CONTRACEPTIVE TECHNOLOGY UPDATE®

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IN THIS ISSUE

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Contraception: To use or not to use isn't the only question for women

Half at risk aren't fully protected from unintended pregnancy

Your last patient has left the exam room with a prescription for birth control in her hand. You counseled on proper use and covered the expected side effects. Is she now protected against unintended pregnancy?

New research indicates that each year, half of women at risk are not fully protected from an unplanned pregnancy.[1] The research, published by the Guttmacher Institute of New York City, shows that 8% use no contraception at all, 15% have gaps in use, and 27% use their method inconsistently or incorrectly.[1]

"Helping women who do not want to become pregnant to use contraceptives more effectively is sound public policy that will reduce unintended pregnancy," says **Jennifer Frost**, PhD, senior research associate at the Guttmacher Institute and the study's lead author. "In order to do that, it is critical to have a better understanding of what is preventing women from using contraception consistently and correctly — or even at all."

According to the new research, which analyzed responses from U.S.

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New research by the Guttmacher Institute indicates that each year, half of women at risk are not fully protected from an unplanned pregnancy.

- Less than 10% of women in the United States use no contraception at all, 15% have gaps in use, and 27% use their method inconsistently or incorrectly.
- For more than 50% of women who have a gap in use of at least one month, the period of nonuse coincides with an important life event, such as the beginning or end of a relationship, a move to a new home, a job change, or a personal crisis.

women and family planning providers, factors include:

• **Life changes.** For more than 50% of women who have a gap in use of at least one month, researchers found that the period of nonuse coincides with an important life event, such as the beginning or end of a relationship, a move to a new home, a job change or a personal crisis.

• **Method problems.** Nearly four in 10 contraceptive users are not very satisfied with their current method, research findings indicate. Dissatisfied users are more likely to put themselves at high risk for unintended pregnancy, by missing oral contraceptives or not using a condom every time, researchers found.

• **Ambivalence.** Nearly one in four women who are not trying to become pregnant say they would be very pleased if they found out they were pregnant. Women who are the least motivated to avoid pregnancy also are the least likely to use oral contraceptives or to use the method consistently, research findings indicate.

• **Access.** Many women report difficulty accessing contraceptive services or say they cannot afford more effective prescription methods of birth control.

• **Disparities.** Having a low level of education, belonging to a racial or ethnic minority, or being on Medicaid are associated with contraceptive behavior that is likely to increase women's risk for unintended pregnancy, say researchers. However, more important than poverty status, race, or ethnicity are women's attitudes toward pregnancy, their satisfaction with their method, and their experiences with contraceptive service providers, they note.[1]

Finding the "right" contraceptive method is not a one-time decision for women; rather, it is a series of choices as women's life circumstances and contraceptive needs change, says Frost.

"Helping women decide which contraceptive method to use can be a starting point for providers to offer ongoing counseling and support to their patients," she notes. "The more we can remove the remaining barriers to consistent use, the better we will be at ensuring that all women can avoid unwanted pregnancies and plan the children they want, when they want them."

How to check for gaps

How can you determine whether a woman has been consistently using her method of birth control? Consider this approach to assessing contraceptive use from **Katharine O'Connell**, MD, MPH, assistant clinical professor of obstetrics and gynecology at New York City-based Columbia University Medical Center:

— Ask "What method of contraception are you using now?" O'Connell says this open-ended approach allows the clinician to follow with a

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question on what has been used in the last year to get a sense if there has been continuous use.

— Ask "Did you take any breaks?" Try to stay away from a "loaded" word such as "gaps," she suggests. "[The word] 'gap' might sound like she did something wrong, and I don't want her to feel like she has to lie to me because that's the answer I want to hear," O'Connell explains.

"We find that when people have a life crisis, have a stop in a relationship, get older, there are so many reasons why it just isn't natural, it isn't easy to stay on a method," she says.

— If a woman indicates there was a break in contraceptive use, ask more questions to determine what led to it.

— If the woman is on oral contraceptives and says she was off pills for a few months, ask her questions such as, "Did you run out of refills?" and, "Was there a problem with the method itself?" advises O'Connell.

— Circle back to what the woman is using now. Check to see if the woman is satisfied with her current method, she suggests. Ask questions such as:

- "How happy are you with it?"
- "Do you have any problems taking it or using it?"
- "Do you want to switch, or are you happy and do you want some refills?"

When 8% of typical users of oral contraceptives who don't want to become pregnant at beginning of the year become pregnant in the course of that year — which may be as many as 1 million women in the United States — one of the important emphases of family planning providers must be to carefully discuss and encourage the five contraceptives in the top tier of contraceptive effectiveness, found in the World Health Organization's *Family Planning: A Global Handbook for Providers*, says **Robert Hatcher**, MD, MPH, professor of gynecology and obstetrics at Emory University School of Medicine in Atlanta.[2] *(Editor's note: The entire guide may be downloaded free of charge online. Go to the web site, www.who.int. Click on "Health Topics," "Contraception," "Family Planning: Department of Reproductive Health and Research Providers," and "Family Planning: A Global Handbook For Providers.")*

Hatcher says these top five are possible choices for women who want to have more children:

- the contraceptive implant (Implanon, Organon; Roseland, NJ);
- vasectomy;
- levonorgestrel intrauterine system (Mirena IUS; Bayer HealthCare Pharmaceuticals, Wayne, NJ);
- female sterilization;
- the copper-bearing intrauterine device (ParaGard IUD, Duramed, a subsidiary of Barr Pharmaceuticals; Pomona, NY).

The reversible options (implant, IUS, and IUD) are good for those women who do want more children at some other point in time, Hatcher says.

Policy changes in the works

In the Guttmacher Institute report, public and private providers note one of the most important things they can do to improve patients' contraceptive use is to provide more and better counseling. Nearly half of private providers report that changing insurance reimbursement to allow more time for counseling would help achieve that goal.[1]

Policy-makers and private insurers can work to increase public funding and private insurance coverage for family planning services, particularly counseling services that can help identify the factors in women's lives that put them at increased risk of unintended pregnancy, say the Guttmacher Institute researchers.

With a projected increase in Title X funding set to be enacted this session by Congress, family planning services might get some much-needed assistance in meeting unmet needs, says **Sharon Camp**, PhD, Guttmacher Institute president and CEO. She also remains hopeful that legislation pending in Congress, the Unintended Pregnancy Reduction Act, will help eliminate the barrier of the Medicaid waiver process. If passed, the legislation will give states authority to expand their coverage of Medicaid family planning services to individuals up to the same income level used by the state to determine eligibility for pregnancy-related care, on a permanent basis and without the need for a waiver. **(*Contraceptive Technology Update* reported on the pending legislation in its "Washington Watch" column; see "Medicaid expansions drive funding growth," April 2008, p. 45.)**

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Epilepsy Rx may impact young women's bones

Recent research findings indicate that young women who use the commonly used epilepsy drug phenytoin for one year showed significant bone loss compared to women taking other epilepsy drugs.[1] What implications, if any, does such research hold for family planning clinicians who prescribe contraception for patients with epilepsy?

To perform the study, researchers examined the bone health of 93 women with epilepsy who were between ages 18 and 40 and were taking the antiepileptic drugs (AEDs) phenytoin, carbamazepine, lamotrigine, or valproate. Bone mineral density was measured at the spine and two areas of the hip (the femoral neck and total hip) at the beginning of the study and one year later. Researchers also analyzed the women's nutrition and physical activity levels, along with other factors that affect bone health.

Findings indicate that women taking phenytoin for one year lost 2.6% of their bone density in the femoral neck of the hip. Women who were taking the other epilepsy drugs did not lose any bone density in the femoral neck. There was no bone loss at the spine or the total hip in any of the groups, researchers report.

The study represents one of a few longitudinal studies to evaluate the individual effects of several commonly used AEDs on bone mineral density (BMD) and markers of bone and mineral metabolism, the researchers note. Other longitudinal studies have evaluated a single drug or have studied patients taking multiple AEDs. In addition, researchers controlled for other factors known to affect bone health, they explain.

An important limitation of the study lies in the fact that researchers did not include a group of women without epilepsy to serve as normal controls and might have missed subtle differences in bone and mineral metabolism. Women who participated in the study were not randomly assigned to the studied drug but were receiving the AED best able to control their seizure activity, researchers note.

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Recent research findings indicate that young women who use the commonly used epilepsy drug phenytoin for one year showed significant bone loss compared to women taking other epilepsy drugs.

- Half of a woman's bone mass is gained during puberty and the first several years after menarche. Peak bone mass is achieved in the early to mid-20s.
- Some antiepileptic drugs enhance hepatic metabolism of contraceptive steroids and increase binding of steroids to serum proteins, which reduces the concentration of biologically active steroid hormone. In regard to bone health, the contraceptive injection has been linked to decreased bone mineral density (BMD). However, BMD appears to recover upon method discontinuation.

Bone health is important

How do such findings come into play for family planning clinicians who prescribe contraception for women with epilepsy?

"I think it's important when considering an AED or, in this case, a contraceptive choice that you consider other comorbidities such as bone," says **Alison Pack**, MD, assistant professor of clinical neurology at the Neurological Institute at Columbia University in New York City and the lead author of the current bone health article. "I think the significance of this work is that you're not just prescribing for the main effect of the medication; you're also subjecting that individual to potential long-term consequences, which may be bone."

Bone health is an important consideration in providing care for all women. Osteoporosis, a condition characterized by low bone mass and structural deterioration of bone tissue, is a key concern for women, particularly as they age. Some 10 million Americans — 80% of them women — have osteoporosis, according to the National Institutes of Health's Osteoporosis and Related Bone Diseases National Resource Center.[2] The center estimates that an additional 34 million Americans have low bone mass (osteopenia), placing them at increased risk for osteoporosis and related fractures.[2] ***(Contraceptive Technology Update* reviewed this topic in the article "Update practice on osteoporosis prevention," January 2007, p. 10.)**

Adolescence is an important time when it comes to bone health: Half of a woman's bone mass is gained during puberty and the first several years after menarche; peak bone mass is achieved in the early to mid-20s.[3]

Family planners must take several things into

consideration when reviewing contraceptive options for women with epilepsy. Epilepsy and AED-related changes in hypothalamic, pituitary, and gonadal hormones have been associated with increased rates of infertility, anovulatory cycles, menstrual irregularity, and polycystic ovaries. Children who are born to women with epilepsy have a higher risk of birth defects, probably related to in-utero exposure to antiepileptic drugs.[4]

Cytochrome P450-inducing antiepileptic drugs enhance hepatic metabolism of contraceptive steroids and increase binding of steroids to serum proteins, which results in a reduction of the concentration of biologically active steroid hormone.[4] Women receiving a liver enzyme-inducing antiepileptic medication have at least a 6% failure rate per year for OCs.[5]

Reports have associated the contraceptive injection depot medroxyprogesterone (DMPA, Depo-Provera, Pfizer; New York City) with a decrease in the frequency of seizures.[6] However, clinicians have been taking a hard look at DMPA use following the Food and Drug Administration's 2004 addition of a "black box" warning to the drug's labeling to highlight that prolonged use may result in the loss of bone mineral density. According to the revised labeling, the injectable contraceptive should be used as a long-term birth control method (longer than two years) only if other birth control methods are inadequate. Women who continue to use Depo-Provera past the two-year mark should have their BMD evaluated, according to the labeling. ***(CTU* reported on the labeling change. See "Be prepared to counsel on use of DMPA and bone health issues," February 2005, p. 17.)**

Research released in 2005 indicates that lower bone density appears to recover in adolescent females once they stop using DMPA.[7] Findings from another study indicate that while BMD may decline in adult users of DMPA, it is followed by substantial recovery after discontinuation.[8] **(See "New research indicates recovery of bone density after teen DMPA use," *CTU*, April 2005, p. 41, and "More research emerges on DMPA and bone health," August 2005, p. 93.)**

Another option for women in epilepsy is to use the copper T-280A intrauterine device (ParaGard IUD, Duramed, a subsidiary of Barr Pharmaceuticals; Pomona, NY) or the levonorgestrel intrauterine system (Mirena IUS, Bayer HealthCare Pharmaceuticals; Wayne, NJ).

Advise women to check for breakthrough bleeding while on hormonal contraception. Such bleeding midcycle may be a sign of ovulation.[9] Provide women with condoms or spermicide as backup contraception.[9] **(See "Check choices for women with epilepsy," *CTU*, October 2005, p. 120.)**

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Research looks at spread of genital warts

The teenager in front of you says she has some bumps on her genital area. A closer inspection shows several flesh-colored, flat growths on her vulva. What's your next move?

If you suspect genital warts caused by human papillomavirus (HPV) infection, don't be surprised. Also called condylomata acuminata, genital warts are a common sexually transmitted disease (STD) caused by specific types of HPV. About 6% of U.S. adults have been diagnosed with genital warts, findings from a new report indicate.[1]

It is estimated that approximately 1% of sexually active adults in the United States has genital warts at any one time; however, prior to this new research, there were no nationally representative

EXECUTIVE SUMMARY

Genital warts are a common sexually transmitted disease caused by specific types of human papillomavirus. About 6% of U.S. adults have been diagnosed with genital warts, a new report indicates.

- Overall, 5.6% of adults surveyed had been diagnosed with genital warts. The rate was three times higher in women, after adjustment for other factors.
- The main risk factor for genital warts was number of sex partners. Risk for infection was nearly eight times higher for adults with more than 10 lifetime partners, compared to those with one to two partners.

data on genital warts, says **Thu-Ha Dinh**, MD, MS, a medical epidemiologist with the Centers for Disease Control and Prevention's (CDC) Division of STD Prevention.

"Using data from the National Health and Nutrition Examination Survey, we determined the percentage of sexually active persons ages 18 to 59 years who reported having a history of genital warts diagnosed by a health care provider and identified key factors associated with a reported history of genital warts in this population," says Dinh, who served as lead author of the report. "The CDC is committed to working to get a better picture of the impact of STDs on Americans; this study contributes another vital piece to that picture."

Review the research

In performing the analysis, researchers reviewed responses from nearly 11,000 sexually active men and women, ages 18 to 59, who provided information on their sexual behavior and medical history, including whether a doctor had ever told them they had genital warts.

Overall, 5.6% of adults surveyed had been diagnosed with genital warts, researchers found. The rate was three times higher in women, after adjustment for other factors. Researchers are uncertain whether this finding reflected a true difference in risk or was related to other factors, such as differences in the recognition or diagnosis of warts.[1]

The prevalence of genital warts was highest (10.5%) among women ages 25-34. In men, prevalence peaked at 6% between the ages of 35 and 44. Risk was also higher among non-Hispanic whites, compared to Hispanics and blacks.

What was the main risk factor for genital warts? Findings indicate the leading cause was number of sex partners: Risk for infection was nearly eight times higher for adults with more than 10 lifetime partners, compared to those with one to two partners.[1]

Shot offers protection

The new report provides a "critical piece of information" about the impact of HPV-related diseases in the United States, states an accompanying editorial.[2] While many studies have looked at the burden of cervical cancer and precancerous lesions caused by HPV infection, there has been little information about the rates, costs, and impact of genital warts, it states.[2]

The HPV vaccine Gardasil (Merck & Co.; Whitehouse Station, NJ) protects against four HPV types, which together cause 70% of cervical cancers and 90% of genital warts. "Because the HPV vaccine currently licensed in the U.S. provides protection against genital warts and cervical cancer, understanding the national burden of genital warts is critical to being able to evaluate the population-level impact of national HPV vaccination campaigns," the editorial states.

According to Merck, about 13 million doses of the vaccine have been distributed globally since its approval in June 2006; of those, 10.5 million doses have been distributed in the United States.[3]

Genital HPV infection can cause genital warts, usually associated with HPV types 6 or 11. The HPV candidate Cervarix (GlaxoSmithKline USA, Philadelphia) is formulated to prevent infection from HPV types 16 and 18.

The company submitted its application for the vaccine in March 2007 to the Food and Drug Administration (FDA). The agency asked for additional information in December 2007. ***(Contraceptive Technology Update* reported on the application submission in the article, "What is next on the HPV vaccine horizon?" June 2007, p. 65.)**

The company expects to submit its response to the FDA's complete response letter regarding Cervarix in the second quarter of 2008 and will continue discussions with the agency regarding the application, says **Liad Diamond**, company spokeswoman.

How to treat?

Treatment of genital warts should be guided by the preference of the patient, the available resources,

and the experience of the health care provider, according to the CDC.[5]

For patient-applied treatment of external genital warts, look at two options:

• **Podofilox 0.5% solution or gel.** Advise patients to apply podofilox solution with a cotton swab, or podofilox gel with a finger, to visible genital warts twice a day for three days, followed by four days of no therapy. This cycle may be repeated, as necessary, for up to four cycles. The total wart area treated should not exceed 10 cm^2, and the total volume of podofilox should be limited to 0.5 mL per day, according to the CDC. If possible, clinicians should apply the initial treatment to demonstrate the proper application technique and identify which warts should be treated.

• **Imiquimod 5% cream.** Patients should apply imiquimod cream once daily at bedtime, three times a week for up to 16 weeks. The treatment area should be washed with soap and water six to 10 hours after the application.[5]

What are some provider-administered treatment options? Consider the following options:

• **Cryotherapy with liquid nitrogen or CryoProbe.** Repeat applications every one to two weeks.

• **Podophyllin resin 10%-25% in a compound tincture of benzoin.** Apply a small amount to each wart and allow it to air dry. The treatment can be repeated weekly, if necessary. To avoid the possibility of complications associated with systemic absorption and toxicity, limit application to < 0.5 mL podophyllin or an area of < 10 cm^2 of warts per session, and be sure there are no open lesions or wounds in the area to which treatment is administered. Some specialists suggest that the preparation should be thoroughly washed off one to four hours after application to reduce local irritation.

• **Trichloroacetic acid or bichloroacetic acid 80%-90%.** Apply a small amount only to the warts and allow it to dry, at which time a white "frosting" will develop. If an excess amount of acid is applied, the treated area should be powdered with talc, sodium bicarbonate, or liquid soap preparations to remove unreacted acid. This treatment can be repeated weekly, if necessary.

• **Surgical removal.** Choose from tangential scissor excision, tangential shave excision, curettage, or electrosurgery.[4]

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Treatment options expand for gonorrhea

The woman in your exam room says she is experiencing a painful, burning sensation when urinating, and reports increased vaginal discharge. The test is positive for gonorrhea. What's your next move?

A single dose of cefixime 400 mg tablets is the only oral treatment for uncomplicated gonorrhea of the cervix, urethra, or rectum recommended by the Centers for Disease Control and Prevention (CDC); however, tablets of the drug have been unavailable in the United States since 2002.

The recent renewed availability of cefixime 400 mg tablets increases clinicians' options to treat gonorrhea, one of the most common sexually transmitted diseases (STDs) in the United States. Since April 2007, the CDC has advised providers not to use fluoroquinolones such as ciprofloxacin, ofloxacin, and levofloxacin for the treatment of gonorrhea, based on data indicating widespread drug resistance in

EXECUTIVE SUMMARY

The renewed availability of cefixime 400 mg tablets increases clinicians' options to treat gonorrhea, one of the most common sexually transmitted diseases in the United States.

- Since April 2007, the Centers for Disease Control and Prevention has advised providers not to use fluoroquinolones such as ciprofloxacin, ofloxacin, and levofloxacin for the treatment of gonorrhea, based on data indicating widespread drug resistance in the United States.
- In 2006, the national gonorrhea rate was 120.9 cases per 100,000 population, representing an increase of 5.5% since 2005 and an increase for the second consecutive year.

the United States.[1] ***(Contraceptive Technology Update* reported on the CDC's action in the article, "New recommendations out for gonorrhea treatment," June 2007, p. 64.)**

When Wyeth Pharmaceuticals in Collegeville, PA, discontinued manufacturing cefixime tablets in 2002, clinicians were limited in their treatment options, since the CDC's recommended treatment options for gonorrhea are limited to a single class of antibiotics, the cephalosporins. ***(CTU* updated readers on the manufacturing suspension in the article, "Treatment options narrow for gonorrhea," June 2003, p. 67.)** The CDC recommends ceftriaxone, available only as an injection, for all types of gonorrhea infection, including genital, anal, and pharyngeal. Cefixime is recommended for genital and rectal gonorrhea.[2]

While Baltimore-based Lupin Pharmaceuticals received Food and Drug Administration (FDA) approval to manufacture and market cefixime in 2004, it has had only an oral suspension form available. The company now has Suprax 400 mg tablets available with wholesalers, ready for ordering by pharmacies as well as clinics, says **Atul Gokhale**, Lupin Pharmaceuticals' general manager of marketing. Public health service pricing is available on the Suprax tablets, says **William Chase**, director of Lupin Pharmaceuticals' trade and managed markets. While pricing is available through the company's customer service line, (866) 587-4617, orders should be placed through clinics' primary wholesalers, says Chase.

Tablet offers option

What does the addition of cefixime tablets represent in the current efforts to curb gonorrhea rates in the United States?

The return of cefixime tablets to U.S. pharmacies is a great assistance in the fight to control the STD, says **Lori Newman**, MD, a medical epidemiologist with the CDC's Division of STD Prevention. Having an oral option allows treatment of gonorrhea in settings where injections are not feasible and provides patients with a drug that is easier to take, she notes.

The CDC is calling for increased vigilance against gonorrhea. Following a 74% decline in the rate of reported cases from 1975 through 1997, overall gonorrhea rates plateaued, then increased for the past two years, the agency reports.[3] In 2006, the gonorrhea rate was 120.9 cases per 100,000 population, representing an increase of 5.5% since 2005 and an increase for the second consecutive year. **(See the *STD Quarterly* supplement article, "Despite progress, STD numbers continue to rise; diseases remain a major challenge," February 2008, p. 1.)**

"While the renewed availability of a gonorrhea drug in tablet form marks progress, there is still only one class of antibiotics currently recommended for the treatment of gonorrhea in the U.S.," says Newman. "More treatment options are needed to combat the spread of this disease, and CDC continues to call for the development of additional gonorrhea treatment options."

The addition of cefixime tablets to pharmacy shelves also gives clinicians another option in treating a non-STD urinary tract infection. The drug may be used for uncomplicated urinary tract infections caused by *E. coli* and *P. mirabilis*.

Use in expedited partner therapy?

The renewed availability of cefixime tablets in the United States will be good news for clinicians whose state laws allow for expedited partner therapy (EPT). In the case of gonorrhea treatment, EPT allows for the delivery of medications or prescriptions by persons infected with the STD to their sex partners. The CDC advises that EPT should not replace other routine notification activities and should not be used for men who have sex with men or partners who require clinical evaluation, such as those with symptoms. *(Editor's note: Get more CDC information on EPT at its web page, www.cdc.gov/std/EPT.)*

A recent report reviewed the legal permissibility of EPT in the United States.[4] It used an examination of existing and prospective legislation and regulations, judicial decisions, and administrative opinions by attorneys general to provide its assessment.

According to the report's analysis:

- EPT is permissible in California, Colorado, Maryland, Minnesota, Mississippi, Nevada, New Mexico, Pennsylvania, Tennessee, Utah, Washington, and Wyoming.
- EPT is "potentially allowable" in Alabama, Alaska, Connecticut, Delaware, District of Columbia, Georgia, Hawaii, Idaho, Indiana, Iowa, Kansas, Maine, Massachusetts, Missouri, Montana, Nebraska, New Hampshire, New Jersey, New York, North Carolina, Oregon, Puerto Rico, Rhode Island, South Dakota, Texas, Virginia, and Wisconsin.
- EPT is "probably prohibited" in Arizona, Arkansas, Florida, Illinois, Kentucky, Louisiana, Michigan, North Dakota, Ohio, Oklahoma, South Carolina, Vermont, and West Virginia.

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Research moves forward to relieve hot flashes

If your clinical practice includes treatment of perimenopausal women, the subject of hot flashes is familiar territory for you. In a 2002 national survey of menopausal women, hot flashes (70%) led the top four reasons for seeking medical attention, followed by night sweats (68%), mood disturbances (50%), and sleep disturbances (49%).[1]

Hormone replacement therapy was once considered the gold standard of treatment for hot flashes. However, results from the Women's Health Initiative (WHI) reduced interest in use of such treatment.[2,3] WHI indicated increased risks for breast cancer, coronary heart disease, thromboembolism, stroke, and dementia for combined hormone (estrogen plus progesterone) treatment, and an increased risk of stroke with no reduction of coronary heart disease risk for estrogen alone.[2,3] **(See the *Contraceptive Technology Update* articles: "Hormone replacement therapy: Review choices in light of new data," September 2002, p. 97; and "Estrogen arm of WHI suspended: What next?"May 2004, p. 53.)**

Science now is eyeing various alternative therapies for managing vasomotor symptoms associated with peri/postmenopause.[4] Just-published research indicates that desvenlafaxine, a serotonin and norepinephrine reuptake inhibitor, might serve as possible treatment for moderate to severe hot flashes.[5] The drug, developed by Wyeth Pharmaceuticals of Collegeville, PA, is under review by the Food and Drug Administration.

A hot flash or flush can be described as a warm sensation that begins at the top of the head and progresses toward the feet, frequently followed by chills. A hot flash may last for a few seconds or for several minutes and might occur as frequently as every hour to several times per week.[4]

To conduct the current study, researchers enrolled 707 healthy, postmenopausal women in a randomized, double-blind, placebo-controlled trial. Women who were experiencing 50 or more moderate-to-severe hot flushes per week were included in the trial. Participants randomly received desvenlafaxine 50 mg, 100 mg, 150 mg, or 200 mg or a placebo daily. The trial duration was 52 weeks. Primary outcomes were change from baseline in average daily number of moderate-to-severe hot flushes and in daily hot flush severity score at weeks 4 and 12.

Findings from the study indicate desvenlafaxine is an effective nonhormonal treatment for vasomotor symptoms in postmenopausal women, with a tolerability profile consistent with that of other serotonin-norepinephrine reuptake inhibitors.[5]

EXECUTIVE SUMMARY

Research indicates that desvenlafaxine, a serotonin and norepinephrine reuptake inhibitor, may serve as possible treatment for moderate to severe hot flashes.

- In a national survey of menopausal women, hot flashes (70%) led the top four reasons for seeking medical attention, followed by night sweats (68%), mood disturbances (50%), and sleep disturbances (49%).
- Science is eyeing various options for managing vasomotor symptoms associated with peri/postmenopause. Such studied methods include paced respiration, use of isoflavones or phytoestrogens, and antidepressants.

Options are needed

Why is it important to have a number of treatment options when it comes to menopausal vasomotor symptoms? The answer is not complicated, says **Leon Speroff**, MD, professor of obstetrics and gynecology at Oregon Health & Science University in Portland.

"There are many women who cannot or do not want to take estrogen, the most effective treatment for hot flushing," says Speroff, who served as lead author of the current research. "A good example is breast cancer survivors; thus, there is a need for effective treatment as a nonestrogen option."

Research has looked at paced respiration,

defined as slow, deep, abdominal breathing, for treatment of hot flashes. Findings indicate such practice can reduce hot flash frequency.[6-9] Because isoflavones or phytoestrogens possess estrogenic properties, researchers have looked at soy products and red clover, as well as black cohosh, as possible treatment options. A 2002 review of 22 controlled studies — 12 on soy and 10 on other botanical compounds — found no consistent improvement of hot flashes relative to placebo.[10]

Antidepressants also have been considered as treatment options. Results from studies of paroxetine and fluoxetine, both selective serotonin-reuptake inhibitors, indicate effectiveness in treatment of hot flashes.[11,12] Clonidine, an antihypertensive agent, also has been shown to be somewhat effective for treating hot flashes in postmenopausal women; however, these trials have been performed in very few patients.[13,14] A 2006 meta-analysis that weighed studies of the efficacy and adverse effects of nonhormonal therapies for menopausal hot flashes concluded that use of such therapies may be most useful for highly symptomatic women who cannot take estrogen but are not optimal choices for most women.[15]

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CME program offered on interstitial cystitis

As a women's health care provider, you are familiar with interstitial cystitis (IC) and painful bladder syndrome (PBS). It is estimated that at least 1 million Americans suffer from IC/PBS, most of them women.[1] There are no definitive tests for IC/PBS; diagnoses generally are made by ruling out other conditions.

The Association of Reproductive Health Professionals (ARHP) and the Interstitial Cystitis Association of Rockville, MD, have launched a joint educational program, *Screening, Treatment, and Management of IC/PBS.* The comprehensive

COMING IN FUTURE MONTHS

- Update on the contraceptive implant
- Clinicians share tips on contraceptive ring
- Talking with teens: ideas on contraceptive counseling
- Research eyes ways to boost daily pill adherence
- Chlamydia screening: Check venue options

program offers CME modules and associated activities and materials for targeted practitioners whose practice covers treatment of this condition.

ARHP speakers are available to present a medical education lecture on IC/PBS at events such as clinical conference or grand rounds session, with speaker honoraria and travel expenses covered by ARHP. Lectures may be requested online by visiting the ARHP web site, www.arhp.org. Highlight "Healthcare Providers," then "Visiting Faculty Programs" and "Screening, Treatment, and Management of Interstitial Cystitis/Painful Bladder Syndrome." For more information, contact the IC/PBS program manager, Allison Tombros, MHS, at (202) 466-3825 or atombros@arhp.org.

ARHP also offers several provider resources on the subject. Under the "What's New" column on the home page, click on "ARHP Launches New Program on IC/PBS" to access links for live and archived web seminar sessions, a slide show set, pertinent issues of ARHP's monograph *Clinical Proceedings* and publication *Quick Reference Guide for Clinicians*, a "Health Matters" patient education sheet, and a "What You Need to Know" health care provider fact sheet.

At the conclusion of the CE modules, participants will be able to define IC/PBS, identify its characteristic symptoms, list six tools frequently used in the basic assessment of IC/PBS, name the three basic components of IC/PBS management, and define four elements of counseling for individuals with IC/PBS.

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CNE/CME Questions

After reading *Contraceptive Technology Upd*ate, 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.

1. What are the five contraceptives in the top tier of contraceptive effectiveness in the World Health Organization publication, *Family Planning: A Global Handbook for Providers*?

A. Contraceptive implant, vasectomy, levonorgestrel intrauterine system, female sterilization, and the copper-bearing intrauterine device
B. Combined oral contraceptives, vasectomy, levonorgestrel intrauterine system, female sterilization, and the copper-bearing intrauterine device
C. Contraceptive injection, vasectomy, levonorgestrel intrauterine system, female sterilization, and the copper-bearing intrauterine device
D. Male condoms, vasectomy, levonorgestrel intrauterine system, female sterilization, and the copper-bearing intrauterine device

2. In a recent study (*Neurology* 2008; 70:1,586-1,593), which epilepsy drug showed significant bone loss compared to women taking other epilepsy drugs?

A. Carbamazepine
B. Phenytoin
C. Lamotrigine
D. Valproate

3. What are two patient-applied treatments for genital warts, according to the Centers for Disease Control and Prevention?

A. Podofilox 0.5% solution or gel or clindamycin cream
B. Metronidazole gel or imiquimod 5% cream
C. Podofilox 0.5% solution or gel or imiquimod 5% cream
D. Metronidazole gel or clindamycin cream

4. Which serotonin and norepinephrine reuptake inhibitor has been studied for possible use in treating hot flashes?

A. Paroxetine
B. Fluoxetine
C. Clonidine
D. Desvenlafaxine

CNE/CME Instructions

Physicians and nurses participate in this continuing medical education (CME) and continuing education (CE) program by:

- reading the articles;
- using the provided references for further research;
- studying the questions at the end of the issue.

Participants should select what they believe to be the correct answers and refer to the list of correct answers to test their knowledge. To clarify confusion surrounding any questions answered incorrectly, please consult the source material.

After completing this activity with the **December** issue, you must complete the evaluation form provided and return it in the reply envelope provided in that issue to receive a certificate of completion. When your evaluation is received, a certificate will be mailed to you. ■

CNE/CME Answers:

1. A; 2. B; 3. C; 4. D.

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

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