CONTRACEPTIVE TECHNOLOGY UPDATE®

A Monthly Newsletter for Health Professionals

THOMSON
AMERICAN HEALTH CONSULTANTS

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Get ready to take cervical cancer screening to the next level

Newly approved human papillomavirus test offers '2-in-1' package

When it comes to the fight against cervical cancer, clinicians can count themselves on the front lines of the battle. It is estimated some 50 million women in the United States are screened on an annual basis with Pap tests.[1] Such effort is warranted: In 2003, the Atlanta-based American Cancer Society (ACS) estimates some 12,200 women will be diagnosed with cervical cancer, and 4,100 will die from the disease.[1]

Clinicians now have another tool in their arsenal with the Food and Drug Administration's (FDA) approval of a new screening test that will help distinguish women at increased risk of developing the disease from those at very low risk. The DNA*with*Pap, manufactured by Digene Corp. of Gaithersburg, MD, combines the company's existing Hybrid Capture 2 High-Risk HPV (human papillomavirus) DNA test with a Pap test.

The FDA approved the new dual test as a primary screening option for women 30 years of age and older. The new test is not intended to substitute for regular Pap screening, nor is it intended to screen women

FemCAP method receives market approval from the Food and Drug Administration

Your next patient is a young married woman who is unable to use hormonal birth control and is not interested in using an intrauterine device. Because she wants to have more children, sterilization is not an option at the present time. What contraceptive methods are available to her?

Family planning providers now can offer the FemCap vaginal barrier contraceptive. The device, which has been approved by the

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EXECUTIVE SUMMARY

A new "two-in-one" DNA Pap test as a primary screening tool has been approved for cervical cancer for women ages 30 and older. DNA*with*Pap (Digene Corp.), which combines the traditional Pap test with a screen for 13 strains of human papillomavirus, previously was available only to women with abnormal Pap smear results.

- The test is not intended to screen women younger than 30 who have normal Pap tests.
- Women with a negative HPV test and a normal Pap smear need not be screened again for three years. Women with a positive HPV test and a normal Pap test should be retested in six months to one year.

younger than 30 who have normal Pap tests, states the FDA.[1]

Information on the dual test already is included in the ACS's new screening guidelines, which were released in November 2002, says **Debbie Saslow**, PhD, director of ACS's breast and gynecologic cancer programs. The ACS guidelines call for Pap tests beginning either at age 21 or three years after a woman first has sexual intercourse.[2] Until age 30, screening should be done every year with the regular Pap test or every two years using the liquid-based Pap test. After age 30, women who have had three normal Pap tests in a row can wait two or three years for their next Pap.

Women with a negative HPV test and a normal Pap smear need not be screened again for three years. Women with a positive HPV test and a normal Pap test should be retested in six months to a year.

The addition of an HPV test to cytology screening will allow women to extend screening intervals to three years with greater confidence, says **George Sawaya**, MD, assistant professor of obstetrics, gynecology, and reproductive sciences at the University of California, San Francisco, who conducted some of the research on which the three-year screening interval was based.[3] It is important to realize, however, that many women with a history of normal Pap smears can do so safely without adding this new test, he notes.

"Women and clinicians need to be thoughtful about the true benefits and potential downsides of adopting this new strategy so that good, informed decisions can be made," observes Sawaya. "The main concern is the uncertainty around the appropriate management of women who test positive for

HPV DNA, but who have a normal Pap test."

Digene Corp. plans a full-scale launch of the new test in the third calendar quarter of this year, says **Charles Fleischman**, company president. Digene is working actively with payers so that widespread coverage and payment for HPV testing quickly becomes available for DNA*with*Pap, he reports. Nearly all health plans cover the $50 HPV test for women with mildly abnormal Pap tests; with FDA approval of wider use, Digene Corp. looks to insurers to follow suit.[4] Digene's test will cost $50-$60, compared with $14-$30 for a Pap-only test.[5]

About 50% of U.S. women with atypical squamous cells of unknown origin (ASC-US) Pap test results are tested with Digene's hc2 HPV Test, according to Digene Corp.; 270 laboratories offer the testing, it states. Reimbursement for the ASC-US indication is available for approximately 90% of the U.S. population with health insurance, the company estimates.

Digene Corp. is launching an educational campaign to inform clinicians and women about the availability of the DNA*with*Pap as a primary screening test for women older than age 30, says Fleischman. Other organizations, such as the American Cancer Society, also are developing information campaigns for clinicians and women, he says.

Clinicians are familiar with the HPV screening technology, which can detect 13 high-risk types of HPV. Since March 2000, the test has been used for women with ASC-US test results.[2]

Studies have shown the effectiveness of the testing,[6,7] and screening with HPV plus Pap tests appears to save additional years of life at reasonable costs compared with Pap testing alone.[8] Research indicates that reflex HPV DNA testing provides the same or greater life expectancy benefits and is more cost-effective than other management strategies for women diagnosed as having ASC-US.[9] **(*CTU* reported on reflex testing in its July 2002 article, "Improve cervical cancer screening; review new terminology, guidelines," p. 73.)**

Who should be tested?

Up to 20% of the sexually active U.S. population is believed to be infected with HPV at any one time, states the FDA.[1] Most women who become infected with HPV are able to eradicate the virus, but some women develop a persistent infection that eventually can lead to pre-cancerous changes in the cervix. Women who have normal Pap test results and no HPV infection are at very low risk (0.2%) for developing cervical cancer.[1] Women who have an abnormal Pap test and a positive HPV test are at a 6%-7% increased risk of developing cervical cancer if not treated.[1]

The risk of HPV progressing and causing changes that could lead to cancer is greater for women older than age 30 than for younger women, says Saslow. HPV infections in younger women tend to go away by themselves. In women older than 30, if an HPV infection has not cleared in a year, clinicians will want to do additional testing and follow-up to see if further treatment is needed, she notes.

With news reports of the FDA approval, expect women to ask you about the availability of the new test. What should you tell them?

"Women can have the test if they want to, but they should not feel like they are missing out if they either decide not to have it, if their doctor does not offer it, or their insurance does not cover it," says Saslow. "The Pap test is still a good test."

RESOURCES

- **For more information on HPV testing,** contact: Digene Corp., 1201 Clopper Road, Gaithersburg, MD 20878. Telephone: (800) 344-3631 or (301) 944-7000. Fax: (301) 944-7121. Web: www.digene.com.
- **The Atlanta-based American Cancer Society (ACS) has collaborated** with other national professional organizations in developing a web-based fact sheet, "What Women Should Know about HPV and Cervical Health." To review the fact sheet, go to the ACS web site, www.cancer.org; click on "Medical Updates," "Cervical Cancer," "FDA Approves New Cervical Cancer Screening Test," and "What Women Should Know about HPV and Cervical Health." The fact sheet is a work in progress with the most frequently asked questions from patients and providers. The organization encourages feedback from consumers, clinicians, and organizations; such information will be incorporated in a print version.

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Hormone therapy: Does it boost quality of life?

New research from the Women's Health Initiative (WHI) indicates that for many postmenopausal women, combined hormone therapy does not have a clinically significant effect on their health-related quality of life.[1]

"Our conclusion is that for most women, long-term use of hormones will not have a significant impact on their quality of life — perceived physical and emotional functioning — and the health risks remain," says lead author **Jennifer Hays**, PhD, director of the Center for Women's Health and associate professor in the department of medicine at Baylor College of Medicine, both in Houston.

Clinicians continue to sort out the findings following the 2002 cessation of the estrogen/progestin arm of the WHI trial. The study was halted after data showed that the overall health risk, particularly of cardiovascular disease and breast cancer, from taking estrogens with progestin was greater than the benefits of lowering the risk of colon cancer and bone fractures.[2] **(Review current data and recommendations on hormone therapy; see *Contraceptive Technology Update's* April 2003 article, "Hormone therapy: Make decisions on a balanced risk to benefit basis," p. 37, and the September 2002 article, "Hormone replacement therapy: Review choices in light of new data," p. 97.)**

EXECUTIVE SUMMARY

Estrogen plus progestin therapy does not have a clinically significant effect on postmenopausal women's health-related quality of life, according to new research from the Women's Health Initiative.

- The study, which included ages 50-79, found no significant effects of hormone therapy on perceived general health, role limitations, vitality, social functioning, mental health, depression, cognitive functioning, or sexual satisfaction.
- The study does not address the impact in perimenopausal women. It also does not include information from the estrogen-only arm of the trial, which is ongoing.

In the trial, a total of 16,608 postmenopausal women 50-79 years old were randomly assigned to receive daily estrogen plus progestin or placebo. Researchers collected information about the participants' quality of life after one year and from a smaller subgroup of 1,511 women at three years. Participants were asked questions about their general health, mental and physical health, role limitations associated with their physical or emotional health, bodily pain, energy and fatigue, social functioning, depression, memory, sleep disturbances, and satisfaction with sexual functioning.

Study findings indicate that combination hormone users had no benefit over placebo recipients on any of the quality of life outcomes, including general health, vitality, mental health, depressive symptoms, or sexual satisfactions. At one year, combination hormone use was associated with statistically significant, but not clinically significant, benefits in sleep disturbance, physical functioning, and body pain. After three years, results were not significant.

How do you proceed?

With the findings from the large-scale trial now in hand, clinicians are deliberating on how to apply them in their care of peri- and postmenopausal women.

"This study has little relevance to the woman most likely to initiate hormone therapy; i.e., the woman with menopausal symptoms," comments **Susan Wysocki**, RNC, NP, president and chief executive officer of the Washington, DC-based National Association of Nurse Practitioners in Women's Health.

RESOURCE

Get fingertip information on the latest in hormone therapy research from the following resource:

- **The Cleveland-based North American Menopause Society offers updates** on scientific literature, as well as information for clinicians and consumers, on its web site, www.menopause.org. The site offers free abstracts of the society's monthly journal, *Menopause*, and web-based access of such publications as its *Menopause Guidebook*. Resource links and scientific news also are included at the site.

The population of women studied were an average of 63 years old, Wysocki points out. Nearly 64% of the women studied in the treatment and placebo groups were 10 or more years past menopause, she observes.

"Secondly, women who reported moderate to severe menopausal symptoms were discouraged from entering the trial," says Wysocki. "Only 12.7% of the treatment group and 12.2% of the placebo group had moderate to severe vasomotor symptoms at baseline."

According to Hays, the study has the following limitations:

• Scientists only enrolled women who were willing to be randomly placed on hormones or a placebo.

"Since about 20% of women seek treatment for menopause, and up to 75% of women in the past were noncompliant with hormone therapy, we believe our results still apply to the majority of postmenopausal women," states Hays.

• The study does not focus on perimenopausal women.

Hot flashes peak during the year in which a woman has her last menstrual period; about 65%-85% of women have hot flashes during that period, observes Hays. Quality of life may be more impacted during perimenopause, she notes.

• The data apply only to combination (estrogen plus progestin) hormone therapy.

The estrogen-only arm of the WHI is ongoing, and the data for that study will not be analyzed until the study is completed, states Hays. The analysis is scheduled for May 2005, she reports. *(CTU* will report on that analysis when it is complete.)

Remember that the WHI is not a study of the impact of short-term hormone use on symptoms in perimenopausal women, notes Hays. When the WHI initially was designed in the early 1990s, hormones typically were prescribed for indefinite or lifelong use for symptom relief, as well as to prevent cardiovascular disease and osteoporosis, she points out. It is only since the Food and Drug Administration revised its guidelines in January 2003 that estrogen plus progestin use has been limited to short-term use for symptoms, says Hays.

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Does EC impact contraceptive use?

When it comes to emergency contraception (EC), does its availability and use impact ongoing contraceptive methods? Initial research from one study indicates that adolescent mothers who are given a supply of EC are no less likely to use condoms and other forms of birth control than teen mothers who are not given EC.[1]

Six-month data from the study, which included 160 teen mothers between ages 14 and 20 in the Los Angeles area, show the importance of advance supply, says **Marvin Belzer**, MD, assistant professor of pediatrics at the University of Southern California's Keck School of Medicine and medical director of the adolescent clinic and HIV services at the division of adolescent medicine at Children's Hospital, both in Los Angeles.

Belzer and his colleagues recruited teen mothers from local teen parenting case management programs and presented them with a short educational program on how to use and obtain EC. After the presentation, one-half of the group received an advance supply of EC.

Availability of EC did not impact the teens' methods of protection, notes Belzer. Six months after they received a supply of EC, teen mothers did not decrease their condom use, he reports. At baseline, 42% in the treatment group who were sexually active used condoms; at six months, 58% used condoms. In the control group, 52% used

EXECUTIVE SUMMARY

Contraceptive use does not decline among teen mothers supplied with emergency contraception (EC), according to a recent study. These findings suggest that EC may lower the rate of unwanted pregnancies without raising the risk that women will substitute the method for others that protect against disease.

- Concerns have been raised about repeat EC use or "abuse" of the method. However, a study of women in the United Kingdom showed that such repeat use is rare.
- Present information on EC when discussing contraceptive methods, and provide EC in advance.

condoms at baseline; 57% reported condom use at six months. While 7% of teens with an advance supply of EC became pregnant six months later, 18% of adolescents who did not receive an advance supply reported pregnancies. The researchers are analyzing 12-month data and will publish findings upon completion, says Belzer.

Do women use EC wisely?

One impediment to the availability of EC has been concern about repeat use or "abuse" of the method.[2] However, a study of women in the United Kingdom showed that such repeat use is rare.[3] In the study, which assigned 553 women to be given an advance supply of EC and 530 women to use EC through a provider visit, very few women in the first group used it more than once, and they were no more likely to do so than those in the control group. In addition, the greater accessibility of the medication did not affect the pattern of conventional contraceptive use.

A more recent California-based study led by **Tina Raine**, MD, MPH, assistant clinical professor of obstetrics, gynecology, and reproductive sciences at the University of California San Francisco shows that young women who have an advance provision of EC are more likely to use it when they need it, but such availability does not appear to increase risky sexual behavior.[4]

The study followed 213 young women ages 16-24 who were at high risk for unintended pregnancy. Study participants were assigned to one of two groups: those receiving educational information about EC along with advance provision of a single treatment dose and those receiving only information. Researchers compared behavior patterns in the two groups over a four-month period.

Researchers report that women who had EC on hand were three times more likely to use it than women who only had received information about it, and they did not have more unprotected sex or use condoms less. Women in the advance provision group were more likely to report using a less-effective method of birth control, such as condoms; 28% of women in the advance provision group reported using less-effective methods at the end of the study compared to the time of enrollment, vs. 17% in the information-only group.[4]

Provide EC in advance

To maximize EC's effectiveness, it is important to provide women with an advance supply, says Belzer. Before his study began, just 7% of study participants said they had used EC. However, 85% of the teens given an advance supply reported they had used it during the following six months if they had uncontracepted sex.

Be sure to present information on EC when discussing contraceptive methods, says Raine. This discussion is particularly important when talking with adolescent patients, she notes.

Teen-agers use less-effective contraceptive methods, observes Raine. They are less likely to use hormonal contraception and are more likely to use barrier methods such as condoms, she points out. Clinicians can counsel on the importance of EC as a backup if teens do choose less-effective birth control methods, she says.

"The other thing is that teen-agers tend to be sporadic users of hormonal methods, so they may use them for a few months and stop; sometimes that coincides with relationship changes," Raine points out. "EC can be something they can use in the interval when they are switching from one method to another [and they have unprotected sex]."

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Treatment options narrow for gonorrhea

With fluoroquinolone-resistant gonorrhea becoming more common in the United States, clinicians have looked to two treatment alternatives, cefixime and ceftriaxone, to combat the sexually transmitted disease (STD). With news that the manufacturer of cefixime has discontinued U.S. production of the drug, clinicians need to review their strategy to battle the infection.

The fluoroquinolones ciprofloxacin, ofloxacin, and levofloxacin are not recommended for treatment of gonorrhea infections acquired in Hawaii, California, Asia, the Pacific, and in other areas with increased prevalence of fluoroquinolone resistance, according to the Atlanta-based Centers for Disease Control and Prevention (CDC).[1] Providers in other areas of the United States can continue to use the drugs for gonococcal infections in areas where the prevalence of fluoroquinolone resistance is less than 1%; however, clinicians should be alert to the possible appearance of fluoroquinolone-resistant strains of the infection. **(Review information on ciprofloxacin-resistant gonorrhea's rise in the June 2002 *Contraceptive Technology Update* article, "Ciprofloaxcin-resistant gonorrhea on the rise," p. 64.)**

"Our current recommendations for the treatment of uncomplicated urogenital *Neisseria gonorrhoeae* infections in the absence of cefixime is to use ceftriaxone," says **Kimberly Workowski**, MD, chief of the guidelines unit in the epidemiology and surveillance branch of the division of STD prevention of the CDC. "Ceftriaxone or the quinolones should be used, except in the known fluoroquinolone-resistant areas where we are not recommending treatment for infection, which are Hawaii, California, Asia, and the Pacific."

Take aim at the STD

Each year, about 650,000 people in the United States are infected with gonorrhea. In 1999, the rate of reported infections was 132.2 per 100,000 persons, a 9.2% increase above 1997 figures.[2] Caused by the bacteria *Neisseria gonorrhoeae*, gonorrhea is considered a "smart" bacteria since it has developed mechanisms to resist other antibiotics, including penicillin. Fluoroquinolones have been top-line treatments since the 1980s, when gonorrhea grew resistant to tetracycline.

EXECUTIVE SUMMARY

Clinicians in Hawaii and California, which have been identified as areas with increased prevalence of fluoroquinolone resistance, have one less drug to use in the treatment of gonorrhea. The manufacturer of cefixime has discontinued production, which leaves ceftriaxone as the only recommended drug for use in fluoroquinolone-resistant areas.

- Clinicians in other areas of the United States can continue to use the fluoroquinolones ciprofloxacin, ofloxacin, or levofloxacin, in addition to ceftriaxone, for treatment of urogenital gonorrhea.
- Public health officials advise vigilance to the possible appearance of fluoroquinolone-resistant strains of gonorrheal infection.

When the CDC issued its revised STD guidelines in 2002, it recommended several single dose treatment options for uncomplicated *Neisseria gonorrhoeae* urogenital infections: cefixime 400 mg orally, ceftriaxone 125 mg intramuscularly, ciprofloxacin 500 mg orally, ofloxacin 400 mg orally, or levofloxacin 250 mg orally.[3] **(*CTU* reviewed the new guidelines in its August 2002 article, "Take your STD skills to the next level with new guidelines," included in the *STD Quarterly* insert.)**

The company that manufacturers cefixime, Wyeth Pharmaceuticals in Collegeville, PA, has discontinued manufacturing cefixime (Suprax) tablets in the United States. In October 2002, the company ceased marketing its 200-mg and 400-mg cefixime tablets because of depletion of company inventory. The company's patent for cefixime expired on Nov. 10, 2002; no other pharmaceutical company manufactures or sells cefixime tablets in the United States, according to the CDC.[4]

What are the options?

Clinicians in the areas identified as fluoroquinolone-resistant now look to use of ceftriaxone, a third-generation cephalosporin antibiotic marketed as Rocephin by Hoffmann-La Roche, based in Nutley, NJ. Rocephin is available in intramuscular or intravenous formulations. According to the company, adverse clinical effects in adults to the drug occur at levels similar to those of other cephalosporins: diarrhea (2.7%), rash (1.7%), and local reactions (≤1%).

Cefixime was a valuable drug in treating gonorrhea because it was available in tablet form, observes **Alan Tice**, MD, associate professor at the John A. Burns School of Medicine at the

University of Hawaii in Honolulu. While ceftriaxone has maintained its effectiveness against the infection, it must be given via injection. Clinicians in fluoroquinolone-resistant areas now will have to have partners of gonorrhea-infected patients come in for a shot, rather than providing pills for them, he notes.

Several clinicians have expressed interest in oral alternatives to cefixime in treatment of gonorrhea, says Workowski. She points to the CDC's alternative oral regimens, which have been posted on the STD division's web site, www.cdc.gov/nchstp/dstd. (Click on the link "Oral Alternatives to Cefixime for the Treatment of Uncomplicated *Neisseria Gonorrhoeae* Urogenital Infections" listed on the opening page.)

For the CDC to recommend a drug for treatment of uncomplicated gonorrhea, it requires two things: The regimen must cure more than 95% of urogenital infections, and studies that document efficacy must have a sufficient sample size so that the lower limit of the confidence interval of the cure rate is above 95%. At the present time, available data do not show that any single-dose oral antimicrobial regimen, other than cefixime or the fluoroquinolones, meet these efficacy criteria for gonococcal urogenital infection, states the CDC.[1]

Fluoroquinolone-resistant gonorrhea constitutes a substantial proportion of total gonorrhea cases in Hawaii and Southeast Asia; about 14% of gonorrhea cases in Hawaii were classified resistant in 2002.[5] Resistance is being noted in other countries as well; preliminary results from the 2002 collection of data in England and Wales show marked increases in resistant strains.[6] Antimicrobial susceptibility monitoring should be routinely performed to ensure that current drug regimens continue to be effective, advises the CDC.

"Prevalence varies by location; it remains important that local communities maintain the capacity to perform testing that will guide their gonorrhea treatment recommendations," says Workowski.

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GUEST COLUMN

New research confirms efficacy of NuvaRing

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Since the NuvaRing contraceptive vaginal ring (Organon, West Orange, NJ) entered the U.S. market in mid-2002, new research has been published that underscores its efficacy and acceptability. Clinicians will need to review this data to better inform patients in their contraceptive counseling sessions.

A multicenter clinical trial, using the ethinyl estradiol (EE)/etonogestrel (ETG) vaginal ring, has shown high levels of efficacy with an overall Pearl Index of 0.65 per 100 women years of use.[1] This clinical finding of contraceptive efficacy is confirmed in studies in which ovarian function has been assessed using transvaginal ultrasound along with serum levels of follicle-stimulating hormone (FSH), estradiol, and progesterone.[2,3] These pharmacodynamic studies have shown inhibition of follicular development with resultant low levels of estradiol, suppressed levels of FSH, and no evidence of ovulation based on serum progesterone levels.

A unique study was carried out that showed that after one month of use of the ring, reinsertion of the ring for three days or three weeks resulted in continued ovarian inhibition during the period of time of ring use, but when the vaginal ring was removed after three days or three weeks, there was a similar rapid reinitiation of follicular development.[4] The average interval between the removal of the ring

and maximum follicular development was approximately 11 days.[4] These data highlight the fact that there is a rapid return of ovarian function with removal of the contraceptive vaginal ring.

Menstrual cycle control is an important aspect of steroidal contraception to the patient and the provider. The cycle control with the EE/ETG vaginal ring has been excellent.[5,6] Unlike oral contraceptives that improve with use, fewer than 5% of women will have bleeding with NuvaRing right from the start. Based on the definition of withdrawal bleeding, the incidence of intended withdrawal bleeding after removal of the ring was approximately 70% of all cycles.[5,6] In contrast, using the same definition for a combination oral contraceptive, the incidence of intended withdrawal bleeding was less than 50% in all cycles.[5,6]

The reason for this excellent cycle control is not clearly known at the present time, but may be due to:

- consistent, stable levels of the hormone in blood in woment using the ring;
- higher compliance with the use of the ring (one insertion and removal per month) compared to daily pill intake for 21 days.

The principal reproductive side effect with the vaginal ring has been vaginal discharge.[1] This may be a welcome change for some women. There was no significant change in cervical cytology (Papanicoulaou smear) with the use of the vaginal contraceptive ring, and the Nugent score to document bacterial vaginosis was unchanged (Archer DF, Darney P, Alexander N unpublished observations).

As for drug interactions, the NuvaRing package insert states that use of a vaginal fungicidal preparation, miconazole nitrate, with the NuvaRing increases the serum levels of ethinyl estradiol and etonogestrel. The concomitant vaginal use of the spermicide nonoxynol-9 did not change absorption of EE or ETG in 12 subjects.[7] These findings suggest that these vaginal products may be used with the ring.

Acceptability in clinical trials has been high with more than 90% of the women reporting a positive experience and 97% indicating they would recommend the vaginal contraceptive ring to others.[8] Few patients or partners feel the ring interferes with coital activity. Few couples remove it for coitus:

- 85% of the women and 71% of their partners never or rarely felt the ring during intercourse;[8,9]
- 94% of the partners never or rarely minded that their partner used the ring.[9]

It should be stressed that the ring may be removed for intercourse and then reinserted afterward. The actual interval of removal that would reduce contraceptive efficacy is not known. The manufacturer states in the package insert that if the ring is out for more than three hours, backup contraception should be used until the vaginal ring has been back in place for seven days. Based on the observed return of ovarian function after removal of the vaginal ring, it may take several days before significant follicular development occurs.[4] This finding suggests continued contraceptive efficacy is likely, even if the removal interval is six to eight hours.

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FemCap approval

(continued from cover)

Food and Drug Administration (FDA), already is available in Germany, Austria, Switzerland, and Great Britain. According to the device's web site, www.femcap.com, a single FemCap with instructional video is $64.85, including shipping and

EXECUTIVE SUMMARY

The Food and Drug Administration has approved the FemCap device.

- The method already is in use in Germany, Austria, Switzerland, and Great Britain.
- The FemCap is a silicone rubber barrier contraceptive shaped like a sailor's hat with a dome that covers the cervix, a rim that fits into the fornices, a brim that conforms to the vaginal walls around the cervix, and a removal strap.

handling; two FemCaps with video are $81.90. **(See the resource box, right, for contact information.)** The device is available in the United States by prescription only.

"This is great news, and I am grateful for the tenacity Dr. Shihata [Alfred Shihata, MD, founder and president of FemCap of Del Mar, CA] demonstrated to gain approval for a new nonlatex barrier method for women," states **Susan Wysocki**, RNC, NP, president and chief executive officer of the Washington, DC-based National Association of Nurse Practitioners in Women's Health.

The FemCap is a silicone rubber barrier contraceptive shaped like a sailor's hat with a dome that covers the cervix, a rim that fits into the fornices, a brim that conforms to the vaginal walls around the cervix, and a removal strap. ***(Contraceptive Technology Update* reported on the device in its March 2000 article, "FemCap in Germany, seeking U.S. approval," p. 35.)**

The device comes in three sizes; the inner diameter of the rim determines its size. The smallest-rim diameter (22 mm) is intended for women who have never been pregnant, while the medium (26 mm) cap is intended for women who have been pregnant but have not had a vaginal delivery, such as those who have had an abortion or who have delivered via cesarean section. The largest (30 mm) is intended for women who have had a vaginal delivery of a full-term baby.

Providers must perform a clinical examination to see that there are no pathological or anatomical contraindications; the three most important contraindications are if the woman has a vaginal abnormality, a cervical abnormality, or has cancer of the cervix.

RESOURCE

For more information on FemCap, contact:

- **FemCap**, 14058 Mira Montana Drive, Del Mar, CA 92014. Fax: (858) 792-2624. E-mail: femcap@yahoo.com. Web: www.femcap.com.

Each FemCap comes with an instructional video, which provides the woman all the necessary information for using the device. Women can review the instructional video in the office or at home to learn how to position the FemCap.

As with all barrier contraceptives, the FemCap must be used correctly and consistently to achieve pregnancy protection. Barrier methods are less effective in preventing pregnancy than hormonal methods with typical use.[1] In a 2002 review that compared the contraceptive efficacy, safety, discontinuation, and acceptability of the cervical cap with that of the diaphragm, the Prentif cap was comparable to the diaphragm in preventing pregnancy, but the first-generation FemCap was not as effective in preventing pregnancy as its comparison diaphragm.[2]

In a clinical trial that looked at the first generation of the device, women were randomized to use the FemCap or a diaphragm, along with nonoxynol-9 spermicide, for 28 weeks. The *six-month* Kaplan-Meier cumulative unadjusted typical use pregnancy probabilities were 13.5% among FemCap users and 7.9% among diaphragm users. The adjusted risk of pregnancy among FemCap users was 1.96 times that among diaphragm users, with an upper 95% confidence limit of 3.01.[3] The two devices were comparable with regard to safety and acceptability, but a six-point difference in the true six-month pregnancy probabilities of the two devices could not be ruled out.[3]

According to Shihata, the FDA approved only the second-generation FemCap, which has a removal strap to enhance its acceptability and increased dimensions of the brim to improve its stability. The

COMING IN FUTURE MONTHS

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- Answering your questions on withdrawal
- Teen contraceptive use: How to boost compliance
- Counseling tips for new contraceptive users

product labeling recommends the use of emergency contraception in the event the woman does not use the FemCap or uses it incorrectly.

Data from an acceptability study reflect that that none of the study subjects or their partners reported any discomfort, trauma, or interference in sexual spontaneity with the cap.[4] Vaginal irritation and infections were reported infrequently.[4]

Review use instructions

To use the FemCap, the woman should apply the bulk of spermicide in the storage groove facing the vaginal opening and then spread it in a thin layer all over the cap except for the spots where the finger and thumb are holding the cap. Squeezing and flattening the device, the woman should then insert the FemCap into the vagina with the bowl facing upward and the long brim entering first. The FemCap then should be pushed down toward the rectum and then downward and back as far as possible to make sure it completely covers the cervix. If the device is correctly placed, a woman may rarely be aware of its presence during her daily activities or during intercourse.

According to the product web site, women should check to make sure that the FemCap is not partway between the vaginal opening and the cervix. They may check the position of the FemCap and insert additional spermicide without removing the cap prior to each repeated intercourse within the next 48 hours.

Women must wait at least six hours after their last act of intercourse before removing the cap.

To ease removal of the device, women should be instructed to squat and bear down, which will bring the cap closer to the finger. The device may then be rotated in any direction that is comfortable. By pushing the tip of the finger against the dome of device, the woman breaks the suction, allowing room to hook the removal strap with the tip of the finger. The device then can be slowly and gently pulled down and out of the vagina. The FemCap should be thoroughly washed with antibacterial hand soap, rinsed with tap water, then allowed to air dry or gently patted dry with a clean, soft towel before storing it in its provided plastic storage container.

Who would be successful in using the FemCap contraceptive? According to the product web site, this group would include those who are highly motivated and educated; cannot tolerate hormonal side effects; have contraindications to intrauterine device use; or who are allergic to latex rubber or do not rely on the male to use a condom. Women who may have a higher failure rate with the device would include those who do not plan or who want to have intercourse on the spur of the moment; have aversions to touching their genitalia; or lack motivation and/or planning, the product web site states.

"The FemCap offers women another contraceptive option, and its design makes FemCap use easier to insert and remove," says **Sharon Schnare**, RN, FNP, CNM, MSN, women's health consultant and clinician with the Seattle King County Health Department in women's and adolescent health care and the International District Community Health Center in Seattle. "I look forward to offering women in my practice this new option."

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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. The semester ends with this issue. To assist readers, we are enclosing the questions for the entire semester. You must complete the evaluation form included in this issue and return it in the provided reply envelope that is addressed **"Education Department"** to receive a certificate of completion. When your evaluation is received, a certificate will be mailed to you. ■

CE/CME Questions

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

- Identify clinical, legal, or scientific issues related to development and provision of contraceptive technology or other reproductive services. **(See "Get ready to take cervical cancer screening to the next level," "Hormone therapy: does it aid quality of life?" and "New research confirms efficacy of NuvaRing" in this issue.)**
- Describe how those issues affect service delivery and note the benefits or problems created in patient care in the participant's practice area.
- Cite practical solutions to problems and integrate information into daily practices, according to advice from nationally recognized family planning experts. **(See "Treatment options narrow for gonorrhea.")**

21. The Food and Drug Administration approved the DNA*with*Pap test for what purpose?

A. As a primary screening option for women 30 years of age and older
B. As a replacement for the conventional Pap smear
C. As a primary screening option for women 21 years of age and older
D. As a diagnostic tool in treating herpes simplex virus

22. What is the key message from the latest from the Women's Health Initiative published in *The New England Journal of Medicine*?

A. The study focuses on the impact of short-term hormone use on symptoms in perimenopausal women and finds that it is effective for such use.
B. Estrogen-only hormone therapy has a positive impact on quality of life symptoms for postmenopausal women.
C. The overall health risk, particularly of cardiovascular disease and breast cancer, from taking estrogens with progestin was greater than the benefits of lowering the risk of colon cancer and bone fractures.
D. For many postmenopausal women, combined hormone therapy does not have a clinically significant effect on their health-related quality of life.

23. What drug is no longer available for treatment of gonorrhea?

A. Ofloxacin
B. Levofloxacin
C. Cefixime
D. Ceftriaxone

24. What is the principal reproductive health side effect of the NuvaRing contraceptive vaginal ring?

A. Vaginal discharge
B. Vaginal itching
C. Local skin irritation
D. Vaginal dryness

Answer key: 21. A; 22. D; 23. C; 24. A.

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