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Hormone therapy offers no benefit on central nervous system outcomes

New WHI information leads to more questions on role of hormone therapy

Expect more questions from patients about hormone therapy (HT) with the publication of three reports from the Women's Health Initiative (WHI), the largest randomized controlled trial conducted to date on the drug therapy.

The studies examine the impact of hormone therapy on central nervous function, using the daily regimen of 0.625 mg conjugated estrogens and 2.5 mg medroxyprogesterone acetate (Prempro, Wyeth Pharmaceuticals, Collegeville, PA) or placebo. The research suggests that use of the combined estrogen and progestin regimen is associated with increased risk of dementia and stroke and offers no improvement in cognitive function.[1-3]

How should clinicians integrate this information in their daily practice? In an accompanying editorial to the three studies, **Kristine Yaffe**, MD, an assistant professor in the department of psychiatry, neurology,

New data link hormone therapy, breast cancer

Just-published papers in the June 25, 2003, *Journal of the American Medical Association* add to heightened concern regarding hormone therapy (HT). In the first paper, which draws from the Women's Health Initiative, researchers report the incidence of total and invasive breast cancer was increased significantly in the estrogen plus progestin group compared with the placebo group. Invasive breast cancers in the two groups were similar in histology and grade, but were larger and at more advanced stages in the estrogen plus progestin group, state the researchers. In the second paper, a population-based case control study focusing on long-term use of HT among older women, results indicate that combination estrogen/progestin HT poses an increase in breast cancer risk, regardless of the pattern of progestin use. Read the September 2003 issue of *Contraceptive Technology Update* for an analysis of these findings. ■

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EXECUTIVE SUMMARY

New information from the Women's Health Initiative (WHI) indicates that the estrogen plus progestin regimen of hormone therapy is associated with increased risk of dementia and stroke and offers no improvement in cognitive function.

- In a study that included women 65 years or older, the risk of probable dementia in the estrogen plus progestin group was twice that in the placebo group during a mean follow-up of four years.
- Scientists found that the risk of stroke was significantly increased in the estrogen plus progestin group overall and in several subgroups of women.

and epidemiology at the University of California, San Francisco, concludes that HT should be prescribed only for temporary use to treat menopausal symptoms.[4]

Research results on the estrogen-alone substudy are expected in about two years, says **Stephen Rapp**, PhD, professor of psychiatry and behavioral medicine at Winston-Salem, NC-based Wake Forest University, who served as lead author on the cognitive function study.

"During that time, we will also continue to follow the women in the estrogen plus progestin substudy to examine the effects of hormone therapy termination on cognition and incident dementia and mild cognitive impairment," he states.

Until more information is available from both the estrogen plus progestin arm and the estrogen-only arm, women should talk with their health care providers about hormone therapy and the benefits and possible risks involved, advises the Washington, DC-based Association of Reproductive Health Professionals (ARHP).

Take a closer look

Two of the new publications are drawn from the WHI Memory Study (WHIMS), which specifically looked at women age 65 and older in the WHI trial. Women in the WHIMS study, like women in the larger WHI study, stopped taking the estrogen plus progestin therapy in July 2002 when it was found that the risks for developing breast cancer, strokes, and cardiovascular disease outweighed the benefits that were studied.[5] At that time, not all of the memory study data have been analyzed, and the dementia risk had not been established.

In the first publication, researchers found that 40 of 2,229 women receiving HT and 21 of 2,303

women on placebo aged 65 or older were diagnosed as having probable dementia. This translated into a significant hazard ratio of 2.05 after an average of 4.05 years of follow-up.[1] Effects of therapy on mild cognitive impairment did not differ between the groups. Translated to a population of 10,000 women taking the combined hormone therapy, there would be an additional 23 cases of dementia per year, researchers conclude.

In the other publication, researchers looked at global cognitive function including concentration, language, memory, and abstract reasoning. In this area, women taking the estrogen plus progestin therapy performed slightly worse than the placebo group.[3]

In a separate study, which looked at the entire population of women enrolled in the estrogen plus progestin arm of the WHI, researchers found that 151 of 8,506 (1.8%) women taking HT and 107 of 8,102 (1.3%) women on placebo had strokes, representing a 31% increased risk of combined ischemic and hemorrhagic stroke among users of HT.[2] Hormone therapy increased risk only of ischemic stroke, findings indicate. The number of strokes was increased in women on HT of all ages, including those ages 50-59.

Weigh benefits, risks

How will you incorporate this new information into your current practice? The ARHP, in a statement issued following publication of the studies, points out the WHIMS study evaluated women who were an average age of 71 at enrollment, far past the average age for women experiencing menopause, which is 51.

Hormone therapy has never been indicated to prevent or treat dementia; it was approved by the Food and Drug Administration only to relieve uncomfortable changes such as hot flashes, night sweats, and vaginal dryness associated with menopause and to prevent osteoporosis, uses unrelated to the focus of the WHIMS research, the organization points out.

"This large randomized trial only emphasizes the need for additional studies on the effects of gonadal steroids. The presumption that data from the WHI apply to all women and to all regimens of HT remains to be established," states a comment from the Washington, DC-based American Society for Reproductive Medicine.

Keep in mind that another recent report[6] from the WHI found some quality-of-life improvement in symptomatic women who used HT, points out

RESOURCE

The Washington, DC-based Association of Reproductive Health Professionals (ARHP) has developed a web-based Hormone Therapy Resource Center (www.arhp.org/hormonetherapy/). The site is designed for health care providers and the general public and is updated daily to include the latest news and research on hormone therapy.

Anita Nelson, MD, professor in the obstetrics and gynecology department at the University of California in Los Angeles (UCLA) and medical director of the women's health care clinic and nurse practitioner program at Harbor-UCLA Medical Center in Torrance.

In that report, among women ages 50-54 with moderate-to-severe vasomotor symptoms at base line, estrogen and progestin improved vasomotor symptoms and resulted in a small benefit in terms of sleep disturbance but no benefit in terms of the other quality-of-life outcomes.[6]

This improvement was unexpected, since the WHI study excluded women who were experiencing severe hot flashes and who would have been precisely the women in whom estrogen's benefits would be most obvious, Nelson observes.

Some have suggested that, in light of findings from WHI, helping patients make decisions regarding hormone therapy has become more complicated than ever. Others, including **Andrew Kaunitz**, MD, professor and assistant chair in the obstetrics and gynecology department at the University of Florida Health Science Center/Jacksonville and director of menopausal services at the Medicus Women's Center, see this situation differently. He points out that the WHI research, along with findings regarding HT risks and benefits, have clarified that the one clear indication for prescribing hormone therapy is to treat menopausal symptoms.

Kaunitz believes that systemic HT remains the most effective therapy clinicians have available to treat vasomotor symptoms and related insomnia; likewise, vaginal estrogen represents the best therapy available to address dryness and discomfort associated with genital atrophy in menopausal women. In contrast, HT has no role in the prevention or treatment of heart disease, he says.

"Regarding subsequent cognitive function, the impact of HT prescribed to perimenopausal and early menopausal women remains uncertain," he states. "Given the WHIMS findings, however, we can be confident that in elderly women, use of

combination HT does not enhance cognitive function and should not be used for the purpose of preventing dementia."

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Research eyes EC regimens, timing issues

EXECUTIVE SUMMARY

New research indicates that the Yuzpe regimen of emergency contraception (EC) works up to 120 hours and in different combinations, which may offer clinicians more flexibility.

- In an observational study, researchers found that the 72-hour cutoff for taking EC after unprotected intercourse may be unnecessarily restrictive. The different success rates for women taking EC within 72 hours or 120 hours of intercourse were not statistically significant.
- In a large, multicenter randomized trial, oral contraceptives containing norethindrone-ethinyl estradiol combinations worked about as well for EC as the standard levonorgestrel-ethinyl estradiol combination used in the Yuzpe regimen.

What is your clinic's protocol when it comes to emergency contraception (EC)? New research indicates that because the Yuzpe EC regimen of combined oral contraceptives (OCs) is at least partially effective when started up to 120 hours after unprotected intercourse, current protocols may be too restrictive.[1]

In a separate report, results of a large multicenter randomized trial found that OCs containing the more common norethindrone-ethinyl estradiol combinations of pills work about as well for EC as the standard levonorgestrel-ethinyl estradiol pills used in the Yuzpe regimen.[2] The regimen is named after Albert Yuzpe, MD, MSc, who conducted early EC research and now is co-director of the Genesis Fertility Centre in Vancouver, British Columbia.

A wider variation in the regimens and timing of EC could benefit women who are unable to obtain EC within 72 hours or who live in areas where it is difficult to obtain the standard Yuzpe combination of hormones, say the authors of the new research. Recent research showed that levonorgestrel and mifepristone also work well for emergency contraception when used between 72 and 120 hours.[3]

What's the next step in EC research?

"The next step in science might be to explore even beyond the (120-hour) time window, depending on where the woman was in her cycle at the time she wanted to start EC," says **Charlotte Ellertson**, MPA, PhD, president of Ibis Reproductive Health in Cambridge, MA, and lead author of the new research.

Any reason for 72-hour cutoff?

Ellertson says her research group wanted to explore extending the Yuzpe regimen window because members were concerned that women were being turned away after 72 hours without a good reason.

"The 72-hour cutoff was just a guess by Dr. Yuzpe when he first started studying the regimen that later came to bear his name, but it got accepted as a rigid deadline in clinical practice," observes Ellertson. Yuzpe conducted his EC research using a hormone combination he already was using for other investigations, and he selected the 72-hour cutoff based on other regimens used in Europe.[4,5]

The new research, based on an observational study, included 111 women who requested emergency contraception between 72 and 120 hours after unprotected sex and chose the Yuzpe regimen over insertion of a copper intrauterine device, which is the standard therapy for women

seeking EC outside the 72-hour window.

Researchers then compared failure rates for this group with rates among 675 otherwise similar women who started the same therapy within 72 hours.

Perfect use (1.9%) and typical use (3.6%) failure rates were low among women presenting between 72 and 120 hours after unprotected intercourse; these rates did not statistically differ from failure rates for the standard Yuzpe regimen (2.0% during perfect use and 2.5% during typical use).

Researchers note that the small sample size yielded just 25% power to detect a doubling in the failure rates (2% to 4%) and 59% power to detect a tripling in the failure rates (2% to 6%). The results are consistent with similar published work,[6,7] says Ellertson.

Look at OC options

When it comes to pill selection for the Yuzpe regimen, results from the new randomized trial may offer support in use of other hormonal combinations outside the original ethinyl estradiol-levonorgestrel dosing. In the Yuzpe regimen, women take one dose within 72 hours after unprotected intercourse and a second dose 12 hours later.

Historically, one-half experience nausea, and one-fifth vomit.[2] Researchers set out to determine whether women could use combined OCs other than those containing levonorgestrel and determine whether eliminating the second dose could improve comfort and convenience.

Women presenting at study centers within 72 hours after unprotected intercourse were randomized to receive the standard two-dose Yuzpe regimen, a variant of the regimen substituting norethindrone for levonorgestrel, or only the first dose of the regimen, followed 12 hours later by a placebo.

Perfect-use failure rates are similar

Perfect-use failure rates were low in all groups and did not differ in a statistically significant way; typical-use failure rates were slightly higher, but also did not differ significantly, report investigators. Side effects were similar across groups, except that women taking the single dose reported half the vomiting. Taking the pills with food did not seem to reduce nausea or vomiting, and the pills were not more effective when started sooner after unprotected intercourse.

Combined pills containing norethindrone-ethinyl estradiol work about as well for EC as levonorgestrel-ethinyl estradiol formulations and should be offered when first-line therapies are not available, researchers conclude.

"The implication of the research is that women who don't have access to a dedicated EC product, or to the exact hormones [ethinyl estradiol and levonorgestrel] that have been so well studied, can go ahead and use these other pills to create their own ECs," says Ellertson.

When reviewing information on the Yuzpe regimen, clinicians should keep in mind that levonorgestrel-only formulations have fewer side effects, says **Anita Nelson**, MD, professor in the obstetrics and gynecology department at the University of California in Los Angeles (UCLA) and medical director of the women's health care clinic and nurse practitioner training program at Harbor-UCLA Medical Center in Torrance.

In a randomized controlled trial of levonorgestrel vs. the Yuzpe regimen, the levonorgestrel regimen was better tolerated.[8]

"Women should still use the tried-and-true methods [levonorgestrel or Yuzpe] if they can get them; but in a pinch, these other [norethindrone-ethinyl estradiol] pills should be better than nothing," says Ellertson.

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New vasectomy clip receives FDA approval

EXECUTIVE SUMMARY

The Food and Drug Administration has given approval to the Vasclip, a small polymeric clip designed to stop the flow of sperm through the vas deferens.

- The manufacturer sees Vasclip as a less invasive alternative to traditional vasectomy because it eliminates cutting, suturing, and cauterizing of the vas deferens. Safety and efficacy research has not been published in any peer-reviewed journal; however, material is being readied for publication, the company says.
- The Vasclip procedure does not require providers to change or modify their preferred methods for scrotal access or closure during the vasectomy. Using commonly practiced vas deferens palpitation and scrotal access techniques, the Vasclip procedure reduces the vasal sheath manipulation necessary to access the vas deferens.

The Food and Drug Administration (FDA) has approved a new device to be used in vasectomy procedures: the Vasclip, a small polymeric clip designed to stop the flow of sperm through the vas deferens.

The Vasclip Co. of Roseville, MN, which manufactures and markets the device, has begun to sell the Vasclip to physicians in select major markets throughout the United States and expects to expand its national availability in the next several months. The company is marketing the device as a less invasive alternative to traditional vasectomy because it claims it eliminates cutting, suturing, and cauterizing of the vas deferens. **(Contact information for the company is available in the resource listing on p. 91.)**

No clinical research on the Vasclip has been published in peer-reviewed journals, according to **Scott Olson**, director of the company's public relations and marketing communication. However, results of the device's clinical study are being drafted for peer-reviewed clinical journal submission during the third quarter of 2003. A paper comparing the socioeconomic benefits of the Vasclip vs. alternative birth control options also is being readied for publication in the same time frame, reports Olson. **(*Contraceptive Technology Update* will report on the results of the research upon publication.)**

With more clinicians moving to evidence-based practice, which relies on identifying and reviewing relevant scientific literature to determine the value of a diagnosis, treatment, or test, availability of peer-reviewed data is necessary in considering any new procedure. Until the Vasclip data are published in peer-reviewed journals, any claims about the device's safety or efficacy are subject to question, observes **Amy Pollack**, MD, MPH, president of the New York City-based EngenderHealth. EngenderHealth, formerly AVSC International, provides information on male and female sterilization as part of its global reproductive health focus.

Examine the results

The company offers results of the clinical study in its promotional literature. That material states that 124 men were enrolled in a prospective, clinical study, in which the complication rate and pain associated with the Vasclip were lower than traditional vasectomy techniques, based on a review of 26 other peer-reviewed reports.

According to the data supplied by the company, less than 1% of the subjects (one of 124) had clinically significant swelling (hematoma); one of the 124 men reported a sperm granuloma. None of the men in the study reported an infection. A total of 116 out of 119 men became azoospermic (clinically infertile) at or after 90 days post-procedure. Three men did not become infertile due to improper placement of the device. Five men were lost to follow-up before the 90-day exam and semen analysis.

In an extension of the study, which included 68 men, 100% tested as infertile at an average of 372 days post-procedure. In a post-study survey, which included responses from 110 of the 124 men, 99% indicated they would recommend the Vasclip procedure to others.

Review the procedure

According to the company, the Vasclip procedure does not require providers to change or modify their preferred methods for scrotal access or closure during the vasectomy procedure. Using commonly practiced vas deferens palpitation and scrotal access techniques, the Vasclip procedure reduces the vasal sheath manipulation necessary to access the vas deferens.

The vas deferens is exposed through the vasal sheath by effacement of the clear side of the sheath, eliminating cutting or management of

the mesenteric bundle. By locking Vasclip around the exposed vas deferens, cutting, suturing, and cauterizing of the vas deferens is eliminated, states the company literature.

"I think that a traditional vasectomy is a fairly straightforward and quick procedure," observes **Robert Brannigan**, MD, assistant professor in the department of urology, Northwestern University Medical School, and head of the division of male reproductive medicine and surgery at Northwestern Memorial Hospital, both in Chicago. "I would say that this definitely takes even less time, and it's certainly more straightforward in that there is no use of cautery and no use of any instruments to divide the vas deferens and tie it off with suture."

Brannigan spoke with *Contraceptive Technology Update* after performing his first Vasclip procedure. Scrotal access and isolation of the vas deferens was the same, says Brannigan, who has performed traditional vasectomies for five years.

"There's something called the vasal sheath which is opened up to isolate the vas deferens itself, and what's different about it is that rather than dividing the vas deferens and tying each end off with suture, the Vasclip device is simply applied across the vas deferens," Brannigan comments. "I would say, with the experience I've had so far, there does seem to be a little bit less manipulation of the vas deferens."

Brannigan prepared for the procedure by reading the physician training manual, reviewing the companion CD-ROM, and using the training kit, which enabled him to practice the procedure by placing the clip on silicone tubing consistent in diameter to a vas deferens. The company also offers the option of having a clinical advisor visit the physician's site to provide counsel and instruction during initial Vasclip procedures.

The device cost is $350; the procedure is a separate charge. According to the New York City-based Planned Parenthood Federation of America, vasectomy fees range between $240-$1,000 for an interview, counseling, examination, operation, and follow-up sperm count; some clinics and doctors use a sliding scale according to income.[1] For the Vasclip procedure, physicians are expected to use one of two CPT-4 procedural reimbursement codes and receive the same reimbursement amount that they currently receive for vasectomy, says Olson. Some payers may not cover reimbursement for the Vasclip device cost; however, the company believes payers will begin to issue coverage, says Olson.

"We have prepared a reimbursement guidelines book for the physician's office, which provides suggestions and samples for proper coding, preauthorizations, letter of medical necessity and denial appeals," reports Olson. "We have hired a reimbursement consultant to assist us in educating payers on the benefits of the Vasclip procedure vs. traditional vasectomy."

RESOURCE

For more information on the Vasclip, contact: Customer Service, 3030 Centre Point Drive, Suite 900, Roseville, MN 55113. Telephone: (866) 827-2547 or (651) 631-1830. Fax: (651) 631-1850. E-mail: mdinfo@vasclip.com. Web: www.vasclip.com.

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1 in 5 teens has sex before 15th birthday

New report underscores teen sexual activity

A 13-year-old female sits in your exam room. On her initial gynecologic exam at age 12, she did not indicate that she was sexually active. On this return visit, which was prompted by complaints of vaginal itchiness and discharge, tests indicate *Trichomonas vaginalis* infection. What is your next step?

Know that this young teen is not the only adolescent who has initiated early sexual activity. According to a new report issued by the Washington, DC-based National Campaign to Prevent Teen Pregnancy, approximately one in five adolescents has had sexual intercourse before his or her 15th birthday.[1] The report also notes that one in seven sexually experienced 14-year-old girls reports having been pregnant.[1]

Despite recent declines, the United States has one of the highest teen pregnancy rates in the developed world. The U.S. teen-age birthrate of 45 per 1,000 women aged 15-19 in 2001, down 27% from its peak in 1991, remains about twice as high as rates in Great Britain and Canada, and five times as high

EXECUTIVE SUMMARY

One in five adolescents has had sexual intercourse before his or her 15th birthday, according to a new report issued by the National Campaign to Prevent Teen Pregnancy. One in seven sexually experienced 14-year-old girls reports having been pregnant.

- Despite recent declines, the United States has one of the highest teen pregnancy rates in the developed world.
- The U.S. teen-age birthrate of 45 per 1,000 women ages 15-19 in 2001, down 27% from its peak in 1991, remains about twice as high as rates in Great Britain and Canada and five times as high as in Sweden and France.

as in Sweden and France, according to the Alan Guttmacher Institute (AGI), the New York City-based research organization. AGI has just issued newly updated data on numbers and rates of teen-age births from 1972-2001 and on teen-age pregnancies, abortions, and miscarriages from 1972-1999.[2]

There is very good reason to be concerned about sexual activity among very young adolescents, says **Sarah Brown**, director of the National Campaign to Prevent Teen Pregnancy.

"We know that as compared to those who delay sexual activity, those who have sex at a young age are more likely to have a greater number of sexual partners over time, thereby increasing their risk of both too-early pregnancy and sexually transmitted diseases [STDs]," Brown observes. "Second, we know that the younger a girl is the first time she has sex, the more likely she is to say that the sex was unwanted."

Eight out of 10 sexually experienced youth ages 12-14 say they wish they had waited longer to have sex,[3] notes Brown. Children who are born to girls age 14 and younger are more likely than children born to older girls and women to have numerous problems as they age, ranging from health problems to father absence to school failure,[1] she points out.

What can you do?

How can clinicians approach the subject of sexuality, particularly when it comes to young teens? **Melanie Gold**, DO, associate professor in pediatrics at the University of Pittsburgh School of Medicine and director of family planning services at the Children's Hospital of Pittsburgh, offers the following suggestions:

- Encourage parents to respectfully ask younger teens about their ideas about love, sex, and future plans and share with them their own values and beliefs. Acknowledge where they see eye to eye and where they do not.
- Advise parents to encourage their younger teens to spend time with same-age peers (same and opposite-gender) in supervised settings and discourage single-couple dating, especially with partners who are three or more years older, until teens are 15 or older.
- Advocate for and demand that schools teach middle school students about sexuality, contraception, and STD prevention in a nonjudgmental, factual way.
- Always provide adolescents, especially those who are 9 to 14 years old, the opportunity to discuss and ask questions about reproductive health issues without a parent or caretaker present.
- Discuss with parents and younger teens the potential risk of forced or unwanted sex when a boyfriend or girlfriend is three or more years older than the teen. Health care providers, parents, and teens should know what constitutes statutory rape in the state in which they live and be aware of the health care provider's legal obligations to report such behaviors.

What is the next step when it comes to preventing teen pregnancy, particularly among young teens?

"At the most fundamental level, these young people need what all adolescents need — close, caring, involved relationships with parents and other adults in their lives; options for the future that are more attractive than early sex, pregnancy, and parenthood; and the opportunity to participate in engaging, useful activities and programs suited for their age group," states Brown.

They also need strong encouragement to delay sexual activity, along with close supervision and connections to positive peer groups and friends, she says.

"They [also] need good information about sex, love, and relationships, including information about the benefits and limitations of contraception," Brown says.

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You can close the gap on unplanned pregnancies

Study says two-thirds were using contraception

"How did this happen?" asks the woman sitting in your office as you share the news from the pregnancy test. "I was using birth control."

Research from a new French survey on contraception underscores this familiar scene. Investigators found that one-third of the pregnancies among women in their study were unplanned and that two-thirds of these pregnancies occurred in contraception users.[1] Improved education by family planning providers remains a major goal to ensure that women use a contraceptive method that will work for them, the researchers conclude.

"The key points for clinicians to keep in mind when counseling on proper contraceptive use is that there exists a difference between theoretical and practical efficiency of contraceptive method, and that they should invite women to take into account their social, affective (emotional) and sexual lifestyle when choosing a contraceptive method," says lead author **Nathalie Bajos**, PhD, research scientist in public health with the Paris-based National Institute for Health and Medical Research.

The cross-sectional population-based survey looked at the characteristics of current contraceptive use, the different types of contraceptive failure, and the reasons reported for not using contraception. A representative sample of 14,704 French households randomly was selected from the telephone directory; all women (n = 1,034) who in the last five years had an abortion or whose last pregnancy was unintended were selected. A total of 1,829 women selected on a random basis.

One-fifth of the unplanned pregnancies happened among women using the Pill; another tenth were among women with intrauterine devices, researchers report. One in eight of the unwanted pregnancies were among women choosing condoms, while one-fifth occurred among those using such methods as withdrawal or avoiding intercourse on fertile days in the menstrual cycle. About one-third of the unwanted pregnancies were among women using no contraception. Half of the unplanned pregnancies ended in abortion, researchers report.

EXECUTIVE SUMMARY

A survey on contraception by French researchers reveals that a third of the pregnancies among surveyed women were unplanned and that two-thirds of these pregnancies occurred in contraception users.

- The cross-sectional population-based survey looked at the characteristics of current contraceptive use, the different types of contraceptive failure, and the reasons reported for not using contraception.
- One-fifth of the unplanned pregnancies happened among women using the Pill. About one-third of the unwanted pregnancies were among women using no contraception.
- The main reasons given for contraceptive failure were misuse of the method or failure of the partner to withdraw, say researchers.

The main reasons given for contraceptive failures were the misuse of the methods or the failure of the partner to withdraw, say researchers. With pill users, 60% said they had forgotten one or more pills, while more than 18% said it was due to illness or taking other medication. One-fifth had no or offered no explanation. More than 57% of the women whose IUD had failed said they did not know what had gone wrong or had no explanation, while more than 30% said the IUD was in the wrong position or fell out, and more than a tenth blamed illness or medication.

The new research should remind clinicians that it is how contraceptives are used that determines how well they function, says **Michael Rosenberg,** MD, MPH, clinical professor of obstetrics and gynecology and adjunct professor of epidemiology at the University of North Carolina at Chapel Hill and president of Health Decisions, a private research firm specializing in reproductive health. Rosenberg has looked at contraceptive use and compliance issues.[2,3]

"One of the more interesting findings was the fact that of all contraceptive users, a relatively high proportion [21% of OC users, 58% of IUD users, and 19% condom users] did not know how their failure occurred," states Rosenberg. "This fact underscores both the importance of adequate initial as well as the need for follow-up counseling."

When discussing contraceptive choices with your patients, remember that "the best method is the one that is medically appropriate and is used

every time by someone happy with the method," a position often stated by the authors of *A Pocket Guide to Managing Contraception.*[4]

Keep the following ideas in mind when helping women make informed contraception choices:

- Be aware of your own biases.
- Each contraceptive method has advantages and disadvantages.
- Effectiveness and safety are important.
- Convenience and ability to use method may determine effectiveness.
- Protection against sexually transmitted infections and HIV needs to be considered for women and men at risk.
- Effects of method on menses may be very important to the woman.
- Ability to negotiate with partner may help determine method and selection.
- Other influences (religion, privacy, past experience, friend's advice, frequency of intercourse) may impact patient's preferences.
- Discuss all methods with patient, even those you may not use in your own practice.
- Consider discussing methods with the couple, particularly if there appear to be issues. Such questions as "Is your partner opposed to this method?" and "Will using this method embarrass your partner?" may help to understand the support available for use of the chosen method.[4]

"Important but underutilized resources include distribution of written materials and access to follow-up after initial counseling/prescribing," adds Rosenberg.

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New AIDS law contains anti-condom provisions

By **Cynthia Dailard**
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At the end of May, President Bush signed into law the "United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act," which is sweeping legislation designed to provide relief for HIV/AIDS in Africa and the Caribbean and authorizing funding of up to $15 billion over five years. While the law represents the first articulation of a U.S. global AIDS policy and is being hailed as landmark legislation by all sides, it contains a number of troublesome provisions that have the potential to undermine established public health strategies to reduce the risk of HIV transmission through condom use.

The action started in the House when Rep. Joe Pitts (R-PA) offered an amendment that would require that no less than 33% of all HIV/AIDS prevention funds be reserved for "abstinence-until-marriage" programs. This controversial provision provoked a heated debate, with opponents arguing that abstinence education that denies people full and accurate information about condoms is tantamount to a death sentence for many people living in sub-Saharan Africa, given its enormously high rates of HIV/AIDS. Nonetheless, the amendment passed by a vote of 220-197.

In addition, Rep. Chris Smith (R-NJ), seeking to elevate the status of faith-based organizations seeking federal HIV/AIDS funding and to accommodate their special concerns, included language in the House bill that specifically exempts any organization from having to "endorse, utilize, or

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participate in" any prevention strategy it may object to on moral or religious grounds. During House debate, Smith made clear that this "conscience clause" would permit organizations receiving federal funds to disparage condoms and to portray them as ineffective.

After House consideration, the bill then moved to the Senate. However, the hopes of family planning and HIV prevention advocates to delete or alter the Pitts and Smith provisions were dashed when the Senate decided to abandon its own version of a global AIDS bill — or even adding its own imprint to the legislation — and to take up the House bill instead. As a result, in the wee hours of night, the Senate passed essentially the same bill as the House. The Senate leadership, under intense pressure from the Bush administration, enforced a no-amendments strategy on the Senate floor that resulted in the defeat of all amendments. This included one authored by Sen. Dianne Feinstein (D-CA) to remove the earmark for abstinence-until-marriage programs and to replace it with language emphasizing the importance of a comprehensive approach to prevention. Thus, at the end of the day, the Pitts abstinence earmark and the Smith conscience clause became law.

Along these lines, the law also includes language authored by Rep. JoAnn Davis (R-VA) requiring an analysis of the prevalence of human papillomavirus (HPV) in sub-Saharan Africa and a study to assess the impact that condom use has had on the spread of HPV. Davis argued that because condoms cannot entirely reduce the risk of HPV, only abstinence until marriage and lifelong monogamy can protect women around the world from cervical cancer deaths related to HPV. Unfortunately, the Davis provision fails to devote any resources to bringing women in sub-Saharan African or other developing nations the cervical cancer screening and treatment programs they need to reduce deaths from cervical cancer.

Finally, on a much more positive note, Sen. Jon Corzine (D-NJ) engaged in a verbal colloquy with Senate Majority Leader Bill Frist (R-TN) during Senate consideration of the bill, where he asked for and received Frist's support for increased funding for microbicide development. Frist joined Corzine in urging the National Institutes of Health to consider establishing a microbicides branch within the National Institutes for Allergy and Infection Diseases. Corzine is the sponsor of the Microbicide Development Act introduced in April that would encourage investment in microbicide research at several federal agencies, expedite the implementation of the National Institutes of Health's five-year strategic plan for microbicide research, and expand coordination among federal agencies already involved in this research.

Now, the Bush administration must take steps to implement the global AIDS bill through the various agencies charged with this responsibility, particularly the U.S. Agency for International Development and the Department of Health and Human Services. To be sure, family planning and HIV prevention advocates will be watching closely. ■

CE/CME instructions

Physicians and nurses participate in this continuing medical education/continuing education program by reading the articles, using the provided references for further research, and studying the questions at the end of the issue. Participants should select what they believe to be the correct answers and refer to the list of correct answers to test their knowledge. To clarify confusion surrounding any questions answered incorrectly, please consult the source material. After completing this activity with the 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. ■

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 "Hormone therapy offers no benefit on central nervous system outcomes" and "New vasectomy clip receives FDA approval" 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. **(See "Research eyes EC regimens, timing issues" and "The war against HIV: scientists, providers seek enhanced prevention.")**
- cite practical solutions to problems and integrate information into daily practices, according to advice from nationally recognized family planning experts.

5. What are the findings from the three studies issued from the Women's Health Initiative?

A. Use of the combined estrogen and progestin regimen is associated with decreased risk of dementia and stroke, and offers marked improvement in cognitive function.
B. Use of the combined estrogen and progestin regimen is associated with increased risk of dementia and stroke, but offers limited improvement in cognitive function.
C. Use of the combined estrogen and progestin regimen is associated with decreased risk of dementia and stroke, but increases a decline in cognitive function.
D. Use of the combined estrogen and progestin regimen is associated with increased risk of dementia and stroke, and offers no improvement in cognitive function.

6. What is the major finding of the Ellertson C, et al. study?

A. Oral contraceptives (OCs) containing the more common norethindrone-ethinyl estradiol combinations work about as well for emergency contraception (EC) as the standard levonorgestrel-ethinyl estradiol pills used in the Yuzpe regimen.
B. OCs containing desogestrel-ethinyl estradiol work about as well for EC as the standard levonorgestrel-ethinyl estradiol pills used in the Yuzpe regimen.
C. OCs containing norgestimate-ethinyl estradiol work about as well for EC as the standard levonorgestrel-ethinyl estradiol pills used in the Yuzpe regimen.
D. OCs containing gestodene-ethinyl estradiol work about as well for EC as the standard levonorgestrel-ethinyl estradiol pills used in the Yuzpe regimen.

7. What is the name of the new vasectomy clip that recently received FDA approval?

A. Hulka clip
B. Vasclip
C. Filshie clip
D. Yoon ring

8. What is the name of the rapid HIV test approved in April 2003 by the FDA?

A. Western Blot
B. OraQuick
C. Reveal Rapid HIV-1 Antibody Test
D. Single-Use Diagnostic System

Answer key: 5. D; 6. A; 7. B; 8.C.

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Table 1: Hormonal Contraceptive Options for Reducing Menstruation

	Continuous or Extended COC*†	DMPA*	LNG IUD*	Combination Transdermal Patch*‡	Contraceptive Vaginal Ring*‡
Effect on Menses	88% amenorrheic at one year	50%-73% amenorrheic at one year	94% ↓ MBL 80% amenorrheic or oligomenorrheic	Similar to COC	Similar to COC
Disadvantages	Breakthrough bleeding/spotting	Irregular bleeding/ spotting	Irregular bleeding/ spotting	Breakthrough bleeding/spotting	Breakthrough bleeding/spotting

EE — ethinyl estradiol
MBL — menstrual blood loss

* All of the uses listed represent off-label indications.
† The application for Seasonale has been accepted by the U.S. Food and Drug Administration and, at press time, was expected to be on the market by fall 2003.
‡ There are no published data on extended use of Ortho Evra or NuvaRing.

Table 2: Four Recent Randomized Clinical Trials of Extended Cycle or Continuous-Use OC Regimens vs. Conventional (21/7) Regimens

OC Formulation	Regimen (N)	Duration	Ref #
20 mcg EE/ 100 mcg LNG (Alesse)	**conventional 21/7 (16) continuous 168/0 (16)**	**Six months**	**1**
20 mcg EE/ 100 mcg LNG (Alesse)	**conventional 21/7 (28) continuous 336/0 (32)**	**12 months**	**2**
30 mcg EE/ 300 mcg NGL (Lo/Ovral-28)	**conventional 21/7 (24) extended 42/7 (29)**	**4 trimesters**	**3**
30 mcg EE/ 150 mcg LNG (Nordette)	**conventional 21/7 (225)**	**12 months**	**4**
30 mcg EE/ 150 mcg LNG (Seasonale)	**extended 84/7 (454)**	**12 months**	**4**

EE — ethinyl estradiol; NGL — norgestrel; LNG — levonorgestrel

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Contraceptive Technology Reports

A supplement to *Contraceptive Technology Update* August 2003, BB #S03163

Introduction

Frequent menstruation is a relatively new biologic state that has emerged as societies have evolved from hunting and gathering to industrialization. Contemporary American women will experience an average of 450 menstrual cycles over their lifetimes — nearly three times more than women living in primitive societies (160).[1] This increased number of menstrual cycles is attributed to earlier menarche, later first birth, fewer pregnancies, shorter duration of breastfeeding, and later menopause.[1]

The burden of menstruation ranges from a monthly nuisance to a major health concern of women. The leading cause of gynecological morbidity in the United States, menstrual disorders affect 2.5 million women ages 18-50 annually and accounted for approximately 11% of hysterectomies performed in 1997.[2,3] Menstrual disorders cost U.S. industry an estimated 8% of the total wage bill, and a 1999 survey found that U.S. women with heavy menstrual flow worked nearly 7% less time than those with lighter or normal flow.[4,5]

Medically reducing the frequency of menstruation holds the promise of decreasing the frequency of menstrual-related disorders such as menorrhagia (whether idiopathic or associated with uterine fibroids, adenomyosis, von Willebrand disease, Factor IX deficiency, hemophilia carrier state, or thrombocytopenia of any etiology), dysmenorrhea, iron deficiency anemia, and catamenial conditions (i.e., migraine headaches and seizures).[6-9] Other chronic diseases that are exacerbated by menstrual cycles also might benefit from extended cycling.[8,10] In addition to women with these disorders, others who might benefit from less frequent menses include adolescents, perimenopausal women, collegiate swimmers, female soldiers deployed to the desert, developmentally delayed women, and any woman who simply would prefer to menstruate less frequently.[8,11-15]

Several recent surveys reflect how women's attitudes regarding monthly menstruation are changing as that option has become available. As part of a 1996 survey of Dutch women, 964 oral contraceptive (OC) users ages 15-49 years were asked what menstrual frequency they would prefer if able to regulate it.[16] Overall, 75% of OC users preferred altering bleeding patterns for less painful periods, shorter periods, or less heavy periods. Seventy-two percent of OC users aged 15-19 years, 60% of those aged 25-34 years, and 59% of those aged 45-49 years preferred less frequent menstruation.

Another survey to assess the attitudes of Chinese, Nigerian, South African, and Scottish women toward amenorrhea and use of a contraceptive method that produces amenorrhea found that health care providers overestimate the importance women place on regular menstruation.[17] With the exception of Black African women, more than half of the 1,001 women surveyed disliked having periods. Reasons cited for disliking periods included inconvenience (65%-85%) and, among Chinese and Scottish women, associated menstrual problems (13%-33%). In contrast to Nigerian women who preferred to bleed monthly, those in other countries preferred to bleed once every three months or not at all.

In the United States, the Washington, DC-based Association of Reproductive Health Professionals commissioned the Rochester, NY-based Harris Interactive to conduct a telephone survey of U.S.

Examination of Extended Hormonal Contraception to Reduce Bleeding

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women regarding their preferences on frequency and characteristics of menstrual bleeding.[18] Of the 491 women ages 18-49 included in the survey conducted in 2002, 44% stated that they would prefer never to menstruate, and this preference increased to 59% when only those aged 40-49 were analyzed.

Fewer than 30% preferred monthly menses. More than one in four women had missed professional, social, athletic, or family-oriented events because of their period, menstrual cramps, or other menstrual effects. Of the 70% of women who currently or previously used OCs, 15% stated that they had used their OC regimen to delay or stop their periods.

Another U.S. study to explore women's attitudes and beliefs about menstruation and menstrual suppression also found that more than two-thirds of the 221 respondents ages 12-30 were interested in reducing menstrual pain and the amount of bleeding, particularly if they were not on hormonal contraception (48% of the sample population).[19] When asked if it was necessary to have a period every month, 52% of those not on a hormonal method said "yes" compared with 37% of those currently using OCs. In fact, 45% of OC users and 32% of women not using a hormonal method thought that it was not necessary to have a monthly period. With regard to menstrual suppression, 57% of respondents strongly agreed or agreed that they were interested. Women currently using OCs were more interested in using a contraceptive for menstrual suppression than those not using OCs.

Hormonal Options for Reducing Menstruation

Several hormonal contraceptive options can reduce menstruation. **(See Table 1, inserted in this issue.)** A substantial proportion of women using an extended OC regimen or depot medroxyprogesterone acetate (DPMA) will be amenorrheic after one year's use.[20-22] Users of the levonorgestrel intrauterine device (LNG IUD) experience substantial reductions in menstrual blood loss, with 80% of users eventually becoming amenorrheic or oligomenorrheic.[23,24] To date, there are no reports on extended use of the combination transdermal contraceptive patch or the contraceptive vaginal ring. However, the good cycle control observed in users of these methods suggests they may become attractive options for extended use, and clinical trials are in progress.[25,26]

Extended-Use OCs to Reduce Bleeding

When use of a progestational agent as a hormonal contraceptive was suggested in the 1950s, the regimen of 21 days of active drug followed by seven drug-free days was designed to mimic the normal menstrual cycle because of concerns that anything perceived to interfere with normal menses might be unacceptable to women, clinicians, and religious leaders.[7] Gregory Pincus, PhD, John Rock, MD, and others who developed OCs understood that the monthly bleeding experienced by pill users was induced by hormone withdrawal and was not biological. During the past 40 years of OC use, many clinicians have come to appreciate that there is no evidence to support the perception that monthly bleeding contributes to the health or general well-being of women. As mentioned earlier, women themselves also are receptive of the idea of manipulating their hormonal contraceptive regimen to reduce or eliminate menstrual bleeding.[16-19,27]

Recent Studies of Extended Cycle or Continuous-Use OC Regimens. Recently, four open-label, randomized, controlled trials using monophasic OCs compared extended cycle or continuous regimens with a conventional 21/7 regimen.[20,28-30] **(See Table 2, inserted in this issue.)** Two of these were small studies that compared a conventional 21/7 regimen of 20 mcg ethinyl estradiol (EE)/100 mcg levonorgestrel (LNG) used for six or 12 cycles with continuous use for 168 or 336 days, respectively.[20,28] In the six-cycle study, women who used the OC continuously for 168 days experienced significantly fewer bleeding days requiring protection (< 2 vs. ~4 days, $P < 0.01$) and were more likely to be amenorrheic than those using the conventional OC regimen.[28] Headache, breast tenderness, nausea, depression, and premenstrual syndrome (PMS) were reported with similar frequency in the two groups; however, compared to women using the conventional OC regimen, those in the continuous use group experienced significantly less bloating (mean 11.1 vs 0.7 days, $P = 0.04$) and menstrual pain (mean 1.9 vs. 13.3 days, $P < 0.01$) overall. The majority (70%) of women in each treatment group were satisfied with bleeding patterns. Moreover, in the continuous group,

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endometrial stripe measurements showed a reassuring mean thickness of 3.3 mm (SD = 0.73).

In the 12-cycle study, amenorrhea occurred in 16% and 72% of continuous OC users during cycles 1-3 and 10-12 compared to 0 and 4%, respectively, of those using the conventional OC regimen.[20] Initially, spotting commonly was reported by those in the continuous group; however, by cycle nine, less spotting was noted in the continuous group than in the conventional OC group. There were no pregnancies, and no evidence of endometrial hyperplasia was observed. Breast tenderness and nausea were infrequent complaints in both groups. However, abdominal pain occurring at least once a month was reported by significantly fewer continuous OC users than conventional OC users who completed the study (26% vs. 72%, $P < 0.001$). At the end of the study, 78% of 32 continuous OC users and 68% of 28 conventional OC users chose to continue their present method.

Another small 12-month study compared a conventional 21/7 regimen and an extended 42/7 regimen of a monophasic OC containing 30 mcg EE/300 mcg norgestrel.[29] The percentages of patients who completed the study were 63% in the extended cycle group and 54.5% in the conventional cycle group. The number of bleeding days was reduced significantly in the extended cycle group beginning in the first trimester (mean 6.4 vs. 10.9 days, $P < 0.001$), and this continued to the fourth trimester (mean 5.8 vs. 11.3 days, $P = 0.005$). The mean number of spotting days was similar in both groups throughout the study. Women in the extended cycle group had significantly fewer total days requiring use of hygiene products than those in the conventional group (27.3 vs. 53.5 days, $P < 0.001$), which corresponded to a lower average annual expenditure for hygiene products of $17.45 compared to $41.45 ($P < 0.001$). At the completion of the study, among women who planned to continue use of hormonal contraception, 52.4% of those in the extended cycle group planned to continue the regimen, and 16.7% of those in the conventional group planned to switch to an extended cycle regimen.

A large (N = 682), one year, multicenter study compared an extended 84/7 OC regimen provided in dedicated packaging (Seasonale) with a comparable conventional OC (Nordette); active pills of both contained 30 mcg EE/150 mcg LNG.[30] The extended 84/7 OC regimen was as effective in preventing pregnancy as the conventional 21/7 regimen and was associated with a comparable amount and number of days of scheduled withdrawal bleeding. Although the frequency of unscheduled bleeding/spotting episodes was higher initially with the extended regimen, it declined over time. No endometrial hyperplasia was noted, and the nonmenstrual side effects reported by women using the extended-cycle regimen were comparable to those reported by users of the conventional regimen.

Patient Counseling

When suggesting extended OC use, it is important to explain that there is no medical rationale for monthly withdrawal bleeding while on hormonal contraceptives and that the conventional OC regimen arbitrarily was designed to mimic the natural menstrual cycle. Myths that hormonal methods are associated with a buildup of menstrual blood or disease of the lining of the uterus should be dispelled. Review the advantages of the extended regimen, particularly those that are most important to the individual patient. For example, painful periods, excessive bleeding, PMS, or menstrual-related migraines may be reduced by reducing the frequency of menses or eliminating the pill-free interval. Moreover, the regimen is convenient; bleeding can be postponed until after particular occasions such as vacations and athletic activities, and fewer hygiene products need to be purchased or carried. Patients should be prepared for the occurrence of unpredictable breakthrough bleeding similar to that with conventional OC regimens initially, which will lessen over time. Be sure to tell the patient that should she spot, the blood will be dark-brown rather than red because it has remained in the vagina longer and may have a different texture.

It may be more difficult for the woman using an extended OC regimen to tell if she is pregnant. She should be told to look for other signs of pregnancy such as breast tenderness, nausea, fatigue, or frequent urination, and she should be reassured that pregnancy tests can be performed if needed.

Conclusion

Surveys show that many women today would prefer to menstruate less. A variety of hormonal contraceptive options can reduce or eliminate menstrual bleeding, including DMPA, the LNG-IUD, and combination OCs. Experience with continuous or extended low-dose OC (≤ 30 mcg EE) regimens indicates that they are as effective as a conventional regimen in preventing pregnancy and produce amenorrhea or infrequent bleeding in a majority of users. Extended OC use is not associated with endometrial hyperplasia and may help improve the health status of many women and, for even more, the quality of life.

As women and their clinicians become more familiar and comfortable with extended hormonal contraception to reduce menses, more women will choose to take advantage of this strategy. The result for some women will be enhanced convenience; others will experience a reduced burden of suffering from gynecologic and medical conditions.

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CME Instructions

Physicians participate in this continuing medical education/continuing education program by reading the article, using the provided references for further research, and studying the questions at the end of the article. Participants should select what they believe to be the correct answers, then 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, you must complete the evaluation form provided and return it in the reply envelope provided in order to receive a certificate of completion. When your evaluation is received, a certificate will be mailed to you.

CME Objectives/Questions

- List a potential benefit of extended oral contraceptive use.
- Identify what percentage of Dutch women ages 25-34 preferred less frequent menstruation.
- List a condition that has NOT been observed with continuous or extended oral contraceptive regimens.

1. Potential benefits of extended oral contraceptive use include which one of the following?

A. Less nausea
B. Less unscheduled bleeding/spotting
C. Less breast tenderness
D. Less anemia

2. What percentage of Dutch women aged 25-34 preferred less frequent menstruation?

A. 20%
B. 30%
C. 60%
D. 90%

3. Which one of the following has NOT been observed with continuous or extended oral contraceptive regimens?

A. Fewer bleeding days requiring protection
B. Endometrial hyperplasia
C. Amenorrhea
D. Less menstrual pain

Answers: 1. D 2.C 3.B

S·T·D QUARTERLY™

The war gears up against HIV: Scientists and providers seek enhanced prevention

Rapid tests speed detection — research advances on vaccine trials

When it comes to the battle against HIV, it's time to redouble your efforts at reducing the number of new HIV infections. Why? Reports show an increase of newly diagnosed infections during 1999-2001, which reverses a several-year decline.[1]

Since the early 1990s, 40,000 new HIV infections have occurred each year in the United States, according to the Atlanta-based Centers for Disease Control and Prevention (CDC).[2] However, during 1999-2001, the number of persons with newly diagnosed HIV infection increased 14% among men having sex with men, and 10% among heterosexuals, in the 25 states with HIV reporting.[1] The number of persons in the United States living with HIV also continues to rise; the CDC estimates that of some 850,000-950,000 persons living with HIV, about 25% are unaware of their serostatus.

The CDC now is implementing a four-pronged initiative, aimed at:

- making HIV testing a routine part of medical care;
- creating new models for diagnosing HIV infections outside medical settings;
- preventing new infections by working with people diagnosed with HIV and their partners;
- decreasing mother-to-child HIV transmission by incorporating HIV testing in the routine battery of prenatal tests.

While progress has been made on the global epidemic, prevention efforts in the United States have stalled, says **Julie Gerberding**, MD, MPH, CDC director.

"We are not making the kinds of ongoing progress in reducing new cases that we would expect to be able to achieve, given some of the recent advances in testing technology," she stated in announcing the new initiative.

EXECUTIVE SUMMARY

New strategies are being developed to reduce the number of new HIV infections, which increased from 1999-2001 after declining for several years.

- The Centers for Disease Control and Prevention has implemented an initiative to make HIV testing a routine part of medical care, create new models for diagnosing HIV infections outside medical settings, prevent new infections by working with HIV patients and their partners, and incorporate HIV testing into routine prenatal tests.
- U.S. and African scientists are launching the Phase I trial of a multi-epitope vaccine from Epimmune. It is the first of its kind to be conducted simultaneously in the two locations.

New tests move forward

Public health officials agree that it is time to break down the barriers when it comes to HIV testing. Many HIV-infected persons do not get tested until late in their infection, and many persons who are tested do not return to learn their test results,

reports the CDC.[2] In 2000, of an estimated 2 million CDC-funded tests for HIV, approximately 18,000 tests represented new HIV diagnoses; 31% with positive tests for HIV did not return to learn their test results, CDC figures show.[2]

Clinicians now have a selection of rapid HIV testing options in diagnosing new infections. The Food and Drug Administration (FDA) gave approval in November 2002 to the OraQuick Rapid HIV-1 Antibody Test (OraSure Technologies, Bethlehem, PA) and issued clearance in April 2003 for the Reveal Rapid HIV-1 Antibody Test, manufactured by MedMira of Halifax, Nova Scotia. ***(Contraceptive Technology Update* reported on the OraQuick approval in the February 2003 article, "Rapid HIV testing method approved — prepare now to apply new strategies," p. 13.)** The Canadian-based MedMira has entered into an agreement with McGaw Park, IL-based Cardinal Health to market the test in the United States. Research indicates positive performance of the Reveal test.[3,4]

The OraQuick test provides HIV results in 20 minutes and can be stored at room temperature. The Reveal test offers HIV results in three minutes and also can be stored at room temperature. While rapid tests facilitate receipt of test results, any HIV-positive rapid test results require confirmation by Western Blot or immunofluorescence assays.[2]

The CDC is committed to working with governmental and community-based organizations to encourage the adoption of HIV testing as a routine part of medical care, says **Robert Janssen**, MD, director of the CDC's division of HIV/AIDS prevention.

"One of the major challenges to implementing routine testing is determining how best to remove barriers that can discourage testing," says Janssen. "In addition to promoting the adoption of simplified HIV testing procedures, which will reduce requirements for comprehensive pre-test counseling, CDC will fund demonstration projects that will offer insight as to how to best implement rapid testing inside and outside of the doctor's office."

Because the rapid HIV test is simple enough to be performed in community settings, the ability to reach those infected with HIV who may not have access to traditional medical settings is greatly expanded, Janssen observes. The CDC anticipates that community-based organizations will begin to play a pivotal role in ensuring newly identified HIV-infected people are linked to appropriate care, treatment, and prevention services, he states.

"Making testing more widely available also will increase opportunities to provide prevention information to both infected individuals and HIV-negative people at risk," states Janssen. "Therefore, while continuing efforts to prevent HIV infection in high-risk negative individuals, CDC will increase emphasis on prevention services for people living with HIV."

Vaccine trial now up

On the prevention front, scientists have launched the first HIV vaccine trial to be conducted simultaneously in the United States and Africa. The Seattle-based HIV Vaccine Trials Network (HVTN), a partnership of investigators, clinical trial sites, and community representatives working with industry and governments for a preventative HIV vaccine, has begun the Phase 1 trial of the HVTN 048 vaccine. The multi-epitope vaccine, also known as EP HIV-1090, is from the San Diego-based pharmaceutical company Epimmune. It will be tested in 42 volunteers in the United States and Botswana. The trial will be conducted at several sites in the Boston area through the Harvard Medical School, in St. Louis through the St. Louis University, and in Gaborone, Botswana, through the Botswana-Harvard Partnership for HIV Research and Education.

"By conducting this trial in two distinct geographies at the same time, we hope to shave precious years off the trial process, therefore expediting the discovery of an HIV vaccine that will save millions of lives in countries around the world, and especially in Africa," says **Lawrence Corey**, MD, HVTN principal investigator. "The HVTN's ability to conduct the trial simultaneously in Africa and the U.S. is a testament to the committed leadership of the Botswana government in finding an HIV vaccine as soon as possible."

The candidate vaccine is assembled from synthetically produced DNA and incorporates small pieces of DNA, which manufacture specific proteins like the ones in HIV. These proteins have elements referred to as epitopes, which in this case prepare the body to recognize real HIV.

No live HIV is used in the vaccine candidate, so there is no way for volunteers to develop HIV from the vaccine.

Research scientists have designed the study as a randomized, double-blinded, multicenter trial.

Participants will be healthy, HIV-uninfected adults between ages 18 and 40, all who will have 12 clinic visits, including four injection dates and 12 blood draws.

Volunteers are being screened to see whether they qualify for enrollment, reports Corey. As each volunteer is enrolled, he or she will receive the vaccine injections over a six-month course followed by a year of observation. Researchers anticipate that preliminary study results will be available in the first half of 2005, Corey estimates. **(*CTU* reported on earlier vaccine trials in its *STD Quarterly* articles, "World's first large-scale HIV vaccine trial doesn't indicate protection for overall population," May 2003 issue, and "HIV vaccines: New generation may reduce transmission of virus," October 2002 issue.)**

In the fight against HIV, vaccine development must be global, stresses Corey, who also serves as professor in the School of Medicine at the University of Washington and head of the program in infectious diseases at the Fred Hutchinson Cancer Research Center, both in Seattle.

"It is of prime importance to establish a truly global enterprise that will facilitate the rapid development and eventual dispersal of vaccines, thus expediting their use in the areas of the world most affected by disease," he says. "HVTN 048 is one of the initial steps in building this needed foundation for global vaccine research."

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Group issues guidelines on chlamydia screening

The push for chlamydia screening has been intensified, with the Washington, DC-based American College of Preventive Medicine (ACPM) issuing a practice policy statement calling for the annual screening of all sexually active women 25 years of age or younger, as well as sexually active women with other risk factors.[1]

Why has the 2,000-physician member professional society issued the new guidelines? The move comes in light of the fact that *Chlamydia trachomatis* infection now is the most common bacterial sexually transmitted disease (STD) in the United States, explains **Katerina Hollblad-Fadiman**, MD, MPH, clinical instructor in the department of medicine at the University of California, San Francisco (UCSF) and lead author of the practice policy statement.

It is estimated that chlamydia affects more than 4 million people yearly at a cost exceeding $2.7 billion.[2,3] Widespread screening is necessary because up to 70% of infected women and 75% of infected men are asymptomatic.[4-6]

With urine-based screening tests and one-dose therapy now available, diagnosis and treatment of the STD now is simplified, says Hollblad-Fadiman.

The society's statement follows similar practice guidelines issued by the Chicago-based American Medical Association (AMA), the Elk Grove Village, IL-based American Academy of Pediatrics (AAP), the Atlanta-based Centers for Disease Control (CDC), and the U.S. Preventive Services Task Force.[7-10] ***(Contraceptive***

EXECUTIVE SUMMARY

The American College of Preventive Medicine has issued a new recommendation that all sexually active women 25 years of age or younger as well as sexually active women with other risk factors be screened annually for chlamydia.

- It is estimated that chlamydia affects more than 4 million people yearly at a cost exceeding $2.7 billion. Widespread screening is necessary since up to 70% of infected women and 75% of infected men are asymptomatic.
- Diagnosis and treatment of the sexually transmitted disease now is simplified with the advent of urine-based screening tests and one-dose therapy.

Technology Update **reported on the latest of these guidelines in the July 2001 article, "Task force calls for chlamydia screening," p. 81.)**

"*Chlamydia trachomatis*, our most common sexually transmitted infection, is an important cause of pelvic inflammatory disease — and its late sequelae of tubal factory infertility and ectopic pregnancy — and pneumonia in infants who are exposed to the infection at birth," says **Julius Schachter**, PhD, professor in the department of laboratory medicine at UCSF and North America representative to the International Union against Sexually Transmitted Infections, a globally based organization seeking international cooperation in the control of STDs.

"The recommendation that sexually active young women be screened annually for genital infections is particularly welcome because young age has consistently been shown to be the most important risk factor for being infected, and programs of screening and treating those found to be infected have been shown to reduce the prevalence of infection and the incidence of PID and perinatal infections," he says.

Review the guidelines

The ACPM's guidelines call for annual screening of all sexually active women 25 or younger, as well as sexually active women with other risk factors. These risk factors include having a new male sex partner or two or more partners during the preceding year, inconsistent use of barrier contraception, history of a prior sexually transmitted disease, African-American race, and cervical ectopy.

These guidelines fall in line with other professional directives: The AMA and the AAP both recommend that all sexually active adolescents be screened annually for the STD[7-8], while the CDC recommends screening all sexually active women younger than 20 for chlamydial infection during routine annual examinations.[9]

The CDC also advocates annual screening of women older than 20 who use barrier contraceptive measures inconsistently and who have new or multiple sex partners during the previous three months.[9] The U.S. Preventive Services Task Force recommends routine screening for all sexually active women age 25 and younger, all asymptomatic pregnant women 25 and younger and/or at high risk for infection, as well as other asymptomatic women at high risk for infection.[10]

High-risk characteristics include being unmarried or African American, having a prior history of STD, having new or multiple sexual partners, having cervical ectopy, and using barrier contraceptives inconsistently.[10]

Health care providers are reminded that while annual screening is an important first step, treatment of sex partners and regular follow-up of those found to be infected should be part of the program, states Schachter.

Because there are excellent diagnostic capabilities in nucleic acid amplification tests and highly effective single dose therapy in azithromycin (1 g orally), "the chlamydia problem is one we can make go away," he says.

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