CONTRACEPTIVE TECHNOLOGY UPDATE®
A Monthly Newsletter for Health Professionals

THOMSON
AMERICAN HEALTH CONSULTANTS

IN THIS ISSUE

NOVEMBER 2004
VOL. 25, NO. 11 • (pages 121-132)

New contraceptives widen choices, but the Pill still is a top selection

Interest in contraceptive patch and vaginal ring continues to grow

(Editor's note: This issue of Contraceptive Technology Update *contains results from the 2004 Contraception Survey, which provides an overview of current family planning methods. Look inside for information on the transdermal contraceptive, the contraceptive vaginal ring, the contraceptive injection, intrauterine contraception, and oral contraceptives, as well as other reproductive health issues. Check the December issue for information on emergency contraception.)*

While the contraceptive transdermal patch (Ortho Evra, Ortho-McNeil Pharmaceutical, Raritan, NJ) and the contraceptive vaginal ring (NuvaRing, Organon, West Orange, NJ) are gaining increased use among women, many providers report that oral contraceptives (OCs) remain a popular form of birth control.

Responses to the 2004 *Contraceptive Technology Update* Contraception Survey reflect the Pill's continued popularity; 39% of survey respondents say more than half of their patients use OCs (compared with 35% in 2003), and about 24% say 26%-50% of patients are pill users, which falls in line with responses from the 2003 survey.

"The number of clients leaving the clinic on pills has stayed stable over

EXECUTIVE SUMMARY

New methods may continue to grow in popularity, but the combined oral contraceptive (OC) pill remains a top choice when it comes to birth control. About 40% of respondents to the 2004 Contraception Survey say 50% or more of their patients leave the office using the Pill each month.

- More than 90% of 2004 survey respondents say their facilities now offer or plan to provide the transdermal contraceptive Ortho Evra this year.
- About 70% say they now offer or plan to offer the contraceptive vaginal ring, NuvaRing.

Contraceptive Technology Update® (ISSN 0274-726X), including **STD Quarterly**™, is published monthly by Thomson American Health Consultants, 3525 Piedmont Road, Building Six, Suite 400, Atlanta, GA 30305. Telephone: (404) 262-7436. Periodicals postage paid at Atlanta, GA 30304. POSTMASTER: Send address changes to **Contraceptive Technology Update**®, P.O. Box 740059, Atlanta, GA 30374.

Subscriber Information

Customer Service: (800) 688-2421 or fax (800) 284-3291, (customerservice@ahcpub.com). Hours of operation: 8:30 a.m.-6 p.m. Monday-Thursday; 8:30 a.m.-4:30 p.m. Friday, EST.

Subscription rates: U.S.A., one year (12 issues), $449. Outside U.S., add $30 per year, total prepaid in U.S. funds. Discounts are available for multiple subscriptions. For pricing information, call Steve Vance at (404) 262-5511. **Back issues**, when available, are $75 each.(GST registration number R128870672.) **Photocopying:** No part of this newsletter may be reproduced in any form or incorporated into any information retrieval system without the written permission of the copyright owner. For reprint permission, please contact Thomson American Health Consultants. Address: P.O. Box 740056, Atlanta, GA 30374. Telephone: (800) 688-2421. World Wide Web: http://www.ahcpub.com.

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. This CME activity is intended for OB/GYNs and other family planners. It is in effect for 36 months from the date of the publication.

Editor: **Rebecca Bowers**.
Vice President/Group Publisher: **Brenda Mooney**, (404) 262-5403, (brenda.mooney @thomson.com).
Editorial Group Head: **Valerie Loner**, (404) 262-5475, (valerie.loner@thomson.com).
Senior Managing Editor: **Joy Daughtery Dickinson**, (229) 551-9195, (joy.dickinson@thomson.com).
Senior Production Editor: **Nancy McCreary**.

Editorial Questions

Questions or comments?
Call **Joy Daughtery Dickinson** (229) 551-9195.

Statement of financial disclosure: **Dr. Hatcher** (editorial board chairman and peer reviewer) discloses that he is a consultant for Pharmacia Corp., performs research for Ortho, and is on the speaker's bureau for Ortho, Wyeth, Organon, Berlex, and Pharmacia Corp. **Dr. Kaunitz** (board member) discloses that he does continuing medical education presentations and publications for Aventis, Organon, Ortho-McNeil, Pharmacia Corp., and Wyeth-Ayerst, is a consultant for Aventis, Barr Laboratories, Berlex, Johnson & Johnson, Lilly, and Pharmacia Corp., and is a stockholder in Aventis and Johnson & Johnson, and performs research for Barr Laboratories, Berlex, Galen, Lilly, Merck, National Institutes of Health, Organon, Parke Davis, Pfizer, Pharmacia Corp., R.W. Johnson Pharmaceutical Research Institute, and Solvay. **Ms. Dominguez** (board member) discloses that she is on the speaker's bureau for Ortho, Pfizer, Roche, and Organon. **Ms. Wysocki** (board member) discloses that she is on the speaker's bureau for Ortho-McNeil, Wyeth Ayerst Pharmaceuticals, Berlex, Organon, Pharmacia Corp., Pfizer, and Bristol Myers Squibb. **Dr. Nelson** (board member) serves on the speaker's bureau for Berlex Laboratories, Gynetics, Eli Lilly & Co., 3M Pharmaceuticals, Ortho-McNeill, Organon, Parke-Davis, Pfizer, Pharmacia Corp., and Wyeth Ayerst; she conducts research for Ortho-McNeil, Pfizer, and Pharmacia Corp. **Dr. Rosenfield** (board member) is a stockholder and board member of Biotechnology General Corp., a consultant for Organon; serves on the speaker's bureau for Organon, Wyeth-Ayerst, and Parke-Davis; and conducts research for Organon, Wyeth-Ayerst, Ortho-McNeil, and Parke-Davis.

This publication does not receive commercial support.

THOMSON
AMERICAN HEALTH CONSULTANTS™

the months; however, the number of clients staying on pills seems to fluctuate with each new method that comes on the market," notes **Judy Nicksich**, women's health care nurse practitioner at Western Wyoming Family Planning, a not-for-profit family planning agency in Rock Springs, WY. She estimates more than 50% of her female patients leave her office using pills each month.

Since its November 2001 approval by the Food and Drug Administration (FDA), the Ortho Evra patch has gained an increasing share of the contraception option mix offered by family planning providers, *CTU* survey results indicate. More than 90% of 2004 survey respondents say their facilities are now offering or plan to provide the Evra contraceptive patch, a slight increase from 2003's 88% figure. It now is the No. 1 prescribed birth control brand in the United States.[1]

"Ortho Evra took off like crazy here," says **Stephani Cox**, APN, CNP, DPS, director of patient services at Planned Parenthood Springfield Area in Springfield, IL. "We could not keep it in stock."

Each transdermal patch contains 20 mcg of the estrogen ethinyl estradiol and 150 mcg of the progestin norelgestromin, the primary active metabolite of norgestimate. Designed to be changed once a week and worn for three weeks, it consists of an adhesive medicated layer worn against the skin, protected by a waterproof polyester layer. Just as pill users take placebos or no pills during the fourth week, patch users go patch-free that week. A placebo patch for the patch-free week would be a welcome addition, says Nicksich.

"The only complaint that I consistently hear is that a placebo patch would be useful so that one is not forced to remember to start patches over again in seven days," she observes. "This seems to be the biggest issue with use."

With growing popularity for the patch, clinics are looking for lower prices to cover the increased demand for the new method. Cost of one cycle of patches is slightly more expensive than one cycle of brand pills, according to *A Pocket Guide to Managing Contraception*.[2]

"Many of our patients love Ortho Evra," says **JoElle Thomas**, WHCNP, nurse practitioner at Custer Family Planning, a not-for-profit family planning agency in Bismarck, ND. "We need to be able to give a lower cost."

According to information recently presented at the annual congress of the Brussels, Belgium-based European Contraception Society, Evra is a

cost-effective method in women who are likely to experience poor compliance with combination OCs.[3] In similar research presented at the 2003 Advances for Reproductive Health forum presented by the Washington, DC-based Association of Reproductive Health Professionals, scientists estimated significant cost savings for the patch based on data showing improved compliance that resulted in increased rates of pregnancy prevention.[4]

Most female patients at the Men's and Women's Health Clinic at Wyoming County Public Health Department, a public health facility in Warsaw, NY, like the patch; however, some have problems with adhesion, says **Donna Gray**, CNM, NP, director of family planning.

In clinical trials, less than 2% of birth control patches had to be replaced because of complete detachment, and less than 3% had to be replaced because of partial detachment.[5] If a patch seems loose, lifts partially up, or falls off, women should be instructed to try to reapply it or apply a new patch immediately if the original patch has been off for fewer than 24 hours.[6] No backup contraception is needed, and the woman's patch change day will remain the same. If the patch is no longer sticky, has been stuck to itself or another surface, has other material stuck to it, or has become loose or fallen off before, it should not be reapplied.[6] Single replacement patches are available through pharmacists.

To apply the patch, women should press down firmly on the patch with the palm of the hand for 10 seconds, and make sure that the edges stick well. To make sure adhesion is secure, instruct patients to run their finger around the edge of the patch.[6]

"If we can convince the clients to spend the extra 10 seconds to put the patch on correctly, they are loving it," says Cox.

About 72% of respondents to the 2004 *CTU* Contraception Survey say their facility is now offering or planning to offer the NuvaRing, a ranking that moves down slightly from 2003's 75% mark.

More women eye ring

"Our number of clients using NuvaRing has grown steadily over the last six months or so," says Cox.

NuvaRing releases a continuous low dose of the estrogen ethinyl estradiol and the progestin etonogestrel at an average rate of 0.120 mg etonogestrel and 0.015 mg ethinyl estradiol per day over a 21-day period of use. With vaginal drug administration, absorption is unaffected by gastrointestinal disturbances, and there is no first-pass hepatic effect.[7]

Women may not be familiar with the anatomy or the physiology of the vagina; they may ask if the ring will get "lost" inside them or if they will able to feel the ring.[7] Encourage patients to insert the ring in the exam room so they see that the device is easy to insert and remove, as well as comfortable to wear.[7]

"Patients are reluctant to use an intravaginal means of contraception," says **Joe Childress**, MD, an obstetrician/gynecologist in private practice in San Antonio. "However, if a patient will allow the device to be inserted in the office, she usually will use the ring."

References

1. IMS Health. National Prescription Audit. Fairfield, CT; April 2004.
2. Hatcher RA, Zieman M, Cwiak C, et al. *A Pocket Guide to Managing Contraception*. Tiger, GA: Bridging the Gap Foundation, 2004.

Survey Profile

A total of 203 providers participated in the 2004 *Contraceptive Technology Update* Contraception Survey, which monitors contraceptive trends and family planning issues among readers. Results were tallied and analyzed by Thomson American Health Consultants in Atlanta, publisher of *CTU* and more than 60 other medical newsletters and sourcebooks.

About 55% of responses came from nurse practitioners or registered nurses. Physicians represented 35% of the responses, with allied health professionals and health educators comprising about 4% of the response group. About 6% listed other professions. Some 76% of respondents identified themselves as care providers, with nearly 12% involved in administration.

More than 41% of the respondents said they were employed at public health facilities, with about 29% working in private practice settings. About 11% listed student health centers as their place of employment, with some 8% working in hospitals. The remaining 9% reported employment in other settings.

When it comes to location of their employment, 34% said they worked in an urban setting. About 33% said they were employed in a suburban facility, while 36% listed a rural location. ■

3. Sonnenberg FA, Hagerty CG, Price MJ, et al. Is Evra, a transdermal, once-weekly, combined contraceptive patch cost-effective compared to combined oral contraceptives? Presented at the Eighth Congress of the European Contraception Society. Edinburgh, Scotland; June 2004.

4. Sonneberg FA. Cost-effectiveness and health outcomes of the transdermal contraceptive patch. Presented at the 2003 Advances for Reproductive Health forum of the Association of Reproductive Health Professionals. La Jolla, CA; September 2003.

5. Zacur HA, Hedon B, Mansour D, et al. Integrated summary of Ortho Evra/Evra contraceptive patch adhesion in varied climates and conditions. *Fertil Steril* 2002; 77(2 Suppl 2):S32-S35.

6. Moore A, Clark B. The transdermal contraceptive system: A unique look at patch users. *Female Patient* 2004; 29:7-11.

7. Alexander NJ, Baker E, Kaptein M, et al. Why consider vaginal drug administration? *Fertil Steril* 2004; 82:1-12. ■

EXECUTIVE SUMMARY

When it comes to oral contraceptives (OCs), respondents to the 2004 Contraception Survey say Ortho Tri-Cyclen Lo is their No. 1 choice for a 21-year-old nonsmoking woman.

- When formulary dictates pill choice, most 2004 survey respondents continue to name Ortho Tri-Cyclen as the top OC.
- While Ortho Tri-Cyclen was the first pill to receive an approved indication for treatment of acne, researchers are now looking at other possible OC candidates for similar therapy.
- When it comes to selecting a pill for a 42-year-old contracepting woman, most 2004 survey respondents named Alesse, a 20 mcg pill.

Pill remains powerful force in contraception

Take a look at the last 10 patient charts in your outbox. If oral contraceptives (OCs) were prescribed, which ones were selected?

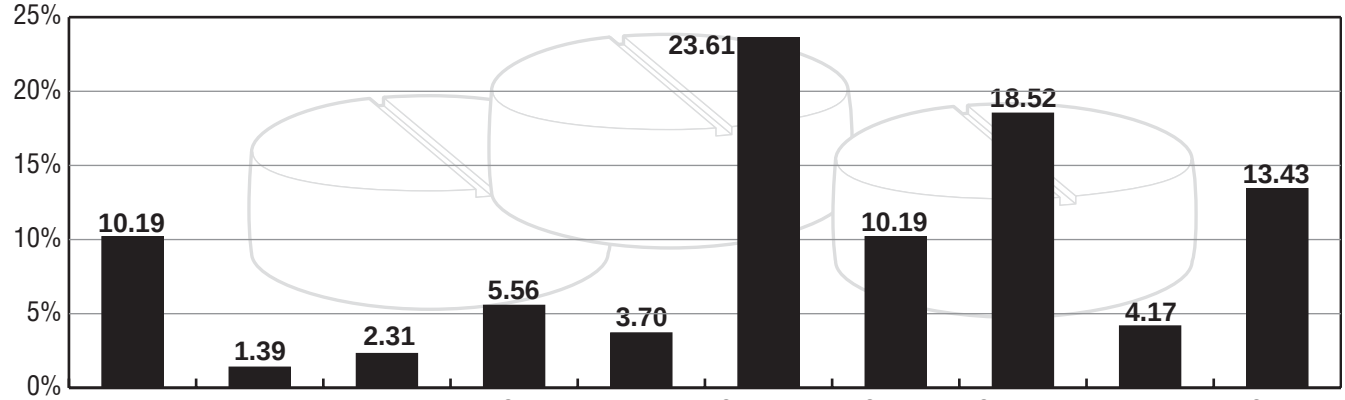
When it comes to prescriptions for younger women, about 24% of respondents to the 2004 *Contraceptive Technology Update* Contraception Survey say their No. 1 pill of choice is Ortho Tri-Cyclen Lo (Ortho-McNeil Pharmaceutical, Raritan, NJ). Ortho Tri-Cyclen Lo provides a daily dose of 25 mcg estrogen for 21 days and three doses of the progestin norgestimate (180 mcg daily/days 1-7; 215 mcg daily/days 8-14; 250 mcg daily/days 15-21). The last seven days contain no active ingredients. The pill won Food and Drug Administration (FDA) approval in 2002.

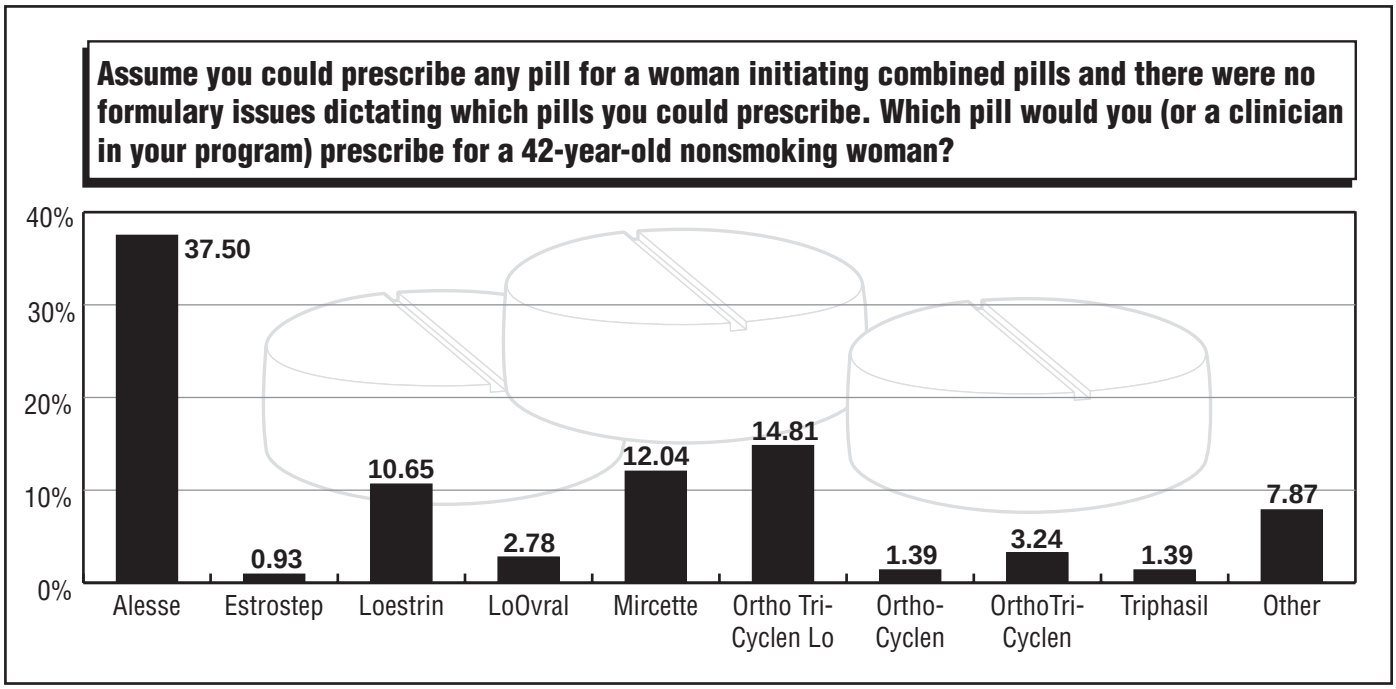
The higher-dose Ortho Tri-Cyclen, a 35-mcg ethinyl estradiol phasic pill also marketed by Ortho-McNeil, was named by 18.5% of survey respondents as their top nonformulary pill choice for a 21-year-old woman. While its numbers have dropped from its 22.6% ranking in the 2003 survey, the pill continues as the No. 1 formulary choice for young women. **(See graphic on top formulary pills, below.)**

As new contraceptive methods enter the marketplace, some family planning providers are seeing a dip in requests for OCs.

"There has been a decline in OC users in the last

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?





year," reports **Carolyn Brown,** RNP, nurse practitioner at Pinal County Health Dept., a public health facility in Florence, AZ. DMPA (Depot medroxyprogesterone acetate, marketed as Depo Provera, Pfizer, New York City) has become very popular, Brown says. Also, the intrauterine device is popular in certain populations, she adds.

However, some providers report that the pill is maintaining or even increasing in popularity. For example, pill prescriptions have increased at the student health center at New Mexico Institute of Mining and Technology, an undergraduate and graduate university in Socorro, reports **Susan Lewark**, CFNP. About 25% of patients now use OCs, she states.

How are pills used?

Ortho Tri-Cyclen was the first oral contraceptive to receive FDA approval for treatment of acne in women seeking contraception. Many clinicians have become used to requests for "the acne pill" following the 1997 FDA indication for the drug.

Other OCs now are being evaluated for possible treatment of acne.[1] Two trials involving Alesse, a monophasic 20-mcg pill from Wyeth-Ayerst Laboratories, Philadelphia, showed total acne improvement of 23% to 40% compared with 9% to 23% with placebo.[2,3]

Researchers also are eyeing the use of Yasmin, a monophasic pill containing 3.0 mg drospirenone and 0.030 mg ethinyl estradiol, marketed by Berlex Laboratories of Montville, NJ. Findings from a recent study indicate the pill may be effective in reducing acne lesions.[4]

Pills for older women?

When it comes to pills for older women, which OCs are selected? Survey respondents continue to name Alesse. About 37% of respondents named the pill as their first nonformulary choice for a 42-year-old nonsmoking woman; about 43% listed it as their No. 1 choice in 2003. **(See graphic on pill choices for older women, above.)**

Ortho Tri-Cyclen Lo moved to the No. 2 spot in the category; about 15% named the pill in their 2004 responses. Loestrin, a monophasic 20-mcg pill from Pfizer of New York City, held the secondary position in 2003 with about 16%; its numbers fell to about 11% in 2004.

Extended regimen OK?

Clinicians are beginning to integrate the first FDA-approved extended regimen OC into their practices. Seasonale, marketed by Barr Laboratories of Pomona, NY, is a 91-day regimen taken daily as 84 active tablets of 0.15 mg levonorgestrel/0.03 mg ethinyl estradiol, followed by seven inactive tablets. It is designed to reduce the number of periods from 13 to four per year.

Since its launch in November 2003, more than 260,000 prescriptions have been filled for the drug, according to Barr Labs. About 15% of 2004 *CTU* survey respondents say they have written prescriptions for the drug in the last six months.

Yasmin also is being evaluated for use in an extended regimen. In a prospective observational six-month study in Germany, cycle control, premenstrual symptoms and general well-being were compared in 1,433 women taking Yasmin in either an extended regimen (63-126 days) or a conventional regimen.[5]

Fluid retention was reduced in 49% of women on the extended regimen compared to 34% of women on the conventional regimen; 50% of those on extended cycle noted a reduction in breast tenderness, compared to 40% on the short-cycle regimen.

One-third of the women on either regimen noticed an improvement in their skin condition.[5]

"I have observed few progestational side effects on Yasmin," says **Joe Childress**, MD, an obstetrician/gynecologist in private practice in San Antonio.

"I like drospirenone, especially for continuous dosing."

References

1. Haider A, Shaw JC. Treatment of acne vulgaris. *JAMA* 2004; 292:726-735.
2. Thiboutot D, Archer DF, Lemay A, et al. A randomized, controlled trial of a low-dose contraceptive containing 20 microg of ethinyl estradiol and 100 microg of levonorgestrel for acne treatment. *Fertil Steril* 2001; 76:461-468.
3. Leyden J, Shalita A, Hordinsky M, et al. Efficacy of a low-dose oral contraceptive containing 20 microg of ethinyl estradiol and 100 microg of levonorgestrel for the treatment of moderate acne: A randomized, placebo-controlled trial. *J Am Acad Dermatol* 2002; 47:399-409.
4. Van Vloten WA, van Haselen CW, van Zuuren EJ, et al. The effect of 2 combined oral contraceptives containing either drospirenone or cyproterone acetate on acne and seborrhea. *Cutis* 2002; 69(4 Suppl):2-15.
5. Sillem M. Yasmin and the extended regimen: Current experience. Presented at the Eighth Congress of the European Contraception Society. Edinburgh, Scotland; June 2004. ■

Providing pills: Readers speak out

When it comes to oral contraceptives (OCs), when should pills be prescribed, and when should they be withheld?

Respondents to the 2004 *Contraceptive Technology Update* Contraception Survey take a cautious approach when it comes to providing pills for older women who smoke. Almost three-quarters (72%) say they will not give pills to smokers ages 35-39, and 86% say they refuse pills to those age 40 and older.

While oral contraceptives represent a safe, effective choice of birth control for many women, smoking raises the risk of cardiovascular complications, particular among women age 35 and older. Results from a 2003 study, which compared women who used higher-dose OCs vs. those who relied on nonhormonal contraception, indicated a moderate increase in the risk of death from ischemic heart disease in smokers who used the Pill compared with nonsmoking pill users.[1] In comparison with nonsmokers, researchers found an increase in death from all causes of about 25% for light smokers and more than a doubling of death risk from all causes for those who smoked more than 15 cigarettes a day.

When combined pills can be safely used, do you consider their noncontraceptive benefits? Use of combined OCs lead to reduced risk of ovarian cancer and endometrial cancer.[2] About 34% of 2004 *CTU* survey respondents indicate they or clinicians in their facility have recommended pills to a woman specifically to decrease risk of cancer of the ovary.

When it comes to counseling on use of combined OCs for a new mother who chooses not to breast-feed, what is your approach? About 41% of 2004 *CTU* survey respondents say they prescribe OCs four to six weeks postpartum, a slight increase from 2003's 39% level. About 30% say they initiate OCs one to three weeks postpartum, with about 12% providing pills upon hospital discharge. About 10% start pills at first menses, with about 3% using other approaches.

EXECUTIVE SUMMARY

When it comes to providing pills, respondents to the 2004 Contraception Survey take a cautious approach for older women who smoke. Almost three-quarters (72%) say they will not give pills to smokers ages 35-39, and 86% say they refuse pills to those who are age 40 and older.

- Pills should remain prescription-only, say 2004 survey respondents. About 63% vote thumbs-down for over-the-counter access.
- Alesse, a monophasic 20-mcg pill, is the leading pill choice for women who have experienced nausea during previous pill use.

For new breast-feeding mothers, about 39% of survey respondents say they choose to initiate progestin-only pills four to six weeks postpartum, with 29% starting such pills at one to three weeks postpartum. Progestin-only pills represent a good option for breast-feeding women who prefer oral contraception, because the progestin does not reduce milk production.[3]

Which OC for nausea?

Which pill would you prescribe if a patient says she wants to use OCs, yet experienced nausea the last time she used the Pill? Respondents to the 2004 *CTU* Contraception Survey say they would prescribe Alesse, a monophasic 20-mcg pill from Wyeth-Ayerst Laboratories, Philadelphia.

"The lower estrogen seems to be better tolerated in teens and never pregnant women than previous pills," reports **Carolyn Brown**, RNP, nurse practitioner at Pinal County Health Department, a public health facility in Florence, AZ.

About 44% named the pill as their first choice in this category; 54% listed Alesse as the leading candidate in the 2003 survey. About 12% said they would use Ortho Tri-Cyclen Lo (Ortho-McNeil Pharmaceutical, Raritan, NJ), while 11.5% listed Mircette (Organon, West Orange, NJ).

If women have experienced nausea with pills, suggest they take their pills at their evening meal or at bedtime to allow them to sleep through high serum levels of hormones.[2] Remind women to take pills consistently; missed pills can increase the incidence of nausea and vomiting.[4]

Pills over the counter?

Should oral contraceptives be made available over the counter (OTC)? Most *CTU* survey respondents continue to say "no" to OTC status for the Pill; About 63% say that pills should remain prescription-only, while 31% affirm support for the move. About 6% did not make a selection in the matter. The responses reflect a slight change from 2003's figures, where about 69% said "no" to an OTC switch.

"Although I seem to be in the minority regarding OTC use of OC, my reasons are these: Unwanted pregnancies are our priority; the easiest access to these methods seems to be the most logical solution to this problem; anyone who can read can follow a manufacturer insert for use," says **Judy Nicksich**, women's health care nurse practitioner at Western Wyoming Family Planning, a not-for-profit family planning agency in Rock Springs, WY.

"I agree that sexually transmitted diseases and pelvic exams are a must, but not at the expense of creating a pregnancy that is unwanted," she says.

References

1. Vessey M, Painter R, Yeates D. Mortality in relation to oral contraceptive use and cigarette smoking. *Lancet* 2003; 362:185-191.
2. Hatcher RA, Zieman M, Cwiak C, et al. *A Pocket Guide to Managing Contraception*. Tiger, GA: Bridging the Gap Foundation, 2004.
3. Blackburn RD, Cunkelman JA, Zlidar VM. Oral contraceptives — an update. *Population Reports*. Baltimore: Johns Hopkins University, School of Public Health, Population Information Program; 2000.
4. Zlidar VM. Helping women use the pill. *Population Reports*. Baltimore: Johns Hopkins University, School of Public Health, Population Information Program; 2000. ■

More women are looking at intrauterine devices

Are more women at your family planning facility requesting information on intrauterine contraception? Chances are you are seeing an increase in interest: Almost 30% of respondents to the 2004 *Contraceptive Technology Update* Contraception Survey say they have performed six to 25 intrauterine device (IUD) insertions in the last year, up slightly from 2003's figures.

The popularity of the levonorgestrel intrauterine system (Mirena IUS, Berlex Laboratories, Montville, NJ) led to an increase in the number of IUD insertions, confirms **Joe Childress**, MD, an obstetrician/gynecologist in private practice in San Antonio. Women in the United States have two choices when it comes to intrauterine contraception: the Mirena and the Copper T 380A IUD (ParaGard, FEI Women's Health, North Tonawanda, NY).

More IUD insertions are being performed at the Pinal County Health Department, a public health facility in Florence, AZ, reports **Carolyn Brown**, RNP, nurse practitioner. The facility uses ParaGard IUDs.

"The number of IUDs has increased," agrees **Gayle Krevel**, RN, MS, CLC, supervisor of women's health at the Winnebago County Health Department, a public health facility in Rockford, IL, "We are not using the Mirena at this time."

More than 25 years have passed since the era of the Dalkon Shield, an intrauterine contraceptive

EXECUTIVE SUMMARY

The T380A Copper T intrauterine device (ParaGard IUD) and the levonorgestrel intrauterine system (Mirena IUS) offer American women effective choices in long-term contraception.

- The ParaGard is approved for 10 years of contraception, and the Mirena is approved for five years of contraception. While upfront costs may appear high, intrauterine birth control offers the greatest net cost benefits of any contraceptive over a five-year period.
- Recent research indicates that nulliparous women can safely use intrauterine contraception. In a study comparing nulliparous women using oral contraceptives (OCs) and the IUS, the safety and acceptability of the IUS was observed to be as good as with OCs, with a high continuation rate.

whose manufacture was halted in the mid-1980s due to product liability issues. Women are now taking a fresh look at the method.[1]

Is cost an issue?

According to package labeling, the ParaGard IUD offers 10 years of contraception; the Mirena is approved for five years of contraception.[2] While upfront costs for both devices can range between $300-$500, intrauterine birth control offers the greatest net cost benefits of any contraceptive over a five-year period.[2]

"Higher price is an issue, even though we try to let them know that over time, the price is negligible," says **Judy Nicksich**, women's health care nurse practitioner at Western Wyoming Family Planning, a not-for-profit family planning agency in Rock Springs, WY.

FEI Women's Health offers a four-part credit card payment program and is developing a patient assistance program to help low-income women who don't have insurance coverage for the device.

"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," states **Kimberly Schillace**, company spokeswoman. "In addition, for physicians who wish to purchase Mirena for patients, payment terms have been extended."

The ARCH (Access and Resources in Contracep-tive Health) Foundation, a not-for-profit Charlotte, NC-based organization funded by Berlex Laborato-ries, operates its own patient assistance program to help financially challenged women obtain Mirena contraception.

"This [program] has made it free to most clients," says **Donna Gray**, CNM, NP, director of family planning at the Wyoming County Public Health Department, a public health facility in Warsaw, NY. "ARCH mails me an IUD with the client's name." **(See the resource box on p. 129 for contact information for the foundation, as well as for device manufacturers.)**

Get over the myths

While the new generation of IUDs offers safe, effective contraception, information on these devices has been slow to disseminate, say clinicians.

"Patients don't seem to be able to overcome the barriers, ancient though they are, about the negative things they have been told about IUDs," observes Nicksich. "Education does not always seem to overcome this."

The experience with IUDs in other countries continues to show that intrauterine contraception is well accepted by many women. In a comparative study of five European countries (Italy, Spain, Poland, Germany, and Denmark), the IUD accounted for 9–24% of all contraceptive use.[3]

For intrauterine contraception to play the role it could play, never-pregnant women should not be excluded from using IUDs, state authors of *A Pocket Guide to Managing Contraception*.[2] Recent research backs this approach: In a study comparing nulliparous women using oral contraceptives and the IUS, the safety and acceptability of the IUS was observed to be as good as with OCs, with a high continuation rate.[4]

"Many clinicians feel that IUDs are not appropriate for nulliparous women; however, the current findings indicate that the highly effective, levonorgestrel-releasing IUD is a safe, appropriate contraceptive choice for motivated, well-counseled, nulliparous women who prefer the convenience or menstrual-suppression effect of this device," states **Andrew Kaunitz**, MD, professor and assistant chair in the obstetrics and gynecology department at the University of Florida Health Science Center/Jacksonville.

References

1. Glassberg H. Safer alternatives dispel fear prompted by Dalkon Shield; looking for alternatives to pill. *The Wall Street Journal,* Aug. 3, 2004:D1.

RESOURCES

For more information on ParaGard, contact:
- **FEI Women's Health**, North Tonawanda, NY 14120. Telephone: (800) 825-6230. Web: www.paragard.com or www.fei-womenshealth.com.

For more information on Mirena, contact:
- **Berlex Laboratories**, 340 Changebridge Road, P.O. Box 1000, Montville, NJ 07045-1000. Telephone: (866) 647-3646 or (973) 487-2000. Web: www.mirena.com or www.berlex.com.

For information on the Access and Resources in Contraceptive Health (ARCH) Foundation, contact:
- **ARCH Foundation**, P.O. Box 220908, Charlotte, NC 28222-0908. Telephone: (877) 393-9071. Fax: (704) 357-0036. Web: www.archfoundation.com.

2. Hatcher RA, Zieman M, Cwiak C, et al. *A Pocket Guide to Managing Contraception*. Tiger, GA: Bridging the Gap Foundation; 2004.

3. Spinelli A, Talamanca IF, Lauria L. Patterns of contraceptive use in 5 European countries. *Am J Public Health* 2000; 90:1,403-1,408.

4. Suhonen S, Haukkamaa M, Jakobsson T, et al. Clinical performance of a levonorgestrel-releasing intrauterine system and oral contraceptives in young nulliparous women: A comparative study. *Contraception* 2004; 69:407-412. ■

New study eyes link to DMPA use, STD risk

Findings from a just-published study indicate that women who use the contraceptive injection depot medroxyprogesterone acetate (DMPA, marketed as Depo-Provera, Pfizer, New York City) appear to have a threefold increased risk of acquiring chlamydia and gonorrhea when compared to women not using a hormonal contraceptive.[1]

Researchers involved in the prospective cohort study analyzed results from 819 women from two Baltimore-area clinics who were allowed to choose a combined oral contraceptive (OC), DMPA, or a nonhormonal contraceptive. Most of the women (77%) were single and nulliparous; about half (52%) were white, while 43% were African American. After enrolling in the study, women were tested for chlamydial and gonococcal infection after three, six, and 12 months.

The issue is whether DMPA increases a woman's risk of sexually transmitted disease (STD), or are the women who choose DMPA are more likely to be at risk for STDs, says **Susan Wysocki**, RNC, NP, president and chief executive officer of the Washington, DC-based National Association of Nurse Practitioners in Women's Health. The study was not a randomized trial; women chose on their method on their own, Wysocki points out.

Clinicians need to keep in mind that while the newly published study is well designed and carefully executed, it is an observational study, advises **James Trussell**, PhD, professor of economics and public affairs and director of the Office of Population Research at Princeton (NJ) University.

"What this observational study shows is the *users* of DMPA appear to be at increased risk of acquiring sexually transmitted cervical infections and not that *use* of DMPA appears to increase that risk," he notes.

If investigators could confidently control for all issues in all behaviors that impact risk of STD acquisition, then the findings of an observational study may well be valid, agrees **Andrew Kaunitz**, MD, professor and assistant chair in the obstetrics and gynecology department at the University of Florida Health Science Center/Jacksonville. "However, as we have learned from the Women's Health Initiative [WHI], that even in the best-done observational studies, there may be important areas that the study is not able to adequately control for, and I am concerned that may be the case here," he says.

Women in the study were not randomized as to their contraceptive method, notes Kaunitz. There is a possibility that women who chose DMPA were different in some ways from the control group, he notes.

The new research underscores an important message for all users of hormonal contraceptives: If

EXECUTIVE SUMMARY

The contraceptive injection depot medroxyprogesterone acetate (DMPA) continues as a top choice for birth control, particularly among adolescents. About 90% of respondents to the 2004 Contraceptive Survey say they would prescribe the injectable for young teens.
- To address potential bone health issues, many survey respondents say they counsel on calcium supplementation and weight-bearing exercise.
- Women may experience an average weight gain of 5.4 pounds in the first year of DMPA use. Counseling on the possibility of weight gain and offering tips on weight management can help women maintain success with the method.

women are not in a mutually monogamous relationship with an uninfected partner, they should limit their number of sexual partners and use condoms correctly and consistently every time they have intercourse.

Family planning involves careful counseling and education in pairing method with user so that women make the best choice that most likely will result in contraceptive success, says Kaunitz.

"DMPA certainly fits that bill for many women, particularly younger women who have difficulty achieving contraceptive success with daily methods," he observes. "The take-home message from a study like this is that hormonal methods may not prevent acquisition of cervical STDs, and for women at risk, we need to continue to reinforce that message about safe sex and consistent condom use."

Reference

1. Morrison CS, Bright P, Wong EL, et al. Hormonal contraceptive use, cervical ectopy, and the acquisition of cervical infections. *Sex Trans Dis* 2004; 31:561-567. ■

DMPA: Check snapshot of current clinical use

The next patient in your exam room is a 16-year-old young woman who says she needs effective contraception. She has tried oral contraceptives (OCs), but she says she has trouble remembering to take a daily pill. What options can you offer her?

The contraceptive injection depot medroxyprogesterone acetate (DMPA, marketed as Depo Provera, Pfizer, New York City) continues as a top choice for birth control, particularly among adolescents. About 90% of respondents to *Contraceptive Technology Update*'s 2004 Contraceptive Survey say they would prescribe the injectable for young teens, holding steady from 2003's level.

The use of DMPA is second only to OCs at Winnebago County Health Department, a public health facility in Rockford, IL, says **Gayle Krevel**, RN, MS, CLC, supervisor of women's health.

"Many teens like Depo," states **JoElle Thomas**, WHCNP, nurse practitioner at Custer Family Planning, a not-for-profit family planning agency in Bismarck, ND. "It is convenient."

What about bone health?

Bone health is an important issue for adolescents: half of a woman's bone mass is gained during puberty and the first several years after menarche.[1]

Women who use DMPA may experience bone loss. A recent study indicates that women using the injectable for two years recorded an approximate 6% decline in bone mineral density of roughly 6%, compared with a loss of 2.6% among women on oral contraceptives.[2] **(For more information, see "New research sheds light on DMPA's impact on bone health," *Contraceptive Technology Update*, October 2004, p. 109.)** While earlier research suggests that such loss is reversible after the method is stopped,[3] providers may want to include recommendations on calcium replacement and exercise to promote bone health.

About half (52%) of *CTU* 2004 survey respondents say they inform patients that DMPA may diminish bone mass; 33% use other methods, such as counseling on calcium supplementation and importance of weight-bearing exercise, in emphasizing a bone-healthy message.

"I have many clients on Depo," says **Donna Gray**, CNM, NP, director of family planning at Wyoming County Public Health Department Men's and Women's Health Clinic, a public health facility in Warsaw, NY. "We tell them all to increase their calcium intake."

Weight gain is the primary reason patients stop DMPA, says **Tina Mladenka**, MSN, OGNP, a Pocatello, ID-based community health nurse practitioner. "DMPA is popular with some of our patients, including teens, but others who have tried it hate it," Mladenka states. "Many of my patients are overweight or obese, and these women seem to have more weight gain problems than the thinner women."

COMING IN FUTURE MONTHS

- New microbicides on the way
- Providing pills in acne treatment
- Nonsteroidal contraception in the research pipeline
- Tips to treat recurrent vaginitis
- How to debunk common contraceptive myths

Counseling on the possibility of weight gain is an important part in helping women stay the course with DMPA, according to *A Pocket Guide to Managing Contraception*. Women may experience an average weight gain of 5.4 pounds in the first year.[4] Be sure to weigh women at each visit to monitor potential weight gain, and use the following tips in a "teachable moment" to help patients manage their weight, advise authors of *A Pocket Guide to Managing Contraception*:

- Eat less; small, frequent meals helps some to lose weight.
- Eat a balanced diet with lots of fruits and vegetables and minimal fats, chips, cookies, pasta, and other carbohydrates.
- Exercise more.
- Find patterns of eating and exercising that you enjoy! You won't do them for long unless you enjoy the process.
- Drink eight to 10 glasses of water daily.
- Check the web site for Overeaters Anonymous, a free resource: www.overeatersanonymous.org.

References

1. DMPA and bone density loss: an update. *Contraception Report* 1999; 10(5). Accessed at: www.contraceptiononline.org/contrareport/article01.cfm?art=86.

2. Berenson AB, Breitkopf CR, Grady JJ, et al. Effects of hormonal contraception on bone mineral density after 24 months of use. *Obstet Gynecol* 2004; 103(5 Pt 1):899-906.

3. Scholes D, LaCroix AZ, Ichikawa LE, et al. Injectable hormone contraception and bone density: Results from a prospective study. *Epidemiology* 2002; 13:581-587.

4. Hatcher RA, Zieman M, Cwiak C, et al. *A Pocket Guide to Managing Contraception*. Tiger, GA: Bridging the Gap Foundation; 2004. ■

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 provisions of contraceptive technology or other reproductive services. (See **"New contraceptives widen choices, but the Pill still is a top selection.")**
- **Describe** how those issues affect service delivery and note the benefits or problems created in patient care in the participant's practice area. (See **"Providing pills: Readers speak out.")**
- **Cite** practical solutions to problems and integrate information into daily practices, according to advice from nationally recognized family planning experts. (See **"Pill remains powerful force in contraception"** and **"More women are looking at intrauterine devices.")**

17. Norelgestromin is the primary active metabolite of:
A. Desogestrel
B. Norgestimate
C. Levonorgestrel
D. Norethindrone

18. What is the progestin used in the oral contraceptive Yasmin?
A. Norethindrone
B. Levonorgestrel
C. Desogestrel
D. Drospirenone

19. Why do progestin-only pills represent a good option for breast-feeding women who prefer oral contraception?
A. The progestin does not reduce milk production.
B. Combined pills increase the risk of diabetes for women with a history of gestational diabetes.
C. Combined pills have adverse effects on the physical, intellectual, and psychological health of infants.
D. Use of progestin-only pills results in lower pregnancy rates than combined pills.

20. According to its package labeling, the ParaGard IUD offers how many years of contraception?
A. 5
B. 10
C. 12
D. 15

Answers: 17. B 18. D 19. A. 20. B.

United States Postal Service

Statement of Ownership, Management, and Circulation

1. Publication Title	2. Publication No.	3. Filing Date
Contraceptive Technology Update	0 2 7 4 - 7 2 6 X	10/1/04
4. Issue Frequency	5. Number of Issues Published Annually	6. Annual Subscription Price
Monthly	12	$449.00

7. Complete Mailing Address of Known Office of Publication *(Not Printer) (Street, city, county, state, and ZIP+4)*
3525 Piedmont Road, Bldg. 6, Ste. 400, Atlanta,
Fulton County, GA 30305

Contact Person: Robin Salet
Telephone: 404/262-5489

8. Complete Mailing Address of Headquarters or General Business Office of Publisher *(Not Printer)*
3525 Piedmont Road, Bldg. 6, Ste. 400, Atlanta, GA 30305

9. Full Names and Complete Mailing Addresses of Publisher, Editor, and Managing Editor *(Do Not Leave Blank)*

Publisher *(Name and Complete Mailing Address)*
Brenda Mooney, 3525 Piedmont Road, Bldg. 6, Ste. 400, Atlanta, GA 30305

Editor *(Name and Complete Mailing Address)*
Rebecca Bowers, same as above

Managing Editor *(Name and Complete Mailing Address)*
Joy Daughtery Dickinson, same as above

10. Owner *(Do not leave blank. If the publication is owned by a corporation, give the name and address of the corporation immediately followed by the names and addresses of all stockholders owning or holding 1 percent or more of the total amount of stock. If not owned by a corporation, give the names and addresses of the individual owners. If owned by a partnership or other unincorporated firm, give its name and address as well as those of each individual. If the publication is published by a nonprofit organization, give its name and address.)*

Full Name	Complete Mailing Address
Thomson American Health Consultants	3525 Piedmont Road, Bldg. 6, Ste 400 Atlanta, GA 30305

11. Known Bondholders, Mortgagees, and Other Security Holders Owning or Holding 1 Percent or More of Total Amount of Bonds, Mortgages, or Other Securities. If none, check box → ☐ None

Full Name	Complete Mailing Address
Thomson Healthcare, Inc.	Five Paragon Drive Montvale, NJ 07645

12. Tax Status *(For completion by nonprofit organizations authorized to mail at nonprofit rates.) (Check one)*
The purpose, function, and nonprofit status of this organization and the exempt status for federal income tax purposes:
☐ Has Not Changed During Preceding 12 Months
☐ Has Changed During Preceding 12 Months *(Publisher must submit explanation of change with this statement)*

PS Form **3526**, September 1998 *See instructions on Reverse)*

13. Publication Name: Contraceptive Technology Update
14. Issue Date for Circulation Data Below: September 2004

15. Extent and Nature of Circulation			Average No. of Copies Each Issue During Preceding 12 Months	Actual No. Copies of Single Issue Published Nearest to Filing Date
a. Total No. Copies *(Net Press Run)*			1516	1425
b. Paid and/or Requested Circulation	(1)	Paid/Requested Outside-County Mail Subscriptions Stated on Form 3541. *(Include advertiser's proof and exchange copies)*	736	698
	(2)	Paid In-County Subscriptions *(Include advertiser's proof and exchange copies)*	6	6
	(3)	Sales Through Dealers and Carriers, Street Vendors, Counter Sales, and Other Non-USPS Paid Distribution	19	20
	(4)	Other Classes Mailed Through the USPS	53	57
c. Total Paid and/or Requested Circulation *(Sum of 15b(1) and 15b(2)*			814	781
d. Free Distribution by Mail *(Samples, Complimentary and Other Free)*	(1)	Outside-County as Stated on Form 3541	25	23
	(2)	In-County as Stated on Form 3541	1	1
	(3)	Other Classes Mailed Through the USPS	0	0
e. Free Distribution Outside the Mail *(Carriers or Other Means)*			24	25
f. Total Free Distribution *(Sum of 15d and 15e)*			50	49
g. Total Distribution *(Sum of 15c and 15f)*			864	830
h. Copies Not Distributed			652	595
i. Total *(Sum of 15g, and h.*			1516	1425
Percent Paid and/or Requested Circulation *(15c divided by 15g times 100)*			94	94

16. Publication of Statement of Ownership
Publication required. Will be printed in the November 2004 issue of this publication. ☐ Publication not required.

17. Signature and Title of Editor, Publisher, Business Manager, or Owner: Brenda Z. Mooney, Publisher — Date: 9/20/04

I certify that all information furnished on this form is true and complete. I understand that anyone who furnishes false or misleading information on this form or who omits material or information requested on the form may be subject to criminal sanctions (including fines and imprisonment) and/or civil sanctions (including multiple damages and civil penalties).

Instructions to Publishers

1. Complete and file one copy of this form with your postmaster annually on or before October 1. Keep a copy of the completed form for your records.
2. In cases where the stockholder or security holder is a trustee, include in items 10 and 11 the name of the person or corporation for whom the trustee is acting. Also include the names and addresses of individuals who are stockholders who own or hold 1 percent or more of the total amount of bonds, mortgages, or other securities of the publishing corporation. In item 11, if none, check the box. Use blank sheets if more space is required.
3. Be sure to furnish all circulation information called for in item 15. Free circulation must be shown in items 15d, e, and f.
4. Item 15h., Copies not Distributed, must include (1) newsstand copies originally stated on Form 3541, and returned to the publisher, (2) estimated returns from news agents, and (3), copies for office use, leftovers, spoiled, and all other copies not distributed.
5. If the publication had Periodicals authorization as a general or requester publication, this Statement of Ownership, Management, and Circulation must be published; it must be printed in any issue in October or if the publication is not published during October, the first issue printed after October.
5. In item 16, indicate date of the issue in which this Statement of Ownership will be published.
6. Item 17 must be signed.

Failure to file or publish a statement of ownership may lead to suspension of second-class authorization.

PS Form **3526**, September 1999 *(Reverse)*

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.*

NATIONAL ASSOCIATION NPWH
National Association of Nurse Practitioners in Women's Health

Association of Reproductive Health Professionals