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OraSure begins shipping rapid HIV test to hospitals

CLIA waiver could come in several months

After years of anticipation, the first of a new generation of rapid HIV tests is being shipped to hospitals and laboratories across the country. At the same time, health officials tell *AIDS Alert* that the OraQuick Rapid HIV-1 Antibody Test soon could receive an Food and Drug Administration (FDA) waiver that would allow the test to be used in outreach settings as well.

"The estimates we are hearing are maybe a couple months," says **Robert Janssen**, MD, acting director of the Division of HIV Prevention for the Centers for Disease Control and Prevention (CDC). "It depends on the criteria the FDA comes up with that the manufactures will have to meet in terms of what studies they have to do."

In November, the FDA approved OraQuick for use by trained personnel as a point-of-care test for diagnosing HIV infection. This simple, 20-minute test, which uses fingerstick whole blood, was categorized as one of moderate complexity under the Clinical Laboratory Improvement Amendment (CLIA).[1]

Tests designated as moderately complex must be performed only by skilled technicians and in a laboratory setting. Without a waiver, the test could not be used where it is needed most — in outreach settings, such as streets and bars, where the promise of instant results can allow those at highest risk to know their HIV status.

William Bruckner, OraSure Technologies spokesman, confirmed that the company had submitted a draft protocol to the FDA proposing what studies are needed to get the waiver. "The FDA has responded

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FDA Notifications

COMING IN FUTURE ISSUES

- The President's proposed HIV/AIDS budget: Here's a look at the HIV funding battle ahead
- ADAPs faltering in some states: Long waiting lists, restrictions, and other problems cited as result of cash-poor state governments, less federal money available
- Retrovirus conference coverage: We'll look at the latest scientific and pharmaceutical news coming from investigators and NIH
- HIV vaccine update: Vaccine research continues around the world, but how close are we to a vaccine solution?
- After years of discussion and controversy, efforts are gearing up to fully integrate HIV care and HIV prevention. But are health care providers willing and ready to tear down the walls?

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and told us how we need to modify the protocol." Once the criteria are finalized, the study could be completed "in a matter of months," he says. "I can't say how fast the FDA will respond but our work is going to be done very quickly."

The study would compare test results in trained versus untrained users, he added.

On June 17, 2002, OraSure announced it had entered into an agreement with Abbott Laboratories for the co-exclusive distribution of the OraQuick test in the United States.

In January, Abbott announced that the first batches of OraQuick were sent to hospitals and physicians' office laboratories around the country. The only other rapid test on the market, SUDS (Murex Single Use Diagnostic System), has not been widely used. It can take up to an hour to receive results and is not as accurate as OraQuick, experts say.

"We think OraQuick offers a lot of advantages. It is easier to do. It can be done on a fingerstick blood sample. And the results can be available in about 20 minutes," said **Harold Jaffee**, MD, director of the CDC's National Center for HIV, STD (sexually transmitted disease), and TB Prevention.

The test was developed as a simple diagnostic tool, similar to a pregnancy test that could be used by outreach social workers targeting hard-to-reach populations. However, its moderately complexity labeling means that OraQuick must be performed in certified clinics and settings where trained technicians can administer and read the test. Dozens of medical and political organizations have urged the FDA to approve the test under a "waived" status under CLIA, enabling its use in the field, counseling centers, family doctors offices and public health clinics.

"Based on our own experiences with the test, we think that some training — not very much — and some quality assurance are needed," Jaffee says, adding that the CDC is working on developing training and quality assurance programs.

However, critics of a waiver note that waived tests are plagued by user errors. A presentation to the CDC from federal health officials showed that half of public health labs operating under waivered certification had some procedural errors. Indeed, quality assurance is a major concern for implementing rapid testing in outreach settings. While OraQuick is considered by many to be no more complex than a pregnancy test, the consequences of errors are greater, experts note.

Another concern is that counseling will be inadequately addressed when testing is performed in nontraditional settings, such as bars and sex clubs. At least one study, from the Denver Health Department, has shown that patients receiving rapid HIV test results were more likely to get a subsequent STD than those tested conventionally. Receiving tests results faster, however, has been shown to reduce the number of patients not receiving a diagnosis. One study found that when the

OraQuick couseling guidance

Here are some key points to keep in mind for anyone using the OraQuick rapid HIV test.

Pretest Counseling
- Good pretest counseling is critical.
- Standard pretest counseling plus counseling specific to OraQuick is needed.
- Client must understand that a false-reactive test is possible (i.e., a reactive test does not equal an HIV diagnosis; a confirmatory test always must be done).

Post-test Counseling[1]
- Have a written protocol.
- Go over again with patients the possibility of false-positive results.
- Get confirmatory test.
- Counsel patients regarding client-centered measures to avoid HIV transmission.
- Get good, reliable contact information.
- Make appointment for backup results.
- Assess psychological needs.
- Maintain contact with client.

Fundamentals of counseling with rapid HIV tests[2]
- Keep the session focused on HIV risk reduction.
- Include an in-depth, personalized risk assessment.
- Acknowledge and provide support for positive steps already made.
- Clarify critical rather than general misconceptions about HIV risk.
- Negotiate a concrete, achievable behavior-change step that will reduce HIV risk.
- Seek flexibility in the counseling technique and process, avoiding a one-size-fits-all approach.

References

1. Keenan P. Paper presented at the Centers for Disease Control and Prevention conference. Atlanta; September 2002.

2. Centers for Disease Control and Prevention, "HIV Counseling with Rapid Tests," Nov. 12, 2002. Web: www.cdc.gov/hiv/pubs/rt-counseling.htm. (Jan. 15, 2003). ■

time for testing in a hospital laboratory averaged 107 minutes, 55% of patients left without their results. When testing was done in an emergency department and waiting time averaged 48 minutes, only 20% left without learning their results.[2]

The CDC estimates that 30,000 HIV tests performed annually in CDC-funded counseling and testing sites are positive. And yet 25% of results go undelivered because clients did not make it to a second visit to receive results. The CDC's new strategic plan has set a goal of reducing new HIV infections by 50% as of 2005. That means 30,000 more people must become aware of their status each year. While rapid testing could help achieve that goal, some experts are concerned that HIV services are so strapped now that these new patients could not receive care. At least 14 states have no funds in their AIDS Drug Assistance Program (ADAP) budgets for new patients, and the number of states is increasing each month.

"If we get these 25% who don't know their status, we could not provide care," explains **Liza Solomon**, director of AIDS administration for the Maryland Department of Health in Baltimore. "If you offer someone a diagnosis and no treatment, that is unethical."

Next year, two out of 10 patients now enrolled in the Texas ADAP will be cut off under a plan to meet an expected $34 million shortfall over the next two years.

Taking another point of view, health professionals point out that identifying the estimated 125,000 people in the United States who don't know they are HIV-positive would create a strong political base from which to lobby for more HIV prevention and treatment funding.

The cost of the moderately complex test has not yet been set, Bruckner says, but will be comparable to current lab-based tests. He was not sure how a CLIA waiver would affect pricing of the test. Estimates have ranged from $6 to $15 per test, compared to several dollars for conventional HIV testing.

The cost of the OraQuick test will be a major factor in whether it gets adopted, public health officials say. The only other approved rapid HIV test, SUDS, costs substantially more than traditional HIV testing. Although SUDS worked well for public health clinics in New Jersey, the state has recently gone back to conventional blood testing, at least at its main clinics, in order to save money, according to state health officials.

"If this thing is too expensive, it's really going to limit its use," says **Dorothy Mann**, director of the Southeastern Pennsylvania Family Planning Council in Philadelphia.

Deanna Sykes, PhD, a research scientist at the California Office of AIDS in Sacramento, has calculated personnel costs in California for rapid HIV testing under the two CLIA categories. Based on specific qualifications required and the state's personnel classification system, hourly wages to perform rapid tests would be $9 if the test gets waived and $17 if it remains moderately complex. (Counseling times were derived from the counseling and testing database.)

She estimates that rapid tests require 15 minutes to perform.[3] Risk assessment (pretest counseling) requires about 20 minutes. Disclosure sessions (post-test counseling) average 15 minutes for HIV-negative people and 45 minutes for HIV-positive.

Annually, a total of 117,667 hours would be required for counseling, and approximately 51,000 hours for rapid testing. If the counselor also performs the test, waived HIV testing would cost California $1,518,000 per year vs. $2,867,339 for a moderately complex test — a $1.35 million difference.

If a person other than the counselor performs the test, additional personnel costs would exceed $408,000 annually if rapid tests were categorized as moderately complex, assuming these people actually spent all hours performing tests, Sykes concludes. "The requirements for reading a moderately complex test is a lab technician, so we would have to hire one to stand by as we tested in various sites — that's a $20-an-hour employee."

The CDC recommends that clinics should consider return rates for standard test results and the urgency of the need for test results (i.e., post-exposure and perinatal prophylaxis) in deciding whether to offer rapid testing.

(Editors' note: The CDC has developed a question-and-answer fact sheet on OraQuick that is posted on its web site at: www.cdc.gov/hiv/pubs/rt-faq.htm.)

References

1. Centers for Disease Control and Prevention. Notice to readers: Approval of a new rapid test for HIV antibody. *MMWR* 2002; 51:1,051-1,052.

2. Kelen G, Shahan J, Quinn T, et al. Emergency department-based HIV screening and counseling. *Ann Emerg Med* 1999; 33:1,27-1,155.

3. Sykes D, Branson B, Truax S. CLIA-waived vs. moderately complex rapid HIV testing: How much will it cost? Presented at the National STD Prevention Conference. San Diego; March 2002. ■

CLIA waiver crucial to rapid test adoption

Study finds numerous errors for waived tests

An unpublished California study has found that more than half of new HIV infections came from sites that would not be able to use the OraQuick HIV rapid test as it is currently labeled.

In 2001, the study found, 629 HIV-positive test results in the state were not delivered to patients. Nearly 400 of those results came from settings where a rapid test of moderate complexity would not be available.

The study underscores just how important it is to have a waiver from the Clinical Laboratory Improvement Amendment (CLIA) for the adoption of the Food and Drug Administration (FDA)-approved rapid HIV test OraQuick.

"My estimation is that we would be lucky to get a moderate-complexity rapid test into one-third of these sites," says **Deanna Sykes**, PhD, a research scientist at the California Office of AIDS in Sacramento.

The state has 450 publicly funded HIV testing sites. Counseling costs alone exceed $1.5 million a year.

The CLIA requirements for a moderately complex test would dramatically increase those costs, primarily because each site would need a phlebotomist to administer the tests and a qualified laboratory to analyze the results. If rapid tests were adopted in those sites, counseling costs could reach $7 million for counseling personnel alone, Sykes says.

California received funding from the Centers for Disease Control and Prevention (CDC) two years ago to evaluate the OraQuick testing in emergency departments. However, the research was not done because any test prior to FDA approval is considered highly complex and, therefore, would need trained personnel to conduct it.

"We would have liked to have been ahead of the game and provided the CDC with data but we couldn't," Sykes says. If adopting the OraQuick tests, providers must address numerous issues, such as pre-testing counseling changes, patient flow, whether one or two staff can conduct the test, and what patients will do while they are waiting for 20 minutes, she says.

"Some sites have talked about not having all counselors actually performing the rapid tests but having only one or two who would specialize in it while others would do the counseling," she explains.

The total time needed for rapid testing should be about the same as traditional testing, Sykes says. The difference will be how it is spread out. Currently, the state's counseling protocol calls for a 20-minute risk assessment at pretest and another 20 minutes at post-test counseling to discuss test results and risk reduction. With rapid testing, risk assessment and test result disclosure will be done in one session.

Perhaps the biggest increase in counseling services will be due to patients who didn't return for test results with conventional testing now will be getting their results and will need post-test counseling, she explains. "We will be increasing test loads but also increasing services."

California is working on various testing and counseling protocols in anticipation that OraQuick will get a CLIA waiver. The big question is over training requirements. "We will change counseling protocols in a handful of sites, and if things work out well we will expand them," Sykes says.

"Either way, none of our counselors can do this without additional training. We don't want to put someone out there in the position of delivering positive results without understanding what it means in their setting and how to do it in compliance with California law," she explains.

Some states have laws that prohibit untrained professionals from giving positive results.

"Our lawyers say we can deliver this type of preliminary positive result as long as we are clear about what we are saying," Sykes points out. ■

HIV prevention summit seeks new strategies

Changes in evaluation, reimbursement discussed

Hoping to refocus and re-energize the nation's HIV prevention strategies, the Centers for Disease Control and Prevention (CDC) in Atlanta recently invited more than 125 HIV prevention experts for a two-day brainstorming session. The December meeting came at a time when public health is facing increased scrutiny over how well it is utilizing HIV prevention dollars.

Although no radical changes were recommended, the diverse group did produce a long

wish list of recommendations that included:

- better reimbursement for HIV prevention services;
- less-restrictive funding;
- a more equitable evaluation process;
- increased research on behaviors for long-term survivors.

"Prevention works, but we know there are 40,000 new patients with HIV every year, so whatever we are doing collectively, it is not enough," CDC director **Julie Gerberding**, MD, told participants of the HIV Prevention Summit.

The CDC is under increased pressure from Congress to show more accountability for the nearly $700 million earmarked for HIV prevention each year in the United States. Five ongoing government audits of prevention programs and services are expected to shed light on where changes are needed most. **(See list, below.)**

"There are people who are, I think, rightly and respectfully — and sometimes not so respectfully — interested in knowing if those investments are having their maximum leverage. As the CDC director, I, too, care and want our HIV dollars spent as effectively as we can," Gerberding said.

While the recommendations carry no official weight, she said the ideas will be shared and discussed internally and intramurally at the CDC. "We will extract from that incubator some new ideas that can at least take us into a new framework for new prevention approaches while sustaining our commitment for the good work already going on," she explained.

In addition to developing new ideas, the meeting was seen as a critical step in mending relations in the prevention community, which has had to evolve as the epidemic shifts into new populations. Pressure also has come as the Bush administration adopts new approaches, such as funding abstinence-only education and faith-based organizations.

The Dec. 4-5 summit was charged to look at four areas: prevention for adolescents; knowledge of serostatus; measuring the effectiveness of HIV programs; and program gaps and research needs.

While the experts in each area agreed on the need for new strategies, there were strong disagreements on several issues, particularly abstinence-only education, HIV exceptionalism (the practice of treating HIV differently than other infectious diseases), and racial inequality in HIV leadership and funding. There was even disagreement over the CDC's decision to post the

Five different audits look at CDC's HIV programs

Critics say they are distracting

The U.S. Office of the Inspector General is conducting four audits of the Center for Disease Control and Prevention (CDC), one of which is about to be completed and another that is soon to start. At the same time, the CDC is conducting its own audit. They are:

- Since March, the Global AIDS Program in developing countries has been audited to determine if funds are being used in the best way. A report is expected in the next few months.
- An ongoing review since April is looking at how the CDC takes indirect charges from various allocations and how those indirect charges for HIV activities compare to other programs. It is not known when it will be completed.
- An audit is looking at the monitoring and oversight of CDC grantees, specifically in their compliance with financial and performance reporting requirements. This is ongoing and is expected to continue into next year.
- An audit, not yet started, will look at whether the CDC is following applicable laws in making its funding decisions. That will begin after the audit of the Global AIDS Program is completed.
- The CDC is looking at a random sample of 26 community-based organizations (CBOs) during the next six months to monitor programmatic and financial compliance with grant guidelines. So far, seven CBOs have been visited. One of them is the Stop AIDS Project in San Francisco, which has been accused of using CDC funds on programs deemed by federal officials to be obscene.

This slew of audits has generated strong feelings among CDC advisors, particularly about how auditors and CBOs were chosen.

"The auditors who visit the program come with a portfolio that may not be neutral in their thinking and which influences their decision on how money should be spent," says **Benny Prim**, MD, director of the Addiction Research and Treatment Corporation in Brooklyn, NY.

Some advisors also expressed frustration that outside audits were distracting and taking resources away from prevention activities. "I think inside auditing is the way to go, not outside auditing that tends to be generated by the political crisis du jour," says **Ward Cates**, MD, president of Family Health International in Research Triangle Park, NC. ■

summit's findings on its web site.

The CDC's new five-year HIV prevention strategy already is up and going, yet amid sexually transmitted disease outbreaks in men who have sex with men, controversial audits, and deep funding cuts at the state level, a sense of urgency permeated the discussions.

"Quite frankly, the strong message we are getting is people want to see declines in new infection and want to be able to say that declines are a result of programs in this area or that area," said **Ron Valdeserri**, MD, deputy director of the agency's Center for HIV and STD Prevention. "In the past, the CDC has used process measures, and most publicly evaluated programs say that's OK, but we are now hearing maybe that it is not OK."

Some experts cautioned that the summit presupposed that HIV prevention is in crisis and needs major changes. "We need to determine what success looks like and not be so hard on ourselves," said **Ross Conner**, PhD, associate professor of social ecology at the University of California at Irvine. "In prevention, we want 100%; and by setting such high standards, we set up ourselves to fail."

Others said science wasn't the problem, but rather the intrusion of politics in determining the future of HIV-prevention programs. "It's important we not throw away things that we have done successfully, and the answer may be that we need to do more of what we haven't been doing as well as we needed to do," said **Terje Anderson**, executive director of the National Association of People Living With AIDS in Washington, DC. "And that includes targeted education that is not afraid to speak honestly about sex and drugs. The political debates over needle exchange is just one example of where politics has triumphed over science."

To put past successes into perspective, Anderson noted that 150,000 new infections were reported each year at the height of the epidemic, compared to 40,000 today. Where prevention has failed, he said, is in maintaining a sense of urgency among communities most affected. "We have to get back to a sense of community mobilization, and my fear is that we have allowed complacency to set in because we don't care as much about the people who are getting infected today compared to 15 years ago."

Others agreed that a sense of urgency has been lost, particularly among youth who have not experienced the high mortality that faced an earlier generation. At the same time, choosing what prevention programs work has never been harder, and more guidance is needed on how to select from the "HIV-prevention supermarket."

"We see a decline in volunteers and in a willingness to jump in and make it your business if

Prevention strategies abound during CDC summit

Knowledge of serostatus covered

After two days of putting their heads together, a diverse group of HIV-prevention experts came up with dozens of proposed strategies. Here are some suggestions offered from one of four topic areas covered at a recent two-day HIV Prevention Summit at the Centers for Disease Control and Prevention in Atlanta.

The topic: "What are other strategies to improve knowledge of serostatus?"

- Establish routine testing in health care settings by integrating it with other routine health services.
- Encourage testing in regular health care by providing adequate reimbursement and making it a measure of performance for managed care organizations.
- Conduct research on educational measures, such as what messages are most effective for bringing specific populations in for testing, and why current educational messages don't work.
- Offer one-stop shopping — testing and care at the same site.
- Remove the restrictions on silo funding streams to conduct testing.
- De-exceptionalize HIV by treating it as other infectious diseases.
- Offer testing in nontraditional, community sites by gaining trust of community and using rapid testing.
- Create demand for testing through public education that is delivered through multiple, culturally appropriate channels.
- Consider mandatory education about HIV testing in all schools. Messages could be mailed to every household similar to former Surgeon General Everett Koop's strategy at the beginning of the AIDS epidemic.
- Make partner counseling and referral part of ongoing service provisions, not just a one-time intervention.
- Build HIV partner notification programs based on the sexually transmitted disease partner notification model. For example, convey the message that notifying partners is an obligation and partners known to providers must be notified. ■

someone else in your community is taking risks," said **Dan Wohlfeiler**, chief of communications for the California Office of AIDS in Sacramento. "What that suggests is we need a lot more hard thinking about strategies we select."

Racism, both institutional and individual, was blamed as a barrier to better prevention successes among minorities, as were poverty and other social ills that have not been addressed. "We have to recognize there is a crisis within a crisis — there are youth who feel alienated from school, family, and society," said **Barbara Welburn**, executive director of the National Association of State Boards of Education in Alexandria, VA. "And we have to recognize there is a lack of positive role models for these individuals in the media and in politics."

One area where the CDC has made recent inroads is working with faith-based organizations. Several examples were shared of how black churches are becoming key players in HIV-prevention efforts. In Columbus, OH, for example, the health department has been assisting the Westside Pastors' Coalition with an eight-week training for pastors at the McCormick Theological Seminary.

This training, "Empowering Our Leaders to Do Good Work," targets pastors of African-American churches on the west and south sides of the city. Topics covered included education and prevention, sexuality, theology, and pastoral care. Ten pastors received certificates and two CEU credits for completing the eight-week course.

In the area of research, the summit spent a good deal of time discussing the Internet and how it offers both opportunities and challenges. One place to begin is by improving the CDC's web site to make it more user-friendly, said **Cynthia Gomez**, PhD, co-director of the Center for AIDS Prevention Studies at the University of California San Francisco.

Another suggestion was to explore targeting on-line prevention messages based on information Internet users include in their profiles, as well as using the Internet for public service announcements.

An important area for more research is understanding behaviors of long-term survivors. Studies have shown, for example, that the ability to maintain safer sex practices diminishes after four years. Research is needed to find out why and what can be done to change this phenomenon.

Another recommendation was that funders of research should consider collaborative ways to provide money for services as well.

The summit group looking at youth strategies recommended HIV prevention professional development be taught not just to teachers but to all school personnel. It also said there must be an integration of multiple approaches in school-based programs.

"In every other discipline of education we advocate multiple approaches to instruction and this is no different," said Welburn. "And it must have comprehensive parental involvement and buy-in as it does with the community." Not only must HIV prevention education be comprehensive (abstinence, plus contraception and condom discussion for those who can't abstain), it must be a sequential and interdisciplinary approach throughout the K-12 grades, she said.

The U.S. Department of Education must also step into the debate and be solicited as a partner in HIV prevention, Welburn said. "We need to make sure that what happens at the CDC is comparable to what happens at the Department of Education." Cultural differences also should be considered in program development, recognizing "this is not just about sex but, in some instances, about relationships and goes deeper than simply HIV prevention," she said.

In one of the more heated exchanges, summit participants debated the pros and cons of whether HIV should continue to be treated differently from other infectious diseases. Many participants argued that HIV exceptionalism had resulted in barriers to testing while others noted that HIV-positive people still are discriminated against.

"Anybody who thinks the stigma against people living with HIV is over is kidding themselves," Anderson said. He noted that people who are HIV-positive still cannot join the Army or the Peace Corp or immigrate to this country. ■

New CDC condom fact sheet invites criticism

What role did politics play in changes?

An ongoing debate over the facts about condoms still is not settled, even though the Centers for Disease Control and Prevention (CDC) has posted an updated version of its on-line condom fact sheet.

The update was posted Dec. 5, and distributed at the HIV Prevention Summit in Atlanta. While there are no major changes in the facts about

condoms, differences are seen in emphasis and placement of existing information. Also, the new sheet is now twice as long and includes a kind of preamble stating that abstinence and monogamy are the only sure ways to avoid sexually transmitted diseases (STDs). For example, the added length of the document comes mainly from a new section that prefaces what made up the old document — a discussion of condom effectiveness in three areas: HIV/AIDS, discharge diseases, and genital ulcer diseases.

A new category, titled "STDs, Including HIV," discusses reasons why condom protection can vary among different STDs, as well as the limitations in studies for non-HIV STDs.

On Dec. 18, a group of 14 Democratic lawmakers sent a letter to Health and Human Services Secretary Tommy Thompson accusing the Bush administration of "playing politics" by eliminating key information on condom use in the new fact sheet and putting more emphasis on abstinence.

David Fleming, MD, the CDC's deputy director for science, defended the actions of the Bush administration, saying that the CDC chose a more neutral introduction for the condom fact sheet because of the "mixed evidence" on the issue. "We specifically tried not to nuance it in the direction of either encouraging or discouraging use of condoms," Fleming told the Associated Press.

The most significant message change is the inclusion of a warning that condoms lubricated with spermicides are no more effective than other lubricated condoms in protecting against STDs. It also emphasizes reasons why condoms are not 100% effective, including incorrect and inconsistent use.

Another change is the emphasis on the ineffectiveness of condoms in protecting against human papillomavirus (HPV) infection, which causes cervical cancer. While the old version mentions HPV only in the last section under genital ulcers and HPV infections, the new update states up front that "while condom use has been associated with a lower risk of cervical cancer, the use of condoms should not be a substitute for routine screening with Pap smears. . . ."

Under the HPV section, the update notes that "while some epidemiological studies have demonstrated lower rates of HPV infection among condom users, most have not."

According to one study, condoms do appear to increase protection against HPV disease.[1] "Available data are too inconsistent to provide precise estimates," the authors wrote. "However, they suggest that while condoms may not prevent HPV infection, they may protect against genital warts and cervical cancer." The findings suggest that condoms may help prevent warts and other HPV-related problems, possibly by cutting down on the amount of the virus transmitted, "but perhaps not actual infection by HPV," the researchers said.

The changing emphasis of the condom update parallels a recent change in the United States' position on population-control language. The U.S. delegates at the Fifth Asian and Pacific Population Conference requested the removal of a phrase advocating "consistent condom use" as a way to prevent HIV infection.

Instead, the Bush administration wants language inserted into the agreement that promotes "natural" family planning methods. As one delegate put it, the administration prefers "abstinence over condoms."

The emphasis on condom failure also can be seen in new state laws on sex education. Last year, for example, New Jersey passed legislation stating that any instruction, including class lectures and pamphlets, which deals with contraceptive use "must include information on their failure rates for preventing pregnancy, HIV infection, and other STDs in actual use among adolescent populations." Those instructions also must stress abstinence as "the only certain method to prevent pregnancy and sexually transmitted diseases."

(Editor's note: An on-line copy of the updated CDC fact sheet on condoms can be found at: http://weblink.cdc.gov/hiv/pubs/facts/condoms.htm.)

Language Highlighted in New Fact Sheet

Here is the new language put up front and bolded in the new Centers for Disease Control and Prevention's condom fact sheet released Dec. 5:

"The surest way to avoid transmission of STDs is to abstain from sexual intercourse, or to be in a long-term mutually monogamous relationship with a partner who has been tested and you know is uninfected.

"For persons whose sexual behaviors place them at risk for STDs, correct and consistent use of male latex condoms can reduce the risk of STD transmission. However, no protective method is 100% effective, and condom use cannot guarantee absolute protection against any STD. . . ."

Source: cdc.gov/hiv/pubs/facts/condoms.htm.

Reference

1. Manhart L, Koutsky L. Do condoms prevent genital HPV infection, external genital warts, or cervical neoplasia? A meta-analysis. *Sex Transm Dis* 2002; 29(11):725-735. ■

Attitude is key part of treatment adherence

Study suggests which attitudes to watch

A small Chicago study suggests that attitudes about HIV and AIDS among HIV-infected people can be broken down into types that are predictive of how well the patients will adhere to their medication regimens.

If the study's findings are confirmed in a larger cohort then it soon will be possible for HIV clinicians to predict which HIV patients will have the most difficulty taking their medications based on their presenting attitudes about HIV disease.

"It's pretty clear to me that adherence is the key, at least in affluent societies like ours that have access to antiretroviral medication," says **John P. Flaherty**, MD, associate professor in the department of medicine at Northwestern University in Chicago.

"The people who do well over the long haul are different from those who don't do well, principally on the basis of being able to take their medications," he states. "I think we spend most of our time in the clinic on that issue with patients."

What HIV clinicians might sense from their experience with HIV patients is that some patient personalities and attitudes appear to do much better in adhering to antiretroviral regimens.

"From my subjective viewpoint and clinical experience, there are people who when you ask them what medications they're on, they're not sure, and you show them pictures and they can't recognize the pills. Right there, you know there's a problem." Another group of patients who appear to have problems with their medication regimens, he says, are those who haven't accepted their HIV diagnosis and who haven't told their friends and family about it.

"They are trying to do everything on their own," Flaherty says. "And I worry about them because it's a big task to go on the medications and to take multiple pills several times a day — that's a tall order, particularly when you're doing it indefinitely."

A study presented in October at the 40th Annual Meeting of the Infectious Diseases Society of America in Chicago, of which Flaherty was involved, discussed the types of patients that he mentions: The first example describes dependent and possibly depressed patients, and the second example describes patients who are in denial about their disease.

The study identified five subjective attitudes that may impact adherence to highly active antiretroviral therapy (HAART): empowered, dependent, ashamed, optimistic, and in denial.[1]

While the study's findings suggested that patients who were dependent and in denial were most likely to have a low adherence, the differences were not statistically significant due to the small cohort of 72 patients, and further studies will need to be conducted to confirm this finding, says **Farheen Ali**, MD, fellow of infectious disease at the University of Chicago. Ali was a co-author of the study.

The study used Q methodology to find shared attitudes among patients that would point to antiretroviral adherence.[1] "We looked at adherence from a patient's point of view," he says. "It's not new, but the Q methodology hasn't been used in medicine until very recently, and it's a good way of studying human subjectivity."

Q methodology has been used extensively in psychology, ethics, and journalism, but the medical community is just discovering it, Ali says. "It's a wonderful way to study human behavior."

Its advantage over the more standard scoring methods of ranking from 1 to 5 is that it gives participants a better opportunity to express extreme agreement and disagreement, which in turn makes it easier to analyze from a statistical standpoint, he says. HIV patients were given 34 statements that they could rank according to how much they agreed or disagreed with them, and their answers were analyzed by a computer program, Ali explains.

The first part of the questionnaire dealt with demographics, the patient's drugs, and illnesses. The second part involved ranking various attitude statements.

Participants were given pieces of paper that each had one of the 34 statements. For each statement, participants were asked to rank the statement from -4 to +4: With -4 meaning they absolutely disagreed with the statement, and +4 indicating they absolutely agreed with it, he explains.

Ali, who did most of these interviews with

participants, sometimes would spend as long as an hour with one person. "It gave them an opportunity to ask questions and talk about HIV," Ali says. "They'd move the paper around, and we asked them to keep talking with us, and once they were satisfied with how they ranked it, then we took down the number."

The rankings, along with the statement sheets of paper were spread across a table, making it easier for patients to move around and change until they were certain they had selected the most accurate rating, Ali says.

Their adherence to HAART was determined by a self-report questionnaire, plus results from viral load and genotypic assays.[1]

The analysis revealed the five different attitudes, which are described as the following:

• **Empowered:** These were patients who clearly knew about HIV and AIDS and why it is important to take antiretroviral medication. The patients who fit into this group had the greatest amount of adherence, Ali says.

• **Dependent:** This group could be described as depressed, and they identified with statements that showed they were very dependent on physicians and family support, Ali says.

"They didn't understand why they were supposed to take the medications, but they did so because they were told to do so." Patients who

CE/CME objectives

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

• identify the main advantages to the newly approved rapid HIV test;

• understand why the FDA is proposing new labeling for a popular spermicide;

• become familiar with the controversy of condom effectiveness and the new CDC condom fact sheet. ■

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 in the answer key, at right. 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.

CE/CME *questions*

If you have any questions about the CE/CME testing method, please contact customer service at (800) 688-2421.

9. Which of the following is *false* about the OraQuick rapid HIV test?
   A. It is faster and more accurate than SUDS, the only other FDA-approved rapid test.
   B. It takes only about 20 minutes to receive results.
   C. It can be tested on both whole blood and oral fluids.
   D. A positive test result needs confirmation with a second test

10. The new CDC condom fact sheet makes which statement about its protection against HIV?
   A. There are not enough data to say it is highly effective in protecting against the virus.
   B. The virus is so small that it may be able to penetrate the condom barrier and cause infection.
   C. No protective method is 100% effective, and condom use cannot guarantee absolute protection against any STD.
   D. The condom is more effective when combined with the spermicide nonoxynol 9.

11. The FDA is proposing labeling changes for contraceptives that contain N-9 because:
   A. The spermicide is not effective against pregnancy.
   B. Women have reported allergic reactions to the product.
   C. N-9 can increase vaginal irritation and thereby make a woman more susceptible to HIV infection.
   D. More studies are needed to determine whether N-9 is effective in protecting against STDs.

12. A study of the relationship between patient attitude towards HIV and AIDS and medication adherence classified patients in which of the following categories?
   A. empowered
   B. dependent
   C. ashamed
   D. optimistic
   E. all of the above

Answer Key: 9. C; 10. C; 11. C; 12. E

fell into this category tended to be slightly less adherent than some of the following attitude groups.

• **Ashamed:** "This group predominantly expressed feelings of shame and guilt about the disease," he says. "They felt they were responsible for contracting HIV in the first place."

Still, this group tended to be more adherent than not adherent, although, again, this difference did not reach statistical significance.

• **Optimistic:** HIV patients who fell into this category could be described as blind optimists, who believed they were OK and who planned to continue taking their medications, Ali says.

While they tended not to know or understand much about their disease, they did appear to be adherent, Ali says.

• **Denial:** This is a group that requires a lot of work on the clinician's part because of the patients' unrealistic expectations and beliefs, Ali says. One of the Q methodology statements was "I will live my natural life span."

The people who fell into the denial group predominantly said they strongly agreed that they would live their natural life span, Ali notes.

"But they all had excuses for missing their medication doses, such as they fell asleep or were out of the house. So it seemed they felt they'd be OK, but didn't want to deal with the medication." The denial group also reported that they had not received all the information they needed from their physicians, and they appeared to have some distrust of the medical community, he adds.

"What I found very interesting was the fact that in Southside Chicago, a more or less homogenous population, we had five different ways of looking at HIV treatment," Ali says.

The study suggests that psychological counseling, assisting patients with depression, and strong patient education are very important to improving adherence, he says.

"A patient's motivation is very important," Ali says. It's also crucial that HIV clinicians are able to refer patients to social workers, psychiatrists, advanced practice nurses, and others who may help them with their psychological issues that impact adherence, Flaherty says.

Reference

1. Ali F, Dau B, Mrtek R, et al. Subjective attitudes and adherence to HAART in HIV-infected adults. Presented at the 40th Annual Meeting of the Infectious Diseases Society of America. Chicago; Oct. 24-27, 2002. Poster 483. ■

FDA Notifications

New labeling for N-9 products?

Based on the results of several clinical trials, the Food and Drug Administration (FDA) has proposed new labeling for over-the-counter vaginal contraceptive drug products that contain nonoxynol 9 (N-9). The warning statements will tell consumers that vaginal contraceptives containing N-9 do not protect against HIV or other sexually transmitted diseases. The trials showed that frequent use of N-9 products raise the risk of infection through increased vaginal irritation. The FDA will seek public input on the proposed statement as part of its ongoing review of over-the-counter drug products. ■