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IN THIS ISSUE

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Progress report: Researchers make strides in global battle against HIV

Scientific advances may aid in stemming spread of disease

Good news on the research front: Results from a major study indicate that treating genital herpes may help keep the AIDS virus under control in women with both infections and may reduce the spread of HIV as well.[1] In the laboratory, scientists have successfully mapped a spot on the surface of HIV that may be vulnerable to an assault by antibodies, which could lead to development of an effective vaccine.[2]

Progress needs to continue at a rapid pace. In 2005, an estimated 4.1 million people worldwide were newly infected with HIV, mostly through heterosexual intercourse.[3] At the end of 2003, an estimated 1,039,000 to 1,185,000 people in the United States were living with HIV/AIDS, with 24%-27% undiagnosed and unaware of their HIV infection.[4]

Why are scientists focusing on the virus that causes genital herpes (herpes simplex virus-2, HSV-2) in relation to HIV? HSV-2 infection almost doubles the risk of HIV acquisition; results from a meta-analysis indicate.[5] Data from Rakai, Uganda, in HIV-discordant couples suggest that, on a per-contact basis, HSV-2 increases the risk of HIV acquisition fivefold.[6]

The problem is compounded when looking at the prevalence of the disease:

EXECUTIVE SUMMARY

The HIV epidemic continues to grow. In 2005, an estimated 4.1 million people worldwide were newly infected with the disease, mostly through heterosexual intercourse.

- Results from a major study indicate that treating genital herpes may help keep the AIDS virus under control in women with both infections and may reduce the spread of HIV.
- In another research advance, scientists have successfully mapped a spot on the surface of HIV that may be vulnerable to an assault by antibodies, which could lead to development of an effective vaccine.

• Approximately one out of five sexually active adults in the United States is HSV-2-seropositive.

• In studies in Latin America and Peru, 60% of HIV-uninfected men who have sex with men are HSV-2-seropositive.

• The rate rises even higher among HIV-infected women in parts of sub-Saharan Africa, South Africa, and Zimbabwe, where the HSV-2 prevalence is 70%.[7]

To conduct the trial among women coinfected with HIV and HSV-2, scientists from the Centre Muraz in Burkina Faso, the University of Montpellier (France), and the London (UK) School of Hygiene & Tropical Medicine enrolled 140 Burkina Faso women who were infected with the herpes and AIDS viruses. The women received valacyclovir or placebo pills for three months. Study findings indicate that having the herpes virus increased the replication of HIV and also revealed that the quantity of HIV in the blood and in the vagina was reduced by continuous anti-herpes treatment over three months.[1]

What is the next step?

These findings open new avenues for the prevention of HIV transmission and for the management of patients coinfected by the two viruses, says **Philippe Mayaud**, a scientist at the London School of Hygiene & Tropical Medicine and co-author of the current paper.

What are the next steps in HSV-HIV research? On the HIV transmission front, scientists will need to demonstrate that the effect seen on infectiousness or transmissibility of the virus actually translates into decreased transmission, says Mayaud. Several trials are ongoing, and results should be available within the next 18 months, he reports. Modeling studies will need to explore the population level impact of these therapies to assess their public health benefit, he notes.

When it comes to HIV disease progression, research should focus on the potential usefulness of using anti-HSV treatment during HIV disease, says Mayaud. For those infected with HSV-2, long-lasting therapies should be developed that do not depend on long-term intake of tablets, Mayaud believes. Safe and effective vaccines that would at least control the replication of HSV— if not prevent it altogether — would go a long way to prevent the transmission of HSV and HIV, he states.

"Such vaccines are currently not available," Mayaud says. "This should be an important priority area of research." ***(Contraceptive Technology Update* reported on herpes vaccine development. See the article "Herpes vaccine research may hold key to stemming STD" in the *STD Quarterly* supplement inserted in the February 2003 issue, p. 1.)**

Progress on the HIV vaccine front has been challenged by the nature of the shape-shifting virus. Scientists led by a team at the National

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Institute of Allergy and Infectious Diseases (NIAID) now say they have been able to identify a key portion of an HIV surface protein as it looks when bound to an infection-fighting antibody.[2] The protein component is stable and appears vulnerable to attack from a specific antibody, known as b12, that can broadly neutralize HIV, researchers report.[2]

The HIV virus mutates rapidly and continuously, which stymies attempts by the immune system to identify and destroy it. To further compound the problem, the virus is covered by sugary molecules, which prevent antibodies from slipping in and blocking the proteins the virus uses to latch onto a cell and infect it.

NIAID researchers have been able to decipher how the b12 antibody is able to bind to an unchanging surface on the tip of the HIV virus. They used an X-ray snapshot of the antibody as it locked into the target site on the virus, then used chemical blocks to provide a 3-D map of the target site.[2] The resulting "map" may give researchers valuable clues in designing an effective vaccine. By understanding the structure of the virus, researchers may be able to improve on nature by designing an antibody that binds better than b12 and is easier for humans to produce.

Tongqing Zhou, PhD, a staff scientist in the NIAID's Vaccine Research Center's Structural Biology Section and lead author of the current research, says, "The detailed atomic level information from the HIV gp120:b12 structure tells us how a 'good' antibody works by attacking this weak link in the HIV armor, and it will guide us in the rational design of a future vaccine."

The next step in science is to use the information in designing and creating vaccines that will stimulate the immune system to generate large amounts of antibodies that would replicate or surpass b12's virus-killing power, says Zhou. However, the creation of such vaccines and the animal/human test processes may take a long time, and there will be many technical bumps ahead, he notes. **(See the *CTU* articles "Progress reported in HIV vaccine development," February 2007, p. 17, and "HIV vaccine trials are now under way," September 2006, p. 103.)**

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New contraceptive ring now in advanced trials

When you prescribe the contraceptive vaginal ring (NuvaRing, Organon; West Orange, NJ), you instruct the patient that the ring is worn for three weeks, then is removed for a one-week ring-free period. When the ring-free period is completed, a new ring must be used. But what if there was a ring that could be used for more than a three-week period?

The Population Council is testing the safety and efficacy of a longer-lasting contraceptive vaginal ring. Two investigations involving 2,200 women at 22 sites on four continents are being conducted prior to application to the Food and Drug Administration (FDA) for market approval. The

EXECUTIVE SUMMARY

The Population Council is testing the safety and efficacy of a longer-lasting contraceptive vaginal ring. Two investigations involving 2,200 women at 22 sites on four continents are being conducted prior to application to the Food and Drug Administration for market approval.

- The ring is formulated with the Population Council's proprietary progestin, Nestorone, and a low dose of ethinyl estradiol.
- Study participants are instructed to keep the contraceptive ring in place for three weeks, then remove it for one week to permit periodic bleeding. Seven days later, the device is to be reinserted.
- The ring is designed for use for one full year.

Population Council is conducting one trial at 10 international sites in collaboration with the World Health Organization, with funding from the U.S. Agency for International Development. It also is working with the National Institutes of Health's National Institute of Child Health and Human Development in conducting a similar study at additional sites across the United States. U.S. organizations participating in the trials include: California Family Health Council, California Women and Children's Hospital, Columbia University, Contraceptive Research and Programs, Jones Institute of Reproductive Medicine, MacDonald Physicians, Magee-Womens Hospital, New York University Medical Center Family Planning Division, Oregon Health Sciences University, San Francisco General Hospital, University of Chicago Hospital, University of Cincinnati College of Medicine, University of Colorado, University of Pennsylvania Medical Center, and University of Texas Southwestern Medical Center.

The ring is formulated with the Population Council's proprietary progestin, Nestorone, and a low dose of ethinyl estradiol, says **Diane Rubino**, council spokeswoman. Study participants are instructed to keep the contraceptive ring in place for three weeks, and then remove it for one week to permit periodic bleeding. Seven days later, the device is to be reinserted. The ring is designed for use for one full year, which is seen as a "clear advantage" by **Ruth Merkatz**, RN, PhD, the council's director of clinical development. "This means convenience for women; they will not need to return frequently to obtain multiple prescriptions," she notes. "This is especially important when access to health care is a problem, which affects many women in the U.S. and worldwide."

The contraceptive vaginal ring represents a method that is under the woman's control and requires a minimum of attention from medical personnel, states Merkatz. "Unlike the pill that women must remember to take every day, or devices that women must use with every act of intercourse to prevent pregnancy, the woman leaves [the ring] in for three weeks every month and leaves it out for one week," she notes.

Review the research

Nestorone and trimegestone are the most potent progestins synthesized to date, followed by two of the older progestins, keto-desogestrel and levonorgestrel.[1] The Nestorone vaginal ring is a thin, flexible product made of silicone rubber. The ring inhibits ovulation by continuously releasing a low dose of hormones through the vaginal walls and into the bloodstream. In a multicenter one-year dose-finding trial that looked at three dose combinations of Nestorone and ethinyl estradiol in a ring delivery system, results indicate that the studied formulations, used on a 21-days-in, seven-days-out regimen, provided women safe and effective contraception.[2] **(*Contraceptive Technology Update* reported on the research in its article, "Progestin eyed for use in contraceptive gel," October 2006, p. 113.)**

Previous research suggests that the ring is safe for use. Results from a 2006 study indicate that a Nestorone contraceptive vaginal ring should be as safe as a combined oral contraceptive when it comes to thrombosis risk.[3]

In studies to date, the Nestorone ring has been shown to be highly effective in inhibiting ovulation and preventing pregnancy, says Merkatz. The large Phase 3 studies will provide more information on efficacy, as well as safety, she states.

Draw the circle wide

The Nestorone studies now under way are designed to include smokers and overweight women in the study populations, two groups that typically have been excluded in studies of hormonal contraception. This inclusive testing model is designed to provide a more comprehensive assessment of the risks and benefits of using the one-year ring, say Population Council officials.

During the study, Population Council researchers will conduct interviews to further assess the method's acceptability among trial participants. An independent data safety monitoring board will review safety and efficacy information on a regular basis. Trials will close in mid-2009.

When could a Nestorone ring be available? If testing indicates that the product is successful and the FDA approves the contraceptive, a one-year ring could be approved for use in about five years, estimate Population Council officials.

Robert Hatcher, MD, MPH, professor of gynecology and obstetrics at Emory University School of Medicine in Atlanta, says he would like to see research on the ring in different regimens."It is unfortunate that this exciting new ring isn't evaluating a better approach than 21/7; I would rather see use in 24/4 or 25/3," Hatcher remarks. "I definitely would like to see an arm evaluate continuous use of the ring."

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Multi-site study of potential EC in gear

Women may have another choice in emergency contraception (EC) if a current multi-site trial of a potential candidate proves successful. HRA Pharma of Paris, France, has initiated a pivotal multicenter Phase III study to evaluate its proprietary second-generation emergency contraceptive.

The open-label investigation will analyze safety and efficacy of the drug, trademarked Ella (CDB-2914), as an emergency contraceptive. Study participants will include women older than age 18 who request EC within 120 hours (five days) of unprotected sexual intercourse or a contraceptive failure. More than 1,000 women are expected to participate in the trial. The company says it expects to complete the study by the end of 2007 and submit findings to the Food and Drug Administration. If the drug is approved, it may be available in United States by 2009.

Seven Planned Parenthood of America (PPFA) affiliates, representing 16 health center sites, are participating in the study, says **Andrea Hagelgans**, PPFA spokesperson. The affiliates and their sites include: Planned Parenthood League of Massachusetts (Boston Planned Parenthood); Planned Parenthood Mar Monte (San Jose Planned Parenthood Mar Monte and Fulton Street); Planned Parenthood of Houston and S.E. Texas (Fannin Health Center and Bryan/College Station); Planned Parenthood of Maryland (Baltimore, Towsen, and Annapolis health clinics); Planned Parenthood of the Columbia/Willamette (S.E. Portland Clinic); Planned Parenthood of the Rocky Mountains (Boulder, Denver-Central, Littleton, Aurora, and Arvada); and Planned Parenthood of Western Washington (Seattle Clinic and University District Clinic).

CDB-2914 is the first compound to have been developed expressly with EC in mind, reports **Vanessa Cullins**, MD, MPH, PPFA vice president for medical affairs. "Planned Parenthood believes strongly that every woman deserves every chance to prevent unintended pregnancy, and we welcome innovations that expand family planning options including backup birth control," she says.

EXECUTIVE SUMMARY

Paris-based HRA Pharma has initiated a pivotal multicenter Phase III study to evaluate its proprietary second-generation emergency contraceptive, Ella (CDB-2914).

- Study participants will include women older than age 18 who request emergency contraception within 120 hours (five days) of unprotected sexual intercourse or a contraceptive failure. More than 1,000 women are expected to participate in the trial.
- The company says it expects to complete the study by the end of 2007. If the trial is successful, the company will seek approval from the Food and Drug Administration.

Look at formulation

Scientists conducted a randomized, double-blinded noninferiority trial of CDB-2914 by enrolling healthy women seeking emergency contraception within 72 hours of unprotected intercourse.[1] Participants were randomly assigned to receive a single 50 mg dose of CDB-2914, plus a placebo 12 hours later, or two doses of 0.75 mg levonorgestrel taken 12 hours apart. Findings indicate that CDB-2914 is at least as effective as levonorgestrel in preventing pregnancies after unprotected intercourse and has a similar side effect profile.[1] **(See the *Contraceptive Technology Update* article, "Progesterone receptor modulator eyed for EC," February 2007, p. 16.)**

The levonorgestrel-only EC Plan B (Barr Pharmaceuticals; Woodcliff Lake, NJ) is now available "behind the counter" — but without a prescription — to consumers 18 years of age and older, and it remains prescription-only for women 17 and younger. **(See the *Contraceptive Technology Update* article, "Shipment of dual-label EC now reaching stores," January 2007, p. 5.)** What role will clinicians now play in EC provision?

Advance provision is still an important factor in successful use of EC, says **Corinne Rocca**, MPH, an epidemiologist with the Women's Global Health Imperative at the University of

California, San Francisco. In a just-published randomized trial evaluating access to EC through advance provision, pharmacies, or clinics, data suggest that advance provision improved promptness and convenience of use.[2]

Findings from several randomized trials[3-5] indicate that women who are given advance provisions to EC are more likely to use it when they need it, says Rocca, who served as lead author of the new study. Having a dose on hand eliminates the need to go to a clinic to get EC or a prescription for EC, she says. For women who have access through pharmacies, it eliminates the need to find and go to a pharmacy to get EC, Rocca points out. "As was illustrated in our clinic-based study, 14% of women did not take EC on an occasion in which they felt it was called for," says Rocca. "Reasons for this included that it was too inconvenient to get EC, the woman did not have EC or a prescription, and the woman could not obtain EC in three days."

Even with dual-status availability of Plan B, clinicians will continue to play a vital part in EC provision, Rocca believes. Clinicians continue to help women understand the need for EC, as well as provide general EC education and provision, even though the drug now is available behind-the-counter (BTC). Most women at risk for unintended pregnancy do not know about EC or know how to obtain it and use it, so clinicians can tell patients about EC and explain where they can obtain it, including which pharmacies are known to carry Plan B, she says.

"Just as we continue to rely on clinicians and health care practitioners to counsel patients about condom use — even though condoms are readily available over the counter — we will continue to rely on them to educate patients about EC, even though it can now be obtained behind the counter," says Rocca.

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New report underscores HPV prevalence in U.S.

About one in four U.S. females between the ages of 14 and 59 may have human papillomavirus (HPV), according to results of the first national estimate of the infection.[1]

HPV is the most common sexually transmitted infection in the United States, and at least 50% of sexually active women and men acquire genital HPV infection at some point in their lives.[2] While most HPV infections clear on their own, some high-risk types that do not can lead to cervical cancer in women. The American Cancer Society estimates there will be about 11,150 cases of cervical cancer in the United States in 2007, and about 3,670 women will die from the disease.[3]

The new research is the first nationally representative study of HPV among women with a broad age range, says **Eileen Dunne**, MD, MPH, a medical officer in the Centers for Disease Control and Prevention's (CDC) National Center for HIV, Viral Hepatitis, STDs, and Tuberculosis Prevention. The research findings indicate a high overall prevalence of HPV infection among females, especially among young women, notes Dunne, lead author of the analysis. Overall, more than one in four women (26.8%, or 24.9 million

EXECUTIVE SUMMARY

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- Findings indicate a significant trend for increasing HPV prevalence with each year of age from 14 to 24 years, followed by a gradual decline in HPV prevalence through age 59. Independent risk factors for HPV detection were age, marital status, and increasing numbers of lifetime and recent sex partners.
- More information is needed about the prevalence of HPV-16/18 in women older than age 26 to help determine whether women in this age group would benefit from immunization.

females) in the United States are infected with at least one type of HPV; almost half of women aged 20-24 are infected, she notes.

These baseline data will allow for future evaluations to monitor changes in prevalence, which would result as an impact of the HPV vaccine, says Dunne. The data also are useful for models on vaccine impact and cost-effectiveness, she states. "The findings also underscore the importance of STD prevention efforts and continued Pap screening to protect women's health."

Review the analysis

CDC researchers and colleagues were able to estimate the prevalence numbers by performing HPV DNA testing on 2,026 self-collected vaginal swabs from women ages 14-59 years who participated in the 2003-2004 cycle of the National Health and Nutrition Examination Survey.

Drawing from 1,921 adequate specimens, analysis showed that 26.8% of the women were positive for any HPV DNA. Researchers then used 2000 U.S. census data to extrapolate the prevalence rate to the population, estimating that approximately 24.9 million females in this age range have prevalent HPV infection.[1] According to the researchers' calculations, prevalence of any HPV infection was highest among females ages 20-24 (44.8%); overall HPV prevalence among women ages 14-24 was 33.8%.

According to the researchers' analysis, there was a significant trend for increasing HPV prevalence with each year of age from 14 to 24 years, followed by a gradual decline in HPV prevalence through age 59. Independent risk factors for HPV detection were age, marital status, and increasing numbers of lifetime and recent sex partners. Overall, HPV types 6, 11, 16, or 18 were detected in 3.4% of the study participants, corresponding with 3.1 million women with prevalent infection in the general U.S. population.

Who gets immunized?

The CDC's Advisory Committee on Immunization Practices has recommended the HPV vaccine for adolescent girls ages 11-12, with catch-up vaccination for those between ages 13 and 26. **(Review the recommendations; see the *Contraceptive Technology Update* article, "HPV vaccine, with nod from FDA, is first one approved to prevent cervical cancer," September 2006, p. 97.)**

According to an accompanying editorial to the new CDC research, more information is needed about the prevalence of HPV-16/18 in women older than age 26 to help determine whether women in this age group would benefit from immunization.[4] Such studies are important not only to evaluate the HPV vaccine's effectiveness, but also to determine whether other high-risk HPV types will fill the ecological niche created by the expected decline in HPV-16 and HPV-18, the editorial states.[4] Editorial co-author **Susan Weller**, PhD, professor of preventive medicine and community health at the University of Texas Medical Branch in Galveston, says, "What we would really like to see is good baseline data, [perhaps] estimates of the oncogenic types and specifically 16/18, for each age group."

Studies of cost-effectiveness of the vaccine have used HPV prevalence estimates from selected populations, including some outside the United States.[5-7] Researchers will need to assess the cost-effectiveness of the HPV vaccine using the new prevalence data, the editorial states.

The best time to get the HPV vaccine is before sexual debut, says **Susan Wysocki**, RNC, NP, FAANP, president and chief executive officer of the National Association of Nurse Practitioners in Women's Health. However, since many family planning providers do not see women until after they are sexually active, they also should keep in mind that the data from the clinical trials demonstrate that most women have not been infected with all four of the HPV types that are covered in the vaccine that is currently available, so most will still benefit from the vaccine, she notes.

"We have a great opportunity to educate the women seen in family planning clinics who have young daughters," states Wysocki. "We have opportunities to make a difference with both the sexually active young women in the 'catch-up' group, as well as young women before sexual debut, through educating their mothers."

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Chlamydia vaccine: What is on the horizon?

Review the number of patients who were screened and treated for chlamydia at your facility in the last two weeks. What if their infection could have been prevented by vaccine?

Chlamydia is the most frequently reported bacterial sexually transmitted disease (STD) in the United States, according to the Centers for Disease Control and Prevention.[1] In 2004, 929,462 chlamydial infections were reported to the agency.[1] About 75% of infected women and half of infected men have no symptoms; if symptoms do occur, they usually appear within one to three weeks following exposure.[1]

Women who do have symptoms may note an abnormal vaginal discharge or a burning sensation when urinating. Men with symptoms might detect a penile discharge or a burning sensation when urinating or may have burning and itching around the opening of the penis.[1] If the infection goes undetected in women, infection may travel from the cervix into the upper genital tract, which can lead to infertility. Men may develop epididymitis if the infection is undetected.

EXECUTIVE SUMMARY

Advances are being made on the research front toward a vaccine for chlamydia, the most frequently reported bacterial sexually transmitted disease in the United States.

- Researchers at two University of Texas institutions report success in administering a chlamydia prevention vaccine in mice. Studies are planned for use of the vaccine in guinea pig models.
- Scientists at Queensland University of Technology in Brisbane, Australia, are looking at certain proteins in protection against chlamydial infection. The Australian group has received a $300,000 grant to continue its research toward developing a vaccine specifically targeting adolescent women.

Researchers at the University of Texas at San Antonio (UTSA) South Texas Center for Emerging Infectious Diseases and the University of Texas Health Science Center at San Antonio (UTHSCSA) are working together to discover a vaccine to prevent chlamydia. **Ashlesh Murthy**, MD, PhD, a postdoctoral fellow in UTSA's biology department, says the research team has found success in administering a chlamydia prevention vaccine in mice.[2] "We have clearly demonstrated the efficacy of our vaccination regimen in accelerated resolution of genital chlamydial infections and reduction of subsequent pathology in the oviducts using mouse models of genital chlamydial infection," Murthy states. "We also have identified the mechanisms of protection."[3-4]

The research team is initiating studies to study the efficacy of the vaccine against infection in guinea pig models, says Murthy. Murthy and **Bernard Arulanandam**, PhD, UTSA associate professor of microbiology & immunology, are working with **Guangming Zhong**, MD, PhD, UTHSCSA professor of microbiology, whose research team has identified antigens or proteins in chlamydia as vaccine candidates. Zhong's team is providing those candidates to the UTSA researchers to analyze for their efficacy.

Scientists at Queensland University of Technology (QUT) in Brisbane, Australia are looking at certain proteins in protection against chlamydial infection.[5] **Peter Timms**, PhD, professor in the university's School of Life Sciences, says, "My research group at QUT has been involved in chlamydia research, including disease in koalas, for over 15 years. We have been working on various aspects of chlamydia vaccine development for much of this period."

The Australian group has received a $300,000 grant to continue its research toward developing a vaccine specifically targeting adolescent women.

Advances on the way

Study of *Chlamydia trachomatis* has proved challenging because the organism, unlike most bacteria, only grows inside the host cell. Scientists have grappled to understand the organism's physiology, structure, developmental biology, and genetics. The availability of the complete *C. trachomatis* genome sequence, published in 1998, has boosted research advances.[6] With the genome sequence in hand, scientists are able to identify and test candidate proteins based on their similarity to proteins important in protective immunity against other

bacterial pathogens.

Scientists were able to use the genetic blueprint of *Chlamydia trachomatis* to identify a gene that encodes a cell-destroying toxin.[7] Researchers believe the presence of the toxin explains why only some chlamydial strains cause chronic illness.

Scientists at Emergent BioSolutions in Rockville, MD, are developing a recombinant protein subunit chlamydia vaccine for all clinically relevant strains of *Chlamydia trachomatis*. Researchers are developing a vaccine candidate to be administered by injection with a novel adjuvant in a three-dose regimen.

BioVeris Corp. of Gaithersburg, MD, has entered into an exclusive, worldwide license agreement with University of Massachusetts Amherst for patent rights to a proprietary chlamydia vaccine candidate developed by researchers in the school's veterinary and animal sciences and microbiology departments. The vaccine under investigation uses a pan-genus antigen that could be effective in preventing infections caused by most or all species of chlamydia. Researchers at the University of Alabama at Birmingham are defining and characterizing chlamydia protective antibody-mediated response in their search for a possible chlamydia vaccine.[8]

More effort is needed to bring a potential vaccine candidate to market, says Murthy. "The incidence rates of genital chlamydial infections have doubled over the last decade, strongly indicating the need for timely development of an efficacious chlamydial vaccine," Murthy states.

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Adding vasectomies: One agency's story

How many men enter the doors of your family planning clinic, and what services can you offer them outside of free condoms? Consider vasectomy: It is simpler, safer, less expensive, and as effective as the currently available methods of female sterilization, according to *Contraceptive Technology*.[1]

Low-income, minority, and less educated men are less likely to be vasectomy recipients due to costs, according to a survey of vasectomized men.[2] The Reproductive Health Program of the Oregon Department of Human Services (DHS) Public Health Division launched a vasectomy pilot project in 2005 to offer low- or no-cost vasectomies to Title X-eligible men. The project, which operates as a collaboration between the state's Reproductive Health program, Title X delegate agencies, and local vasectomy providers, has provided more than 130 vasectomies since its inception, says **Lesli Leone Uebel**, MPH, CHES, a DHS

EXECUTIVE SUMMARY

Low-income, minority, and less educated men are less likely to be vasectomy recipients due to costs, according to a survey of vasectomized men. Oregon public health officials launched a vasectomy pilot project in 2005 to offer low- or no-cost vasectomies to Title X-eligible men.

- In the Oregon project, the state provides procedural guidelines, forms for project enrollment and informed consent, vasectomy education materials, and an optional client satisfaction questionnaire.
- Agencies participating in the project are responsible for outreach, sterilization education, and counseling to interested men, as well as set up agreements with local vasectomy providers.

RESOURCE

For more information on the Oregon Vasectomy Project, contact:

- **Rian Frachele**, Family Planning Program Manager, Oregon Office of Family Health Family Planning Program, Portland, OR. Phone: (971) 673-0364. E-mail: Rian.Frachele@state.or.us.

social marketing coordinator. Those numbers may be higher; with mandated 30-day waiting periods for the procedures, more men are set to receive services, Uebel explains.

Eight Oregon county health departments — Baker, Grant, Hood River, Jefferson, Lane, Linn, Malheur, and Tillamook counties — along with Planned Parenthood of Columbia-Willamette and Planned Parenthood of Southwestern Oregon, signed up for the pilot project. Kicked off with a $50,000 grant from federal Title X monies, the project was awarded a similar amount from Title X for the current fiscal year. It has now been opened to other interested Title X clinics in the state, notes **Rian Frachele**, DHS family planning program manager.

What is involved?

In developing the pilot project, Oregon officials looked at a similar program operated by the Washington State Department of Health's Family Planning and Reproductive Health Section. Introduced in 1995, the Washington project has offered low or no-cost vasectomies to state residents who are eligible for medical assistance and who are not covered under any insurance plan for vasectomy. (*Editor's note: To learn more about the Washington state project, see the state Department of Health's Family Planning & Reproductive Health's page on the subject, www.doh.wa.gov/cfh/FPRH/vasectomy.htm.)*

In the Oregon project, the state provides procedural guidelines, forms for project enrollment and informed consent, vasectomy education materials, and an optional client satisfaction questionnaire. Agencies participating in the project are responsible for outreach as well as sterilization education and counseling to interested men. Agencies also set up agreements with local vasectomy providers. When men have received vasectomy counseling, they are referred to the local provider. After the federally mandated 30-day waiting period, the provider performs the vasectomy as well as the recommended post-vasectomy sperm counts. The agencies then are responsible for invoicing the state for costs of the counseling and the actual vasectomy service. Oregon reimburses participating agencies $105 for counseling services and $300 for vasectomy procedures, says Uebel.

What do men say?

How have participating agencies gotten the word out about the vasectomy project? According to Uebel, word of mouth has been very effective. Many men have come as a referral from a partner or family member who has used family planning clinic services. About 80% of men participating in the pilot phase of the project said their vasectomy counseling visit was their first time at that particular clinic.

Men have been very pleased with the service, says Uebel. A survey was designed to measure satisfaction in five areas: welcome from clinic staff, ability to ask questions, usefulness of the written material about vasectomy, degree to which the client's questions or concerns were addressed, and whether the client would recommend the clinic to others. Almost all responses were positive, she notes.

Project billing data indicate that about 94% of men who were counseled went on to receive a vasectomy. This is good news for unintended pregnancy prevention, given the reported contraceptive practices of the men and their partners, note Oregon public health officials. In surveying men who participated in the pilot phase, 11% said that they and their partners were not using any form of birth control prior to considering vasectomy; about 48%

CE/CME Instructions

Physicians and nurses participate in this continuing medical education/continuing education program by reading the articles, using the provided references for further research, and studying the questions at the end of the issue. Participants should select what they believe to be the correct answers and refer to the list of correct answers to test their knowledge. To clarify confusion surrounding any questions answered incorrectly, please consult the source material. After completing this activity with the **June** issue, you must complete the evaluation form provided and return it in the reply envelope provided in that issue to receive a certificate of completion. When your evaluation is received, a certificate will be mailed to you. ■

were using less effective methods, such as condoms, withdrawal, or rhythm.

"One man said in his survey, 'Thank you for helping me to get a free vasectomy and for helping a small family live better,'" said Uebel. "Men recognized the value of the service that they were getting, and they were extremely appreciative of it." **(See resource listing on p. 58 for project contact information.)**

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CTUPDATES
News ■ Resources ■ Events

Add colorectal cancer screening for 50+ women

If your practice includes women ages 50 and older, be sure to remind them to be screened for colorectal cancer, advises the American College of Obstetricians and Gynecologists (ACOG).

Colon and rectal cancer, which affects the large intestine and rectum, is the third-leading cause of cancer death among women in the United States and the second-leading cause of cancer deaths overall for all adults. In most cases, the disease develops slowly over time, often beginning with tissue growth (polyps) in the colon or rectum. Routine screening helps detect these polyps so that they can be removed before they turn into cancer.

While the disease may be asymptomatic, educate your patients to look for the following symptoms: change in bowel habits, bleeding from the rectum, blood in the stool, stools that are more narrow than usual, abdominal discomfort (bloating, cramps, or frequent gas pains), loss of appetite, and weakness

CE/CME Questions

After reading *Contraceptive Technology Update*, the participant will be able to:

- **identify** clinical, legal, or scientific issues related to development and provisions of contraceptive technology or other reproductive services.
- **describe** how those issues affect services and patient care.
- **integrate** practical solutions to problems and information into daily practices, according to advice from nationally recognized family planning experts.

17. What drug did researchers use in the trial among Burkina Faso women coinfected with HIV and herpes simplex virus Type 2?
A. Famciclovir
B. Metronidazole
C. Valacyclovir
D. Ceftriaxone

18. What are the most potent progestins synthesized to date?
A. Nestorone and desogestrel
B. Trimegestone and desogestrel
C. Desogestrel and levonorgestrel
D. Nestorone and trimegestone

19. What drug was used in the comparison trial of the progestin CDB-2914?
A. Levonorgestrel
B. Methotrexate
C. Mifepristone
D. Danazol

20. What are common symptoms of chlamydial infection in females?
A. Painless ulcerative lesions.
B. Abnormal vaginal discharge or a burning sensation when urinating.
C. Chancre at the infection site.
D. Diffuse, malodorous yellow-green discharge.

Answers: 17. C; 18. D; 19. A; 20. B.

COMING IN FUTURE MONTHS

- Condom mishaps common in young men
- Human papillomavirus diagnostic tests under review
- Focus: Medications that interact with contraceptives
- Contraception options for obese women
- Abnormal uterine bleeding: When to treat

and feeling tired.

ACOG recommends that all women age 50 and older be screened for colorectal cancer by one of the following methods:

- annual patient-collected fecal occult blood test (FOBT) or fecal immunochemical test (FIT);
- flexible sigmoidoscopy once every five years;
- annual patient-collected FOBT or FIT plus a flexible sigmoidoscopy once every five years;
- double-contrast barium enema once every five years;
- colonoscopy once every 10 years.

Some women may need to be screened for colorectal cancer before age 50 if they:

- have a first-degree relative younger than age 60 with colorectal cancer or colon polyps;
- have two or more first-degree relatives of any age with colorectal cancer or colon polyps;
- have had colorectal cancer;
- have had colon polyps;
- have had inflammatory bowel disease (IBS), chronic ulcerative colitis, or Crohn's disease;
- have a family history of familial adenomatosis polyposis or hereditary nonpolyposis colon cancer.

In early 2006, the National Colorectal Cancer Roundtable published an evidence-based guide, *How to Increase Colorectal Cancer Screening Rates in Practice*. It is available free. Go to the National Colorectal Cancer Roundtable web site, www.nccrt.org, and click on the link, *How to Increase Colorectal Cancer Screening Rates in Practice: A Primary Care Clinician's Evidence-Based Toolbox and Guide*. The guide offers current screening guidelines and features checklists, chart prompts, tracking sheets, and other practice tools. ■

Contraceptive Technology Update *is endorsed by the National Association of Nurse Practitioners in Women's Health and the Association of Reproductive Health Professionals as a vital information source for health care professionals.*