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Note: New CNE/CME procedures, see p. 83 for details.

IN THIS ISSUE

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Data emerges on drospirenone pills: How to counsel on their use

Review similar VTE studies, weigh risks and benefits

Results of two case-control studies indicate that women without risk factors for venous thromboembolism (VTE) who use oral contraceptives (OCs) containing drospirenone have an increased risk for nonfatal VTE compared with those who use levonorgestrel OCs.[1,2]

Drospirenone is the progestin contained in the Yaz/Yasmin line of oral contraceptives from Bayer HealthCare Pharmaceuticals of Wayne, NJ. The line is the best-selling combination birth control pill in the United States. According to IMS Health, sales of Yaz in 2009 reached $782 million, accounting for 23% of the top five products in the combined oral contraceptive category.[3] The progestin also is found in the North Wales, PA-based Teva Pharmaceuticals pills Ocella and Gianvi, the generic equivalents of Yasmin and Yaz, as well as in the Parsippany, NJ-based Watson Laboratories' Zarah, the generic equivalent of Yasmin. In 2010, Bayer received Food and Drug Administration approval for two new

EXECUTIVE SUMMARY

Results of two case-control studies indicate that women without risk factors for venous thromboembolism (VTE) who use oral contraceptives (OCs) containing drospirenone have an increased risk for nonfatal VTE compared with those who use levonorgestrel OCs.

- Drospirenone is the progestin contained in the Yaz/Yasmin line of oral contraceptives, and their generic counterparts, Ocella, Zarah, and Gianvi. In 2010, two new drospirenone pills with added folate, Beyaz and Safyral, received regulatory approval.
- The two new studies follow two similar analyses published in 2009. All suggest that drospirenone increases the risk of venous thromboembolism compared with levonorgestrel. However, results from two earlier prospective, comparative cohort postmarketing surveillance studies do not indicate such risk.

drospirenone pills with added folate, Beyaz and Safyral. Beyaz contains 20 mcg of ethinyl estradiol, while Safyral contains 30 mcg of ethinyl estradiol; both pills contain 3 mg of drospirenone. *(Further coverage is contained in the* Contraceptive Technology Update *article, "New year, new oral contraceptives: 2 new OCs join birth control options," January 2011, p. 1.)*

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Editorial Questions

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The current observational database studies looked at women ages 15-44 years who received an oral contraceptive containing drospirenone or levonorgestrel. Cases were women with current use of a study oral contraceptive and a diagnosis of venous thromboembolism in the absence of identifiable clinical risk factors. Up to four controls were matched to each case by age and calendar time.

Prescription data on 55 million

For the first study, researchers looked at the U.S.-based PharMetrics database, which contains prescription data on 55 million people reaching back to 1995.[1] Data for the second study came from the United Kingdom (UK)-based General Practice Research Database, which contains data from more than 3 million people.[2]

In the U.S. study, there were 186 case patients and 681 control patients. In the case-control analysis, the conditional odds ratio for VTE comparing use of drospirenone pills compared with use of levonorgestrel pills was 2.3 (95% confidence interval [CI] 1.6 to 3.2). The incidence rates for VTE in the study population were 30.8 (95% CI 25.6 to 36.8) per 100,000 woman years among drospirenone pill users and 12.5 (9.61 to 15.9) per 100,000 woman years among levonorgestrel pill users. The age-adjusted incidence rate ratio for VTE for current use of drospirenone OCs compared with those containing levonorgestrel was 2.8 (2.1 to 3.8).

The risk of non-fatal VTE among users of drospirenone pills seems to be about twice that of users of levonorgestrel pills, after the effects of potential confounders and prescribing biases have been taken into account, researchers conclude. Researchers note limitations of the study include a lack of primary record review, inability to determine the effect of smoking, lack of data on height and weight, and lack of data on a family history of VTE.[1]

In looking at the UK database, 61 case patients were identified, along with 215 control patients. In the case-control analysis, current use of the drospirenone pill was associated with a threefold higher risk of non-fatal idiopathic VTE compared with levonorgestrel use. The odds ratio adjusted for body mass index was 3.3 (95% CI 1.4 to 7.6). Subanalyses indicate that referral, diagnostic, first time user, duration of use, and switching biases were unlikely explanations for this finding, researchers note. The crude incidence rate was 23.0 (95% CI 13.4 to 36.9) per 100,000 woman

years in current users of drospirenone pills and 9.1 (6.6 to 12.2) per 100,000 woman years in current users of levonorgestrel OCs. The age-adjusted incidence rate ratio was 2.7 (1.5 to 4.7). Limitations of this study include a relatively small number of case patients and lack of information regarding a family history of VTE.[2]

Weigh risks, benefits

The two new studies follow two similar analyses published in 2009. All four studies suggest that drospirenone increases the risk of venous thromboembolism compared with levonorgestrel.[4,5] *(Read about the earlier research; see "Review data on Pill use and thrombosis risk," November 2009, p. 123.)* However, results from two earlier prospective, comparative cohort postmarketing surveillance studies do not indicate such risk.[6,7]

Bayer has affirmed the benefit/risk profile of its oral contraceptives. The company has sponsored and is sponsoring several independently conducted, large-scale, post-marketing studies examining the cardiovascular risks associated with the use of not only its own combination oral contraceptives, but also other prescribed pills, says company spokesperson **Rose Talarico**.

Three of the studies that are ongoing include the Long-Term Active Surveillance Study for Oral Contraceptives, the International Active Surveillance Study of Women Taking Oral Contraceptives, and the International Active Surveillance Study — Folate in Oral Contraceptives Utilization Study, says Talarico.

The clear answer

Is there going to be more information coming out over the next several years that might change providers' stance on use of drospirenone pills? **Susan Jick**, DSc, MPH, director of the Boston Collaborative Drug Surveillance Program at Boston University School of Medicine and professor of epidemiology at the Boston University School of Public Health, says, "I don't know the answer, but to me, it is pretty clear that these drospirenone pills increase the risk relative to the levonorgestrel pills." Jick served as a co-author of the two current papers.

As with any oral contraceptive, providers and their patients need to weigh the risks and benefits of drospirenone pills. Even though the relative risk of thrombosis with OCs is increased, pill users face a low absolute risk because VTE is a rare event.[8] The absolute risk of VTE for women on low-dose oral contraceptives is about 12-20 per 100,000 women years of use.[9]

In an editorial accompanying the two new studies, **Nicholas Dunn**, MD, senior lecturer in medical education in the Faculty of Medicine at the UK-based University of Southampton, comments that "in light of the new data, it appears sensible to prescribe an oral contraceptive with a well-known favorable safety profile (one that contains levonorgestrel) unless there is a persistent reason to use another type."[10]

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EC: Healthcare providers are not counseling

A just-published study indicates that many providers are failing to counsel women on the availability of emergency contraception (EC). Among the 63% of women who reported having received a Pap test or pelvic examination in the past 12 months, just 4% reported receiving counseling about EC.[1]

Researchers analyzed data from the 2006-2008 National Survey of Family Growth, a periodic government survey, to perform the study. Their analysis indicates that while use of emergency contraception in the United States has increased after its prescription status changed in 2006, providers aren't offering adequate counseling about the availability of EC.

Despite the over-the-counter (OTC) availability of emergency contraception for most women, a significant proportion of women still might be unaware that EC exists or of when and how to access it, based on the low rates of having received counseling about this method reported among women in this study, says the study's lead author, **Megan Kavanaugh**, DrPH, MPH, senior research associate at the Guttmacher Institute in New York City. Additionally, study data indicates use was highest among higher-income women, she notes. This suggests that the cost of the method still might be a barrier for poorer women, despite this group's increased need for emergency contraception due to higher rates of contraceptive failure and unintended pregnancy, Kavanaugh states.

The "very sad news"

It is "very sad" that clinicians are not providing prescriptions of emergency contraception in advance of need, states **Anita Nelson**, MD, professor in the Obstetrics and Gynecology Department at the David Geffen School of Medicine at the University of California in Los Angeles. Advance prescriptions remind women about its existence and enables insurance to cover the costs, she notes.

"The OTC status is helpful for episodic problems, but the foundation of emergency contraception should be laid by the clinician who either provides methods that don't need EC — such as intrauterine devices and implants — or provides prescriptions for EC to be filled as soon as possible and stored in the medicine cabinet next to the bandages," Nelson says. "Accidents happen."

Providers need to be aware that emergency insertion of a Copper T 380A intrauterine device (ParaGard IUD, Duramed Pharmaceuticals, Pomona, NY) is more effective than emergency contraceptive pills and can provide 12 years of excellent contraception for a woman if she finds the IUD an acceptable method, says **Robert Hatcher**, MD, MPH, professor of gynecology and obstetrics at Emory University School of Medicine in Atlanta. Results of 2007 systematic review indicate that while increased access to emergency contraceptive pills enhances use, it has not been shown to reduce unintended pregnancy rates, Hatcher notes.[2]

Will restrictions lift?

The Food and Drug Administration (FDA) in 2006 approved the levonorgestrel-only EC pill Plan B (Teva Pharmaceuticals, Woodcliff Lake, NJ) for "behind-the-counter" sales to adults 18 and older, which allowed purchase without a prescription. The age restriction was later lowered to 17 in 2009. *(Read more about the 2009 action. See the* Contraceptive Technology Update *article "New emergency contraception options are here, but how are you to use them?" September 2009, p. 97.)*

Teva filed a request with the FDA in February 2011 to make the drug available to women of all ages. The request is under review at the FDA, says **Denise Bradley**, Teva spokesperson. In filing its request, Teva provided the regulatory agency additional data based on a study of actual use of the contraceptive in girls and teenagers ages 11-16.

"Although FDA's request for new data from the

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company before removing the age restriction was unwarranted and unnecessary, we hope the FDA finally has all the information it needs to make a decision and will use this opportunity to confirm their ongoing commitment to public health and scientific integrity," said **Kirsten Moore**, president & chief executive office of the Washington, DC-based Reproductive Health Technologies Project, in a statement issued after the application filing.[3]

The New York City-based Center for Reproductive Rights filed a motion for contempt against the FDA in November 2010 for failing to follow a court order regarding access to emergency contraception for women of all ages. Judge Edward Korman of the U.S. District Court for the Eastern District of New York issued a ruling in March 2009 that the FDA's decision to limit OTC access to Plan B to women over 18 was based on politics rather than science, and he ordered the agency to reconsider its decision. *(*CTU *reported on the 2009 court action; see "Check progress of emergency contraception," May 2009, p. 51.)* **Nancy Northup**, president of the Center for Reproductive Rights, said in a February 2011 statement, "We certainly support any actions that will increase women's access to emergency contraception, but Teva's application does not absolve the FDA of its responsibility to comply with the court order. There's enough scientific evidence before the agency to decide whether to make Plan B available over-the-counter, and there has been for 10 years."[4]

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New HPV test gains approval from FDA

Add another human papillomavirus (HPV) test to the clinical arsenal. The Food and Drug Administration (FDA) has approved the Roche cobas HPV Test. The new test individually identifies genotypes 16 and 18, the two highest-risk HPV genotypes responsible for more than 70% of cervical cancer cases, while simultaneously detecting 12 other high-risk HPV genotypes.

The cobas HPV test received FDA approval on April 19 and became commercially available on May 2, says Michael Weist, spokesperson for the Basel, Switzerland-based company. The test relies on amplification of target DNA by polymerase chain reaction (PCR) and nucleic acid hybridization for the detection of 14 high-risk (HR) HPV types in a single analysis. The test specifically identifies types HPV 16 and HPV 18 while concurrently detecting the other high-risk types: 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68.

How will its cost compare with comparable HPV tests? "The cost for patients will be similar to what they pay now for HPV testing, which is comparable to the cost of a Pap test, but the value of the cobas HPV test will be much greater because physicians will get more information and get it faster," says Weist. "Because the test could mean fewer return visits, less re-testing, and earlier identification of women at risk, it could have a significant impact on reducing healthcare costs overall."

When should it be used?

Test results may be used in women age 30 and over, or women age 21 and older with borderline cytology results to determine the need for additional follow-up and diagnostic procedures. Test results should be used with a provider's assessment of cytology history, other risk factors, and professional guidelines, according to material from the FDA.

When should it not be used? The cobas HPV Test is not intended for use as a screening device for women under age 30 with normal cervical cytology, to substitute for regular cervical cytology screening, or for use in determining the need for treatment of the cervix in the absence of high-grade cervical dysplasia.

Data from the Addressing The Need for Advanced HPV Diagnostics (ATHENA) study,

EXECUTIVE SUMMARY

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which involved more than 47,000 women in the United States, indicates that one in 10 women age 30 and older who tested positive for HPV 16 and/or 18 by the cobas HPV Test actually had cervical pre-cancer, even though they showed normal results with the Pap test.[1]

Anita Nelson, MD, professor in the Obstetrics and Gynecology Department at the David Geffen School of Medicine at the University of California in Los Angeles sees a narrow band for use of the test. It might be helpful if a patient over age 30 is HPV-positive with a normal Pap smear, Nelson notes.

Other tests available

The Roche tests join other HPV tests on the U.S. market. The digene HC2 HPV Test from Hilden, Germany-based Qiagen NV emerged in 2003 as the first molecular diagnostics test to receive FDA approval. It is used to determine the need for colposcopy/biopsy referral for women with borderline abnormal cytology results and for co-testing with cytology to screen women age 30 and over to assess risk of cervical cancer caused by persistent unresolved HPV infection. *(*Contraceptive Technology Update *reported on the test in the article, "Get ready to take cervical cancer screening to the next level," June 2003, p. 61.)*

In 2009, the FDA approved two tests from Bedford, MA-based Hologic. *(Read more about these tests; see "Get ready for changes in HPV DNA testing,"* CTU*, June 2009, p. 67.)* The Cervista HPV HR test was approved for screening patients with atypical squamous cells of undetermined significance (ASC-US) cervical cytology results to determine the need for referral to colposcopy, and as an adjunct with cervical cytology to screen women 30 years and older to assess the presence or absence of high-risk HPV types.

The second test, the Cervista HPV 16/18 test, was approved for use in women age 30 and older as an adjunctive test with the Cervista HPV HR test in combination with cervical cytology to assess the presence or absence of specific high-risk HPV types. It also was approved as an adjunctive test with the Cervista HPV HR test in patients with ASC-US cervical cytology results, to assess the presence or absence of specific high-risk HPV types. The results of this test are not intended to prevent women from proceeding to colposcopy.

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Is your radar up regarding herpes risk?

Results of a new study indicate patients who have tested positive for herpes simplex virus type 2 (HSV-2) but don't have symptoms or genital lesions still experience virus shedding during subclinical episodes.[1] What is the implication for healthcare providers? It's time to increase screening for genital herpes, because there is a high risk of transmission from persons with unrecognized HSV-2 infection.

To conduct the study, researchers compared the rates and patterns of genital HSV shedding in 498 immunocompetent HSV-2-seropositive persons between March 1992 and April 2008. Each participant obtained daily self-collected swabs of genital secretions for at least 30 days. The rate of viral shedding, defined as the presence of virus that is actively replicating and can be transmitted to another person, was measured by polymerase chain reaction, a testing method for viral DNA.

Study data indicate the bulk of days of shedding in persons with asymptomatic HSV-2 is unrecognized, and people might engage in sexual activity not knowing that they are at risk for transmitting the virus to sexual partners.[1]

How can people take preventive measures if they do not know their HSV status? asks **Anna Wald**, MD, MPH, professor of medicine, epidemiology and laboratory medicine at the University of Washington in Seattle. Wald served as lead author of the current analysis. Providers need to realize that patients are interested in being tested, says Wald. Before preventive strategies can be employed, patients need to know their infection status, she states.

Robert Hatcher, MD, MPH, professor of gynecology and obstetrics at Emory University School of Medicine in Atlanta, reminds providers that there are five sexually transmitted infections for which young men and women are at risk, all of which are transmitted more than 50% of the time by a completely asymptomatic person infected with herpes, HPV, hepatitis B, HIV, or chlamydia. For this reason, condoms should be used almost routinely by young, sexually active couples, he advises.

Look closely at results

In performing the analysis, researchers report that HSV-2 was detected on 4,753 of 23,683 days (20.1%) in 410 persons with symptomatic genital HSV-2 infection, compared with 519 of 5,070 days (10.2%) in 88 persons with asymptomatic infection. Genital HSV was detected at least once in 342 of 410 persons (83.4%) with symptomatic HSV-2 infection and in 60 of 88 (68.2%) persons with asymptomatic infection.

Subclinical genital shedding rates were higher in persons with symptomatic infection compared with asymptomatic infection (2,708 of 20,735 [13.1%], compared to 434 of 4,929 [8.8 %]), researchers note. The median amount of HSV detected during subclinical genital shedding episodes was similar in persons with symptomatic and asymptomatic infection, they observe.

Patients with symptomatic infection had more frequent genital shedding episodes (median 17.9 episodes per year) compared with persons with asymptomatic infection (12.5 episodes per year), the analysis shows. Days with lesions accounted for 2,045 of 4,753 days (43.0%) with genital viral shedding among persons with symptomatic genital HSV-2 infection, compared with 85 of 519 days (16.4%) among persons with asymptomatic infection.

Why don't more providers test for genital herpes? There are no recommendations to routinely test for HSV-2, says Wald.

While there are type-specific antibody tests that distinguish HSV-1 from HSV-2, there are important testing tricks and details that providers need to know before they begin expanded testing/screening, says study co-author **Terri Warren**, RN, NP, owner of the Westover Heights Clinic in Portland, OR. There also are excellent new types of swab tests that put cultures to shame in terms of sensitivity, she states. *(The American Social Health Association of Research Triangle Park, NC has developed several helpful provider resources for herpes testing. To access them, visit the organization's web site, www.ashastd.org and click on "Herpes Resource Center." At the center web page, you can click on "Herpes Blood Test Guide" to download a free two-page listing of tests. Also at the center web page, you can check out other testing resources by selecting "The Herpes Testing Toolkit online.")*

Keep up to date on testing

Stay abreast of current information on HSV-2 testing, advises Warren, who is the author of *The Good News About the Bad News* (New Harbinger Publications), a book designed to provide updated information to those who have been diagnosed with HSV-2 infection. Providers should be aware of low positive/false positive issues with serologic testing, says Warren. Only 50% of people who test in the 1.1 to 3.5 range are infected, she notes.

"I spend a ton of time these days ordering Western blots [which detects the IgG blood antibody] for people around the country who test positive in this range," says Warren. "The same is true with IgM tests [which detects the IgM blood antibody], only even a high rate don't confirm."

EXECUTIVE SUMMARY

Results of a new study indicate patients who have tested positive for herpes simplex virus type 2 (HSV-2) but don't have symptoms or genital lesions still experience virus shedding during subclinical episodes.

- Study data indicate the bulk of days of shedding in persons with asymptomatic HSV-2 is unrecognized, and people might engage in sexual activity not knowing that they are at risk for transmitting the virus to sexual partners.
- When patients learn that they have herpes, be sure to include adequate information on asymptomatic viral shedding. Discuss condom use, daily valacyclovir therapy, and disclosure of HSV-2 serostatus to help cut the risk of HSV-2 transmission.

When people find out they have herpes, they must be adequately informed about asymptomatic viral shedding, says Warren. Condom use, daily valacyclovir therapy, and disclosure of HSV-2 serostatus can cut the risk of HSV-2 transmission and help patients live successful lives, she notes.

Past research indicates that an unwillingness to discuss sexual issues can keep providers from offering important information on herpes, notes Wald.[2] "People are uncomfortable talking about sexual issues, and that certainly has been documented in many different studies," says Wald. "You sort of have to 'go there' if you are going to be talking about genital herpes."

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New approach eyed for recurrent UTIs

One woman in five develops a urinary tract infection (UTI) during her lifetime, according to the National Institute of Diabetes and Digestive and Kidney Diseases.[1] About one-third of women develop frequent recurrent episodes, which can call for repeated rounds of antimicrobial treatment.[2]

Science is now eyeing the use of probiotics in UTI treatment.[3] A depletion of vaginal lactobacilli has been associated with urinary tract infection risk. Scientists have theorized that replenishing these bacteria might be beneficial. Researchers conducted a double-blind placebo-controlled trial to investigate this theory, with positive results indicated for use of a Lactobacillus crispatus intravaginal suppository now under development.

"The next step for us is a larger study, pure and simple," says the paper's lead author, **Ann Stapleton**, MD, FACP, professor in the Division of Allergy & Infectious Diseases at the University of Washington School of Medicine in Seattle. "We would like to confirm our data in a larger group of women."

To perform the study, researchers enrolled women ages 18-40 with current, symptomatic, uncomplicated cystitis and a history of recurrent urinary tract infections. The women were randomized to receive a Lactobacillus crispatus intravaginal suppository probiotic *(Lactin-V, under development by Osel, Mountain View, CA)* or a placebo for five days, then once a week for 10 weeks.

Findings indicate the probiotic intravaginal suppository might reduce the rate of recurrent UTI in UTI-prone women by about one-half. Researchers report that among the 50 women who received Lactin-V, the rate of culture-confirmed UTI was 15%, as compared with 27% among women who received placebo (relative risk [RR] 0.5; 95% confidence interval [CI] .2–1.2). Women who used the suppository who achieved a high-level L. crispatus vaginal colonization pattern had a significant reduction in recurrent episodes compared with those who didn't. Women who used the placebo drug didn't experience such a reduction, regardless of their pattern of colonization.

What is the next step?

While the current study did not compare Lactin-V to prophylactic antibiotics, a 2008 meta-analysis of 10 randomized controlled trials that looked at continuous antimicrobial prophylaxis found rates of recurrent UTI reduced to 12% (24 of 195 participants) compared with 65% (116 of 177 participants) among placebo recipients. The 2008 meta-analysis showed a relative risk of recurrent UTI (RR, 0.21; 95% CI, 0.13-0.33) that is comparable to the findings of the current probiotic study.

EXECUTIVE SUMMARY

A depletion of vaginal lactobacilli has been associated with urinary tract infection risk. Scientists have theorized that replenishing these bacteria might be beneficial. Researchers recently conducted a double-blind placebo-controlled trial to investigate this theory, with positive results indicated for use of a Lactobacillus crispatus intravaginal suppository now under development.

- One woman in five develops a urinary tract infection during her lifetime, according to the National Institute of Diabetes and Digestive and Kidney Diseases.
- About one-third of women develop frequent recurrent episodes, which can call for repeated rounds of antimicrobial treatment.

Lactin-V is being developed as an investigational new drug for prescription use for specific medical indications in women's health, says **Peter Lee**, MD, founder of Osel and associate professor of medicine in the Department of Medicine at Stanford University. The primary focus of the probiotic's research is on recurrent urinary tract infections; however, investigators also are looking at its potential use against bacterial vaginosis, says Lee.

Osel plans to undertake a Phase III multi-center trial, says Lee. The company is seeking funding for the research, he says.

Recurrence — what to do?

For women who have three or more recurrences in a year, urologic evaluation is indicated to rule out pelvic and gynecologic abnormalities. Radiographic and cystoscopic evaluation can check for anatomical abnormalities. Postmenopausal women also should be evaluated for renal function and emptying.

When abnormalities are ruled out, providers can choose from several therapeutic options for recurrent infections.[4] Chronic low-dose antibiotic symptomatic treatment with the antibiotics nitrofurantoin or trimethoprim-sulfamethoxazole can be used. Either of these drugs can be used for 6-12 months, followed by an antibiotic-free period and a re-evaluation for return of infection.[5]

Drinking cranberry juice might prevent Escherichia coli, Staphylococcus aureus, and other UTI-causing bacteria from adhering to the urinary tract and forming biofilms in it, according to a 2010 study.[6] Researchers had study participants drink water or cranberry juice cocktail, then they studied the effects of their urine on bacteria. Scientists used an atomic force microscope probe to measure the bacteria's ability to adhere, which is the beginning step necessary for the biofilm formation seen in UTIs.

Researchers report urine from volunteers who drank cranberry juice cocktail prevented bacterial adhesion and biofilm formation. Bacteria treated with urine from volunteers who drank water were able to stick to the probe and form biofilms.[6]

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Providers look to help from workforce program

By **Adam Sonfield**
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For four decades, safety-net providers such as community health centers have turned to the National Health Service Corps (NHSC) for help with maintaining a well-trained and credentialed workforce. Specialized family planning centers have had little access to NHSC-supported clinicians, but additional funding for the program might provide an opportunity to change that, according to **Rachel Benson Gold**, MPA, director of policy analysis at the Guttmacher Institute.[1]

All safety-net providers are hindered in recruiting and retaining clinicians because their limited budgets put them at a disadvantage in competing with hospitals and private-sector providers. The recession and government budget woes have added to these problems, as has a national shortage of primary care providers. Beyond these general problems, family planning centers must maintain a workforce (primarily, nurse practitioners, physician assistants, and nurse midwives) with training

specific to the delivery of family planning services. They also must deal with additional local problems, such as low demand and long commutes in rural areas and clientele who speak a wide variety of languages in urban areas. One important program to help address these workforce issues, a training program funded for three decades by the Title X family planning program, has been phased out, largely because of a movement toward increased credentialing standards for nurse practitioners.

Congress created the NHSC in 1970 to address these workforce challenges for safety-net providers in areas designated by the federal government as Health Professional Shortage Areas (HPSAs). It does so through two programs: one providing upfront scholarships, and a second one providing loan repayments, both in exchange for two or more years of service at sites in these HPSAs. The programs support more than 8,000 clinicians, including physicians, physician assistants, nurse practitioners, and certified nurse midwives.[2]

Requirements for sites

For an NHSC-supported clinician to be placed at a specific service site, that site must receive approval from the program. Sites must meet such requirements as being located in a HPSA; participating in Medicaid and the Children's Health Insurance Program; accepting all patients, regardless of ability to pay, on a discounted sliding-fee scale; and demonstrating workforce needs and difficulties in recruitment. The program traditionally has had limited funds and has set second-tier conditions for a site to receive priority. Notably, priority sites must provide primary care — broadly defined by the program to include services related to family medicine, internal medicine, or obstetrics and gynecology, among other areas — and must be part of "a system of care that provides a continuum of services, including comprehensive primary health care and appropriate referrals or arrangements for secondary and tertiary care."[3]

Community health centers, many of which receive funding through the Title X program, traditionally have received large numbers of NHSC placements. Specialized family planning centers have had far more difficulty receiving approval as an NHSC site. Yet, most of those located in an HPSA should be able to meet the core requirements for participation, and in fact, the Title X program includes many similar requirements, such as a sliding fee scale. Most of the criteria for priority status also can be readily met. The continuum-of-services condition is likely the most problematic, as many family planning centers are not formally part of a comprehensive primary care agency. However, Title X requires programs to refer clients for care outside their expertise, something that family planning centers facilitate through referral arrangements with other providers in the community. Indeed, family planning centers often serve as an entry point to the healthcare system, with six in 10 of their clients viewing the center as their usual source of medical care.[4]

Going forward, there might be more opportunities for new sites, including specialized family planning centers, to receive NHSC placements, even if they do not entirely meet all of the program's conditions for priority status. The program has received two major boosts in federal funding: a $300 million expansion under the stimulus legislation enacted early in 2009, and another $1.5 billion over five years under the 2010 healthcare reform legislation.[5,6] To improve their chances for approval as NHSC placement sites, and to otherwise adapt to health reform and other changes in the U.S. health care system, family planning centers might wish to reevaluate and bolster their relationships with other local providers.

COMING IN FUTURE MONTHS

- What can you do to promote breastfeeding?
- Immediate oral antiretroviral therapy — HIV prevention tool?
- Use webinar to focus on adolescent reproductive health
- HIV vaccine: Where are vaccines in the research pipeline?
- Check your IQ when it comes to immunizations for women

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CTUPDATES
News ■ Resources ■ Events

FDA issues warning on fraudulent STD drugs

The Food and Drug Administration (FDA) and the Federal Trade Commission have issued a joint call to remove products from the market that make unproven claims to treat, cure, and prevent sexually transmitted diseases (STDs). Among the targeted products are Medavir, Herpaflor, Viruxo, C-Cure, and Never An Outbreak.

The agencies have issued letters to the drug manufacturers warning that their products violate federal law. These products, sold online and in retail outlets, have not been evaluated by the FDA for safety and effectiveness.

CNE/CME INSTRUCTIONS

To earn credit for this activity, please follow these instructions.

1. Read and study the activity, using the provided references for further research.
2. Log on to www.cmecity.com to take a post-test; tests can be taken after each issue or collectively at the end of the semester. First-time users will have to register on the site using the 8-digit subscriber number printed on their mailing label, invoice or renewal notice.
3. Pass the online tests with a score of 100%; you will be allowed to answer the questions as many times as needed to achieve a score of 100%.
4. After successfully completing the last test of the semester, your browser will be automatically directed to the activity evaluation form, which you will submit online.
5. Once the completed evaluation is received, a credit letter will be e-mailed to you instantly. ■

CNE/CME OBJECTIVES

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;
- provide practical information that is evidence-based to help clinicians deliver contraceptives sensitively and effectively.

CNE/CME QUESTIONS

1. What are the two combined oral contraceptives with folate use drospirenone as their progestin?
   A. Beyaz and Safyral
   B. Ocella and Gianvi
   C. Yasmin and Yaz
   D. Yaz and Zarah

2. The Roche cobas HPV Test performs what tests?
   A. It only identifies genotypes 16 and 18.
   B. It individually identifies genotypes 16 and 18, while simultaneously detecting 12 other high-risk HPV genotypes.
   C. It detects 12 high-risk HPV genotypes, but not 16 and 18.
   D. It detects genotype 16 alone.

3. Which three strategies have been shown to cut the risk of transmission of herpes simplex virus-2?
   A. Condom use, daily acyclovir therapy, and disclosure of HSV-2 serostatus.
   B. Condom use, daily famciclovir therapy, and disclosure of HSV-2 serostatus.
   C. Condom use, daily valacyclovir therapy, and disclosure of HSV-2 serostatus.
   D. Condom use, daily tinidazole therapy, and disclosure of HSV-2 serostatus.

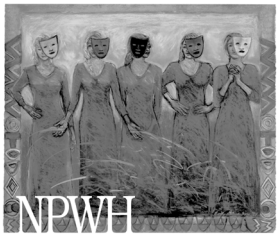
4. How many women will develop a urinary tract infection in their lifetime?
   A. One woman in five
   B. One woman in 15
   C. One woman in 20
   D. One woman in 50

The products claim to treat a range of STDs, including herpes, chlamydia, genital warts, HIV, and AIDS. While some of the companies market these products as dietary supplements, all are considered drug products under the Federal Food, Drug, and Cosmetic Act, because they are offered for the treatment of disease. Such products might not be introduced into interstate commerce without an FDA-approved new drug application.

"These products are dangerous because they are targeted to patients with serious conditions, where treatment options proven to be safe and effective are available," said Deborah Autor, director of the Office of Compliance in FDA's Center for Drug Evaluation and Research, in a statement issued by the two agencies. "Consumers who buy these products may not seek the medical attention they need and could spread infections to sexual partners."

To see a list of the products, as well as pictures of them, go to the FDA web site, www.fda.gov. Select "Drugs," then " under "Consumer Resources," select "Resources for You." Select "Buying & Using Medicines Safely," then "Medication Health Fraud." Under "Fraudulent Products for Serious Diseases," select "Fraudulent Products: Sexually Transmitted Diseases" to access links to photos, a question-and-answer sheet, and other resources. ■

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 healthcare professionals.



S·T·I
QUARTERLY

HIV prevention trial halted — What's the next step in clinical research?

FEM-PrEP study stopped — Interim results indicate unlikely effectiveness

Investigators have discontinued the FEM-PrEP study of oral emtricitabine and tenofovir disoproxil fumarate (Truvada, Gilead Sciences, Foster City, CA) to prevent HIV infection in women in Africa after interim results indicated the research would be unlikely to prove effectiveness in the study population.

The study was a randomized, placebo-controlled, clinical trial of the effectiveness of daily, oral Truvada for HIV prevention among HIV-uninfected women in Kenya, South Africa, and Tanzania, lead by the Research Triangle Park, NC-based Family Health International (FHI). FEM-PrEP began in July 2009 with plans to enroll about 3,900 women; final results were anticipated in 2013. As of February 2011, the study had screened 3,752 women and enrolled 1,951: 739 in Bondo, Kenya; 764 in Pretoria, South Africa; 432 in Bloemfontein, South Africa; and 16 in Arusha, Tanzania. FEM-PrEP was funded by the U.S. Agency for International Development, with early support from the Bill & Melinda Gates Foundation.

As part of the final analysis, the study team will assess whether adherence to the study drug was sufficient to measure an effect of Truvada, says **Timothy Mastro**, MD, FACP, DTM&H, FHI vice president of health and development sciences. Adherence to study product is measured in three ways, says Mastro: participant self-report, on which FHI already has shared preliminary data; pill counts; and the presence of tenofovir and emtricitabine in blood samples. If adherence was low, then the study team will need to understand why women chose not to take their study pills, especially given the focus on participant-centered and goal-oriented adherence counseling, Mastro explains.

The study team also will attempt to analyze contraceptive hormone levels in blood specimens among Truvada users compared with placebo users, including hormone levels prior to pregnancy. In ad-

EXECUTIVE SUMMARY

Investigators have discontinued the FEM-PrEP study of oral emtricitabine and tenofovir disoproxil fumarate, known as Truvada, to prevent HIV infection in women in Africa after interim results indicated the research would be unlikely to prove effectiveness in the study population.

- The study was a randomized, placebo-controlled, clinical trial of the effectiveness of daily, oral Truvada for HIV prevention among HIV-uninfected women in Kenya, South Africa, and Tanzania.
- Other trials continue to look at use of Truvada and other antiretroviral drugs. The Vaginal and Oral Interventions to Control the Epidemic trial is examining use of oral tenofovir and Truvada taken daily, as well as tenofovir 1% vaginal gel.

Statement of Financial Disclosure:
Consulting Editor **Robert A. Hatcher**, MD, MPH, Author **Rebecca Bowers**, and Executive Editor **Joy Dickinson** report no consultant, stockholder, speaker's bureau, research, or other financial relationships with companies having ties to this field of study. **Sharon Schnare** (Nurse Reviewer) discloses that she is a retained consultant and a speaker for Barr Laboratories, Berlex, and Organon; she is a consultant for 3M Pharmaceuticals; and she is a speaker for FEI Women's Health, Ortho-McNeil Pharmaceuticals, and Wyeth-Ayerst Pharmaceuticals.

dition, the team will assess factors associated with pregnancy including use of study product, the use of other medications, contraceptive adherence, and adverse events, Mastro notes. All women in the trial were using effective contraception; 66% were using injectables, and 30% were using oral contraceptives.

Among women who were randomly assigned to the Truvada arm and used oral contraceptives, researchers report observed pregnancy rates were higher than among women randomly assigned to the placebo arm. This finding is unexpected and inconsistent with known drug interactions involving tenofovir and contraceptive hormones, and with known metabolic effects of emtricitabine, they note. Some possible explanations include differential pill adherence by group, previously undefined drug-drug interactions, chance, or a combination of factors.

"The sexual behaviors among trial participants will also be analyzed to determine if study participation resulted in risk compensation," Mastro states. "Risk compensation occurs when a participant increases risky behaviors because she feels the study pill will protect her from HIV."

Why didn't it work?

There are several possible reasons for the FEM-PrEP study findings, suggest FHI officials. These include including low adherence to study regimen, a true lack of effect of the product among women, or other factors still to be determined.

HIV prevention experts held much hope for the FEM-PrEP trial following release of the Pre-exposure Prophylaxis Initiative (iPrEx) trial. In that study, researchers found that among men who have sex with men who took Truvada, subjects experienced an average of 43.8% fewer HIV infections than those who received a placebo pill.[1] *(To read more about the iPrEx trial, see the* STI Quarterly *supplement article, "Update: use of HIV drugs shrinks infection risk in uninfected people," March 2011, supplement 1.)*

The FEM-PrEP trial, despite its early closure, yet might provide useful scientific and behavioral insights, says **Yasmin Halima,** MPH, director of the Washington, DC-based Global Campaign for Microbicides. "Despite our excitement over the iPrEx results last year that showed that oral daily Truvada reduced HIV transmission in men who have sex with men, FEM-PrEP did not show conclusive proof that daily Truvada helps protect women from HIV," she notes.

Why is it important that research continue in prevention interventions? The huge level of new HIV infections that occur in women living in Sub-Saharan Africa underscores the urgent need for interventions that work in women, says Halima. "One in five women who screened for FEM-PrEP were not able to join the trial because they already came infected with HIV," she notes. "So it is imperative that we continue our search."

Look to more research

Scientists might be close to learning whether Truvada or another antiretroviral drug, tenofovir, helps to prevent HIV in women, says Halima. For example, in the VOICE (Vaginal and Oral Interventions to Control the Epidemic) trial, scientists are looking at oral tenofovir and Truvada taken daily, as well as tenofovir 1% vaginal gel, says Halima. *(See more on the VOICE trial in the* Contraceptive Technology Update *article, "Tenofovir gel makes strides in development," January 2011, p. 5.)* Such investigation will help researchers understand not only whether these interventions are effective in women, but also about women's preferences — whether women like an oral pill versus topical microbicide, she notes.

VOICE is continuing to enroll participants in its study; more than 4,200 women have been enrolled to date. The study began in September 2009 and will involve about 5,000 women. Researchers expect to report results in early 2013.

Another ongoing trial, which is evaluating Truvada, as well as oral tenofovir, is the Partners PrEP study. This study includes men and women in Kenya and Uganda in serodiscordant relationships, in which one partner is HIV-infected and the other is not. The study has reached its target enrollment of 4,700 couples; study results are expected in early 2013. The Centers for Disease Control and Prevention is sponsoring a study in Thailand to assess the safety and efficacy of daily tenofovir to prevent parenteral HIV infection among injection drug users. That trial is continuing to enroll participants.

Prevention specialists are heartened by the results of the 2010 CAPRISA 004 clinical trial of tenofovir gel. In that study, the microbicide was found to be 39% effective in reducing a woman's risk of becoming infected with HIV during sex and 51% effective in preventing genital herpes infections in the women participating in the study.[2] Results of that clinical trial represent the first "proof of concept" for a vaginal microbicide. *(Read more about the CAPRISA 004 trial; see the* CTU *article, "HIV breakthrough: Trial results offer promise," October 2010, p. 114.)*

There are several novel antiretroviral-containing candidates in the pipeline, such as slow-release vaginal rings and long-acting agents, which might offer more options for women, says Halima. Research

must continue, given the scope of the epidemic, says Halima.

"The Global Campaign for Microbicides continues to advocate for the development of new tools designed for women, particularly women who remain most vulnerable to HIV," she notes. "We as scientists, government, and advocates can't and won't stop until we collectively meet that challenge."

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Heighten awareness to lower chlamydia numbers

What will it take to drive down the number of chlamydia infections in young women? While routine chlamydia screening is recommended for all sexually active females age 24 years and younger, only about half (49.9%) were screened during 2008-09, according to data collected in more than 1,000 U.S. health plans.[1]

To reach young people directly in the places where they're already talking, the Centers for Disease Control and Prevention (CDC) is working with MTV and others on the Get Yourself Tested (GYT) campaign. The goal of GYT is to create a social movement to reduce stigma and get young people tested for sexually transmitted diseases (STDs), says Nikki Mayes, CDC spokesperson. *(Read more about the GYT campaign; see the* Contraceptive Technology Update *article, "Boost efforts to close STD prevention gaps," in the June 2009* STD Quarterly *supplement, p. 2.)*

CDC is expanding its focus on chlamydia screening in young women through the GYT program. It has awarded nine subcontracts, valued up to $20,000 each, to support implementation and evaluation of local strategic social marketing plans to promote chlamydia and other STD screenings. Funding has been allocated to the Jackson County Health Department in Murphysboro, IL; Johns Hopkins University in Baltimore; Metro TeenAIDS in Washington, DC; Planned Parenthood of Kentucky in Lexington; Planned Parenthood of Metropolitan New Jersey in East Orange; Sacramento County — Department of Health and Human Services in Sacramento, CA; Sanford Health in Sioux Falls, SD; the University of California, San Francisco; and the University of Missouri in Columbia.

"We know that testing is among the most effective, yet underused, tools we have to prevent the spread of STDs," says Mayes. "The reality is, any sexually active person can be infected with STDs, and young women are particularly at risk for the devastating consequences of untreated STDs like chlamydia and gonorrhea — both of which can lead to painful pelvic inflammatory disease and, in some cases, infertility."

The good news is most STDs are treatable and many are curable, but early detection through testing is critical, Mayes notes. Due to scientific advances, STD testing has never been easier, she points out. Testing is fast, often confidential, and free or low-cost, says Mayes. *(How can you get across the need for chlamydia screening? Use the tips on p. 4.)*

When chlamydia is transmitted from an infected individual to an uninfected individual, more than half the time, the infected individual has no symptoms, says **Robert Hatcher**, MD, MPH, professor of gynecology and obstetrics at Emory University School of Medicine in Atlanta. Since this situation also is true in the transmission of the other major sexually transmitted infections, young couples should almost routinely use condoms, says Hatcher.

Minnesota takes aim

Minnesota public health officials have joined hands with other community partners to develop

EXECUTIVE SUMMARY

Many types of outreach are being developed to get more young women to be tested for chlamydia.

- The Centers for Disease Control and Prevention is promoting the Get Yourself Tested campaign, which is designed to create a social movement to reduce stigma and get young people tested for sexually transmitted diseases (STDs). The agency has awarded nine subcontracts to support implementation and evaluation of local strategic social marketing plans to promote chlamydia screening.
- Minnesota public health officials have joined hands with other community partners to develop The Minnesota Chlamydia Strategy: Action Plan for Reducing and Preventing Chlamydia in Minnesota, a comprehensive, statewide action plan to address the state's chlamydia epidemic.

The Minnesota Chlamydia Strategy: Action Plan for Reducing and Preventing Chlamydia in Minnesota, a comprehensive, statewide action plan to address the state's chlamydia epidemic.

A new report from the Minnesota Department of Health underscores the need for such action: chlamydia reached a record level of 15,294 cases in the state in 2010. This figure not only represents a 6% increase from the previous year, it stands as the highest number of cases ever recorded in the state in a single year since officials began tracking chlamydia statistics in 1986. Of even more concern: about 70% of 2010 cases occurred in teens and young adults ages 15 to 24, say state public health officials.

Chlamydia numbers have been rising in Minnesota for the last four or five years, says **Candy Hadsall**, RN, MA, STD screening specialist with the Minnesota Department of Health. Public health officials began networking with community members in 2010 to develop the Minnesota Chlamydia Partnership, a statewide stakeholder group, as a fresh approach to the problem.

Hadsall says they thought it was imperative to go out and ask people in the community for their help, "not only about what should be done, but what could they do. We recognize that chlamydia is really a social problem, as well as a medical problem."

The Partnership held a statewide summit in the summer of 2010, with groups charged to develop the action plan. Released in April 2011, the document is the result of more than 300 individuals and several organizations from across Minnesota who have worked together to create a common framework to reduce the burden of chlamydia in the state. *(Review the document; go to the Partnership web page, www.health.state.mn.us/divs/idepc/diseases/chlamydia/mcp and click on the document link.)*

The plan includes five long-term goals: reduce rates of chlamydia and gonorrhea in Minnesota, especially in people ages 15-25; increase awareness of chlamydia in the general public; change the behavior of adolescents so that they are reducing their risk for contracting and transmitting diseases; reduce the stigma, shame, and secrecy that surrounds STDs; decrease health inequities, especially in communities most affected by chlamydia and gonorrhea; and remove systemic barriers that contribute to high rates of STDs.

Raising public awareness about chlamydia is a key part of the plan, says Hadsall. "The general public doesn't have a very good understanding of chlamydia; that may be partially healthcare providers' fault," observes Hadsall. "Since it looks like a medical topic, people assume that people in medicine will take care of it."

Education plays a strong role in the state plan. Advocates are pushing for education in the home and in school regarding chlamydia screening, treatment and prevention. "I don't think we've done a good job of educating people that the same reasons people have unprotected sex and get pregnant are the same reasons that they have unprotected sex and get STDs," says Hadsall. "It is a multi-faceted problem, and it takes more than just a public health approach."

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Use fast facts to boost chlamydia screening

Use these short, motivating messages developed through research conducted by the Centers for Disease Control and Prevention and the Los Angeles County, CA, Department of Public Health to help young women understand the importance of chlamydia screening:

- Chlamydia is a sexually transmitted disease that can have serious consequences. It can affect your fertility, prevent you from having children, and hurt your unborn child.
- Chlamydia is very common. More than one million women are diagnosed each year.
- Chlamydia usually has no symptoms. You can have it and not even know it.
- Chlamydia testing is not automatic. You need to ask for it and have a test every year.
- The test is simple, quick and painless. It is often inexpensive or free, and it can be done with a urine test.
- You should be tested because chlamydia can be cured. A simple antibiotic pill is used for treatment.

SOURCE:

National Chlamydia Coalition. Getting More Young Women Screened for Chlamydia: Findings from Qualitative Research. Accessed at http://www.prevent.org/data/images/ncc/ncc%20research%20brief%203.pdf. ■