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Hormone therapy: Make decisions on a balanced risk-to-benefit basis

Use new product labeling, recommendations for guidance

Family planning clinicians have found their care of postmenopausal women has changed dramatically since the July 2002 cessation of the estrogen/progestin arm of the Women's Health Initiative (WHI). The estrogen/progestin arm of the landmark study was halted after findings showed that the overall health risk, particularly of cardiovascular disease and breast cancer, from taking estrogens with progestin was greater than the benefits of lowering the risk of colon cancer and bone fractures. **(*Contraceptive Technology Update* reported on the study cessation in its September 2002 article, "Hormone replacement therapy: Review choices in light of new data," p. 97.)**

"The beneficial outcome of the WHI thus far is to have changed the nature of the conversation between health provider and consumer so that indications are more precise and decisions are being made on a balanced risk-to-benefit consideration," says **Wulf Utian**, MD, PhD, executive director of the Cleveland-based North American Menopause Society.

EXECUTIVE SUMMARY

The July 2002 cessation of the estrogen/progestin arm of the Women's Health Initiative continues to impact postmenopausal women. The Food and Drug Administration has revised labeling on estrogen and estrogen plus progestin products, and the U.S. Preventive Services Task Force has revised recommendations on use of such medications.

- When estrogen or estrogen-plus products are being prescribed solely for symptoms of vulvar and vaginal atrophy, the new labeling recommends that topical products be considered.
- When these drugs only are used for osteoporosis prevention, the new label specifies that the risks for osteoporosis must outweigh the risk of estrogen or estrogen with progestin.

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Clinicians now have new product labeling from the Food and Drug Administration (FDA) as well as updated recommendations from the U.S. Preventive Services Task Force (USPSTF) to help guide their use of hormonal steroids in postmenopausal women. Examine the following new information and integrate it into your daily practice.

As now approved by the FDA, estrogen products are indicated for use in relieving vasomotor symptoms of menopause such as hot flashes and night sweats; symptoms of vulvar and vaginal atrophy such as dryness, itching, and burning; and prevention of postmenopausal osteoporosis. In January, the FDA implemented new safety changes to labeling of all estrogen and estrogen with progestin products for use by postmenopausal women to incorporate information from the WHI study.

The new labeling information has been incorporated in physician prescribing information and patient information leaflets for Premarin, Prempro, and Premphase, all hormone products manufactured by Wyeth Pharmaceuticals of Collegeville, PA. However, the FDA is asking all manufacturers to update their labeling with WHI's results because all estrogen and progestin products are believed to have similar risks. The agency is revising its formal guidances for the industry in two related areas: labeling for all estrogen and estrogen with progestin products for postmenopausal women, and recommendations for conducting clinical trials to develop new products for postmenopausal women.

The new product labeling features a boxed warning that reflects new risk information, and includes changes to the approved indications to emphasize individualized decisions for balancing the benefits and the potential risks involved. The boxed warning, the highest level of warning information in labeling, highlights the increased risks for heart disease, heart attacks, strokes, and breast cancer. This warning also emphasizes that these products are not approved for heart disease prevention.

Check label changes

Of the three approved indications, two have been revised to include consideration of other therapies:

- The indication for treatment of moderate to severe vasomotor symptoms associated with menopause has not changed.
- The indication for treatment of moderate to severe symptoms of vulvar and vaginal atrophy associated with menopause has been modified.

Use the web for hormone therapy information

Check out the following Internet resources for more information on hormone therapy:

1. National Institutes of Health (NIH). Web: www.nih.gov.

Click on "Menopausal Hormone Therapy" at the opening page of the NIH web site to access a collection of related web sites, including the Women's Health Initiative (WHI), the full text of the first WHI research paper reviewing the findings of the estrogen/progestin study arm, and the U.S. Preventive Services Task Force's recommendation on hormone therapy. The NIH site also includes links to information on osteoporosis, alternative therapies, and ovarian cancer.

Clinicians also may be interested in viewing the videocast of a fall 2002 workshop on hormone therapy sponsored by the NIH. Click on "News" at the opening page, "VideoCasting," and "Past Events" to download the "Menopausal Hormone Therapy" sessions that were held Oct. 23 and 24. RealPlayer software (which can be downloaded free of charge) is needed to view the sessions.

2. *Annals of Internal Medicine*. Web: www.annals.org.

Click on "Journals" at the opening page of this publication's site, then "Past Issues," "2002," and "Aug. 20, 2002" to gain public access to "*Postmenopausal Hormone Replacement Therapy and the Primary Prevention of Cardiovascular Disease,*" one of the review articles published by members of the U.S. Preventive Services Task Force.

The issue also offers "*Postmenopausal Hormone Replacement Therapy To Prevent Chronic Conditions: Recommendations from the U.S. Preventive Services Task Force,*" a patient handout explaining the recommendations from the task force. The handout may be reproduced for not-for-profit educational purposes only.

3. MEDLINE Plus. Web: www.medlineplus.gov.

Click on "Health Topics," "H," then "Hormone Replacement Therapy" to go to a collection of links to news articles and web sites dealing with the topic of hormone therapy. Visitors also may use the site to search the National Library of Medicine's MEDLINE service for recent articles on estrogen and estrogen-progestin replacement therapy.

4. *Journal of the American Medical Association*. Web: www.ama-assn.org.

At the opening page of the American Medical Association, use the pull-down menu under "Physicians" to move to "Clinical Practice Tools" then "*JAMA* Patient Page" to access the publication's patient education pages. These pages, available in Adobe Acrobat Portable Document Format, may be freely copied and distributed for patient education. Use the pull-down menu to access the patient page on hormone replacement therapy, which is available in English and Spanish.

5. Food and Drug Administration. Web: www.fda.gov.

At the opening page of this government web site, click on "More FDA News," "Archives," then "FDA Approves New Labels for Estrogen and Estrogen with Progestin Therapies for Postmenopausal Women Following Review of Women's Health Initiative Data [Jan. 8, 2003]," which provides the agency's press release on its new product labeling. From this page, visitors can access a freely reproducible fact sheet, "FDA Approves New Labeling and Provides New Advice to Postmenopausal Women Who Use or Who Are Considering Using Estrogen and Estrogen With Progestin." ■

When these products are being prescribed solely for the treatment of symptoms of vulvar and vaginal atrophy, topical vaginal products should be considered, advises the FDA.

• The indication for prevention of postmenopausal osteoporosis has been modified. When products are being prescribed solely for the prevention of postmenopausal osteoporosis, the new labeling advised that approved nonestrogen treatments should be carefully considered, and estrogens and combined estrogen-progestin products only should be considered for women with significant risk of osteoporosis that outweighs the risks of the drug.

Additional drugs that are FDA-approved for the prevention of postmenopausal osteoporosis include the bisphosphonates alendronate (Fosamax, manufactured by Merck & Co. of West Point, PA) and risedronate (Actonel, manufactured by Procter & Gamble Pharmaceuticals of Cincinnati), and

the selective estrogen receptor modulator raloxifene (Evista, manufactured by Eli Lilly & Co. of Indianapolis). Calcitonin (Miacalcin, manufactured by Novartis Pharmaceuticals, East Hanover, NJ) carries an indication for treatment of the disease.

The new labeling also advises health care providers to prescribe estrogen and combined estrogen with progestin drug products at the lowest dose and for the shortest duration for the individual.

See new recommendation

The U.S. Preventive Services Task Force has issued a revised recommendation against the use of combined estrogen and progestin hormone replacement therapy for preventing cardiovascular disease and other chronic conditions in postmenopausal women. The independent panel also has concluded that the evidence is insufficient to recommend for or against the use of estrogen alone to prevent the chronic conditions in postmenopausal women who have had hysterectomies.

The new guideline is a change from the task force's 1996 recommendation, which stated there was insufficient evidence to recommend for or against hormone therapy for all postmenopausal women. Task force members began reviewing information in 1999, and the recommendation was released in October 2002, states **Heidi Nelson**, MD, MPH, associate professor of medicine at the Oregon Evidence-based Practice Center at the Portland-based Oregon Health & Science University. The task force continued to update the report throughout the process even while the final paper was in press, says Nelson, who served as one of the leaders of the research teams involved with the review.

Two papers have been published containing the research reviewed by the task force. One article primarily addresses cardiovascular disease, while the other provides an overall summary of the risks and benefits of hormone therapy.[1,2]

The reviews did not examine the use of hormone therapy to treat menopausal symptoms or specific conditions such as osteoporosis. The USPSTF will not issue a recommendation about treating menopausal symptoms because it is not a prevention issue and therefore out of its scope, says Nelson. In October 2002, the panel gave unopposed estrogen for prevention of chronic conditions an "I" rating (insufficient evidence) because current evidence is not adequate to determine the overall benefit/harm balance, she states.

When more data become available, particularly from the WHI, the USPSTF likely will revisit this recommendation, says Nelson.

Review steroid use

What is the future for hormone therapy? For a number of years, there had been increasing off-label use of such medications for the prevention of cardiovascular disease, and some clinicians even were using it in the hope that it would prevent Alzheimer's disease and cognitive decline, observes **Margery Gass**, MD, professor in the obstetrics/gynecology department of the University of Cincinnati and current president of the North American Menopause Society.

"The results of the WHI have demonstrated that hormone therapy does not prevent cardiovascular disease, and furthermore, has some serious side effects, [such as] invasive breast cancer, venous thrombolic events, cardiovascular disease [CVD], and stroke," says Gass. "Thus, it should no longer be used for prevention of CVD."

Preventive use of hormonal steroids at this time should be directed at osteoporosis only, pending data on coronary heart disease and Alzheimer's, says Utian. In this instance, the latest FDA labeling requirements are clear, he states; clinicians should consider the risks and benefits of all options, decide on a therapy, and follow up appropriately. Estrogen-only or hormone therapy remains a viable option, and most certainly it is an option in younger women or women who cannot tolerate bisphosphonates, as well as for most women for up to five years of use, he maintains.

"The therapeutic role [of hormonal steroids] relates to the true estrogen deficiency symptoms, namely the vasomotor, vaginal atrophy, and possibly the enhanced quality of life components," he notes.

Clinicians now await the estrogen-only arm outcome of the WHI to determine whether the added continuous progestin was the culprit, observes Utian. Look for clinical practice to be "tremendously influenced" by that arm of the study, he predicts.

While it will be some years before information from the estrogen-only arm is available, look to the publication of detailed analyses of the estrogen/progestin arm of the WHI for further understanding, says Utian. These analyses, which will focus on the regimen's impact on cardiovascular disease, cancer, osteoporosis, cholelithiasis,

degenerative arthritis, sexual function, cognition and dementia, and quality of life, will be "crucial" since the initial published data[3] did not provide the nuances that only such analyses can give, he states.

"In the interim, the last nail has *not* been driven into the hormone therapy coffin, and these products remain an essential component of contemporary practice," states Utian.

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Maintain confidential care for adolescents

Your practice includes confidential care for adolescents, including provision of contraceptives and testing/treatment for sexually transmitted diseases (STDs). But are your office staff communicating the confidentiality of this information correctly to prospective teen patients? If they are not, adolescents may fail to access these important services.

A just-published survey of physicians and their office staff at 170 pediatric, family medicine, and internal medicine practices found that in as many as 63% of practices, office staff answering telephones gave responses that contradicted doctors' responses when asked if they offer confidential services to adolescents.[1]

Such findings are troubling, because teens should know they have a right to confidential care and because the information they receive about confidentiality when trying to schedule an appointment may be a deciding factor in whether to seek health care, says **Tina Cheng**, MD, MPH, director of general pediatrics and adolescent medicine at Baltimore-based Johns Hopkins University. Whether or not teen-agers suspect they may have HIV, or if they are simply looking for contraceptive information, any delay to medical care could have serious consequences, she notes.

EXECUTIVE SUMMARY

Teens seeking confidential health care for conditions such as pregnancy or sexually transmitted diseases (STDs) frequently get inaccurate information about their provider's confidentiality policies, according to a just-released study. Teens may fail to get needed care if privacy is in question.

- Laws developed in the United States during the last 30 years support the provision of confidential health care to minors in many circumstances.
- All states legally entitle adolescents to consent for treatment for "medically emancipated conditions" that may include contraception; pregnancy; diagnosis and treatment of STDs, HIV, or reportable diseases; treatment of substance abuse problems; and mental health issues.

"In most cases, it is best for teens to discuss their concerns with parents or guardians; however, if this is not possible, it is desirable that youth get the health care they need," states Cheng. "Legal statutes have recognized this need, and each state legally entitles adolescents to consent to treatment for medically emancipated conditions that may include contraception, pregnancy, diagnosis and treatment of STDs, HIV, substance abuse, and mental health problems."

Providing confidential care for adolescents can be challenging for health practitioners, Cheng acknowledges. Some of the challenges include limited time for office visits; difficulties in maintaining confidentiality in billing, medical records, and follow-up communication; and lack of training in adolescent issues among providers and staff.

"To provide confidential care for teens requires addressing the above challenges and development and dissemination of an office policy," she explains. "Office staff should be aware of the confidentiality policy, and confidentiality should be discussed with parents and teens."

Adolescents are more willing to communicate with and seek health care from physicians who ensure confidentiality. According to a randomized controlled trial in three suburban public high schools, teens are more willing to disclose general information, as well as information about sensitive topics, and more likely to make a return visit if such confidentiality is clearly communicated.[2]

According to a study of adolescent female

Definition of Key Terms

- *Confidentiality* in a health care setting is defined as an agreement between patient and provider that information discussed during or after the encounter will not be shared with other parties without the explicit permission of the patient. It is best classified as a rule of biomedical ethics that derives from the moral principle of autonomy and accompanies other rules such as promise keeping, truthfulness, and privacy.
- *Privacy* means freedom from unsanctioned intrusion. In a health care setting, it involves psychological, social, and physical components in addition to confidentiality.
- *Informed consent* describes the process during which the patient learns the risks and benefits of alternative approaches to management and freely authorizes a course of action proposed by the clinician. Informed consent has ethical and legal derivations. Although usually bound together in clinical encounters, confidentiality and consent are different. Confidentiality can occur during an encounter whether or not specific informed consent for a treatment or intervention is given. For example, contraceptive options may be confidentially discussed before informed consent is given for any specific choice.

Source: Society for Adolescent Medicine. A position paper of the Society for Adolescent Medicine. Confidential health care for adolescents. *J Adol Health* 1997; 21:408-415.

patients at Wisconsin family planning clinics, the majority of teens said they would stop using sexual health services if they had to inform their parents that they were seeking contraceptive care.[3] The study also found that 99% of girls who would stop going to the clinics said they would continue to have sexual intercourse.

"Not only would these adolescents be using less-effective contraceptive means or nothing at all, but it also would have an impact on the spread of sexually transmitted diseases because some of the girls indicated that they were getting tested for sexually transmitted diseases and would stop doing that," says **Diane Reddy**, PhD, associate professor and director of health psychology at the University of Wisconsin-Milwaukee and lead author for the paper.

A legal framework developed in the United States during the last 30 years supports the provision of confidential health care to minors in many circumstances.[4] All 50 states legally entitle adolescents to consent for treatment for "medically emancipated conditions" that may include contraception; pregnancy; diagnosis and treatment of STDs, HIV, or reportable diseases; treatment of substance abuse problems; and mental health issues.

According to the New York City-based Alan Guttmacher Institute (AGI), many states specifically authorize minors to consent to contraceptive services, testing and treatment for HIV and other sexually transmitted diseases, prenatal care and delivery services, treatment for alcohol and drug abuse, and outpatient mental health care. According to a 2000 review of individual state laws, the institute found:

• Twenty-five states and the District of Columbia have laws or policies that explicitly give minors the authority to consent to contraceptive services. (To review AGI's table of state laws, go to its web site, www.agi-usa.org, click on "The Guttmacher Report," "Archive," and "August 2000." Click on the article "Minors and the right to consent to health care."

• Twenty-seven states and the District of Columbia have laws or policies that specifically authorize a pregnant minor to obtain prenatal care and delivery services without parental consent or notification.

• All 50 states and the District of Columbia specifically allow minors to consent to testing and treatment for STDs, including HIV. (In three states — California, New Mexico, and Ohio — minor consent law does not apply to HIV treatment.)[5]

According to the Institute's survey, no state explicitly requires parental consent or notification for any of these services. However, two states, Texas and Utah, prohibit the use of state funds to provide contraceptive services to minors without parental consent, and Iowa law calls for parental notification if a child receives a positive HIV test. **(See definitions of privacy, confidentiality, and informed consent as they pertain to adolescents, above left.)**

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The Pill and bone health: What is the impact?

Combined oral contraceptives (OCs) help decrease a woman's risk for epithelial ovarian cancer and endometrial cancer, reduce her risk of pelvic inflammatory disease and ectopic pregnancy, and lessen menstrual cramps and pain. But what is their impact on bone mineral density (BMD)?

Several studies have suggested that OC use may stabilize or even increase bone density.[1] A new analysis indicates that exposure to the estrogen from OCs during the premenopausal years may have a small beneficial effect on the skeleton in white women.[2]

The new information is consistent with clinicians' evolving perspective on combination OC use and bone health, states **Andrew Kaunitz**, MD, professor and assistant chair in the obstetrics and gynecology department at the University of Florida Health Science Center/Jacksonville.

"In estrogen-replete, healthy ovulatory women, use of combination OC has minimal, but if anything, positive, impact on bone mineral density," observes Kaunitz. "However, we know from other data that in hypoestrogenemic premenopausal women, e.g., perimenopausal women, use of OC has a positive impact on BMD and prevents future osteoporotic fractures."[3,4]

EXECUTIVE SUMMARY

Several studies have suggested that use of combined oral contraceptives (OCs) may stabilize or even increase bone density.

- A new analysis indicates that exposure to the estrogen from OCs during the premenopausal years may have a small beneficial effect on the skeleton in white women.
- Research is under way to determine the impact of OCs on the bone mineral density in female distance runners, who are potential candidates for what has been described as female athlete triad, a condition marked by disordered eating, menstrual irregularities, and osteoporosis.

Review the analysis

To examine the OC-BMD link, researchers in the current analysis looked at 216 white and 260 black women enrolled in the Coronary Artery Risk Development in Young Adults study, a long-term examination of the evolution of cardiovascular disease risk factors in young adults.

In the current analysis, researchers looked at 216 white and 260 black women ages 25-37 who had bone mineral densities measurements taken at the spine, hip, and whole body by dual-energy X-ray absorptiometry. Three years later, whole-body BMD was measured again in 369 of the women. Researchers also checked the women's oral contraceptive history, including length of use and estrogen dose.

In their analysis, researchers found that cumulative estrogen from oral contraceptives explained 4% of the variation in spine BMD among white women, but it did not explain any of the variance in BMD among black women. Cumulative oral contraceptive estrogen dose was associated with a decreased risk for low bone density (lowest quartile) at the spine, hip, and whole body in white women. When women in the highest quartile of cumulative oral contraceptive estrogen exposure were compared with those in the lowest quartile, the odds ratios were 0.08 at the spine, 0.23 at the hip, and 0.37 at the whole body. There was no relation between oral contraceptive use and low bone density among black women, and oral contraceptive use did not predict longitudinal changes in whole body bone mineral density among white or black women.

A valuable contribution of the study is recognition of the importance of OC use duration as a determinant of bone health, says Kaunitz.

More research planned

The impact of the Pill on bone mineral density is a topic of interest for **Kristin Cobb**, PhD, a lecturer in the department of health research and policy at Stanford University in Palo Alto and lead author of the analysis.

Cobb is involved in an ongoing examination of the effect of oral contraceptives on BMD in female distance runners, who have low bone density because they do not menstruate, part of what is

defined as the female athlete triad.

First described at a meeting of the American College of Sports Medicine in 1992, the triad consists of disordered eating, menstrual irregularities, and osteoporosis.[5] Although the triad can occur in any athlete, certain groups, such as distance runners and swimmers, are at particularly high risk due to the significant energy deficits that go along with their activities.[6]

The randomized trial is assigning women runners to two groups, those who use OCs and those who do not, and following them for two years, says Cobb.

"It's tricky to recruit for this because we wanted fairly young women runners who were at the age where it could influence their bone density to a certain extent," she states. "We hope to have some interesting results from it, because I think this will be the first randomized trial with a large enough number to look at oral contraceptive use as a possible treatment for bone density loss in women runners."

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Getting men on board: one facility's approach

If the number of men on your patient rosters is low, take a look at the approach used by Planned Parenthood of San Antonio and South Central Texas. In the first year of its marketing initiative, the number of its male patients nearly doubled from 2% to 3.7% of total patients served, says **Polin Barraza**, director of clinic operation for the San Antonio-based agency.

Many federally and state-funded reproductive health programs are designed to serve women and do not offer male services, according to a 2002 analysis issued by the New York City-based Alan Guttmacher Institute.[1] Women often begin seeing a heath care provider for routine reproductive health care services after they become sexually active, and they become linked to the health system when they are pregnant and giving birth. Men do not have a similar routine channel for obtaining sexual and reproductive health services, according to the analysis.[1] **(*Contraceptive Technology Update* reviewed the analysis in its June 2002 article, "Missing men: Address sexual health care needs"; see p. 67.)**

Men are a challenge in general when it comes to seeking regular preventative care, observes **Earnie Blackwell**, RNC, director of patient care for Planned Parenthood of San Antonio and South-Central Texas.

"They are even more fearful and embarrassed about sexual health care," says Blackwell. "We are trying to get the message out in our community via advertising and word-of-mouth that Planned Parenthood is for men, too."

What led the San Antonio agency to increase its marketing to men? Several factors played into the decision, says Blackwell. The agency was fielding calls from men seeking affordable health care in an environment that offered quality and confidential care. Clinicians were reporting that female patients were returning to the clinics with repeated sexually transmitted diseases (STDs). Clinicians wanted to bring the male partner into

EXECUTIVE SUMMARY

Many federally and state-funded reproductive health programs are designed to serve women and do not offer male services.

- Women often begin receiving routine reproductive health care services after they become sexually active and become linked to the health system when they are pregnant and giving birth. Men do not have a similar channel.
- Planned Parenthood of San Antonio and South-Central Texas used an innovative marketing strategy and nearly doubled the number of male clients served in 2002.

RESOURCE

- **For more information on the Planned Parenthood of San Antonio and South Central Texas program**, contact: Sandy Ward, Marketing and Communications Manager, Planned Parenthood of San Antonio and South Central Texas, 104 Babcock Road, San Antonio, TX 78201. Telephone: (210) 736-2244. Fax: (210) 736-0011. E-mail: sandy.ward@ppfa.org. Web: www.plannedparenthood.org.

the treatment picture, rather than simply sending medication with the women for her partner.

"We wanted to be proactive in our health care," notes Blackwell. "By educating men on birth control methods and STDs, we hoped to engage them in the family planning process and create support for their partner."

The agency now offers its male patients physical exams, testicular cancer screening with education on how to do a testicular self-exam, STD testing and treatment, HIV testing, family planning education, and partner/couple appointments, reports **Rachel Goeres**, MSN, RN, vice president for client services. It also has a referral system for vasectomy and other services outside its current clinical services menu.

"The response from agency staff has been very positive after an initial period of adjustment to implement the new protocols," she notes. "The staff sees firsthand the need and importance of providing health care to men."

What are some tips for initiating such a program? Goeres offers the following suggestions:

- Give your staff the training and support that any new program would require.
- Realize and anticipate that any type of change can be stressful.
- Allow people to work through the changes and be successful.

To get the word out on male services, external advertising efforts now include advertising that focuses on men only and advertising that focuses on couples, states **Sandy Ward**, marketing and communications manager. The agency uses general services advertising on two popular pop/rock stations. Estimated costs for marketing male health care services in 2002 was $3,600, about 10% of the agency's marketing budget, she says.

"We feature STD testing and treatment for couples in print ads, which appear in our city's alternative and college newspapers," says Ward. "We have advertised 'Planned Parenthood — for men too' on the web site of a popular rock station, which has a predominately male listenership."

Clinic waiting rooms at the agency now feature a listing of health care services, including male exams, says Ward. Information on male services is included on all printed educational materials, brochures, and fliers found in the literature racks.

"We strive to make our clinics inviting to men," Ward states. "Our after-hours phone messages are inclusive of the needs of men; the opening line of the after-hours greeting says, 'Thank you for calling Planned Parenthood — providers of high-quality health care for women and men.'"

Staff members routinely insert promotional male services fliers in patient re-supply pharmacy bags. The fliers promote male exams and testing and STD treatment. To overcome the stereotype that family planning centers only are for women, the agency now uses the tagline, "Planned Parenthood: It's Not Just a Girl Thing."

The message about male services is getting out, reports Ward. "We conducted a male patient survey last year," she states. "Of the 99 respondents, 88 were new patients. This is a healthy sign that our outreach efforts are working."

(Editor's note: Visit the Contraceptive Technology Update *web site, www.contraceptiveupdate.com, to view the male patient services survey developed by Planned Parenthood of San Antonio and South-Central Texas.)*

Reference

1. Alan Guttmacher Institute. *In Their Own Right: Addressing the Sexual and Reproductive Health Needs of American Men.* New York: 2002. ■

ASK THE EXPERTS

Answers to questions on OC use, DMPA impact

[Editor's note: What's the impact of concomitant medications on combined oral contraceptives (OCs)? Commenting this month are ***Andrew Kaunitz****, MD, professor and assistant chair in the obstetrics and gynecology department at the University of Florida Health Science Center/Jacksonville;* ***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; ***Sharon Schnare****, RN, FNP, CNM, MSN, women's health consultant and clinician with the Seattle King County Health Department in women's and adolescent health care and the International District Community Health Center in Seattle;* ***Felicia Stewart****, MD, adjunct professor in the department of obstetrics, gynecology, and reproductive sciences at the University of California-San Francisco and co-director of the Center for Reproductive Health Research & Policy; and* ***Susan Wysocki****, RNC, NP, president and chief executive officer of the Washington, DC-based National Association of Nurse Practitioners in Women's Health.]*

Question: I have several patients who are on short or long-term antibiotics, are on the Pill, and use backup condoms. My question: Should a woman on oral contraceptives (who hasn't missed any pills and taken them consistently) and antibiotics use emergency contraception (EC) if her condom fails?

Kaunitz: Contrary to what many of us have been taught, standard courses of single antibiotics, including doxycycline, ampicillin, quinolones, and metronidazole, have not been found to lower estrogen/progestin levels in women using combination OCs.[1] Keep in mind, however, that the studies that generated the above reassuring findings were performed in women taking one (not two) antibiotics. In contrast with other antibiotics, use of rifampin (sometimes used to treat tuberculosis or other infections) without question lowers steroid levels in OC users; when this hepatic enzyme-inducing antibiotic is prescribed, women using OCs (or patches, rings, or the combination injectable) should use barrier backup contraception. ***(Editor's note:*** *Kaunitz served as a consultant in the development of the Washington, DC-based American College of Obstetricians and Gynecologists practice bulletin,* The Use of Hormonal Contraception in Women with Coexisting Medical Conditions, *referenced above.)*

Nelson: Since she does not need to use the condom for birth control in the first place, she does not need to use EC if the condom breaks. I assume she is using it for protection against sexually transmitted diseases, since every study has shown us that the antibiotics that are typically used for long-term treatment of acne do not reduce the serum levels of hormones to the subtherapeutic range.[2]

Schnare: No, she need not use backup condoms when taking OCs and using antibiotics. The only medications associated with OC failure include rifampin, griseofulvin, and anticonvulsants (except valproic acid).

Stewart: This is certainly being "extra" careful! The only antibiotics that have been shown to reduce pill efficacy are the anti-tuberculosis drugs such as rifampin. There is no real research evidence that use of common short or long-term medications such as doxycycline, urinary tract infection treatment, or penicillin have any effect. That said, there is no harm in using condoms as a back up, and EC for condom failure as well. The general rule I use is to provide EC whenever the woman wants to use it — even if we think the chance of pregnancy is really low. It's her call.

Wysocki: This is a pretty typical question, for which there is NO evidence to support that common antibiotics — tetracycline, in particular — cause Pill failure. Please see the guidelines issued by the World Health Organization (WHO). Griseofulvin and rifampin are the only antibiotics that may affect the Pill per WHO guidelines. [To access the guidelines, "*Improving Access to Quality Care in Family Planning. Medical Eligibility Criteria for Contraceptive Use*," on-line, go to the WHO web site (www.who.int/en/), click on "WHO Sites," "Reproductive Health & Research," "Family Planning," and "Family Planning Materials." Click on the publication title, which will allow you to browse the publication by chapter.]

References

1. *Clinical Management Guidelines for Obstetrician-Gynecologists.* The use of hormonal contraception in women with coexisting medical conditions. Washington, DC: American College of Obstetricians and Gynecologists; 2000. *ACOG Practice Bulletin;* 18.

2. Zieman M, Nelson A. Combination OCs and prescribed antibiotics. *The Female Patient* 2002; 27:40-41. ■

COMING IN FUTURE MONTHS

- Check out new Pap technology
- Review safety information on oral contraceptives
- Will Medicaid cuts impact family planning care?
- Contraception for postpartum and lactating women
- Implant update: Will U.S. see new technology?

CTUPDATES

News ■ Resources ■ Events

Enter abstracts for ARHP annual conference

Prepare abstracts now for presentation at the Association of Reproductive Health Professionals' (ARHP) annual meeting, "Reproductive Health 2003." The meeting will be held Sept. 10-13 in La Jolla, CA.

Advances in Reproductive Health, scheduled for Sept. 11 from 2-5:30 p.m., will feature oral and poster presentations. All accepted abstracts will appear in ARHP's journal, *Contraception*. In addition, ARHP will award a physician/clinician/researcher award of $1,000 and a student/resident award for $500 for an outstanding clinical paper.

Abstracts should contain information about new research in reproductive health, including current issues in contraception and new methods of contraception in development; diagnosis and treatment of reproductive infections in women and men; specific strategies and means for reducing unintended pregnancies and sexually transmitted infections; new developments in medical and surgical abortion techniques; and appropriate methods of treatment for sexual dysfunction in men and women.

Deadline for abstract submission is June 13. All abstracts must be submitted on-line at the ARHP web site, www.arhp.org; click on "healthcare providers," then "conferences," then "submit your research."

For more information about submitting an abstract or the ARHP annual meeting, telephone ARHP at (202) 466-3825 or send e-mail to conferences@arhp.org. ■

New payment options announced for Mirena

New payment options have been announced for Mirena, the levonorgestrel-releasing intrauterine system (IUS) manufactured by Berlex Laboratories of Montville, NJ.

Women who do not have contraceptive coverage can take advantage of a credit card payment plan for Mirena that will allow them to pay for the system in four monthly, interest-free payments rather than paying the entire cost up front. In addition, for physicians who wish to purchase Mirena for patients, payment terms have been extended from 30 to 90 days. Providers should note that the IUS is available through the wholesale pharmacy, TheraCom Pharmacy, based in Bethesda, MD.

While Mirena is extremely cost-effective when used over several years (the system costs less than $8 per month if used for five years), some women without insurance may find the one-time, upfront payment of $444 prohibitive. Under the new plan, the woman's initial payment is $174, and subsequent payments are approximately $90 per month for the next three months. TheraCom will bill the woman's credit card accordingly and ship the system to the prescribing health care professional for insertion.

"Because insurance coverage for contraception is not universal, we are pleased to offer new payment alternatives with the option of credit card payments, which we hope will increase access to this innovative, hassle-free birth control method," said **Reinhard Franzen**, vice president and general manager of female healthcare at Berlex Laboratories. "Mirena is effective for up to five years, but even if a woman chooses to use the system for three years, the method can still be more cost-effective than many other contraceptives."

More information about Mirena is available by calling (866) 647-3646 or visiting the product's web site, www.mirena.com. ■

CE/CME instructions

Physicians and nurses participate in this continuing medical education/continuing education program by reading the articles, using the provided references for further research, and studying the questions at the end of the issue. Participants should select what they believe to be the correct answers and refer to the list of correct answers to test their knowledge. To clarify confusion surrounding any questions answered incorrectly, please consult the source material. After completing this activity with the June issue, you must complete the evaluation form provided in the June issue 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.
- describe how those issues affect service delivery and note the benefits or problems created in patient care in the participant's practice area.
- cite practical solutions to problems and integrate information into daily practices, according to advice from nationally recognized family planning experts.

13. What is an approved indication for the use of estrogen/estrogen plus progestin therapy in menopausal women?

A. Prevention of cardiovascular disease
B. Prevention of Alzheimer's disease
C. Prevention of degenerative arthritis
D. Treatment of moderate to severe vasomotor symptoms associated with menopause

14. Which of the following statements is correct?

A. Adolescents in all 50 states and the District of Columbia must have parental consent prior to testing for sexually transmitted diseases (STDs) and HIV.
B. All 50 states and the District of Columbia specifically allow minors to consent to testing and treatment for STDs, including HIV.
C. All 50 states and the District of Columbia specifically allow minors to consent to testing and treatment for STDs, but adolescents must have parental consent for HIV testing and treatment.
D. All 50 states and the District of Columbia specifically allow minors to consent to testing and treatment for STDs, including HIV, but providers must notify parents if patients test positive for any disease.

15. Which of the following is the correct definition of the female athlete triad?

A. Disordered eating, menstrual irregularities, and osteoporosis
B. Chronic fatigue, menstrual irregularities, and osteoporosis
C. Disordered eating, asthma, and osteoporosis
D. Alopecia, menstrual irregularities, and osteoporosis

16. What two medications decrease steroid levels in women taking combined oral contraceptives?

A. Griseofulvin and ampicillin
B. Rifampin and metronidazole
C. Griseofulvin and rifampin
D. Griseofulvin and quinolone antibiotics

Answer key: 13. D; 14. B; 15. A; 16. C.

This continuing education offering is sponsored by Thomson American Health Consultants (AHC), which is accredited as a provider of continuing education in nursing by the American Nurses Credentialing Center's Commission on Accreditation. Thomson American Health Consultants is an approved provider by the California Board of Registered Nursing for approximately 18 contact hours (provider #CEP10864).

Thomson American Health Consultants (AHC) designates this educational activity for a maximum of 18 hours in Category 1 credit toward the AMA Physician's Recognition Award. Each physician should claim only those credits that he/she actually spent in the activity.

Thomson American Health Consultants is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians. This CME activity was planned and produced in accordance with the ACCME Essentials.

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.*

CONTRACEPTIVE TECHNOLOGY UPDATE®
A Monthly Newsletter for Health Professionals

URGENT

Please Give Us 9 Minutes of Your Time

Contraceptive Technology Update's 2003 Contraception Survey

Fill in — don't circle — your answers on the answer form with a pencil. **Note: If you receive this survey through another channel, please do not fill out more than one**. Please return the survey in the postage-paid envelope as soon as possible.

1. Please describe your clinic's activities regarding the provision of emergency contraceptive pills (ECPs):

A. We don't/can't discuss it.
B. We provide counseling only.
C. We counsel and refer to another provider for prescriptions.
D. We prescribe on site in an emergency only.
E. We prescribe on site and provide ECPs at any time.

2. In the past year, how many times have you (or the clinician in your program you work most with) prescribed a Copper-T IUD for emergency contraception?

A. 0
B. 1-5
C. 6-10
D. 11-15
E. More than 15

3. About how many women leave your office using pills each month?

A. 0
B. 1%-10%
C. 11%-25%
D. 26%-50%
E. More than 50%

4. Would you (or a clinician in your program) prescribe combined oral contraceptives to a healthy patient age 35 to 39 who smokes 10 cigarettes/day?

A. Yes
B. No
C. I don't know

5. Would you (or a clinician in your program) prescribe combined oral contraceptives to a healthy patient age 40 or older who smokes 10 cigarettes/day?

A. Yes
B. No
C. I don't know

6. In the past year, how many intrauterine devices have you personally inserted?

A. 0 If answer is 0, why?_____
B. 1-5
C. 6-10
D. 11-25
E. More than 25

7. In the past year, how many intrauterine devices have you personally removed?

A. 0
B. 1-5
C. 6-10
D. 11-25
E. More than 25

8. Given the advantages and disadvantages of such a change, should oral contraceptives be available over the counter?

A. Yes
B. No

9. In your written instructions, do you recommend that women who continue pills after developing vomiting or diarrhea use a backup contraceptive until their next period?

A. Yes
B. No If no, why?_____

10. In the past year, have you (or clinicians in your program) recommended pills to a woman specifically to decrease her risk of cancer of the ovary?

A. Yes. For about how many women has a history of ovarian cancer been an important part of the decision to prescribe pills? (write # here) _____
B. No
C. I don't know

11. After what period of time postpartum do you usually recommend that a woman who is not breast-feeding start taking combined oral contraceptives?

A. On hospital discharge
B. One to three weeks postpartum
C. Four to six weeks postpartum
D. After first menses
E. Other (specify)_____

12. After what period of time postpartum do you usually recommend that a woman who is breast-feeding start taking progestin-only oral contraceptives?

A. On hospital discharge
B. One to three weeks postpartum
C. Four to six weeks postpartum
D. After first menses
E. Other (specify)_____

13. Is your facility now offering or planning to offer in 2003 the Evra contraceptive patch?

A. Yes
B. No

14. Is your facility now offering or planning to offer in 2003 the NuvaRing contraceptive vaginal ring?

A. Yes
B. No

15. Given the possibility that Depo-Provera may diminish bone mass, what kind of precaution do you (or clinicians in your program) take against this, if any?

A. We do not take precautions.
B. We only inform patients of this possible side effect.
C. We inform patients and give women with a low estrogen level estrogen replacement therapy.
D. We inform and give women with a low estrogen level combined oral contraceptives.
E. Other (specify) _____

16. Would you prescribe Depo-Provera for young teens?
A. Yes
B. No

17. Is your facility now offering or planning to offer in 2003 the Lunelle monthly contraceptive injectable?
A. Yes
B. No

18. Please mark the title that best describes you.
A. Physician
B. Nurse/practitioner
C. Allied health professional
D. Health educator or counselor
E. Other (specify)_____

19. What is your primary role in your discipline?
A. Care provider
B. Case management
C. Administrator or supervisor
D. Faculty/teacher/student
E. Other (specify)_____

20. In what type of facility do you work?
A. Hospital/hospital-based clinic
B. Private practice
C. Public health clinic/agency/health department/community center
D. Health professions academic institution/student health center
E. Other health care (specify)_____

21. What is the location of your employment setting?
A. Urban
B. Suburban
C. Rural
D. Other (specify) _____

Use these pill choices for questions 22-29.

A. Alesse	F. Ortho-Cept
B. Estrostep	G. Ortho-Cyclen
C. Loestrin	H. Ortho Tri-Cyclen
D. LoOvral	I. Triphasil
E. Mircette	J. Other (specify in questions 22-29)

If a patient has experienced rather bothersome nausea on pills but can't tell you the name of the pills, which oral contraceptive would you (or a clinician in your program) prescribe?

22. Choice No. 1 (see list above)
Other (please mark option J and write the pill name here) _____

23. Choice No. 2 (see list above)
Other (please mark option J and write the pill name here) _____

Assume you could prescribe any pill for a woman initiating combined pills and there were no formulary issues dictating which pills you could prescribe. Which pill would you (or a clinician in your program) prescribe for a 21-year-old nonsmoking woman?

24. Choice No. 1 (see list above)
Other (please mark option J and write the pill name here) _____

25. Choice No. 2 (see list above)
Other (please mark option J and write the pill name here) _____

Assume you could prescribe any pill for a woman initiating combined pills and there were no formulary issues dictating which pills you could prescribe. Which pill would you (or a clinician in your program) prescribe for a 42-year-old nonsmoking woman who wants to use combined pills?

26. Choice No. 1 (see list above)
Other (please mark option J and write the pill name here) _____

27. Choice No. 2 (see list above)
Other (please mark option J and write the pill name here) _____

In your clinic, HMO, or office, there may be limits on the pills you prescribe to routine patients. Given the pills that are readily available to you, which pill would you (or a clinician in your program) prescribe for a 21-year-old nonsmoking woman?

28. Choice No. 1 (see list above)
Other (please mark option J and write the pill name here) _____

29. Choice No. 2 (see list above)
Other (please mark option J and write the pill name here) _____

30. Please note which pill(s) you have prescribed or provided most often in the past six months.

A. Alesse	D. Apri
B. Mircette	E. Cyclessa
C. Levlite	F. Yasmin

31. If your clinic is dispensing emergency contraceptive pills (ECPs), which pill is being used?
A. Preven
B. Plan B
C. Other (specify)_____

Is your facility or practice now using or planning to offer in the next year any of the following?

32. Herbal medicine	A. yes	B. no
33. Chiropractic	A. yes	B. no
34. Massage/touch therapy	A. yes	B. no
35. Acupuncture	A. yes	B. no

Other, please specify _____

36. Is the use of alternative medicine by patients becoming accepted in your practice or facility?
A. Yes
B. No

May we contact you for further information? If so, please provide the following information:

Name: _____

Facility: _____

City/State: _____

Phone: _____

E-mail: _____

Thank you for participating in this survey.
VERY IMPORTANT: Don't forget to return this form and the answer form in the postage-paid envelope. Both forms are needed to compile your answers.