviors among youths, minorities, and men who have sex with men. The conference also featured studies showing that many at-risk individuals are being tested late for HIV infection. These factors point to a possible increase in AIDS cases and deaths soon. . . . . Cover

### New studies focus on increases in risk behaviors

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### Late detection of HIV key issue for some groups

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### *Special Report: Prevention Conference Coverage*

## Research shows that United States may be due for resurgent HIV epidemic

*Also, too many HIV infected people are tested late*

**H**IV prevention efforts of the past two decades have scored two grades of "A," but there are even more "needs to improve" grades.

Researchers and public health officials speaking at the Centers for Disease Control and Prevention's 2nd National HIV Prevention Conference, held in Atlanta on Aug. 12-15, 2001, presented mixed news about the success of previous prevention efforts and hope for the future.

The latest CDC data show a leveling off of AIDS cases and deaths, and recent studies involving sexually transmitted diseases (STDs) among HIV-infected and at-risk individuals indicate the possibility of a future upswing in AIDS rates. (See **estimated AIDS incidence and deaths chart, inserted in this issue.**)

"Data continues to mount suggesting there is a true increase in risk behaviors," says **Helene Gayle**, MD, MPH, director of the National Center for HIV, STD and TB Prevention at the CDC.

"Several studies show HIV-infected men getting other STDs, which is evidence of risk behavior in a population that already has HIV," Gayle adds.

On the positive side, mother-to-child transmission has been reduced to levels that haven't been seen since the early years of the epidemic, a significant improvement from the peak rates of the early 1990s. (See **perinatally acquired AIDS cases chart, inserted in this issue.**)

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### New hope is raised involving OTC antiviral lubricants

After the disastrous findings involving nonoxynol-9 and its use as an antiviral vaginal lubrication, clinicians may have been tempted to think there was very little possibility of finding a spermicide that could kill HIV. However, the possibility of finding a safe and effective antiviral lubricant was given new life by a recently published study by researchers at The University of Texas Medical Branch at Galveston . . . . . 133

### Benefits shown from routinely screening patients for HIV

Following up on its 1993 recommendations that hospitals and clinics in areas with high rates of HIV prevalence offer routine HIV testing to patients, the Centers for Disease Control and Prevention conducted a recent study of such a practice. From March 20 to Sept. 1, 2000, clinicians in Atlanta were encouraged to recommend HIV testing to all urgent-care clinic patients between the ages of 18 and 65 . . . . . 134

### Role of IL-7 studied in course of HIV disease progression

San Francisco investigators have been studying interleukin-7 (IL-7) and its role in HIV disease progression in hopes of better understanding how T-cell production is regulated and how this knowledge might be applied to therapeutic intervention and immunosuppression in either AIDS patients or bone marrow transplant patients. This interest has led to the discovery that IL-7 is produced in response to T-cell depletion, thus facilitating T-cell production — but simultaneously fostering HIV-1 disease progression . . . . . 135

## COMING IN FUTURE ISSUES

- **Behavioral intervention program improves safe-sex practices:** One group intervention model directed at HIV-positive people showed good results in reducing high-risk sexual behaviors
- **Grassroots HIV prevention among Caribbean nations:** Pan-American partnership and individualized prevention efforts are making some headway in this hotbed of the HIV epidemic
- **Baltimore mobile van ventures into high-HIV-prevalence areas:** Van offers HIV testing, counseling, and other health screening and educational services to troubled neighborhoods, local detention centers, and other high-risk settings
- **North Carolina HIV prevention program collaborates with local groups:** HIV testing isn't the only service offered to at-risk individuals, who could also receive screening for blood glucose, blood lead levels, sickle cell anemia, and sexually transmitted diseases
- **HIV prevention program visits the homeless:** Program results in AIDS case rate increasing by 60% from 1991 to 1997

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### Editorial Questions

For questions or comments, call **Melinda Young** at (828) 859-2066.

(Continued from cover page)

Also, there is increasing evidence that a majority of men who have sex with men (MSM) are continuing to use condoms consistently, some two decades into the epidemic, notes **Cynthia Gomez**, PhD, of the Center for AIDS Prevention Studies at the University of California - San Francisco.

However, young MSM are not reducing their sexual risk behaviors as consistently, Gomez says. "This is a generation that has not received the intensive prevention message that the other men in their 40s have received, and it is not the same epidemic, so we can't repeat what we did in the 1980s and expect it to be effective."

The younger generation of MSM is a much faster-moving and -acting group, and they receive a great deal of information through advanced technology. This leads to risk behaviors associated with meeting other MSM through Internet web sites.

For example, the CDC has observed that some recent outbreaks of STDs has been associated with people using the Internet to "hook up" with sexual partners, says **Ron Valdiserri**, MD, MPH, deputy director of the National Center for HIV, STD and TB Prevention.

"The Internet is the 21st century version of anonymous sex, and it's equally important to use that venue to provide information and reinforce messages about safer sex," Valdiserri adds.

In other good news, injection drug users (IDUs) residing in New York City have had a substantial decline in HIV incidence rates in recent years. That success story is directly attributed to legislative and funding changes that have made syringe exchange programs readily available to IDUs in most of the city's boroughs.

"The HIV/AIDS epidemic among IDUs in New York City is one of the biggest local epidemics in the developed world, with over 50,000 cases of AIDS among IDUs, their partners, and their children, representing about 8% of all AIDS cases in the United States," says **Don Des Jarlais**, PhD, a investigator from Beth Israel Medical Center in New York City.

"That's more cases than has occurred in any European country," Des Jarlais says. "It got started in the 1970s with the introduction of HIV into the injection drug-using population, and the percentage of infected injectors went rapidly up to about 50% by 1983 and stayed at 50% through 1991."

Early prevention work included illicit needle-exchange programs, but the HIV incidence rate

remained at a high rate: 4% to 5% of HIV-negative IDUs became infected each year, he says.

Then in 1992, the state legalized and funded needle-exchange programs. Prevention efforts, including voluntary HIV counseling and testing programs, began to show significant improvement in HIV rates.<sup>1</sup> About 40% to 50% of injectors used the exchange programs, resulting in a substantial decline in risk behaviors. This, in turn, has resulted in a dramatic decrease in HIV infection rates, Des Jarlais says.

"The percentage of IDUs infected has gone from 50% in 1990 to currently 20% of injectors who are infected," Des Jarlais says. "The new infection rate has declined from 4% to 5% per year in the 1980s to about 1% per year."

This data is based on a meta-analysis of 12 different studies with more than 6,000 person-years at risk. During the at-risk period, there were only 52 new HIV infections. The total percentage of IDUs infected is based on six studies with more than 11,000 participants.

### ***STDs, risk behaviors still increasing***

Despite these two areas of positive prevention news, the overall picture regarding new HIV infection rates is grim, according to the conference participants.

Other research presented in August showed a high HIV incidence among MSM ages 23-29 and resurgence of other sexually transmitted diseases, unprotected sex, and late HIV testing across various at-risk populations. (See related story on late testing, p. 132.)

All of these factors indicate that prevention efforts are not reaching everyone who needs to hear the message, CDC officials say.

"Men who have sex with men continues to be the highest-risk group, and we're seeing troubling signs of resurgent epidemic among gay men, with increases in STDs and risk behaviors," Gayle says.

Worse, the declines in AIDS incidence and deaths are over until new treatment advances come to light, Valdiserri says.

"Very significant numbers of people are learning they have HIV very late in the course of their infections, and even those who report risk to their doctors are often not getting the prevention and testing and counseling they need," Valdiserri says.

"To make progress in reducing AIDS cases, as well as new HIV infections, it is essential to reach these individuals with earlier testing and better

prevention and care, as well as prevention services tailored to meet their specific needs,” he adds.

Several reports highlighted the problem of late HIV testing. For instance, the CDC reviewed behavior data from 12 states and local health departments participating in a supplemental HIV/AIDS surveillance project. The CDC found from 18,850 interviews that 40% of people diagnosed with AIDS from 1990 to 1999 first discovered they were infected with HIV within one year of the time they found out they had AIDS, says **Michael Campsmith**, a CDC investigator.

Late testing was common in all groups, regardless of age, ethnicity, gender, or HIV risk exposure category, Campsmith says.

“Given that without treatment AIDS typically develops 10 years after infection, this means that many of these patients had gone as long as a decade without appropriate medical support or prevention services,” Campsmith adds.

The large cohort interview found that 40% of men and 41% of women were tested late. About 46% of black and Hispanic men tested late, compared with 32% of white men. Also, 42% of black women and 44% of Hispanic women reported late testing, compared to 36% of white women. When divided by risk category, researchers found that 39% of MSM, 40% of IDUs, and 51% of people who were exposed to HIV through heterosexual contact were tested late, Campsmith says.

In a similar CDC study presented at the prevention conference, late testing was found to be especially true for men, certain ethnic groups, and people over age 30.<sup>2</sup>

That study showed that 45% of men had been tested late compared with 31% of women, and that 53% of people age 45 or older tested late compared with 26% of those who were under age 30.

### ***Kaiser weighs in on late testing***

Late testing was also the subject of a recent study by the Kaiser Permanente National Consortium Chair, which was formed by Kaiser Permanente of Oakland, CA.

A large health care insurer, Kaiser provides health insurance to 12,000 HIV-infected people and used this database to determine best practices in HIV care.

“We identified all cases of HIV infection newly diagnosed in 1998 among Kaiser Permanente members who had been members for at least one year,” explains **Leo Hurley**, MPH, a data analyst with Kaiser.

After identifying 434 HIV cases nationwide, investigators reviewed these patients’ medical records for up to five years prior to diagnosis, looking for clinical events and patient characteristics that might have been expected to trigger an earlier test for HIV, Hurley says.

They found that nearly half of the cases had AIDS-defining CD4 cell counts at diagnosis, and these patients may have benefited from earlier detection.<sup>3</sup>

“We found that 44% of the cases had immunological AIDS at first diagnosis of HIV,” Hurley says. “And 40% of the case had either risk factors or clinical signs of possible underlying HIV infection noted 12 or more months prior to diagnosis.”

Also, according to chart notes, many of these cases had been identified as being at risk for HIV infection on one or more occasions, but not all of the people were subsequently tested for the virus. Some were tested and found negative, but others were offered HIV testing that they declined, and others were not offered testing, Hurley adds.

### ***Early warning signs missed***

“Our third finding was that after diagnosis, it was determined that 80% of the cases belonged to the highest-risk category of male-to-male sex, and this was noted in the chart prior to diagnosis less than half of the time,” Hurley says.

“The bottom line of the study is that even among persons with reasonable access to quality health care, HIV may go undetected for several years after infection,” Hurley adds.

The study’s seven diagnostic clinical events were oral infection, pneumonia, unexplained fever, herpes zoster, seborrheic dermatitis, night sweats, and unexplained weight loss.

The CDC prevention conference highlighted a few programs that have successfully reached at-risk populations with testing, counseling, and treatment referrals. These include a North Carolina outreach project that targets the homeless and a Maryland HIV testing van program that visits areas where HIV prevalence is higher.

HIV-positive and at-risk individuals also fall through health care system cracks with regard to condom use counseling, according to some studies presented at the CDC conference. (**See story on recent prevention studies, p. 125.**)

“People who are newly diagnosed with STDs may not know that they are at increased risk for transmitting HIV to partners,” says **Thomas Lampinen**, PhD, an investigator from the

University of Washington in Seattle.

A solution might be for HIV clinics to regularly include a drug and sexual risk assessment on an annual basis and use this information to enhance and supplement prevention counseling, Lampinen says.

In a Chicago study, researchers found that a significant number of MSM and high-risk heterosexuals who were infected with primary syphilis were not being tested for HIV. That indicates that real and perceived barriers to HIV testing need to be addressed as part of prevention efforts, says **Carol Ciesielski**, MD, a physician with the Chicago Department of Health and author of a study conducted about HIV infection among men with syphilis in Chicago.

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## *Special Report: Prevention Conference Coverage*

# New studies focus on increased risk behaviors

*Here's the latest data on the HIV prevention front*

**E**vidence is mounting that men who have sex with men (MSM) and other groups at high risk for HIV infection are increasingly taking risks through unsafe sexual contacts.

Seven studies presented at the Centers for Disease Control and Prevention's 2nd National HIV Prevention Conference, held in Atlanta on Aug. 12-15, 2001, demonstrated significant sexual risks being taken by individuals in eight large American cities.

Studies presented at the conference also dealt with HIV testing among men with infectious syphilis, negotiated safety and risk reduction, and risk reduction counseling.

Here are summaries of some of the prevention studies presented at the conference:

• **High HIV incidence among young MSM (YMSM):** Results from the 1998-2000 Young Men's Survey, which included 2,823 MSM ages 23-29 in six cities, show a high HIV incidence rate and prevalence among this cohort, particularly among African-Americans and other men of color.<sup>1</sup>

The HIV incidence rate was 5% overall, with a 16% incidence rate among African-Americans, 7% among men who identified themselves as mixed/other race, and 5% among Hispanics. These compare with a 3% incidence rate among white YMSM surveyed.

Prevalence levels were 30% among African Americans, 10% among men of mixed/other race, 15% among Hispanics, 7% among whites, and 3% among Asian-Americans.

Investigators had interviewed YMSM at public venues, providing participants with counseling and drawing blood for HIV testing. Incident infections were determined by having HIV-positive specimens tested with the Serologic Testing Algorithm for Recent HIV Seroconversions (STARHS). Out of 294 positive specimens that were STARHS-tested, 43 were incident infections.

• **Increased drug use and anonymous sex among MSM:** San Francisco researchers distributed a self-administered survey on drug use and sexual behavior to a sample of MSM patients undergoing rectal gonorrhea screening at San Francisco municipal STD clinics from January to October 2000.

Investigators found that 7% of the 566 MSM patients who finished the survey had a positive gonorrhea diagnosis, and those with gonorrhea were more likely to be HIV-positive.<sup>2</sup>

MSM with gonorrhea also were more likely to report anonymous receptive anal sex in the past two weeks and were more likely to report having met their most recent sexual partners anonymously, including at bathhouses and over the Internet.

MSM with gonorrhea also were more likely to report injection drug use over the past three months and non-injection drug use during sex, although these behaviors were lower among HIV-positive MSM with gonorrhea than among HIV-negative MSM with gonorrhea.

- **HIV risk behaviors among African-American women:** African-American women ages 17-44 in Atlanta were surveyed about their HIV risk behaviors. The preliminary findings showed that 70% of the 250 women surveyed reported they were sexually active. Of those, 65% said they had not used a condom every time they had sex.

Also, 67% said they intended to use a condom during the next six months, although about 45% said they had not used a condom at all during the past two months.<sup>3</sup>

About 49% of those surveyed said their sexual partners had not been tested for HIV or that they didn't know whether their partners had been tested. About 1% said their partners had been tested and were positive for HIV. Among the women, about 23% said they had never been tested for HIV, and 3% said they had tested positive for the virus.

- **High prevalence of HIV and associated risk behaviors among YMSM:** Using a three-stage residential probability-sampling scheme of MSM ages 18-29 in Miami Beach, investigators interviewed 100 men who completed a questionnaire and provided a specimen of oral mucosal transudate for HIV antibody testing.

HIV prevalence was 16%, with similar rates for whites and Hispanics. Nearly 46% of YMSM said they had engaged in unprotected anal intercourse within the previous 12 months.<sup>4</sup>

About 49% said they had cruised for sex at least once a month; 43% reported having had four or more anal partners in the last 12 months; and about 49% said they had had sex while high on drugs or alcohol during the last 12 months.

While two-thirds of the YMSM who tested positive for HIV said they had known they were HIV-positive, those who tested positive were almost as likely as those who tested negative to engage in unprotected anal intercourse, with rates of 40% for those who tested positive and nearly 47% for those who tested negative.

- **HIV infection and unsafe sex among older MSM in Miami Beach:** The same researchers who conducted the Miami Beach study of YMSM also looked at MSM ages 30 or older in an area of Miami that has been identified as a gay hotspot.

Using a three-stage residential probability sampling scheme, investigators interviewed 113 MSM and had them complete a questionnaire and provide a specimen for HIV antibody testing.<sup>5</sup>

Of the 105 older MSM who were enrolled in the study, about 98% had been previously tested

for HIV, and about one-third tested HIV-positive. Nearly 47% of the MSM reported engaging in unprotected anal intercourse while high on alcohol or drugs, and about 45% said they had engaged in unprotected anal intercourse within the past year.

Those who reported engaging in unprotected anal intercourse were more likely to have had a primary partner and to have agreed with the statement "sex does not feel as good when I wear a condom."

### ***Unsafe sex increases in Seattle***

- **Resurgence in unprotected sex among Seattle MSM:** Researchers gathered behavioral data from 13,145 MSM who presented for testing at Seattle's main publicly funded alternative testing sites between 1994 and 2000.

In that period, the proportion of MSM testers who reported unprotected receptive anal intercourse was 43%, while 47% reported unprotective insertive anal sex. Since then, there has been an upward trend of MSM testers reporting unprotected anal sex.<sup>6</sup>

In the 1998-1999 period, 51% of MSM testers reported unprotected receptive anal intercourse and 54% reported unprotected insertive anal sex, with the greatest increases occurring among young MSM ages 14-25 and men of color.

Also, there was a 28% increase from 1994 to 2000 among MSM reporting six or more male sex partners within the previous year.

- **Condom use among HIV-positive MSM:** Between July 1996 and December 1999, 314 men infected with HIV were enrolled in an open cohort study that had participants complete questionnaires every four months, measuring partner-specific sexual activity and condom use.

Initially, the percentage of men reporting unprotected anal intercourse was stable, ranging from 32% in 1996 to 29% in 1998. But in 2000 this increased to 43% of men reporting unprotected anal intercourse.<sup>7</sup>

HIV-positive MSM with serodiscordant partners used condoms for 64% of 9,771 acts with HIV-seronegative partners and for 62% of 1,832 acts with partners of unknown HIV status. These rates are higher than rates of condom use for acts with HIV-seropositive partners. HIV-positive MSM used condoms for only 19% of 8,277 sexual acts with HIV-seropositive partners.

*(Continued on page 131)*

# AIDS GUIDE

## For **Health Care Workers\***

### Guidelines to help you better detect HIV-positive patients

#### *Too many lost opportunities*

**R**esearchers at the Centers for Disease Control and Prevention's 2nd National HIV Prevention Conference, held in Atlanta on Aug. 12-15, presented various studies showing how clinicians often miss opportunities to identify patients who are HIV-infected.

Large nonprofit health insurer Kaiser Permanente of Oakland, CA, has also investigated these types of missed opportunities and found that there are seven clinical events that indicate the patient should be tested for HIV infection: oral infection, pneumonia, unexplained fever, herpes zoster, seborrheic dermatitis, night sweats, and unexplained weight loss.

Based on these clinical events, national screening guidelines, and the company's research, Kaiser Permanente has developed clinical practice guidelines for HIV care. With Kaiser Permanente's permission, *AIDS Alert* presents these

excerpts from the guidelines, which address HIV and STD screening and initial evaluation of HIV-positive adults:

#### **Diagnosing HIV Infection**

##### **Screening for Human Immunodeficiency Virus Infection**

HIV infection continues to have significant impact on morbidity and mortality. Early detection and treatment are extremely important for the population infected. Early detection of HIV may also prevent further transmission. Perinatal transmission can be dramatically reduced with early detection and intervention. Screening for HIV is recommended for all pregnant women and those contemplating pregnancy. Individuals focused on risk-reduction strategies are most effective in reducing subsequent risk behaviors. All HIV test pre- and post-counseling and results for purposes of risk reduction should be provided

by appropriately trained medical professionals.

Screening tests that have high sensitivity, specificity, and reliability are available. The initial screening test to detect antibodies to HIV is the enzyme immunoassay (EIA or ELISA). If HIV exposure of less than three months or acute retroviral syndrome is suspected, HIV viral load testing is recommended. Although the sensitivity of currently available tests for detecting HIV infection has improved, a true negative test is best assured by re-testing four to six months after the last possible exposure.

Patient history is an imperfect way to assess risk for HIV. Patients may conceal high-risk behaviors (e.g. injection drug use, men in heterosexual relationships who also have sex with men). Others, especially women, may be unknowingly at risk from an infected sexual partner. Using the following practice steps can assist clinicians in screening their patients for HIV infection.

### **Practice Steps for Infection Screening and STD and HIV Prevention and Counseling**

- Take a sexual history as part of routine and periodic health examinations, using questions such as these:
  - “Are you currently or were you recently in a sexual relationship?”
  - “Have you had sex with men, women, or both?”
  - “With how many men or women have you had sex in the last six months? Last year?”
  - “What proportion of the time have you used a condom during sexual activity over the past six months? Last year?”
- Determine last possible exposure.
- Identify and screen patients at risk for HIV infection, including but not limited to:
  - Anyone who acknowledges having unprotected sexual activity.
  - Patients with current or previous STD.
  - Patients with history of recreational or intravenous drug use.
  - Men who have sex with men.
  - Patients who receive transfusions of blood products in the United States (except immune globulin) between 1975 and 1985. Currently, transfusion continues to be a risk in many other parts of the world.
- In addition, consider screening for HIV infection in adults less than 60 years old with pneumococcal pneumonia, shingles, thrush, hairy leukoplakia, generalized adenopathy, unexplained fever or weight loss, seronegative mono-like illness, seborrheic dermatitis, hepatitis B, hepatitis C, and/or tuberculosis.

- Take a drug use history as part of routine and periodic health examinations.
- Women who are pregnant or considering pregnancy should be offered testing with informed consent. Voluntary testing is recommended for all pregnant women.
- Counsel all sexually active adults and teens on the potential risk of STD and HIV infection and means of reducing risk.
  - Create a personalized plan for STD risk reduction:
    - Create a realistic plan that maximizes safety.
    - Motivate patients for behavioral change.
    - Avoid language that may be insensitive to patient differences and which may impair disclosure.
  - Screen for STDs and HIV as indicated.
  - If patient is HIV-positive, provide immediate counseling and refer to an HIV specialist for further evaluation.
  - Be alert for signs of depression and for a history of use of drugs and alcohol during sex — all of which may impair safer sex practices.
  - Offer latex condoms and information on appropriate handling and lubricants to all sexually active persons.
  - Assist the patient in creating a personalized plan for HIV risk reduction:
    - Avoid false reassurance.
    - Motivate patients for behavioral change.
    - Avoid language that may be insensitive to patient’s background and which may impair further disclosure.
    - Counsel regarding drug use, especially injection drug use.

— Offer latex condoms and information on appropriate handling and lubricants to all sexually active persons.

- Reassess sexual practices at future visits and plan for repeat testing (if person is HIV-negative), as appropriate.

### **Initial Evaluation of Adults with HIV Infection**

This information is provided for the primary care provider faced with the initial evaluation of a patient with newly diagnosed HIV infection. It can also be used by the provider at the initial visit of a patient with known HIV disease entering the provider’s practice. Refer the patient to an HIV specialist for consultation and treatment. Below is the full evaluation that should be completed on all patients with HIV infection.

#### **The Initial History**

- Establish how and where the HIV diagnosis was made.
- Ask if the patient had a history compatible with an acute retroviral illness (or prior negative test) and thereby make an estimate as to the length of HIV infection.
  - Ask about infections that may be related to HIV, e.g., thrush, oral hairy leukoplakia, recurrent HSV, VZV, recurrent vaginitis, cervical cancer or CIN, molluscum contagiosum, PCP, or other OIs.
  - Ask about history of malignancy such as Kaposi’s sarcoma or non-Hodgkin’s lymphoma.
  - Ask about any hematological complications such as ITP, neutropenia, or anemia.
  - Review sexually transmitted diseases:
    - Syphilis: how diagnosed and when; where and how

treated; establish last titer of RPR. Has patient ever had a spinal tap to rule out neurological syphilis, gonorrhea, chlamydia, HSV, chancroid, hepatitis A, B, C, or condylomata.

- Inquire about:
  - Last Pap smear.
  - Exposure to TB: last PPD.

If positive, was patient treated with medication? Establish type and duration of therapy. Document date of last negative PPD.

— Immunization history:

Pneumovax, hepatitis A vaccine, hepatitis B vaccine, influenza vaccine, DPT, MMR, polio.

— Last eye (dilated retinal) exam: important if patient has fewer than 100 CD4 cells and is therefore at risk for CMV disease.

— Last dental visit.

— Psychiatric history: especially regarding depression, anxiety, suicidal ideation, or psychiatric hospitalization.

— Any prior experience with HIV therapy-specific drugs, duration of therapy, complications, or side effects from therapy.

#### **Medications**

- History of previous medications.
- Any use of alternative agents (nutritional, psychological, herbal, acupuncture).

#### **Allergies**

- Dates and types of reactions.

#### **Social History**

(Some or all of this information may be gathered by clinical support personnel):

- Ethnicity.
- Health-related behaviors: tobacco, alcohol, and drugs.
- Patient birthplace and residence history.
- Travel history: Establish

risk for reactivation of geographically endemic infections such as histoplasmosis and coccidioidomycosis.

- Any history of donated blood, organs, or semen.
- Pet/animal exposure.
- Employment history.
- Establish how the patient was infected by asking the following nonjudgmental questions:

— Have your sexual partners been women, men, or both?

— Do you have a history of injection drug use?

— Have you shared needles for injection drug use?

— Have you had a transfusion or received blood products, especially between 1975 and 1985?

— Have you been the recipient of artificial insemination by an unidentified donor?

- Review specific sexual practices and discuss safer sex techniques.
- Determine marital/relationship status and partner's health status and their access to health care, including HIV testing and whether the spouse/partner is aware of patient's seropositive status.

- Determine who knows about the partner's HIV status/diagnosis.

- Determine participation in any HIV support groups.

- Review diet and unusual dietary habits; review good nutrition and high-risk foods.

- Inquire about exercise.
- Inquire about insurance.

#### **Review of Signs and Symptoms**

A complete review of systems should be performed, with special attention paid to the areas listed below:

- Skin: skin discoloration, seborrheic dermatitis, psoriasis, new pigmented lesions, folliculitis, pruritus, vesicular lesions, nodules, straightening of hair in African-Americans, onychomycosis.

- Lymph nodes: localized or generalized enlargement of lymph nodes, a recent decrease in size of previously enlarged nodes.

- Eyes: vision change or loss.
- Mouth: oral sores, gum disease, aphthous ulcers, white areas on tongue (Candida, OHL), generalized oral pain.
- Neurologic and psychiatric: persistent and severe headaches, memory loss, loss of concentration, depression, apathy, paresthesias, paralysis or weakness, cognitive difficulties, seizures and sleep disorders, mood swings.

#### **Physical Examination**

A complete physical examination should be performed on all patients. It is common in the asymptomatic patient to have a normal physical examination. Special attention should be paid to the following areas: skin, lymph nodes, eyes, oropharynx, abdomen, genitourinary, anorectal, and neurologic.

#### **Baseline Laboratory Tests**

- HIV serology (strongly recommended if no prior confirmation is available and patient is asymptomatic with a normal CD4 cell count).

- CBC with differential and platelets.

- T-lymphocyte panel (CD4 count and %, CD8 count and %, and CD4:CD8 ratio).

- HIV viral load.

- Liver enzymes: ALT (=SGOT).

- Serum creatinine.
- RPR.

- Hepatitis A IgC and hepatitis B core antibody (Hepatitis B surface antigen and hepatitis B surface antibody if core antibody is positive) and hepatitis C antibody.

- Toxoplasma IgG (to identify patients at risk for reactivation).
- PPD (positive > 5mm).
- Pap smear.
- Lipid panel.
- Blood sugar.

*[Editor's note: For more information about Kaiser's guidelines, contact the company's Department of Quality and Utilization at (510) 987-2475 or at 1800 Harrison, Suite 410, Oakland, CA 94612.] ■*

## Rapid HIV tests make comeback

Rapid HIV tests will again allow hospitals to quickly determine the need for post-exposure prophylaxis (PEP) after needlesticks. The Abbott Murex Single Use Diagnostic System (SUDS) HIV-1 test, the only rapid HIV test currently licensed for the U.S. market, was re-released in May. It had been withdrawn in October due to manufacturing problems. The Centers for Disease Control and Prevention and the Food and Drug Administration (FDA) are encouraging the entry of other HIV tests into the U.S. market. About 60 rapid HIV tests are available in other countries.

By using more than one rapid HIV test, hospitals could reduce the likelihood of false positives and improve confidence in the test, says **Bernard Branson**, MD, a medical epidemiologist in CDC's division

of HIV/AIDS prevention.

Rapid HIV tests offer results in as little as 10 or 15 minutes, allowing clinicians to respond quickly with appropriate PEP. However, HIV experts remain concerned about false positives and unnecessary use of PEP in low-prevalence populations.

If the specificity of the test is 99.6%, that means "four out of a thousand will be false positives," notes Branson. If a low-prevalence area has an HIV rate of .4%, or four out of a thousand in the population, the testing of a thousand people would produce four true positives and four false positives, he explains. "Half of your positives would be false positives."

That problem can be resolved by using more than one type of rapid HIV test, he says. "If the first [test] was positive, you would retest with the second one. If they're both positive, you have a very high degree of confidence that it's truly positive."

In rare cases, a hospital might need a third rapid HIV test to resolve a discrepancy between the two, he says. "The majority would only need to be tested once," Branson says. "A positive would need to be tested and, if those two disagreed, it would need to be tested a third time."

For the first time, the use of multiple rapid HIV tests is possible, at least for some hospitals. Trinity Biotech in Dublin, Ireland, received an Investigational Device Exemption for its Uni-Gold HIV test and is recruiting 20 hospitals to participate in the limited trial.

The Uni-Gold, which is used worldwide but has not yet been approved by the FDA, has a simple protocol and produces

results in about 10 minutes, says **Ron Cruver**, Uni-Gold product development manager for Trinity Biotech USA in Jamestown, NY. The CDC has been conducting comparative studies on six investigational tests, including the Uni-Gold.

Hospitals also are reporting results with the currently available SUDS test. At the University of Virginia (UVA) Health System in Charlottesville, in a low HIV-prevalence area, 884 SUDS tests performed after needlesticks from January 1999 to September 2000 produced only one false positive, says **Heidi Flanagan**, RN, HIV and bloodborne pathogen coordinator.

While the SUDS test was off the market, 132 tests of source patients using the EIA (enzyme-linked immunoassay) test also produced one false positive, says Flanagan, who presented her results at the April meeting of the Society for Healthcare Epidemiology of America.

Even with rapid HIV tests, the CDC recommends follow-up testing with an EIA, Branson says.

*(Editor's note: Information about the Uni-Gold IDE is available on the Trinity web site, [www.trinitybiotech.com](http://www.trinitybiotech.com).) ■*

*AIDS Guide for Health Care Workers is written especially for the person working in the health care setting. It explains important issues concerning AIDS in a thorough, yet easy-to-understand style.*

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- **Risk reduction counseling of HIV-positive MSM:** The same open cohort study of 314 HIV-positive MSM who completed questionnaires every four months also attempted to determine how regularly these men were targeted for regular STD screening and sexual risk assessment and the extent to which they were counseled about sexual risk reduction behaviors.

Researchers found that of 273 men who had a private provider for their HIV-related care, 89% had been sexually active during the previous year, with a median of four partners, although the range was from one to 150. Of the 190 men who said they'd had anal intercourse during the previous four months, 55% reported having unprotected anal intercourse.<sup>8</sup>

Prior health care provider counseling was received by 77% of these sexually active men, but during follow-up questioning, counseling was reported at only 11% of 1,714 study visits in which an interim health care provider visit was noted.

The study concluded that only a minority of HIV-positive MSM who report unprotected anal intercourse receive risk reduction counseling, and intervals between repeat counseling appear to be long.

- **Negotiated safety and risk reduction within HIV-negative seroconcordant primary relationships:** Negotiated safety has emerged as an alternative HIV prevention strategy among MSM in primary relationships. This typically means the partners agree to consistent condom use or avoidance of anal sex in any sexual relationships outside of the primary partnership.

In the San Francisco Bay Area, investigators recruited 316 HIV-negative MSM for a study of these behaviors. Of these, 30% reported a current primary relationship with an HIV-negative man for at least six months. Of the 94 men in a primary relationship, 39% had a negotiated safety agreement, 27% always used condoms, 24% had no anal sex, and 11% didn't always use condoms and had inadequate negotiated safety rules.<sup>9</sup>

Of the 37 men in a negotiated safety relationship, 60% complied with their set of rules and agreed to disclose rule-breaking, but 40% were not fully compliant. Researchers found that men under age 30 were more likely to be in a negotiated safety relationship than in a 100% condom use/no anal sex primary relationship, and that this likelihood was higher for men under 30 than for men 30 and older.

Investigators concluded that while negotiated safety is an alternative prevention strategy, it potentially exposes some MSM to HIV/STD risks because of their partners' failures to comply with the rules.

- **HIV testing and infection among men with syphilis in Chicago:** Chicago investigators collected data on 897 men with infectious syphilis who had reported to the Chicago Department of Public Health between Jan. 1, 1998, and July 31, 2000.

They found that 18% of the men with infectious syphilis were MSM and 82% were heterosexual. Of the 897 men, 39% knew their HIV infection status, including 55% of MSM and 36% of heterosexual men. Of 90 MSM, 48% were HIV-infected. Of heterosexual men, 6% were HIV-positive.<sup>10</sup>

Men who had more than five recent sex partners were more likely to be HIV-positive, as were MSM.

Researchers concluded that 34% of the men with infectious syphilis who had high-risk behaviors had never been tested for HIV. This included 30% of MSM and 35% of heterosexuals.

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## Late detection of HIV key for older nonwhites

### *Latest research uses large cohort*

**E**vidence that late HIV testing is a major problem, particularly for certain groups of HIV-infected people, was bolstered by a recently published study based on the HIV Cost and Service Utilization Study.

The new study, published in the *American Journal of Public Health*, found that older, non-white people often had been first diagnosed with HIV after they already were ill.<sup>1</sup>

“Prior studies have principally focused on looking at older HIV patients, principally among minorities, and these were small samples,” says **David S. Zingmond**, MD, MA. Zingmond is Star Research Fellow and clinical instructor in the department of medicine in the division of general, internal medicine and health services research at the University of California - Los Angeles.

The UCLA study, by contrast, had a nationally representative probability sample of 2,864 HIV-infected adults receiving care in the United States. About 11% of the patients who completed the baseline survey were at least 50 years old, and half of those patients were nonwhite, including Hispanics.<sup>1</sup>

The older subjects reported more disability and more often lived alone than the younger subjects of the survey. While the younger HIV patients reported more drug dependency within the past year, the older HIV patients reported similar rates of heavy alcohol use.

Older HIV patients, particularly those who were nonwhite, were more likely to have been ill before being diagnosed with HIV infection.

### *Older patients report fewer symptoms*

The study was unable to determine precisely why older nonwhite HIV patients were diagnosed later in their disease, but one possible answer might lie in the finding that older patients, particularly nonwhite ones, tend to report fewer symptoms to clinicians, Zingmond says.

“The implication could be they report fewer symptoms because they’re healthier, or they report fewer symptoms because they disregard the symptoms,” Zingmond says. “In HIV and non-HIV literature it is true that older individuals report fewer symptoms, but how to put that together is not clear.”

What is clear from the survey is that older non-white HIV patients are being diagnosed at a later stage of disease despite having a regular source of health care, and this leads to more rapid disease progression, Zingmond says.

This fact alone suggests that clinicians need to screen older nonwhite patients more carefully, asking specific questions about symptoms and risk factors that the patient may otherwise fail to disclose.

“If you’re older and poorer and less educated and socioeconomically disadvantaged, then you’re more likely to have health care problems, and this is a general observation across diseases,” Zingmond says.

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# New hope raised for OTC antiviral lubricants

## *Three sexual lubricants destroy HIV in vitro*

After the disastrous findings involving nonoxynol-9 and its use as an antiviral vaginal lubrication, clinicians may have been tempted to think there was very little possibility of finding a spermicide that could kill HIV-infected cells.

However, the possibility of finding a safe and effective antiviral lubricant was given new life by a recently published study by researchers at the University of Texas Medical Branch (UTMB) at Galveston.

Investigators found in test-tube experiments that three over-the-counter sexual lubricants inhibited HIV production by more than a thousandfold when studied in vitro.

“We screened 22 of these preparations, and using two to three criteria we brought it down to three from different companies that would have this protective effect,” says **Samuel Baron, MD**, professor of microbiology/immunology at UTMB.

“We mimicked an in vivo situation by using seminal fluid with HIV-infected cells in the fluid or HIV free virus,” Baron explains.

By layering the lubricants on HIV-infected white blood cells, investigators were able to reduce viral output by more than 30 times. When the lubricants were mixed with HIV-infected cells, the viral output was reduced by more than one thousand times.

The three lubricants found to meet all criteria also are in the Food and Drug Administration’s safest category for such products, Baron says.

## *Lesions permitted HIV transmission*

The problem with the spermicide nonoxynol-9, which also showed potent antiviral capabilities in vitro, was that it irritated mucous membranes of the vagina and rectum. That caused lesions that permitted transmission of HIV from seminal fluid, which led to higher rates of HIV infection among one study’s participants who used the product, Baron says.

UTMB investigators theorized that if a product designed to be used in the vagina or anus during intercourse could be found that would not irritate

skin, then perhaps it still could successfully block HIV transmission.

“We needed a similarly highly active material against HIV without any of the irritating properties, so we did a simple study trying to identify all the lubricants that had various preservatives and surfactants and materials that make them slippery and potentially as potent as nonoxynol-9,” Baron explains.

The lubricants, sold as Astroglide, Silken Secret, and Vagisil, significantly reduced viral output when mixed with HIV-infected cells, according to a study published in *AIDS Research and Human Retroviruses* on July 20, 2001.

“Our report is to point out that there is a very high potential for these materials, which have already been tested and distributed throughout the world,” Baron says. “They’re potentially very inexpensive and deserving of a field trial like the one nonoxynol-9 had, and we’re trying to arrange that with various government agencies, which isn’t easy.”

The Texas researchers also have contacted international health organizations about the potential benefits of studying these products.

## *Poor nations could benefit greatly*

Future published papers will address which of the three lubricants’ chemical components were potent against HIV. This information would enable poor nations to make the same products for a fraction of the current cost of supplying such products, Baron says.

“No one is advocating avoiding condoms, because condoms are clearly the best way to go, but the addition of a lubricant which has additional supplemental activity would likely enhance the protection of condoms,” Baron says.

Also, because the three lubricants found to have effective antiviral qualities can be purchased by anyone, and because they are considered by the FDA to be in the safest category of any lubricants sold in the United States, then there is ample reason for physicians to let patients know that, in addition to a condom, these three lubricants may provide protection against HIV transmission, Baron adds.

While a field trial still is needed to prove whether these lubricants will reduce HIV transmission among at-risk populations, it may not be necessary for at-risk individuals to wait until all studies are complete before adding the use of these products to their safer sex practices. ■

# Routine testing shows benefits in urban hospital

*Atlanta effort finds more HIV-positives*

Following up on its 1993 recommendations that hospitals and clinics in areas with high rates of HIV prevalence offer routine HIV testing to patients, the Centers for Disease Control and Prevention in Atlanta conducted a recent study of such a practice.

From March 20, 2000, to Sept. 1, 2000, clinicians at Grady Memorial Hospital in Atlanta were encouraged to recommend HIV testing to all urgent-care clinic patients between the ages of 18 and 65. Those who had been tested for HIV within the previous six months were not included in the recommendation.

CDC researchers compared the HIV-positive results for this 24-week period with a 24-week period in 1999 in which HIV testing was conducted only when clinicians were concerned about patients' symptoms or risk behaviors.

The study found that in 2000, 1,687 more patients were tested, 27 more infections were newly detected, and twice as many HIV-positive patients entered into medical care.<sup>1</sup>

"The 1999 data was our comparison group, and because it was data retrospectively collected, physicians were not aware we were looking at that information," says **Sheryl Lyss**, MD, an epidemiologist formerly with the CDC's Division of HIV/AIDS Prevention. Lyss was an author of the CDC study, published in the *Morbidity and Mortality Weekly Report*.

The CDC study was prompted by findings in 1997, also from a study done at Grady Memorial Hospital, that nearly two-thirds of inpatients newly diagnosed with AIDS had received medical care within the Grady health system during the 12 months preceding admission, Lyss says.

"That was a wake-up call," she explains. "These were opportunities to diagnose them before they become symptomatic, and the earlier we diagnose them, the earlier we can help them take advantage of medical care to protect their own health and to encourage them to adopt behaviors that will protect their partners."

Both the 1999 and 2000 periods that were studied had about 20,000 clinic visits. During the study period, the hospital displayed posters encouraging patients to be tested for HIV. Patients

also were given a brochure about HIV testing. When patients accepted testing, they provided written consent and were not charged for the test, which was conducted with either a Single Use Diagnostic System HIV-1 test or a standard enzyme immunoassay. All positive tests were confirmed with Western blot.

Based on these data, the CDC continues to encourage routine HIV testing at clinics located in areas with high HIV prevalence. The recommendation is even more important now than it was in 1993, Lyss says.

"The HIV landscape has changed considerably to make this recommendation more important, more feasible, and more necessary," Lyss says. "First, we have HIV therapy now to offer infected individuals, and we know now that HIV counseling services can help patients protect their partners, and we know that more of the public is aware of HIV."

However, the CDC is aware of the fact that various barriers may impede routine testing. These include the following:

- Even the rapid HIV test didn't have results quickly enough to provide most patients with an HIV diagnosis during their urgent care visit. About 27% received their rapid test results on the same day. "We think that if there were a test available in which patients could be tested and receive results rapidly, the clinicians would more strongly recommend the HIV test," Lyss notes.

- Clinicians are unaware of the benefits of routine HIV testing in these high-prevalence areas. The Atlanta hospital had a 2.7% HIV-positive rate among the HIV tests conducted, and physicians need to be taught how this is a very high rate from an epidemiological perspective, Lyss says.

"I think clinician education is one way of addressing barriers both in terms of helping them integrate this into their clinical routine in a positive and not time-consuming way and to help them understand the importance of this kind of approach," Lyss adds.

- The cost of HIV testing also is a barrier. While it may provide a cost savings to society in the long term, it requires individual health care institutions to absorb a short-term cost that may be difficult to justify given the current tight financial restraints facing many health care systems, Lyss says.

"We hope this data will encourage more collaboration between public health departments and clinical settings, and perhaps public health departments through their financial and human

resources could help in the implementation of this kind of strategy,” Lyss explains.

CDC investigators will continue to assess the routine HIV testing results, studying patients’ exit interviews to determine how they felt about HIV testing and what their issues were with regard to acceptance and barriers, Lyss says.

“In our study, 60% of patients declined HIV testing, so a 40% acceptance is a pretty high rate, but we think there is room for improvement there,” Lyss adds. “Certainly one of our hopes is that by incorporating HIV test recommendations routinely in clinical settings, it will help to make HIV testing more routine and more acceptable to patients.”

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# Investigators study role of IL-7 in HIV progression

## *Findings suggest good news/bad news*

San Francisco investigators have been studying interleukin-7 (IL-7) and its role in HIV disease progression in hopes of better understanding how T-cell production is regulated and how this knowledge might be applied to therapeutic intervention and immunosuppression in either AIDS patients or bone marrow transplant patients.

This interest has led to the discovery that IL-7 is produced in response to T-cell depletion, thus facilitating T-cell production — but at the same time fostering HIV-1 disease progression.

“The regulation of T-cell production is not well-understood,” says **Laura Napolitano**, MD, staff scientist with Gladstone Institute of Virology and Immunology in San Francisco.

“We really don’t understand how T-cell production might be regulated, and this is of increasing interest as we have more and more patients with immunodeficiency,” Napolitano says.

Several years ago, researchers involved in this project studied HIV patients’ thymuses to determine whether they could be made functional in adults, Napolitano says. They found that the

thymus was larger in HIV patients than in non-HIV infected people of the same age.

“That raised the premise in our mind that perhaps the thymus is getting larger because it’s trying to make new T-cells,” Napolitano says.

In the most recent study, researchers asked the question: “As T-cells fall in HIV disease or other conditions, does the body at some point sense that and send a signal that says it needs more T-cells that could result in increased production and expansion of T-cells?” Napolitano relates.

Previous research has shown that IL-7 is crucial for the production of T-cells. IL-7 is produced in the thymus, bone marrow, and lymph nodes. There are also low but detectable levels of IL-7 circulating in the blood.

Investigators analyzed the blood of 158 HIV patients to determine whether a rise in IL-7 would follow a decline in CD4 cell counts. “We found that there was a strong correlation so that if the CD4 cell count fell, the other would rise,” Napolitano says, adding that this result should be assessed cautiously. “There are other possible interpretations as well,” she notes.

The researchers eventually concluded that it was logical to assume that IL-7 was made in the lymph nodes, so they did a marker test, taking microscopic sections and looking for cells producing IL-7.

“We found that there was a lot more IL-7 in those samples that didn’t have T-cells,” Napolitano says.

Further results suggested that as the T-cells become depleted from the lymph nodes, these cells respond by producing IL-7, resulting in T-cell production and expansion, she adds.

While this would appear to be a potential area of clinical application, the findings weren’t that simple.

“We looked at 168 patients, who were all adults with HIV infection, we found that those with higher IL-7 levels tended to have higher viral loads, which suggests that something is going on there and needs to be better investigated,” Napolitano says.

Possible reasons for this problem could be that IL-7 acts to accelerate HIV infection by stimulating the proliferation of T-cells and making them more susceptible to HIV infection. Alternatively, IL-7 might somehow interact more directly with the virus to enhance its replication, Napolitano speculates.

“It’s a theoretical concern, and we need to learn more about what that interaction is and

how it occurs, then take into consideration whether this is something that would be a concern if IL-7 were to be given to individuals with HIV infection,” Napolitano explains.

“The bottom line for clinicians is there is definitely progress being made in our understanding of how the production of T-cells is regulated,” Napolitano says. “And hopefully over the next decade this will lead to trials where therapeutic interventions are developed with factors that might be interleukin-7 or other factors considered more suitable to stimulate T-cell expansion.” ■

## HIV resistance testing benefit is shown

**T**ibotec-Virco NV of Belgium has presented results of a study showing that its Virco resistance tests can predict clinical response to HIV treatment for up to two years.

Carried out on 681 HIV-positive patients at the Chelsea and Westminster Hospital HIV Clinic of London, the study entailed the use of Virco’s proprietary VirtualPhenotype and Antivirogram resistance tests to estimate the number of drugs to which each patient’s virus was still susceptible over a 96-week period.

The viral load and CD4 cell counts were then compared for patients receiving none, one, two, three, or four active drugs. The two tests were found to be equal and significant predictors of outcomes over 96 weeks. Patients receiving three or four active drugs experienced significantly greater reductions in viral load and increases in CD4 cell count during the period of the study, and a higher proportion of these patients saw their viral loads fall to undetectable levels.

The Virco VirtualPhenotype test combines both phenotyping and genotyping. It reads the patient’s genetic code and detects all resistant mutations. The data are fed into Virco’s computer system, which searches a database of some 100,000 genotypes and phenotypes for virus samples with the same mutation patterns. The system retrieves the corresponding phenotypes for the mutations found in the patient (typically thousands for each drug) and calculates the average resistance score for each drug. It thus produces a quantitative estimate of the patient’s resistance to every available drug. ■

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## CE objectives

**A**fter 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. ■

Source: Centers for Disease Control and Prevention, Atlanta.

Source: Centers for Disease Control and Prevention, Atlanta.