25th Anniversary

CONTRACEPTIVE TECHNOLOGY UPDATE

A Monthly Newsletter for Health Professionals

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IN THIS ISSUE

■ **Pill choices:** What are the top OCs?. 127

■ **Survey profile**: 2005 Contraception Survey participants. 128

■ **Providing OCs:** Readers share strategies 129

■ **Intrauterine contraception:** Method sees upswing in use 131

■ **DMPA:** What is the status of the shot? 132

■ **Washington Watch:** Update on OTC status for emergency contraception 133

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Patch and ring make inroads on birth control pill's popularity

New birth control options give women expanded contraceptive choices

As you review the list of contraceptive options available at your family planning facility with your next female patient, which one most likely will receive the nod from her?

According to respondents to the 2005 *Contraceptive Technology Update* Contraception Survey, more women are choosing the transdermal contraceptive (Ortho Evra, Ortho-McNeil Pharmaceutical, Raritan, NJ) and the contraceptive vaginal ring (NuvaRing, Organon, West Orange, NJ).

The growth in use of these methods has come at the expense of the Pill's popularity. In 2000, almost half of *CTU* survey participants said 50% or more of their patients left the office with oral contraceptive (OC) prescriptions in hand. In 2005, 37% of participants reported similar levels of Pill usage; about 33% say 26%-50% of patients are pill users.

"I think the number of OC users has declined in the last year," reports **Marlene Michalowski**, OGNP, a nurse practitioner at the Planned Parenthood of Northern Michigan in Mount Pleasant. "We still have more than

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The on-line home of *Contraceptive Technology Update* has moved. *CTU* Online now can be found on the newly revamped Thomson American Health Consultants web site. The old familiar address is the same: **www.contraceptiveupdate.com**. The new location offers access to an expanded number of online resources all in one place, including the *CTU* archives, free subscriber CE and CME testing through TESTweb, links to other sites for CE and CME testing, and links to helpful women's health resources. Your user name is your subscriber number from your mailing label. Your password is ctu (lowercase) plus your subscriber number (no spaces). Visit your new home on the web today!

EXECUTIVE SUMMARY

The contraceptive vaginal ring and the transdermal contraceptive are finding growing acceptance among U.S. women. Almost 93% of 2005 Contraception Survey participants say their facility offers the transdermal contraceptive, while 76% report use of the vaginal ring.

- A new pharmacokinetic comparison of ethinyl estradiol released from the transdermal patch, an oral contraceptive, and the vaginal ring indicates that estrogen exposure with the ring is 3.4 times lower than observed with the patch and 2.1 times lower than observed with the oral contraceptive.
- Scientists are researching extended use of the patch and ring.

50% OC users, but many, many clients are using the NuvaRing."

Almost 93% of 2005 survey participants say their facility offers the transdermal contraceptive, while 76% report use of the contraceptive vaginal ring. Both methods show slight gains over 2004's respective figures of 91% and 72%.

Ring draws interest

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.

The contraceptive vaginal ring has become extremely popular at Planned Parenthood of Northern Michigan in Traverse City, says **Patty Bauer**, MSN, RNC, a nurse practitioner.

"The teenagers have really appreciated this method; there is lots of word of mouth convincing others to try it," she says. "I think it's the best thing since sliced bread."

Side effects often may impact success with a chosen method. Results of a pharmacokinetic comparison of ethinyl estradiol released from the transdermal patch, an oral contraceptive, and the NuvaRing suggest that estrogen exposure with the ring is 3.4 times lower than observed with the patch and 2.1 times lower than observed with the oral contraceptive.[1]

The study evaluated multiple measurements of ethinyl estradiol serum levels in women randomly assigned to use the ring, the patch, or a 30 mcg pill. Women using the ring had a lower fluctuation in serum estrogen levels than with the other methods; women using the Pill had the highest degree of variation in serum concentrations. Women who used the patch reported a higher incidence of estrogen-related side effects, including nausea and breast tenderness, than those in the pill and ring groups.[1]

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Editorial Questions

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A study examining the number of patient callbacks in the first three months after the initiation of vaginal rings, transdermal patches, or oral contraceptives reports that ring users generated the least amount of callbacks.[2] Women participating in the study selected the contraceptive methods of their choice; all patients were given standard counseling and reference handouts. Participants had never used or had discontinued hormonal contraception for at least one month prior to the study.[2]

Evra often is selected by younger women who have read about it and want to try it, says **Martha Kleinerman**, RNC, MS, health services director at the Planned Parenthood League of Massachusetts in Boston.

Each transdermal patch contains 20 mcg of the estrogen ethinyl estradiol and 150 mcg of the progestin norelgestromin, the primary active metabolite of norgestimate. The patch is designed to be changed once a week and worn for three weeks followed by one patch-free week. It consists of an adhesive medicated layer worn against the skin, protected by a waterproof polyester layer.

Patients on Ortho Evra generally love it and continue with it, reports **Julia McAndrew**, NP, a nurse practitioner at the Cattaraugus County Health Department Family Planning Clinic in Olean, NY. Patient complaints center on adhesive problems with the patch itself, either in difficulty in removing or difficulty in keeping it adhered, she says.

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 be certain adhesion is secure, instruct patients to run their finger around the edge of the patch.[3]

Baby oil removes the patch's adhesive and can help lift it off if it gets stuck, says **Anita Nelson**, MD, professor in the obstetrics and gynecology department at the University of California in Los Angeles (UCLA) and medical director of the women's health care programs at Harbor-UCLA Medical Center in Torrance.

Clinicians have been fielding questions about the patch's safety after a media report claimed that the death rate for the method is three times that expected for oral contraceptives. Remember that the same precautions and danger signals for combined oral contraceptives apply to the patch and the ring. Use the "ACHES" mnemonic (abdominal pain, chest pain, headaches that are severe, eye problems, severe leg pain) to teach women these danger signals.[4]

With the advent of extended or continuous regimens of oral contraceptives, researchers also are examining the potential use of such regimens for the transdermal contraceptive and the contraceptive vaginal ring.[5,6] Neither Ortho Evra nor NuvaRing has received Food and Drug Administration approval for such extended use.

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Pill power: Clinicians speak out on OC choices

The young woman sitting in front of you is in good health and says she would like to use a birth control pill. Which pill do you prescribe?

Almost 25% of respondents to the 2005 *Contraceptive Technology Update* Contraception Survey say their No. 1 oral contraceptive (OC) of choice for a 21-year-old nonsmoker is Ortho Tri-Cyclen Lo (Ortho-McNeil Pharmaceutical, Raritan, NJ). With a daily dose of 25 mcg of 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 pill maintains its top position for the second year, with similar figures to 2004's percentages.

Ortho Tri-Cyclen Lo generally is well tolerated, has a low estrogen content, and few side effects, says **Julia McAndrew**, NP, a nurse practitioner at the Cattaraugus County Health Department Family Planning Clinic in Olean, NY.

"If problems occur, patients can be switched to

EXECUTIVE SUMMARY

When it comes to oral contraceptives (OCs), participants in the 2005 Contraception Survey say Ortho Tri-Cyclen Lo is their No. 1 choice for 21-year-old nonsmoking women.

- When formulary dictates pill choice, most 2005 survey participants continue to name Ortho Tri-Cyclen as the top OC for young contracepting women.
- The Food and Drug Administration has issued approvable letters for Yaz and Seasonique, two pills with unique dosing regimens. The agency is considering a new drug application for a pill designed to be taken every day without a placebo phase.

a different OC," she notes. "Also, for the younger patients especially, I think the advertising for this product is helpful in pill recognition and assisting in compliance with use."

Other leading choices in the category include Yasmin, a monophasic pill containing 3 mg drospirenone and 0.030 mg ethinyl estradiol from Berlex Laboratories, Montville, NJ; Alesse, a monophasic 20-mcg pill from Wyeth Pharmaceuticals, Collegeville, PA; and Ortho Tri-Cyclen, a 35 mcg ethinyl estradiol phasic pill also marketed by Ortho-McNeil. **(See the graphic on p. 129 about top nonformulary pills.)**

When bound by formulary, about 30% of 2005 survey participants say they write prescriptions for Ortho Tri-Cyclen Lo for young nonsmoking women. Ortho Tri-Cyclen (16.75%), Alesse (13.09%), and Yasmin (7.33%) followed in the 2005 formulary category.

Extended regimen in use

Clinicians continue to look at extended regimens of oral contraceptives for their patients; about 18% of 2005 survey participants say they have prescribed Seasonale (Barr Pharmaceuticals, Woodcliff Lake, NJ), the first dedicated extended regimen pill, in the last six months. **(For tips on extended regimens, see "You can help women achieve success with extended regimen contraception," *Contraceptive Technology Update*, August 2004, p. 85.)** Survey participants also named Yasmin (22%), Mircette (18%, Organon, West Orange, NJ), Cyclessa (11%, Organon) and Apri (11%, Barr Pharmaceuticals) as the pills most often provided in the noted time span.

Barr Pharmaceuticals has received an approvable letter from the Food and Drug Administration (FDA) for another extended regimen contraceptive pill, Seasonique (levonorgestrel/ethinyl estradiol tablets 0.15 mg/0.03 mg for 84 days and ethinyl estradiol tablets 0.01 mg for seven days.)

To obtain final approval, Barr has been requested to provide additional data to support Seasonique's unique regimen of 84 days of combination therapy, followed by seven days of unopposed estrogen.[1]

Wyeth has just announced that it has filed a New Drug Application with the FDA for a new combination oral contraceptive containing levonorgestrel/ethinyl estradiol with a first-of-its-kind dosing regimen. The pill is designed to be taken every day, without a placebo phase, and eliminates the menstrual cycle.

According to the company, data from two one-year Phase III clinical trials were included in the drug's application support documentation. The trials enrolled a total of 2,775 women and evaluated the safety and efficacy of the product for contraception; in addition, one of the secondary endpoints included was menses inhibition.[2]

The most commonly reported adverse events in the trials included headaches, vaginal bleeding, and cramps, states the company.[2]

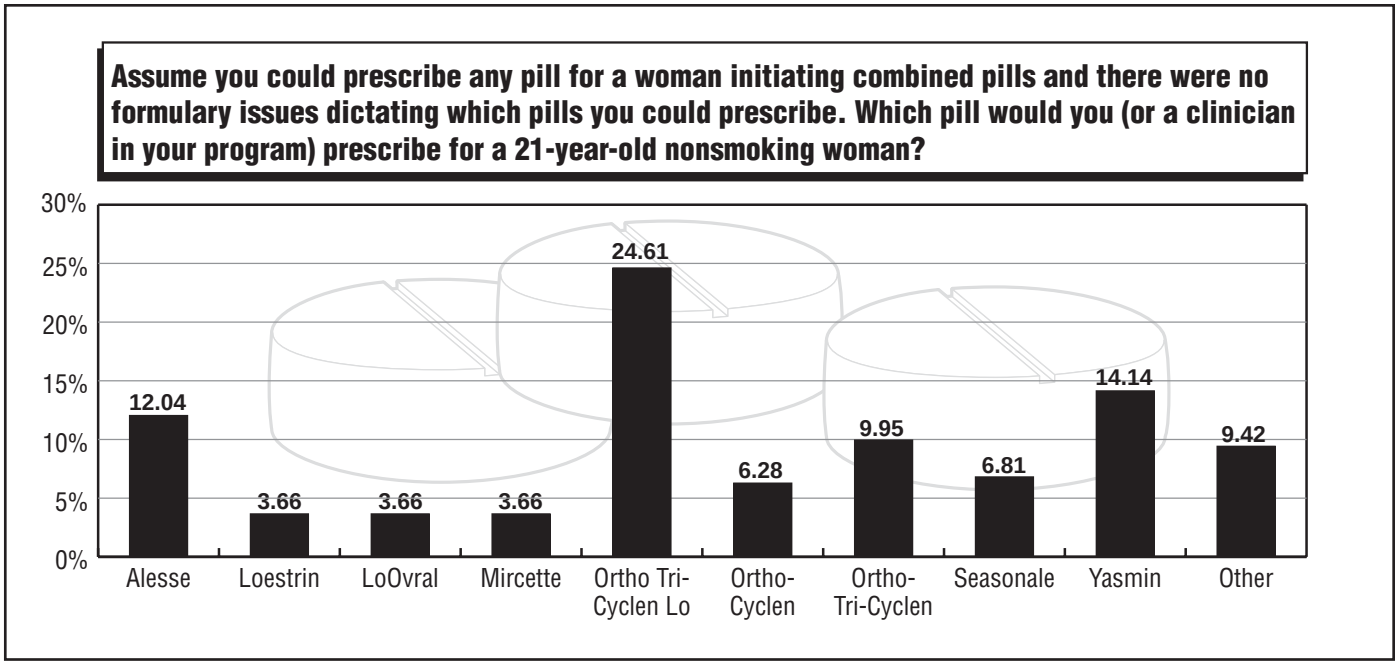
Survey Profile

A total of 191 providers participated in the 2005 *Contraceptive Technology Update* Contraception Survey. Results were tallied and analyzed by Thomson American Health Consultants in Atlanta, publisher of *CTU*.

About 55% of responses came from nurse practitioners or registered nurses. Physicians represented about 37% of the responses, with allied health professionals and health educators making up about 2% of the response group. About 7% listed other professions. Some 76% of respondents identified themselves as care providers, with nearly 18% involved in administration.

More than 44% of the respondents said they were employed at public health facilities or community centers (including Planned Parenthood facilities), with about 31% working in private practice settings. About 11% listed student health centers as their place of employment, with some 7% working in hospitals.

When it comes to location, 34% said they worked in an urban setting. About 35% said they were employed in a rural facility, while 27% listed a suburban location. ■



The year 2005 marks the initial addition of Yasmin to the Contraception Survey pill list; the pill has gained wide usage following its 2001 approval by the FDA.

Yasmin has been studied for potential use in treating premenstrual syndrome, says **Anita Nelson**, MD, professor in the obstetrics and gynecology department at the University of California in Los Angeles (UCLA) and medical director of the women's health care programs at Harbor-UCLA Medical Center in Torrance. It also is eyed as a preferred pill for women with polycystic ovary syndrome, says Nelson.

Yasmin soon may be joined by another drospirenone pill; the FDA issued an approvable letter for Yaz, a 20 mcg pill also developed by Berlex Laboratories, in November 2004. The agency has asked Berlex for further documentation on the pill's unique dosing regimen: 24 days of active pills followed by four days of placebo pills. In addition to seeking an indication as an oral contraceptive with its FDA submission, Berlex also is asking for approval of Yaz as a treatment option for women with symptoms of premenstrual dysphoric disorder (PMDD) who desire pregnancy prevention.

"The FDA is currently reviewing Yaz and we expect to hear back by the end of the year," reports **Kim Schillace**, company spokeswoman.

Scientists believe Yaz's effectiveness in relieving PMDD symptoms lies in its shortened pill-free interval of its dosing regimen, combined with its progestin, drospirenone (3 mg), which exhibits antimineralocorticoid and anti-androgenic activity.[3]

In a just-published study, results from a multicenter, double-blind, randomized clinical trial suggest the drug improves symptoms associated with premenstrual dysphoric disorder.[4]

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How to use OCs? Readers share pill strategies

As you check the chart of a new patient, you note that she has previously experienced nausea on birth control pills, but can't remember the brand name of her prescribed oral contraceptive (OC). She would like to re-establish pill use. Which OC will you suggest?

Almost half (44%) of 2005 *Contraceptive Technology Update* Contraception Survey participants pick

EXECUTIVE SUMMARY

When it comes to providing pills, participants in the 2005 Contraception Survey say Alesse, a monophasic 20-mcg pill, is the leading pill choice for women who have experienced nausea during previous pill use. Alesse also was named as the top choice for a 42-year-old contracepting woman.

- Survey participants vote thumbs-down when it comes to providing oral contraceptives for older women who smoke.
- Pills should remain prescription-only, say most 2005 survey participants.

Alesse, a monophasic 20-mcg pill from Wyeth Pharmaceuticals, Collegeville, PA, as their top pill choice for women who have experienced nausea on previous OCs.

Alesse continues to lead all choices in this survey category; it has held the top spot since 1999. Other ranking selections in the 2005 survey include Ortho Tri-Cyclen Lo (13.61%, Ortho-McNeil Pharmaceutical, Raritan, NJ), Loestrin (9.95%, Organon, West Orange, NJ), and Yasmin (5.76%, Berlex Laboratories, Montville, NJ).

Why Alesse?

"I like the levonorgestrel pills in conjunction with 20 mcg of estrogen to minimize the estrogen effect related to nausea," says **Martha Kleinerman**, RNC, MS, health services director at the Planned Parenthood League of Massachusetts in Boston.

Take the time to discuss the hormonal components of different oral contraceptives, as women need a better understanding of what is inside their birth control pills, contraceptive experts say. According to a 2005 survey of 400 women who have used the Pill, 65% said they have switched two or more times between different types of birth control pills, with just more than one-third switching because of side effects.[1]

Which contraceptive pills come to mind when it comes to women older than age 40? Most (41%) participants in the 2005 survey look to Alesse; other top 2005 choices include Loestrin (11.52%), a monophasic 20 mcg pill from Pfizer of New York City, Ortho Tri-Cyclen Lo (10.99%), Mircette (7.85%), and Yasmin (6.81%).

Smoking can impact clinical decisions on whether older women can safely use combined oral contraceptives. Three-quarters of 2005 survey participants say they will not write prescriptions for women ages 35-39 who smoke 10 cigarettes a day, with numbers rising to almost 91% for women ages 40 and older who smoke.

Such thinking falls in line with the latest medical eligibility criteria from the Geneva-based World Health Organization (WHO). According to the WHO guidance, women aged 35 and older who smoke fewer than 15 cigarettes a day are ranked at 3, where "use of the method not usually recommended unless other, more appropriate methods are not available or acceptable," while women in the same age category who smoke 15 or more cigarettes a day are ranked at 4, where the "method [is] not to be used."[2]

What options do you discuss with these women?

"Due to risk of cardiovascular problems, smokers ages 35 and older are not prescribed combined oral contraceptives in our clinic," says **Julia McAndrew**, NP, a nurse practitioner at the Cattaraugus County Health Department Family Planning Clinic in Olean, NY. "We discuss progestin-only pills, Depo-Provera, intrauterine devices, diaphragms, condoms, and natural family planning as options."

What about new moms?

When it comes to initiating combined OC use in postpartum women who are not breast-feeding, about 40% of 2005 survey participants say they will begin pill use four to six weeks after delivery. About 28% say they start pills one to three weeks postpartum, while about 15% begin OC use upon hospital discharge.

For breast-feeding women who wish to use progestin-only pills, about 38% indicate they will initiate pill use four to six weeks postpartum, while about 27% say they begin pill use one to three weeks following delivery. About 21% state they start minipills upon hospital discharge.

While oral contraceptives provide reliable birth control, they also offer noncontraceptive benefits; use of combined OCs can lead to reduced risk of ovarian cancer and endometrial cancer.[3]

Josefina Tan-Domingo, MD, a physician at Lewis County General Hospital in Lowville, NY, estimates she has written 10 Pill prescriptions in the past year specifically to decrease the risk for ovarian cancer.

"Patients are accepting of this approach," says Tan-Domingo. "Many respond they have never heard of this use of OCs."

When it comes to increasing access to contraception, most 2005 *CTU* survey participants draw the line when it comes to moving oral contraceptives from their prescription-only status. About

72% say they are not in favor of such a move, up from 2004's 63% level.

If OCs were moved to over-the-counter status, they might be taken by smokers older than age 35, or women with uncontrolled hypertension or previous clots, says **Debbie Cline**, RN, OGNP/FNP, a nurse practitioner at the Roanoke City (VA) Health Department.

"If OCs were over the counter, women would need to watch a visual and have a simple written 'how-to-do' sheet," comments **Lynn Fair**, RNC, WHNP, a nurse practitioner at the Columbia/Boone Health Department in Columbia, MO. "Could a pharmacy offer this? I think it is possible, but they would need 'how-to-do' education."

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Intrauterine method sees upswing in use

More women are choosing long-term birth control through use of intrauterine contraception, say participants in the 2005 *Contraceptive Technology Update* Contraception Survey. About 35% of participants say they have performed six or more insertions in the past year, up from the 30% level reported in 2004.

Two intrauterine contraceptives are available in the United States: the Mirena levonorgestrel intrauterine system (Mirena LNG IUS, Berlex Laboratories, Montville, NJ) and the Copper T 380A intrauterine device (ParaGard IUD, FEI Women's Health, North Tonawanda, NY). The ParaGard IUD is approved for 10 years of contraception; the Mirena is approved for five years of birth control.[1]

Increased interest has allowed facilities to add the method to their contraceptive menus; intrauterine devices soon will be offered at the Southern Iowa Family Planning/Women & Men's Health Care Clinic in Ottumwa, reports **Pam Miller**, ARNP, a nurse practitioner at the facility.

EXECUTIVE SUMMARY

More women are moving toward long-term, reversible contraception with the T380A Copper T intrauterine device (ParaGard IUD) and the levonorgestrel intrauterine system (Mirena IUS). About 35% of 2005 Contraception Survey participants say they have performed six or more insertions in the past year.

- Updated labeling for ParaGard has just been approved. The device is now approved for nulliparous women in stable relationships from age 16 through menopause.
- It is no longer contraindicated for women with a history of sexually transmitted diseases or pelvic inflammatory disease (PID) unless a patient currently has acute PID or engages in sexual behavior suggesting a high risk for PID.

Kim Wagenaar, RN, MSN, women's health coordinator at Lake County Health Department in Waukegan, IL, estimates her facility performs about 100 insertions each year. The cost of providing the Mirena IUS precludes its regular use at the clinic, she reports.

The clinic has been able to perform some IUS insertions with devices provided by the ARCH (Access and Resources in Contraceptive Health) Foundation, a not-for-profit Charlotte, NC-based organization funded by Berlex Laboratories. The ARCH Foundation's patient assistance program helps financially challenged women obtain LNG IUS contraception.

While clinicians are reporting an uptick in intrauterine contraception use, many women remain unaware of the method's benefits. In a national survey, 70% of women were unaware of a reversible contraceptive option that is as effective as sterilization.

The Food and Drug Administration (FDA) has just approved updated labeling for ParaGard:

- The device is approved for nulliparous women in stable relationships from age 16 through menopause.
- ParaGard no longer is contraindicated for women with a history of sexually transmitted diseases (STDs) or pelvic inflammatory disease (PID) unless a patient currently has acute PID or engages in sexual behavior suggesting a high risk for PID.
- Mutual monogamy no longer is a user requirement, although use by women in a stable relationship is encouraged.[2]

What information do you need to present about intrauterine contraceptives? According to information presented at the recent Association of Reproductive Health Professionals' Reproductive Health 2005 conference, there are many myths about this method. In fact, intrauterine contraceptives:

- are not abortifacients;
- do not cause ectopic pregnancies;
- do not cause pelvic infection;
- do not decrease the likelihood of future pregnancies.[1]

In addition, intrauterine contraceptives can be used for women with previous ectopic pregnancies, do not need to be removed for PID treatment, and do not have to be removed if actinomyces-like organisms are noted on a Pap smear.[1]

Who are appropriate candidates for intrauterine contraception? Women of any reproductive age who are seeking long-term, highly effective contraception can consider the method.[1] The ParaGard IUD is a good selection for women who don't want hormonal contraception, while the Mirena LNG IUS represents a suitable choice for women who request less menstrual flow and/or who experience dysmenorrhea.[1]

Women who may be poor candidates for intrauterine contraception include those with known/suspected pregnancy, puerperal sepsis, immediate post-septic abortion, unexplained vaginal bleeding, cervical or endometrial cancer, uterine fibroids that distort uterine cavity, and known pelvic tuberculosis.[1]

Counsel women on potential side effects. During insertion, women may have variable pain and/or cramping and vasovagal reactions, with the possibility of light bleeding and mild cramping during the first few days following the procedure. Intermenstrual bleeding and cramping also may occur during the first few months of device use. Those who choose the Copper T 380A IUD may have heavier or prolonged menses, while women who use the LNG IUS may see a gradual decrease in menstrual flow.[1]

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DMPA: Survey offers snapshot of shot use

Rewind to November 2004: the Food and Drug Administration (FDA) announces the addition of a "black box" warning to the labeling for the injectable contraceptive depot medroxyprogesterone acetate (DMPA, Depo-Provera, Pfizer, New York City and MedroxyPROGESTERone Injection, Teva Pharmaceuticals USA, North Wales, PA). The warning highlights that prolonged use may result in the loss of bone mineral density (BMD). What has been the impact on use of the contraceptive shot?

More clinicians are not in favor of prescribing DMPA for young teens, according to results of the 2005 *Contraceptive Technology Update* Contraception Survey. About 86% say they are in favor of the practice; about 94% approved of such use in 2000.

"Depo popularity has gone down due to the bone density issue and the potential weight gain and the irregular bleeding," reports **Lynn Fair**, RNC, WHNP, a nurse practitioner at the Columbia/Boone Health Department in Columbia, MO. She attributes the drop in use due to word of mouth.

The revised label states that bone loss in women who use Depo-Provera is greater with increased duration of use and may not be completely reversible. The injectable contraceptive should be used as a long-term birth control method (longer than two years) only if other birth control methods are inadequate, the label

EXECUTIVE SUMMARY

Strengthened warning information concerning the possible impact on bone mineral density may be impacting the use of depot medroxyprogesterone acetate (DMPA). About 86% of participants in the 2005 Contraception Survey say they will prescribe the injectable for young teens; about 94% approved of such use five years ago.

- According to a new statement from the World Health Organization (WHO), there should be no restriction on the use of DMPA, including no restriction on duration of use among women ages 18-45 who otherwise are eligible to use the method.
- The advantages of using DMPA generally outweigh the theoretical safety concerns regarding fracture risk among adolescents and women older than age 45, according to WHO.

advises. Women who continue to use Depo-Provera past the two-year mark should have their BMD evaluated, according to the labeling.

New research has emerged in 2005 regarding the BMD question. One study's findings indicate that lower bone density appears to recover in adolescent females once they stop using the contraceptive injection.[1] Data from a long-term cohort study comparing BMD in adult DMPA users and nonusers suggest that while bone mineral density declines in current DMPA users, it is followed by recovery after discontinuation.[2]

In light of questions regarding the impact of contraceptive use on bone health, the World Health Organization has issued a statement on the subject. Its recommendations regarding DMPA state:

- there should be no restriction on the use of DMPA, including no restriction on duration of use, among women ages 18-45 who are otherwise eligible to use the method;
- among adolescents (menarche to younger than 18 years old) and women older than age 45, the advantages of using DMPA generally outweigh the theoretical safety concerns regarding fracture risk. Since data are insufficient to determine if this is the case with long-term use among these age groups, the overall risks and benefits for continuing use of the method should be reconsidered over time with the individual user.[3]

Most (60%) participants in the 2005 *CTU* survey say they only inform women that DMPA may diminish bone mass. About 30% say they take other precautions as well, such as advising dual-energy, X-ray absorptiometry (DEXA) scans to check bone density. About 7% report they provide women with a low-estrogen estrogen replacement therapy drug or a low-dose combined oral contraceptive along with the contraceptive shot.

DMPA has proven to be a popular form of contraception. Among females who received services in Title X-funded clinics during 2003, 16% relied on the contraceptive injection as their primary method of birth control.[4]

It will be interesting to see if decreased bone density also could be influenced by the fact that many teens using DMPA are part of the "Mountain Dew" generation, says **Jackie Bodden**, RN-C, APNP, program director and nurse practitioner at the Reproductive Health Care Center in Platteville, WI. Many teens have been drinking soft drinks instead of milk since grade school, she observes.

Clinicians at the Platteville center stress adequate calcium intake for teens, since most adolescents already are not getting the recommended daily amount of calcium, says Bodden. Counseling also stresses daily exercise such as walking to stimulate long bones, she notes.

"Switching off Depo-Provera after two years when this has been their method of choice has only resulted in dissatisfaction and unintended pregnancy," states Bodden.

References

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FDA fails to rule on EC OTC status . . . again

By **Cynthia Dailard**
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(Editor's note: About 86% of the 2005 Contraception Survey respondents say their facility prescribes emergency contraception on site and provides the method at any time. About 57% say they now include advance emergency contraception provision in their practice.)

On Aug. 26, the U.S. Food and Drug Administration (FDA) announced that it would indefinitely postpone its decision to allow

nonprescription status for the emergency contraceptive pill Plan B — popularly known as the "morning-after pill." The agency explained it would delay any action to make the product available over-the-counter (OTC) while it gathers public comments on the legality and feasibility of a regulatory scheme that the agency recommended the manufacturer, Barr Laboratories, pursue.

The move — which came more than a year and a half after two of the agency's expert advisory panels voted overwhelmingly to recommend OTC status for the drug — prompted a fierce outcry among women's health advocates, scientists, and key members of Congress, who denounced it as another example of the Bush administration putting politics before science. In fact, an editorial in the *New England Journal of Medicine* deemed the announcement "a sad day for science at the FDA" and said the "decision — or nondecision — deserves serious scrutiny, since it appears to reflect political meddling in the drug-approval process."[1]

Plan B's journey to OTC status has been long and torturous. In response to Barr's April 2003 application for OTC status, an FDA expert advisory panel in December of that year unanimously deemed the drug safe for OTC use and voted overwhelmingly that the drug should be made available OTC. When asked specifically about whether the product should be available to adolescents OTC, only three of the panel's 28 members objected and claimed that the evidence did not adequately assess the impact of wider access on adolescent sexual behavior, especially among younger adolescents. These objections came even though the committee had before it scientific studies showing that the drug is safe for young teenagers and that advanced access to emergency contraception did not increase unprotected sex.

Under enormous political pressure from social conservatives to reject the recommendations of its own advisory panel, the FDA announced in February 2004 that it would delay a decision for 90 days while it reviewed the data on adolescents. In May, the agency officially rejected the application. At that time, it encouraged Barr to resubmit an application pursuing a dual marketing plan that would permit the OTC sale of Plan B without a prescription for women aged 16 and older, while maintaining the prescription status for women aged 15 and younger.

RESOURCE

To submit an on-line comment regarding Plan B to the Food and Drug Administration, go to the web site www.fda.gov. Next to "More FDA News," click on "Press Releases." Next, under the heading "Press Releases," click on "August 2005." Click on "FDA Takes Action on Plan B: Statement by FDA Commissioner Lester M. Crawford." Click on "Online Comment Form." Comment deadline is Nov. 1, 2005.

Barr's application for dual status, however, would languish at the agency for months with no response. In fact, the agency's failure to act prompted two influential members of Congress — Sens. Hillary Clinton (D-NY) and Patty Murray (D-WA) — to prevent Lester Crawford's nomination to head the FDA from moving forward until they were assured by Health and Human Services Secretary Michael Leavitt that the FDA would render a yes or no decision by Sept. 1.

Back to the future

Yet only days before that Sept. 1 deadline, the agency announced that it might not in fact have the legal authority to grant the dual status scheme that it had recommended Barr pursue. It stated that it would postpone any decision on Barr's application, and it opened a 60-day comment period. It invited public input on the feasibility and legality of the dual-status and related enforcement issues. **(See resource box, above, for instructions on submitting comments to the FDA.)**

This turnabout infuriated Sens. Clinton and Murray. Angered by what they perceived to be a personal betrayal and political double-cross, the senators have urged Michael Enzi (R-WY), chairman of the Senate Health, Education, Labor, and Pensions Committee, to hold a hearing on the FDA's decision-making process. Thirteen senators also sent a letter urging the Government

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Accountability Office (GAO) to quickly conclude the investigation they requested in June 2004 into why the FDA rejected the application to make Plan B available OTC to women of all ages. The GAO responded within a week that it would release those findings by October.

Another casualty of the FDA announcement was Susan Wood, assistant commissioner for women's health and director of the FDA Office of Women's Health, who resigned in protest over how the FDA has handled the Plan B application for OTC status. In an interview with the *Chicago Tribune*, Wood explained her decision. "I couldn't stand quietly as head of women's health while this decision, which is contrary to women's health, was made," she said.[2]

What will happen after the conclusion of the 60-day public comment period remains to be seen. As each day goes by, it is looking more and more dubious that Plan B will ever be available over-the-counter to U.S. women — of any age. This represents both a great loss for American women and a significant blemish on the record of the FDA.

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2. Lara AN. Dismay over delay spurred FDA officer. *Chicago Tribune*, Sept. 7, 2005: Accessed at: www.chicagotribune.com/features/printedition/chi-0509070010sep07,1,1821274.story. ■

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.
- **Describe** how those issues affect service delivery and note the benefits or problems created in patient care in the participant's practice area. (See **"Intrauterine method sees upswing in use"** and **"DMPA: Survey offers snapshot of shot use.")**
- **Cite** practical solutions to problems and integrate information into daily practices, according to advice from nationally recognized family planning experts. (See **"Patch and ring make inroads on birth control pill's popularity"** and **"Pill power: Clinicians speak out on OC choices.")**

17. What is the release rate of estrogen found in the NuvaRing contraceptive vaginal ring?
A. 0.015 mg ethinyl estradiol per day over a 21-day period of use
B. 0.020 mg ethinyl estradiol per day over a 21-day period of use
C. 0.025 mg ethinyl estradiol per day over a 21-day period of use
D. 0.030 mg ethinyl estradiol per day over a 21-day period of use

18. What is the dosing regimen for the oral contraceptive Yaz?
A. 22 days of active pills followed by six days of placebo pills
B. 24 days of active pills followed by four days of placebo pills
C. 26 days of active pills followed by two days of placebo pills
D. 28 days of active pills with no placebo pills

19. What is the updated information on the labeling for the ParaGard intrauterine device?
A. The device is contraindicated for women who have a previous history of sexually transmitted diseases.
B. Women are required to be in a mutually monogamous relationship to use the method.
C. The device now is approved for nulliparous women in stable relationships from age 16 through menopause.
D. The device now is approved for nulliparous women in stable relationships from age 12 through menopause.

20. According to a July statement from the World Health Organization, what is its position on use of depot medroxyprogesterone acetate (DMPA)?
A. The injectable contraceptive should be used as a long-term birth control method (longer than one year) only if other birth control methods are inadequate.
B. There should be no restriction on the use of DMPA, including no restriction on duration of use, among women ages 18-45 who are otherwise eligible to use the method.
C. The injectable contraceptive should be used as a long-term birth control method (longer than three years) only if other birth control methods are inadequate.
D. The injectable contraceptive should be used as a long-term birth control method (longer than five years) only if other birth control methods are inadequate.

Answers: 17. A; 18. B; 19. C; 20. B.

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