CONTRACEPTIVE TECHNOLOGY UPDATE®

A Monthly Update on Contraception and Sexually Transmitted Diseases

Special: Coverage of 2008 Contraception Survey

AHC Media LLC

While use of new methods grows, OCs remain lead contraceptive choice

Ring, implant, and patch increase reversible options

While new methods are gaining favor with women, oral contraceptives (OCs) continue to be a popular method of birth control, say respondents to the 2008 *Contraceptive Technology Update* Contraception Survey. About 42% of survey participants report over half of their patients leave the office with an OC prescription in hand.

"We still have more than 50% combined oral contraceptive users; however, the NuvaRing and intrauterine contraception, especially Mirena, are being requested more often than last year," says **Shirley LeBlanc**, WHNP-BC, a women's health nurse practitioner at Planned Parenthood of Waco/Central Texas. NuvaRing, the contraceptive vaginal ring, is manufactured by Organon in West Orange, NJ. Mirena, the levonorgestrel intrauterine system, is manufactured by Bayer HealthCare Pharmaceuticals in Wayne, NJ.

About half (51%) of 2008 survey respondents said their facility now is offering or is planning to offer the contraceptive implant (Implanon, Organon; Roseland, NJ), which is slightly less than 2007's 53% statistic.

IN THIS ISSUE

Statement of Financial Disclosure:
Consulting Editor **Robert A. Hatcher**, MD, MPH, Author **Rebecca Bowers**, Associate Publisher **Coles McKagen**, Senior Managing Editor **Joy Dickinson**, **Adam Sonfield** (Washington Watch Columnist), and **Melanie Gold**, DO, and **Kaityi Duffy**, MPH (Authors, Teen Topics) report no consultant, stockholder, speaker's bureau, research, or other financial relationships with companies having ties to this field of study. **Sharon Schnare** (Nurse Reviewer) discloses that she is a retained consultant and a speaker for Barr Laboratories, Berlex, and Organon; she is a consultant for 3M Pharmaceuticals; and she is a speaker for FEI Women's Health, Ortho-McNeil Pharmaceuticals, and Wyeth-Ayerst Pharmaceuticals.

JANUARY 2009
VOL. 30, NO. 1 • (pages 1-12)

Contraceptive Technology Update debuts new adolescent health column

Be sure to check out "Teen Topics," our new quarterly adolescent health column, on **p. 10**. The column is co-written by **Melanie Gold**, DO, clinical associate professor of pediatrics at the University of Pittsburgh School of Medicine and staff physician at the University of Pittsburgh Student Health Service, and **Kaiyti Duffy**, MPH, assistant director of medical education for Physicians for Reproductive Choice. Also look ahead to the February 2009 issue, where the "Washington Watch" column will provide a forecast of the incoming administration's impact on family planning issues. ■

A small, thin, hormonal contraceptive that is effective for up to three years, Implanon was approved in July 2006 by the Food and Drug Administration (FDA). **(Read the *CTU* article "Bulletin: Single-rod contraceptive implant Implanon gets Food & Drug Administration's OK," September 2006, p. 97.)** The device, made of a soft medical polymer, contains 68 mg of the progestin etonogestrel. Implanted in the inner side of a woman's upper arm during an in-office procedure, the matchstick-sized device releases the drug in a low, steady dose. Its efficacy is comparable to sterilization.[1]

Implanon is in use at the Portales (NM) Public Health Office, reports **Carol Morgan**, RN, nurse manager; 10 devices had been inserted in 2008, with two more scheduled at press time, she says. "We have had to remove one Implanon due to excessive bleeding," says Morgan. "The others seem to be doing well."

While Implanon is available at the Knoxville (TN) Center for Reproductive Health, **Corinne Rovetti**, RNCS, FNP, family nurse practitioner and co-director, says little interest has been expressed for the method. "Our facility takes only limited insurances, and I believe that is the major obstacle to its use," says Rovetti. *(Editor's note: Some insurance companies have yet to include coverage for Implanon. To determine coverage, go to www.implanon.com. Select "U.S. Consumers," then "Is Implanon right for me?" and then "Determining your health plan coverage.")*

Why is implantable contraception a good choice for many women? Consider the following points listed by **Lee Shulman**, MD, professor in obstetrics and gynecology and chief of the Division of Reproductive Genetics in the Department of Obstetrics and Gynecology at the Feinberg School of Medicine of Northwestern University in Chicago, who presented at the 2008 annual meeting of the Association of Reproductive Health Professionals:

- long duration of action;
- not patient-dependent;
- continuous steady-state steroid levels;
- avoidance of first-pass effect from gastrointestinal absorption and hepatic metabolism;

EXECUTIVE SUMMARY

While new methods are gaining favor with women, oral contraceptives (OCs) continue to be a popular birth control method, say respondents to the 2008 *Contraceptive Technology Update* Contraception Survey. About 42% of survey participants report more than half of their patients leave with an OC prescription.

- About half (51%) of survey respondents say their facility is now offering or is planning to offer the contraceptive implant Implanon.
- About 92% of 2008 survey participants say they now offer NuvaRing.
- About 86% of survey participants said their facility offers the contraceptive patch.

Contraceptive Technology Update® (ISSN 0274-726X), including **STD Quarterly**™, is published monthly by AHC Media LLC, 3525 Piedmont Road, Building Six, Suite 400, Atlanta, GA 30305. Telephone: (404) 262-7436. Periodicals Postage Paid at Atlanta, GA 30304 and at additional mailing offices.

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. E-mail: (customerservice@ahcmedia.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), $499. Add $17.95 for shipping & handling. Outside U.S., add $30 per year, total prepaid in U.S. funds. Discounts are available for group subscriptions, multiple copies, site-licenses or electronic distribution. For pricing information, call Tria Kreutzer at 404-262-5482. **Back issues**, when available, are $75 each.(GST registration number R128870672.)

Editor: **Rebecca Bowers**.
Associate Publisher: **Coles McKagen** (404) 262-5420 (coles.mckagen@ ahcmedia.com).
Senior Managing Editor: **Joy Daughtery Dickinson** (229) 551-9195 (joy.dickinson@ahcmedia.com).
Senior Production Editor: **Nancy McCreary**.

Editorial Questions

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

• high bioavailability.[2]

Potential candidates include women who desire long-term contraception, high effectiveness, rapid reversibility, and estrogen-free contraception, said Shulman. Contraindications include known or suspected pregnancy, current or past history of thrombosis or thromboembolic disorders, hepatic tumor or active liver disease, undiagnosed abnormal genital bleeding, known or suspected carcinoma of the breast or history of breast cancer, and hypersensitivity to the components of the implant.[2]

The contraceptive vaginal ring (NuvaRing, Organon; West Orange, NJ) continues to gain ground among women since its FDA approval in 2001. About 92% of 2008 survey participants say they now offer NuvaRing, similar to last year's figure.

NuvaRing remains quite popular with patients at the Family Planning of the Big Horns, a reproductive health care clinic in Sheridan, WY, states **Ullainee Hartman**, WHNP, a women's health nurse practitioner at the facility.

Women who have been satisfied with combined oral contraceptives and are interested in a nondaily method are more likely to continue using the contraceptive ring than the contraceptive patch (Ortho Evra, Ortho-McNeil Pharmaceutical; Raritan, NJ), results of a 2008 study indicate.[3] To conduct the study, 500 women were randomly assigned to use the ring or the contraceptive patch for four consecutive menstrual cycles, starting with their next menses. Participants returned for a single follow-up visit during the fourth cycle for an evaluation, which included a questionnaire to assess acceptability and adverse effects.

Results suggest that women in the study were happier with the ring than the patch. Ring users reported fewer complications, and the majority preferred the ring to their pill.[2] On the other hand, patch users were twice as likely to discontinue using the product by the end of the third cycle, and they were seven times more likely to say they had no wish to continue the method once the study was completed.[3]

Use of the contraceptive patch increased slightly in 2008. About 86% of survey participants said their facility offered the method, compared to about 84% in 2007. The patch is a popular choice among adolescents. An analysis of national surveys of trends in contraception prescriptions for 11- to 21-year-old females showed the patch and one oral contraceptive, Yasmin (Bayer HealthCare Pharmaceuticals; Wayne, NJ), accounting for a steadily increasing proportion of prescriptions.[4]

The FDA revised Ortho Evra's labeling in November 2005 with a bolded warning that the patch exposes women to higher total amounts of estrogen than a typical birth control pill containing 35 mcg estrogen. In September 2006, the drug's label was revised to include the results of two epidemiologic studies.[5,6] One study found that the risk of nonfatal VTE events associated with use of the patch was similar to the risk associated with the use of OCs, while the other study showed an approximate twofold increase in the risk of VTE events in users of the patch compared to OC users.

The labeling was amended again in 2008 to include results of a third epidemiologic study, as well as additional information on the risk of VTE in patch users in one of the original studies.[7,8] Results from the third study shows an increased risk for VTE among patch users compared to those taking OCs.[7] ***(CTU* reported on the updated labeling; see "FDA updates study data information on Ortho Evra contraceptive patch labeling," April 2008, p. 37.)**

References

1. Raymond EG. "Contraceptive Implants." In: Hatcher RA, Trussell J, Nelson AL, et al. *Contraceptive Technology*: 19th revised edition. New York City: Ardent Media; 2007.
2. Shulman L. New developments in contraception: The single-rod implant. Presented at the 2008 annual meeting of the Association of Reproductive Health Professionals. Washington, DC; September 2008.
3. Creinin MD, Meyn LA, Borgatta L, et al. Multicenter comparison of the contraceptive ring and patch: A randomized controlled trial. *Obstet Gynecol* 2008; 111(2 Pt 1):267-277.
4. O'Brien SH, Kaizar EE, Gold MA, et al. Trends in prescribing patterns of hormonal contraceptives for adolescents. *Contraception* 2008; 77:264-269.
5. Jick SS, Kaye JA, Russmann S, et al. Risk of nonfatal venous thromboembolism in women using a contraceptive transdermal patch and oral contraceptives containing norgestimate and 35 mcg of ethinyl estradiol. *Contraception* 2006; 73:223-228.
6. Cole JA, Norman H, Doherty M, et al. Venous thromboembolism, myocardial infarction, and stroke among transdermal contraceptive system users. *Obstet Gynecol* 2007; 109(2 Pt 1):339-346.
7. Boston Collaborative Drug Surveillance Program. Postmarketing study of ORTHO EVRA and levonorgestrel oral contraceptives containing hormonal contraceptives with 30 mcg of EE in relation to nonfatal venous thromboembolism, ischemic stroke, and myocardial infarction. Accessed at www.clinicaltrials.gov/ct2/show/NCT00511784.
8. Jick S, Kaye JA, Li L, et al. Further results on the risk of nonfatal venous thromboembolism in users of the contraceptive transdermal patch compared to users of oral contraceptives containing norgestimate and 35 microg of ethinyl estradiol. *Contraception* 2007; 76:4-7. ■

Check OC options: Readers share views

Where do generic oral contraceptives fit in your facility's formulary? About 70% of participants in the 2008 *Contraceptive Technology Update* Contraception Survey say their facilities have increased the use of generic oral contraceptives due to budget constraints, up 5% from 2007's statistic.

While the Casper Natrona County Health Department in Casper, WY, has increased its use of generic oral contraceptives, **Tia Hansuld**, nurse practitioner and clinic director, says it has not significantly impacted clinicians' practice. **Carol Morgan**, RN, nurse manager at the Portales (NM) Public Health Office, agrees that the switch to generic pills has not impacted clinical practice at her facility.

"We do provide the generic or the brand name contraceptive, depending on availability and cost," states Hansuld. "The generics work well for most clients. There are a few that have a problem, and we will switch to another brand."

A woman should be able to request and obtain the oral contraceptive that she and her provider decide best addresses her individual needs, according to a 2007 committee opinion released by the American College of Obstetricians and Gynecologists.[1] If a provider or pharmacist switches a patient's OC prescription for cost, insurance coverage, compliance, or any other reason, the patient always should be notified, the opinion states. The opinion supports patient or clinician requests' for branded OCs or continuation of the same generic or branded pill "if the request is based on clinical experience or concerns regarding packaging or compliance, or if the branded product is considered a better choice for that individual patient."[1]

Most family planning providers are familiar with generic oral contraceptives from Barr Pharmaceuticals of Pomona, NY, and Watson Pharmaceuticals of Corona, CA. However, look for changes in the generic landscape: Barr has struck a deal with German pharmaceutical firm Bayer to produce generic versions of the company's Yasmin and Yaz birth control pills in the United States prior to their patent expiration. Barr now is marketing the generic equivalent of Yasmin as Ocella; Barr's generic form of Yaz is set to debut in 2011.

In July 2008, Barr's board of directors agreed to sell the company to Jerusalem, Israel-based Teva Pharmaceutical Industries, the world's largest generic drug maker and biggest pharmaceutical supplier to discount giant Wal-Mart.[2] Another manufacturer is set to enter the generic OC marketplace. Pittsburgh-based Mylan announced in August 2008 that it has completed an agreement

EXECUTIVE SUMMARY

About 70% of participants in the 2008 Contraception Survey said their facilities have increased the use of generic oral contraceptives due to budget constraints. This number is up 5% from 2007's statistic.

- When bound by formulary, about 30% of 2008 survey participants say they write prescriptions for Ortho Tri-Cyclen Lo for young nonsmoking women, similar to 2007's statistic. About 13% named Ortho Tri-Cyclen; others named Yaz, Alesse, and Loestrin.
- Ortho Tri-Cyclen Lo was the leading nonformulary pick for young women, followed closely by 2007's top pick, Yasmin.

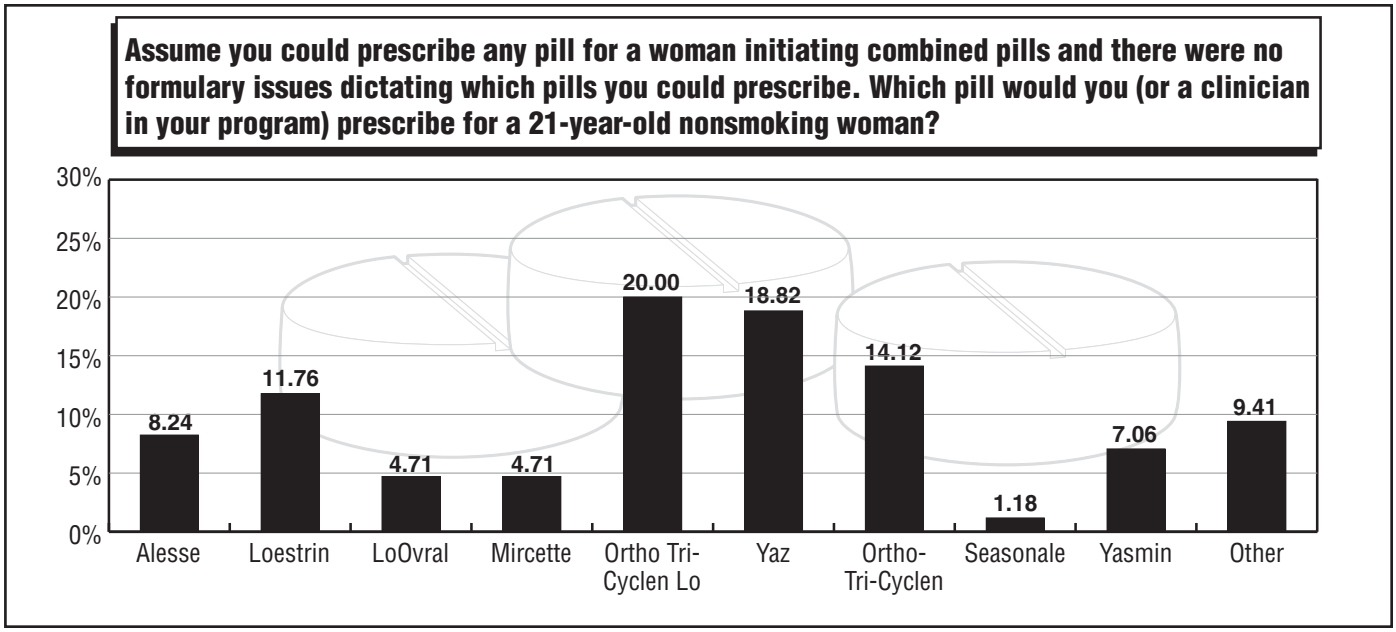
Survey Profile

A total of 99 providers participated in the 2008 *Contraceptive Technology Update* (*CTU)* Contraception Survey, which monitors contraceptive trends and family planning issues among readers. Results were tallied and analyzed by AHC Media LLC in Atlanta, publisher of *CTU* and more than 50 other medical newsletters and sourcebooks.

About 54% of responses came from nurse practitioners or registered nurses. Physicians represented about 39% of the responses; with health educators/counselors comprising about 1% of the response group. About 6% listed other professions. About 78% of respondents identified themselves as care providers, with nearly 10% involved in administration.

Some 32% of the respondents said they were employed at private practice settings, with about 30% working in public health facilities. About 11% listed student health centers as their place of employment, with some 10% working in hospitals. The remaining 17% reported employment in other settings.

When it comes to location of their employment, about 35% said they worked in a suburban location. About 31% said they were employed in a rural facility, while about 30% listed an urban setting. ■



with Famy Care Ltd., a global, India-based manufacturing leader of women's health care products, to develop and supply 22 OCs to U.S. customers.[3]

Which pill do you pick?

The young woman sitting in front of you tells you she is interested in using oral contraceptives (OCs). She's 21, a nonsmoker, and is in good health. If formulary issues are not in play, which pill would you prescribe?

When bound by formulary, about 30% of 2008 survey participants say they write prescriptions for Ortho Tri-Cyclen Lo (Ortho-McNeil Pharmaceutical; Raritan, NJ) for young nonsmoking women, similar to 2007's statistic. About 13% named Ortho Tri-Cyclen, another triphasic pill, as a formulary OC. Yaz (Bayer HealthCare Pharmaceuticals), Alesse (Wyeth Pharmaceuticals; Collegeville, PA), and Loestrin (Barr Pharmaceuticals) each represented about 10% of the total response for the category.

Ortho Tri-Cyclen Lo reclaimed its top spot in the 2008 Contraception Survey as the leading nonformulary pick for young women, followed closely by 2007's leader, Yasmin, a monophasic pill containing 3 mg drospirenone and 0.030 mg ethinyl estradiol from Bayer HealthCare Pharmaceuticals, Wayne, NJ. Ortho Tri-Cyclen Lo, a triphasic pill that contains 25 mcg estrogen for 21 days and three different doses of the progestin norgestimate (180 mcg daily/days 1-7; 215 mcg daily/days 8-14; 250 mcg daily/days 15-21), had led the category for two years beginning in 2004. Yasmin moved ahead in 2006. **(See chart, above, of top nonformulary pills.)**

References

1. Committee on Gynecologic Practice, American College of Obstetricians and Gynecologists. ACOG Committee Opinion No. 375: Brand vs. generic oral contraceptives. *Obstet Gynecol* 2007; 110(2 Pt 1):447-448.

2. Todd S. Barr deal seen as a boon for Teva. *Star Ledger*, July 19, 2008: Accessed at www.nj.com/business/index.ssf/2008/07/barr_deal_seen_as_a_boon_for_t.html.

3. Mylan. Mylan creates new women's health care franchise; signs agreement with Famy Care to develop and supply 22 oral contraceptive products. Press release. Accessed at investor.mylan.com/phoenix.zhtml?c=66563&p=irol-newsArticle&ID=1184120&highlight=. ■

Strategies for the Pill: Providers share views

When it comes to oral contraceptives (OCs), what is your current practice when it comes to prescribing pills in extended- or continuous-regimens? More providers are prescribing pills in this manner, say respondents to the 2008 *Contraceptive Technology Update* Contraception Survey. About 62% say they increased use of such pill regimens in the last year.

Look for another dedicated extended regimen pill to enter the marketplace. In October 2008, the Food and Drug Administration approved Pomona, NY-based Barr Pharmaceuticals' New Drug Application for LoSeasonique, a new extended-cycle oral contraceptive. Under the pill's extended-cycle regimen, women take combination tablets containing 0.10 mg levonorgestrel and 0.02 mg

EXECUTIVE SUMMARY

More providers (62%) are prescribing pills in extended or continuous regimens, say respondents to the 2008 Contraception Survey.

- Look for another dedicated extended regimen pill to enter the marketplace in 2009: LoSeasonique. Under the pill's extended-cycle regimen, women take combination tablets containing 0.10 mg levonorgestrel and 0.02 mg of ethinyl estradiol daily for 84 consecutive days, followed by 0.01 mg ethinyl estradiol tablets for seven days.
- When it comes to initiation of pills, most participants in the 2008 survey say they are using the Quick Start method, which is directly observed immediate initiation of pills before start of the next menses. A total of 65% of readers use Quick Start, which is an increase from 2007's 62% figure. **(Review adolescent Quick Start information in the new "Teen Topics" column on p. 10.)**

of ethinyl estradiol daily for 84 consecutive days, followed by 0.01 mg ethinyl estradiol tablets for seven days. The company says the new pill will be shipped to trade customers and be available by prescription in the first quarter of 2009.[1]

One pill is packaged for continuous use: Lybrel from Wyeth Pharmaceuticals of Collegeville, PA. The drug, which won approval in 2007, is designed to be taken 365 days a year, without a placebo phase or pill-free interval. Other dedicated extended-regimen pills include Barr/Duramed's Seasonale and Seasonique, and Quasense, manufactured by Watson Pharmaceuticals of Corona, CA.

What has led to the uptick in use of such regimens? **Ullainee Hartman**, WHNP, a women's health nurse practitioner at Family Planning of the Big Horns, a reproductive health care clinic in Sheridan, WY, says it is a combination of her increased awareness of the benefits of such regimens, as well as patients' requests.

The menstrual benefits of suppressing periods include a reduction in dysmenorrhea, menorrhagia, premenstrual syndrome, and perimenopausal symptoms, such as hot flashes, night sweats, and irregular monthly periods. Nonmenstrual benefits include a reduction in menstrual migraines, endometriosis, and acne, as well as an improved sense of well-being.[2]

Women want the option of fewer periods. Results of a 2008 national survey show that while about three-quarters of women polled would prefer to get their period less often, just 8% report having tried extended or continuous contraceptive pills.[3]

When counseling a woman on when to start her first pill pack, what is your strategy for pill initiation? Most participants in the 2008 Contraception Survey say they are using the Quick Start method, which is immediate initiation of pills before start of the next menses. A total of 65% of responses indicated such use, an increase from 2007's 62% figure.

Quick Start is a user satisfaction issue, observes **Mimi Zieman**, MD, clinical associate professor in the Department of Gynecology and Obstetrics at Emory University School of Medicine in Atlanta. In speaking on the subject at the recent *Contraceptive Technology* Quest for Excellence Conference, Zieman noted that being able to provide multiple pill packs upon Quick Start initiation aids in helping women continue with the method.[4]

Many women might experience nausea when beginning use of a new OC. Which pill do survey participants prescribe for women who have experienced nausea on previous OCs?

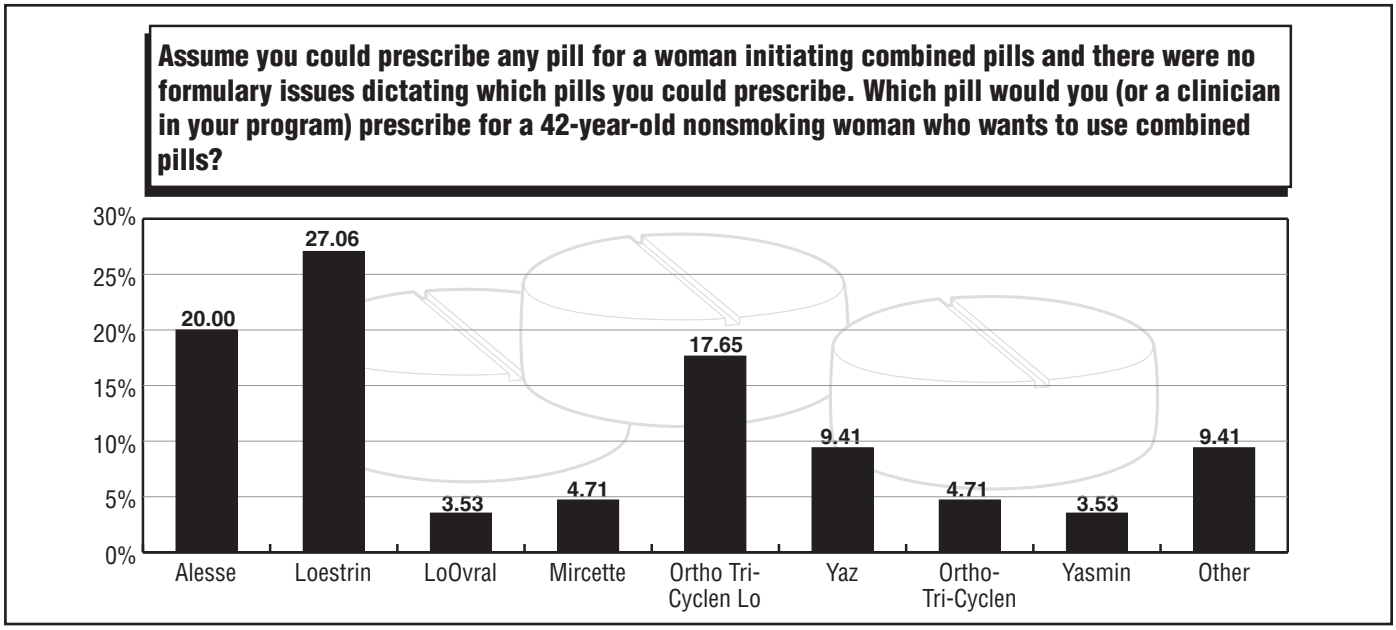
While Alesse, a monophasic 20 mcg pill from Wyeth Pharmaceuticals, Collegeville, PA, continues to lead in this category, its 33% ranking declined from 2007's 56%. Other top choices included Loestrin (19.8%), a 20 mcg pill from Barr/Duramed, and Ortho Tri-Cyclen Lo (9.3%), a multiphasic 25 mcg pill from Ortho-McNeil Pharmaceutical, Raritan, NJ.

If a woman is in her 40s, healthy, and a nonsmoker, she is a potential candidate for combined oral contraceptives. When it comes to pill options for older women, 2008 survey participants named Loestrin (27%), followed by Alesse (20%). This standing reverses positions held by the two pills in the 2007 survey (19% and 44%, respectively). Ortho Tri-Cyclen Lo remained in the third spot (17.6%). **(See the graphic, p. 7, on top pills for older women.)**

When it comes to women who smoke and the Pill, about 78% of survey participants say they will not write prescriptions for women ages 35-39 who smoke 10 cigarettes a day. For women ages 40 and older who smoke 10 cigarettes a day, about 92% say they will not prescribe OCs, which falls in line with similar figures in 2007.

When talking with patients about smoking, share these facts from the American Lung Association:

- In 2006, 20.2 million (17.8%) of women smoked in the United States. Annually, cigarette



smoking kills an estimated 178,408 women in the United States.

• Women who smoke double their risk for developing coronary heart disease. Women who smoke also have an increased risk for developing cancers of the oral cavity, pharynx, larynx, esophagus, pancreas, kidney, bladder, and uterine cervix.[5]

While oral contraceptives provide reliable birth control, they also offer noncontraceptive benefits. Use of combined OCs leads to reduced risk of ovarian cancer and endometrial cancer.[6] About 30% of 2008 survey participants says they specifically prescribed the Pill in the last year to help women decrease their risk of cancer of the ovary.

When it comes to initiating combined OC use in postpartum women who are not breast-feeding, about 49% of 2008 survey participants say they will begin pill use four to six weeks after delivery. About 20% say they start combined pills one to three weeks postpartum, while about 18% begin OC use upon hospital discharge.

For breast-feeding women who wish to use progestin-only pills, about 48% indicate they will initiate pill use four to six weeks postpartum, while about 25% say they begin progestin-only pill use one to three weeks following delivery. About 15% state they start minipills upon hospital discharge. Two percent initiate progestin-only pill use at first menses; 10% list other options.

References

1. Barr Pharmaceuticals Inc. FDA Approves Duramed's LoSeasonique Oral Contraceptive. Press release. Accessed at phx.corporate-ir.net/phoenix.zhtml?c=60908&p=irol-newsArticle&ID=1217588&highlight=.

2. Sulak PJ, Kuehl TJ, Ortiz M, et al. Acceptance of altering the standard 21-day/7-day oral contraceptive regimen to delay menses and reduce hormone withdrawal symptoms. *Am J Obstet Gynecol* 2002; 186:1,142-1,149.

3. Harris Interactive, prepared for The National Women's Health Resource Center. Menstrual Management Survey Report. Aug. 29, 2008. Accessed at www.healthywomen.org/Documents/MenstrualManagementReport.pdf.

4. Zieman M. Quick Start, extended regimens and shortened pill-free interval: New products and protocols for contraceptive management. Presented at the *Contraceptive Technology* Quest for Excellence Conference. Atlanta; October 2008.

5. American Lung Association. Smoking and women fact sheet. Accessed at www.lungusa.org/site/pp.asp?c=dvLUK9O0E&b=33572.

6. Nelson A. "Combined Oral Contraceptives." In: Hatcher RA, Trussell J, Nelson AL, et al. *Contraceptive Technology*: 19th revised edition. New York City: Ardent Media; 2007. ■

Intrauterine devices — More women eye option

Use of intrauterine contraception is slowly gaining ground among U.S. women. About 45% of respondents to the 2008 *Contraceptive Technology Update* Contraception Survey say they inserted six or more devices in the last year, compared to 2007's 40% figure. About 40% reported no insertions in 2008, similar to 2007's statistic.

A recently published review sees intrauterine contraception undergoing a renaissance in the United States, with its role expanded as new devices and systems are developed and as old biases among clinicians and women are erased.[1]

EXECUTIVE SUMMARY

Use of intrauterine contraception is slowly gaining ground among U.S. women. About 45% of respondents to the 2008 Contraception Survey say they inserted six or more devices in the last year, compared to 2007's 40% figure. About 40% reported no insertions in 2008, similar to 2007's statistic.

- The Copper T IUD is a good method for women who do not want hormonal contraception or want contraception for more than five years.
- The LNG IUS represents a good option for women who request less menstrual flow and/or experience dysmenorrhea or dysfunctional uterine bleeding.

Corinne Rovetti, RNCS, FNP, family nurse practitioner and co-director of the Knoxville (TN) Center for Reproductive Health, a comprehensive reproductive health center, is seeing an increased interest and request for insertion for intrauterine devices (IUDs). Patients are requesting the Copper T 380A intrauterine device (ParaGard IUD, Barr Pharmaceuticals; Pomona, NY) and the levonorgestrel intrauterine system (Mirena LNG IUS, Bayer HealthCare Pharmaceuticals; Wayne, NJ).

"I think, finally, we are moving past the outdated information that kept people fearful of using this method, so the new marketing for these systems has had a positive effect on the increased interest and usage," she says.

Shirley LeBlanc, WHNP-BC, a women's health nurse practitioner at Planned Parenthood of Waco/Central Texas, says her facility is seeing more insertions of IUDs. More women would choose the method if more flexible payment plans were offered by the manufacturing companies. **(See resource listing, at right, for current assistance programs.)**

Clinicians continue to need updating when it comes intrauterine contraception, according to information presented by **Barbara Clark**, PA-C, MPAS, a certified physician assistant at Knox OB-GYN, in Galesburg, IL, at the 2008 annual meeting of the Association of Reproductive Health Professionals.[2]

Myths still exist about intrauterine contraception, according to Clark's presentation. Selection of candidates is unduly restrictive, and misinformation about intrauterine contraception among providers and patients is common, she states.

Confusion still circles around potential candidates for IUD use. The World Health Organization eligibility criteria classes use of IUDs in young women ages 20 and younger, as well as for nulliparous women, as a "2" — which means the advantages of using the method generally outweigh the theoretical or proven risks.[3]

When talking with patients about intrauterine contraception, question them about where they have received information about the method. A 2008 study that looked at the accuracy of video clips and viewer-posted comments about IUDs on YouTube found that many scientific claims were unsubstantiated and several viewer comments were negative toward the method.[4]

Who is a suitable candidate for intrauterine contraception? Women of any reproductive age seeking long-term, highly effective contraception, according to Clark. The Copper T IUD is a good method for women who don't want hormonal contraception or want contraception for more than five years, while the LNG IUS represents a good option for women who request less menstrual flow and/or experience dysmenorrhea or dysfunctional uterine bleeding.[2]

IUDs are underused in the United States, especially by adolescents, reports a recent paper.[5] Because adolescents contribute disproportionately to the epidemic of unintended pregnancy, IUDs should be considered as a first-line contraceptive choice regardless of parity, the paper's authors state. The LNG IUS represents a good option for teens due to its noncontraceptive benefits such as decreased menstrual bleeding, dysmenorrhea, and pain associated with endometriosis. More research in the use of the IUD among adolescents should be pursued, the authors advocate.[5]

RESOURCES

- **The ARCH Foundation is a Charlotte, NC-based not-for-profit foundation** established to assist low-income patients who do not have insurance coverage for the Mirena intrauterine contraceptive system. For patients who meet specific eligibility criteria, the ARCH Foundation may be able to provide Mirena free of charge. Confidential messages may be recorded for a patient case coordinator, 24 hours a day, seven days a week. Contact the foundation at P.O. Box 220908, Charlotte, NC 28222-0908. Phone: (877) 393-9071, Monday through Friday 9 a.m. to 5 p.m. Eastern Time. Web: www.archfoundation.com.
- **If a patient's insurance provider does not cover the ParaGard intrauterine device**, or if she does not have insurance, the ParaGard Patient Payment program allows the patient to pay for the device with 12 monthly payments. Call toll-free (877) 727-2427 for more details.

References

1. MacIsaac L, Espey E. Intrauterine contraception: The pendulum swings back. *Obstet Gynecol Clin North Am* 2007; 34:91-111, ix.
2. Clark BJB. A clinical update on intrauterine contraception. Presented at the 2008 annual meeting of the Association of Reproductive Health Professionals. Washington, DC; September 2008.
3. World Health Organization. *Medical eligibility criteria for contraceptive use*. Geneva: World Health Organization; 2004.
4. Luttrell K, Zite N, Wallace L. Myths and misconceptions about intrauterine contraception on YouTube. *Contraception* 2008; 78:183-183.
5. Gold MA, Johnson LM. Intrauterine devices and adolescents. *Curr Opin Obstet Gynecol* 2008; 20:464-469. ■

Shot makes its mark in contraceptive options

When it comes to choosing an effective contraceptive, many women look to the contraceptive injection depot medroxyprogesterone acetate (DMPA, Depo-Provera Pfizer; New York City, Medroxyprogesterone Acetate Injection, Teva Pharmaceuticals USA; North Wales, PA), say respondents to the 2008 *Contraceptive Technology Update* Contraception Survey. The shot remains a popular option for younger women. About 91% of survey respondents say they would prescribe the injectable for young teens, up from 2007's 87% statistic.

In November 2004, the Food and Drug Administration added a "black box" warning to the drug's labeling to highlight that prolonged use may result in loss of bone mineral density (BMD). The warning advised that bone loss in women who use Depo-Provera is greater with increased duration of use and might 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 updated label advised.

EXECUTIVE SUMMARY

Many women look to Depo-Provera, the contraceptive injection, for contraception, say respondents to the 2008 Contraception Survey.

- About 91% of survey respondents say they would prescribe the injectable for young teens, up from 2007's 87% statistic.
- Concerns about the effects of the contraceptive injection on bone mineral density should not prevent clinicians from prescribing the method, nor should its use be limited to two years, according to a committee opinion released in 2008 by the American College of Obstetricians and Gynecologists.

The "black box" warning has made its impact on providers: According to results of a survey of Florida physicians, 46% of those surveyed said they place a time limit on DMPA use, and 66% stated that the limit was based on the label warning.[1] Sixty-five percent of respondents ordered BMD testing solely due to the use of DMPA, with 58% indicating that this decision was based on the black box warning.

Concerns about the effects of the contraceptive injection on BMD should not prevent clinicians from prescribing the method, nor should its use be limited to two years, according to a committee opinion released in 2008 by the American College of Obstetricians and Gynecologists (ACOG).[2]

The ACOG opinion falls in line with a similar review issued by the World Health Organization (WHO) in 2005.[3]

As with pregnancy and lactation, use of DMPA is associated with loss of bone mass in current users, says **Andrew Kaunitz**, MD, professor and associate chair in the Obstetrics and Gynecology Department at the University of Florida College of Medicine — Jacksonville. "Fortunately, declines in bone mass with DMPA use, as with pregnancy and lactation, are reversible," he notes. "Of interest, bone mass recovers more rapidly when teens discontinue DMPA, or wean their baby, than with adult women."

About 57% of survey respondents say they only inform patients that DMPA may diminish bone mass. About 30% use other methods, such as counseling on calcium supplementation and weight-bearing exercise, to encourage bone health.

What is your facility's protocol for late DMPA re-injections? A woman may return after 13 weeks plus a four-week grace period (17 weeks from her last injection), indicate findings from a 2008 study.[4]

New guidance issued by WHO states: "A woman may have an injection of the progestin-only depot-medroxyprogesterone acetate (DMPA) up to four weeks late (17 weeks after the last injection). There is no need for other indications that she is not pregnant. Her next appointment still should be planned for three months. (Previous guidance said that she

could have her DMPA reinjection up to two weeks late.)"[5] The WHO still recommends that women be rescheduled for injections at 13 weeks. It does not recommend that women routinely return at 17 weeks.

References

1. Paschall S, Kaunitz AM. Depo-Provera and skeletal health: A survey of Florida obstetrics and gynecologist physicians. *Contraception* 2008; 78:370-376.

2. ACOG Committee Opinion No. 415: Depot medroxyprogesterone acetate and bone effects. *Obstet Gynecol* 2008; 112:727-730.

3. World Health Organization. *Technical Consultation on the Effects of Hormonal Contraception on Bone Health*. Geneva; 2005. Accessed at www.who.int/reproductive-health/publications/hc_bonehealth/consultation_rpt.pdf.

4. Steiner MJ, Kwok C, Stanback J, et al. Injectable contraception: What should the longest interval be for reinjections? *Contraception* 2008; 77:410-444.

5. World Health Organization Department of Reproductive Health and Research (WHO/RHR) and Johns Hopkins Bloomberg School of Public Health/Center for Communication Programs (CCP), INFO Project. *Family Planning: A Global Handbook for Providers* (2008 update). Baltimore and Geneva: CCP and WHO; 2008. ■

CNE/CME Instructions

Physicians and nurses participate in this continuing medical education/continuing education program by reading the articles, using the provided references for further research, and studying the questions at the end of the issue.

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

After completing this activity with the **June** issue, you must complete the evaluation form provided 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. ■

Teen TOPICS

Get focused on status of teen sexual health

By **Melanie Gold**, DO
Clinical Associate Professor of Pediatrics
University of Pittsburgh School of Medicine
Staff Physician, University of Pittsburgh Student Health Service
and **Kaiyti Duffy**, MPH
Assistant Director of Medical Education
Physicians for Reproductive Choice
New York City

To prevent pregnancy and disease in adolescents, health professionals seek to help teens delay sexual activity and increase condom and contraception use among those who are sexually active. Throughout the 1990s, those efforts appeared successful.

However, in the last several years, these advances have slowed. The most recent Youth Risk Behavior Survey (YRBS) data released in June 2008 reveal that 49% of high school students in 2007 had initiated sexual activity — a percentage that is virtually unchanged since 2001. Since 2003, rates of reported condom use at last intercourse also have remained statistically unchanged (63% in 2003 vs. 62% in 2007). Additionally, between 1997 and 2007, the percentage of high school students who reported being taught about HIV and AIDS in school declined from 92% to 90%. In general, there were no improvements in the percentage of students who reported engaging in sexual risk-taking behaviors (including having had four or more partners and substance use at last sex) between the 2005 and 2007 YRBS data cycles.[1] It still is unknown how these recent trends will affect reproductive health outcomes, but

COMING IN FUTURE MONTHS

- Snapshot: Who's getting HPV shot?
- Check behavioral counseling to prevent STDs
- Status report: HIV vaccines in pipeline
- Increase information on urinary tract infections
- Research eyes menopause symptom treatments

researchers remain vigilant.

In August 2008, the Centers for Diseases Control and Prevention released the newest HIV incidence surveillance rates.[2] In 2006, 27 per 100,000 young people ages 13-29 became infected with HIV. Men who have sex with men (MSM) were disproportionately represented among those rates, which make it even more important to address this subpopulation in prevention efforts. Male circumcision might not be a useful strategy for decreasing rates of infection in that population as was previously believed. In a study published in October 2008, researchers analyzed the strength of the association between male circumcision and HIV infection and other sexually transmitted infections in MSM.[3] The authors concluded that there is insufficient evidence to support the premise that male circumcision protects against HIV infection or other sexually transmitted infections.[3]

To avert negative reproductive health outcomes, providers need to gain a deeper understanding of the confounding factors that increase adolescents' sexual risk level. In a November 2008 study, researchers examined the impact of viewing sexual content on television on a teen's risk of pregnancy.[4] Results indicated that teens who watched high levels of television sexual content (those in the 90th percentile) were twice as likely to experience a pregnancy in the subsequent three years, compared with those who watched lower levels of television (those in the 10th percentile).[4]

In addition to assessing psychosocial factors that contribute to teen pregnancy, it is essential for providers to help youth successfully use contraception. Intrauterine devices (IUDs) can be pivotal in achieving this goal; however, recent research indicates that young women still are unaware of that contraceptive option.[5] Researchers found that only 40% of participants aged 14-24 years had ever heard of the intrauterine device (IUD). Women younger than 18 years old were even less likely to report familiarity with the method. However, after receiving education about IUDs, most young women in study began to view IUDs in a more positive light.[5]

Providers also can address factors that affect lack of contraceptive adherence among adolescents. A study published in 2008 investigated whether immediate initiation of oral contraceptives would lead to improved continuation rates and subsequent decreased pregnancy rates among 539 adolescents ages 12-17.[6] Researchers found that directly observed, immediate initiation of oral contraceptives (OCs), called QuickStart, with adolescents briefly improved continuation, although overall

CNE/CME Questions

After reading *Contraceptive Technology Upd*ate, the participant will be able to:

- **identify** clinical, legal, or scientific issues related to development and provisions of contraceptive technology or other reproductive services.
- **describe** how those issues affect services and patient care.
- **integrate** practical solutions to problems and information into daily practices, according to advice from nationally recognized family planning experts.

1. The efficacy of the Implanon contraceptive implant is comparable to:

A. sterilization.
B. condoms.
C. Evra contraceptive patch.
D. NuvaRing contraceptive vaginal ring.

2. The extended-regimen oral contraceptive LoSeasonique uses which formulation?

A. 0.10 mg levonorgestrel and 0.03 mg of ethinyl estradiol daily for 84 consecutive days, followed by 0.01 mg ethinyl estradiol tablets for seven days
B. 0.10 mg levonorgestrel and 0.02 mg of ethinyl estradiol daily for 84 consecutive days, followed by 0.01 mg ethinyl estradiol tablets for seven days
C. 0.10 mg levonorgestrel and 0.02 mg of ethinyl estradiol daily for 84 consecutive days, followed by 0.02 mg ethinyl estradiol tablets for seven days
D. 0.20 mg levonorgestrel and 0.02 mg of ethinyl estradiol daily for 84 consecutive days, followed by 0.01 mg ethinyl estradiol tablets for seven days

3. The World Health Organization (WHO) eligibility criteria classes use of intrauterine devices in young women ages 20 and younger, as well as for nulliparous women, as a:

A. 4 — a condition that represents an unacceptable health risk if the contraceptive method is used.
B. 3 — a condition in which the theoretical or proven risks usually outweigh the advantages of using the method.
C. 2 — a condition in which the advantages generally outweigh the theoretical or proven risks.
D. 1 — a condition for which there is no restriction for use of the contraceptive method.

4. Guidance issued by WHO regarding the grace period for DMPA reinjections states: "A woman may have an injection of the progestin-only depot-medroxyprogesterone acetate (DMPA) up to ____ weeks late."

A. one
B. two
C. three
D. four

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

continuation rates were discouraging low. Only 26% of adolescents continued OC use at six months, and 45 pregnancies were identified at follow-up.[6]

Health care providers could use this simple contraceptive initiation strategy at the time of an office visit when adolescents wish to start oral contraceptives. However, the low six-month OC continuation rate highlights the need to identify novel and more effective ways of facilitating adolescents' successful initiation and consistent use of contraception.

References

1. Centers for Disease Control and Prevention. Youth Risk Behavior Surveillance — United States, 2007. *MMWR Surveillance Summaries* 2008; 57(SS-4):1-131.

2. Hall HI, Song R, Rhodes P, et al. Estimation of HIV incidence in the United States. *JAMA* 2008; 300:520-529.

3. Millett G, Flores S, Marks G, et al. Circumcision status and risk of HIV and sexually transmitted infections among men who have sex with men. *JAMA* 2008; 300:1,674-1,684.

4. Chandra A, Martino S, Collins R, et al. Does watching sex on television predict teen pregnancy? Findings from a national longitudinal survey of youth. *Pediatrics* 2008; 122:1,047-1,054.

5. Whitaker AK, Johnson LM, Harwood B, et al. Adolescent and young adult women's knowledge of and attitudes toward the intrauterine device. *Contraception* 2008; 78:211-217.

6. Edwards SM, Zieman M, Jones K, et al. Initiation of oral contraceptives — Start now! *J Adolesc Health* 2008; 43:432-436. ■

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.*