

30th
Anniversary

CONTRACEPTIVE TECHNOLOGY

U P D A T E[®]

A Monthly Newsletter for Health Professionals



Reproductive health forecast: Look for more options on the horizon

Look for new pills, patches, rings in the contraceptive pipeline

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When *Contraceptive Technology Update* began publication in 1980, U.S. women had few choices when it came to birth control. Since that time, however, a wide range of options have emerged, including new pills, a female condom, two types of intrauterine contraception, a contraceptive patch, a vaginal ring, and an implant. What new methods can clinicians look to add to their arsenal of family planning options in the upcoming years?

Get ready to see additional options, says **Jeffrey Jensen, MD, MPH**, director of the Women's Health Research Unit of the Center for Women's Health at Oregon Health and Science University in Portland. Jensen is presenting on future methods of contraception in the research pipeline at the upcoming *Contraceptive Technology* conferences in San Francisco and Boston. (*Editor's note: The San Francisco conference is March 24-27, followed by the Boston conference April 14-17. Register at www.contemporaryforums.com.*)

Jensen will report on several options under development, including estradiol-containing oral contraceptives, use of the novel progestogen Nestorone in ring and transdermal applications, a levonorgestrel patch, as well as a new female condom and a new emergency contraceptive.

One of the most pressing needs for women on a global basis is a female-controlled form of prevention against HIV/AIDS. In mid-December 2009,

Contraceptive Technology Update celebrates 30th anniversary

This issue marks the 30th anniversary of *Contraceptive Technology Update*. Gain perspective from a forecast of what's on the horizon for reproductive health, as well as get an overview of current clinician practice, shaped by the responses to the annual Contraception Survey. We hope you enjoy this special edition of *CTU*.

FEBRUARY 2010

VOL. 31, NO. 2 • (pages 13-24)

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the UK-based Microbicides Development Programme (MDP) announced results of its MDP 301 trial, which showed that a potential microbicide candidate, PRO 2000, was safe, but did not reduce women's risk of acquiring sexually transmitted HIV. The trial had enrolled more than 9,000 women in four African countries. Full results of the trial will be submitted for presentation at

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), \$449. 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.)

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Editorial Questions

Questions or comments?
Call **Joy Daugherty Dickinson**
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international conferences in 2010, as well as for publication in a peer-reviewed scientific journal.

In a press statement regarding the trial results, **Jonathan Weber**, FMedSci, FRCP, FRCPATH, co-chair of the MDP Programme Management Board from the Division of Medicine at Imperial College London, said, "It is unfortunate that this microbicide is ineffective at preventing HIV infection, but it's still vital for us as scientists to continue to look for new ways of preventing HIV. There are many research groups exploring different avenues to tackle HIV; it is a slow process, but we are making progress. Now that we know this microbicide is not the answer, we can concentrate on other treatments that might be."

What's next in the microbicide pipeline? Officials at Arlington, VA-based CONRAD, a cooperating agency of United States Agency for International Development, which is involved in reproductive health research, point to ongoing studies of tenofovir gel, being conducted by the Centre for the AIDS Programme of Research in South Africa, and the VOICE (Vagina and Oral Interventions to Control the Epidemic) trial of tenofovir gel and oral antiretrovirals, conducted by the Microbicide Trials Network.

What is next in line for new contraceptives? Look to see new progestins in use in contraceptives. One such progestin is Nestorone, a synthetic progestin similar to the natural hormone progesterone, now under development by the New York City-based Population Council for use in vaginal ring and transdermal delivery systems.

Most advanced in the pipeline is the council's vaginal ring. A thin, flexible product made of silicone rubber, the ring delivers Nestorone and a low dose of ethinyl estradiol. It inhibits ovulation by continuously releasing a low dose of hormones through the vaginal walls and then the bloodstream. Earlier

EXECUTIVE SUMMARY

Get ready to see additional options in contraception for women. New options under development include estradiol-containing oral contraceptives, use of the novel progestogen Nestorone in ring and transdermal applications, a levonorgestrel patch, as well as a new female condom and a new emergency contraceptive.

- The search continues for a female-controlled method for HIV/AIDS prevention.
- Results of a large-scale trial of potential microbicide candidate PRO 2000 show that while the candidate was safe, it did not reduce women's risk of acquiring sexually transmitted HIV.

research indicates the device, used on a regimen of 21 days in and seven days out, provided women safe and effective contraception.¹ The council is preparing to submit data to the Food and Drug Administration (FDA) for review, says **Ruth Merkatz**, RN, PhD, the Population Council's director of clinical development.

Another progestin, dienogest, is being developed in a combination oral contraceptive. Now available in European countries as Qlaira, the estradiol valerate/dienogest pill is manufactured by Bayer Schering Pharma AG. Research presented during the 2008 annual clinical meeting of the American College of Obstetricians and Gynecologists (ACOG) indicates the 4-phasic oral contraceptive is effective, safe, and well tolerated.²

Two patch options using the progestin levonorgestrel are under development by Agile Therapeutics.

One option, a once-weekly, low-dose transdermal contraceptive patch using ethinyl estradiol and levonorgestrel, is moving into Phase III development. The patch is designed to use in a 28-day regimen, with one patch worn once per week for three weeks, with a patch-free week. It can be applied to the abdomen, buttocks, or upper torso. Efficacy, safety, and tolerability data presented at the 2009 ACOG clinical meeting indicate the patch is safe and effective.^{3,4}

The other patch is in clinical development and is designed as a progestin-only patch. Researchers are looking at the progestin-only patch for use in women desiring contraception who are breastfeeding or for women when estrogen-containing contraceptives are contraindicated, inappropriate, or unwanted.

Clinicians now have in hand the second generation of the FC1 Female Condom. The FDA approved the FC2 condom in March 2009. The new condom is less noisy than the original condom, clinicians note. Women might see an additional female condom in the future. The Program for Appropriate Technology in Health (PATH) is pursuing research of a female condom.

The Woman's Condom is a 9-inch thin, pliable plastic pouch that conforms to the shape of the vagina. The Woman's Condom is ready for a combined Phase 2/3 clinical trial, say PATH officials.

U.S. women might see a second dedicated emergency contraceptive as well. The European Commission granted marketing authorization in May 2009 for HRA Pharma's emergency contraceptive, ellaOne (ulipristal acetate). Research indicates the drug, a second-generation progesterone

receptor modulator, is at least as effective as levonorgestrel in preventing pregnancies after unprotected intercourse and has a similar side effect profile.⁵ The company has said it will seek FDA approval for U.S. use.

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The Pill remains popular, despite newer options

You've discussed the latest birth control options with your female patient and touched on information on the contraceptive patch, vaginal ring, implant, and injection, as well as intrauterine contraception, barrier methods, and abstinence. The counseling also includes a discussion about oral contraceptives (OCs). Which method will your patient choose?

Look to the Pill, say respondents to the 2009 *Contraceptive Technology Update* Contraception Survey. More than half (57%) report more than 50% of their patients leave their office with OC prescriptions in hand, up from 2008's 42% figure.

"The NuvaRing [Merck & Co., Whitehouse Station, NJ] is well accepted, but the Pill is still by far the most often-used method," notes **Mary Blasingame**, RNP, APN, a nurse practitioner at Hot Spring County Health Department in Malvern, AR.

For women younger than 30, the Pill is the leading method of birth control, according to

EXECUTIVE SUMMARY

More than half (57%) of respondents to the 2009 *Contraceptive Technology Update* Contraception Survey report more than 50% of their patients leave their office with oral contraceptive prescriptions in hand, up from 2008's 42% figure.

- About 55% of survey respondents say their facilities were offering or planning to offer Implanon, the contraceptive implant, by the end of 2009, slightly up from 2008's 51% figure.
- Many family planning facilities now offer the contraceptive vaginal ring (88%) and the contraceptive patch (83%). Both methods showed slight declines from 2008's 92% and 86% figures.

national data. By age 35, more women rely on sterilization.¹

When it comes to new methods, many clinicians report the addition of the contraceptive implant Implanon (Merck & Co.) to their formularies. About 55% of survey respondents say their facilities were offering or planning to offer the contraceptive implant by the end of 2009, slightly up from 2008's 51% figure.

What are the features of Implanon? Highly effective and rapidly reversible, it requires no daily or coitus-related action. Implanon contains no estrogen, and it can be used during lactation.² Its disadvantages include unscheduled vaginal bleeding, which clinicians might choose to describe as "irregularly irregular" cycles.² To manage bleeding, consider such options as addition of oral estrogen or use of nonsteroidal anti-inflammatory drugs.²

Women do look hard at using Implanon because it is less to deal with, says **Lenore Cappelluti**, MSN, WHNP-BC, a nurse practitioner at Sheppard Air Force Base, Wichita Falls, TX. For success with the method, talk about the bleeding issues during the contraceptive counseling session, Cappelluti advises.

Even with careful counseling, some women might choose to forego the method due to bleeding issues. Many teens become disgusted with Implanon's breakthrough bleeding and ask for removal in six months, notes **Sandra Ransom**, RN, WHNP, a nurse practitioner at Planned Parenthood, Texas Central Region in Austin.

Few women at Wyoming County Health Department in Silver Springs, NY, are willing to use Implanon due to the irregularity and unpredictability of bleeding, and some don't like the idea of something in their arm, says **Donna Gray**,

CNM, NP, a nurse practitioner and certified nurse midwife at the facility.

What about patch, ring?

Many family planning facilities now offer the vaginal ring and the contraceptive patch (Ortho Evra, Ortho Women's Health & Urology; Raritan, NJ). About 83% of 2009 survey respondents say their facilities are offering or plan to offer the Evra contraceptive patch (down slightly from 2008's 86%), with about 88% now offering or planning to offer the NuvaRing (down from 2008's 92% figure.)

The patch delivers 150 mcg of the progestin norelgestromin and 20 mcg of ethinyl estradiol per day. Pharmacokinetic data indicate that the release of ethinyl estradiol (EE) from this first-generation patch is associated with a substantially higher area under the curve for EE than low-dose oral contraceptives.³⁻⁶ Following the addition of this information to the Evra package insert, reports emerged that the method might be associated with a higher risk of thromboembolic disease than oral contraceptives.

Patients might mention hearing television reports about Evra's side effects, but after a discussion, these fears usually are relieved, says Blasingame.

NuvaRing releases 120 mcg of the progestin etonogestrel and 15 mcg of EE daily. NuvaRing may be purchased with a prescription at a drugstore or clinic. It costs about \$15-\$50 a month.

Deborah Mathis, MSN, CRNP, women's health administrative chief at the University of Pennsylvania Student Health Service in Philadelphia, says, "Our patients love the NuvaRing, they just do not like the price. The nurse practitioners in our practice are enthusiastic about NuvaRing and do much teaching, which encourages patients to try it. Once they try it, most are very happy with their choice."

The Pennsylvania student health center is facing the challenge of higher contraceptive costs following the 2005 federal Deficit Reduction Act, which tightened eligibility for nominally priced drugs. While 2009 federal legislation has restored the conditions enabling companies to offer deeply discounted contraception, many companies have not reinstated nominal pricing.

Before the Pennsylvania student health center lost nominal pricing in December 2006, NuvaRing was its leading new start method, with more than 800 rings a month, reports Mathis. Since then, its numbers have significantly decreased, she states.

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Intrauterine method use is moving upward

Look back to results of the 2004 *Contraceptive Technology Update* Contraception Survey: Just 30% of survey respondents said they inserted six or more intrauterine contraceptives in the past year. Now results of the 2009 survey indicate about 54% of survey respondents say they inserted a similar number of devices.

“What I notice in my practice is that more of my patients are proactively indicating an interest in IUD [intrauterine device] use,” comments **Andrew Kaunitz**, MD, professor and associate chair in the Obstetrics And Gynecology Department at the University of Florida College of Medicine — Jacksonville. “When I bring up the option of IUD use, patients appear more aware and receptive than five years ago.”

What has led to the upswing in use? Advertising has led more women to consider the Copper T-380A intrauterine device (ParaGard Copper T 380A IUD; Duramed Pharmaceuticals, Pomona, NY) or the Mirena levonorgestrel intrauterine system (LNG IUS; Bayer HealthCare Pharmaceuticals,

Survey Profile

A total of 105 providers participated in the 2009 *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 60 other medical newsletters and sourcebooks.

About 83% of responses came from nurse practitioners or registered nurses. Physicians represented about 9% of the responses; with health educators/counselors comprising less than 1% of the response group. About 6% listed other professions. About 85% of respondents identified themselves as care providers, with nearly 7% involved in administration and 4% in teaching.

More than half (54%) said they worked in public health facilities, with about 12% employed at private practice settings. About 6% listed student health centers as their place of employment, with about 9% working in hospitals. The remaining 19% reported employment in other settings.

When it comes to location of their employment, about 44% said they worked in a rural location. About 28% said they were employed in an urban facility, while about 26% listed a suburban setting. ■

Wayne, NJ), say clinicians. **Dodie Delaney**, ANP, a nurse practitioner at Fairbanks (AK) Regional Public Health Center, says television advertising for Mirena has led more women to inquire about intrauterine contraception.

“Yes, the IUD demand has been steadily growing,” agrees **Crystal Wilmhoff**, CNP, a nurse practitioner at Planned Parenthood Southwest Ohio Region in Cincinnati. “Women want a long-term method of birth control that is hassle-free.”

Frayda Diamond, CNM, WHNP, a Montgomery Village, MD, clinician serving in private practice and hospital-sponsored clinic settings, says she is seeing more IUD insertions because she is talking about the method more with her patients.

Women have moved past the stigma associated with the Dalkon Shield, says **Pat Jewell**, CNM, a certified nurse midwife at Kalihi-Palama Health Center in Honolulu. The Dalkon Shield has been off the market since 1974, when numerous safety issues led the Food and Drug Administration to call for its removal. Women are now hearing more positive reactions to IUDs, she notes.

Some clinicians might continue to cling to old myths about intrauterine contraception. One of the

EXECUTIVE SUMMARY

Respondents to the 2009 *Contraceptive Technology Update* Contraception Survey report an upswing in use of intrauterine contraception. About 54% of survey respondents said they inserted six or more intrauterine contraceptives in the past year.

- Large-scale studies have disproved the myth that a woman with an intrauterine device in place is at higher risk of developing pelvic inflammatory disease.
- Global eligibility criteria categorizes use of both forms of intrauterine contraception in 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.

most persistent myths is that a woman with an IUD in place is at higher risk of developing pelvic inflammatory disease. Results from large studies, conducted by the World Health Organization (WHO), indicate that this is not the case.¹

Confusion still circles around potential candidates for IUD use. Results of a 2008 survey of 1,246 physicians, nurse practitioners, and physician assistants serving more than 100 contraceptive patients per year in the California state family planning program show that fewer than half of clinicians (46%) consider nulliparous women appropriate candidates for IUD use.² The WHO eligibility criteria categorizes use of the Copper-T and the LNG IUS in young women age 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 The ParaGard IUD is now approved for use for nulliparous women in stable relationships from age 16 through menopause.

In the same 2008 study, only 39% of providers believed that post-abortion women could safely use IUDs.² Evidence indicates there is no difference in complications for immediate vs. delayed insertion after a therapeutic abortion.⁴ Immediate post-abortion device insertion is a safe, practical, and underutilized intervention that can reduce repeat unintended pregnancy and repeat abortion by two-thirds, according to researchers.⁵

If women are considering surgical sterilization, review the reversible option of intrauterine contraception with them. Research indicates that the characteristic most often associated with post-sterilization regret is the youthfulness of the patient; women under 30 are twice as likely to

regret their decision as those who are older than 30 at the time of sterilization.⁶

“For young women who have had children and who are considering sterilization, we talk to them about the fact that there are alternatives to sterilization that are reversible,” says **Lenore Cappelluti**, MSN, WHNP-BC, a nurse practitioner at Sheppard Air Force Base in Wichita Falls, TX. “We discuss both the Mirena and ParaGard.”

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What are the options when it comes to OCs?

When not constrained by your clinic’s formulary, which oral contraceptive (OC) do you pick for a 21-year-old nonsmoking woman? Look to Ortho Tri-Cyclen Lo (Ortho-McNeil Pharmaceutical; Raritan, NJ), which continues its No. 1 spot in

EXECUTIVE SUMMARY

Ortho Tri-Cyclen Lo continues its No. 1 spot in the 2009 *Contraceptive Technology Update* Contraception Survey as the leading nonformulary and formulary pick for a 21-year-old nonsmoking woman.

- For a 42-year-old nonsmoking woman, most respondents selected Alesse, a 20 mcg pill.
- Use of generic oral contraceptives remain strong among family planners. About 68% say they have increased use of generic brands due to budget constraints, down from 2008’s 77% statistic.

the 2009 *Contraceptive Technology Update* Contraception Survey.

Participants again selected the triphasic pill, which contains 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), as the top nonformulary pick for young women, as well as the top formulary pill for this age category. (See graphic, below.) In the nonformulary category for young women, Ortho Tri-Cyclen Lo captured 22% of the 2009 survey responses, followed by Alesse (17%), and Loestrin (13%). In 2009, less than 10% of survey participants named Yasmin or Yaz, both manufactured by Bayer HealthCare Pharmaceuticals, Wayne, NJ, as top choice OCs for young nonsmoking women. In 2008, Yaz was the No. 2 choice in the CTU nonformulary category. This popularity ties in with national marketing data: Yaz was the leading OC dispensed in the United States in 2008, according to data from IMS Health.¹

What might have led to the dip in pill preference? Some women might have heard media reports in 2009 regarding drospirenone, the progestin found in Yaz and Yasmin, and the generic form of Yasmin, Ocella, from Teva Pharmaceuticals USA; North Wales, PA. Findings from two 2009 observational studies indicate the risk of venous thrombosis in women who use OCs differs by type of progestin, estrogen dose, and length of use.^{2,3} However, two earlier, large studies compared safety data from women using Yasmin with other oral contraceptive users. Both of the earlier studies

RESOURCE

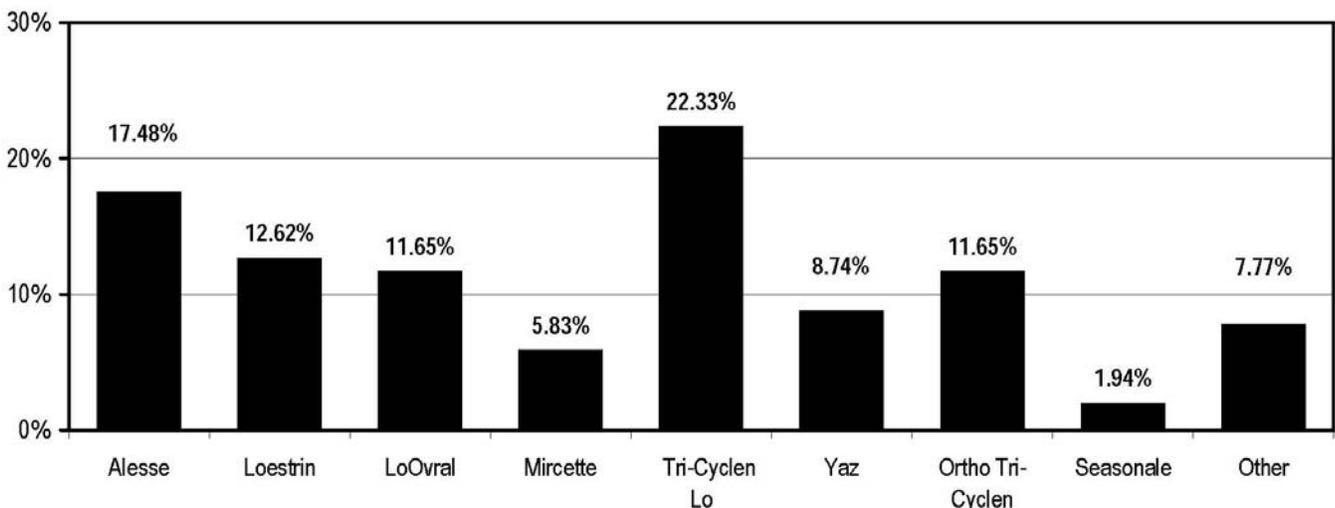
Bridging the Gap Communications offers a Contraceptive Options wall poster in two sizes (11 by 17 inches and 24 by 36 inches) that has color photographs of pill packaging to help identify pills. Cost for the smaller poster is \$5 (minimum order is four), and the larger poster is \$19.95. Shipping and handling charges determined by amount ordered. Go to www.managingcontraception.com and click on "Products" for further order information.

confirm the risk for adverse cardiovascular outcomes for Yasmin does not differ from those associated with the use of oral contraceptives.^{4,5} (See the *Contraceptive Technology Update* article, "Review data on Pill use and thrombosis risk," November 2009, p. 123.)

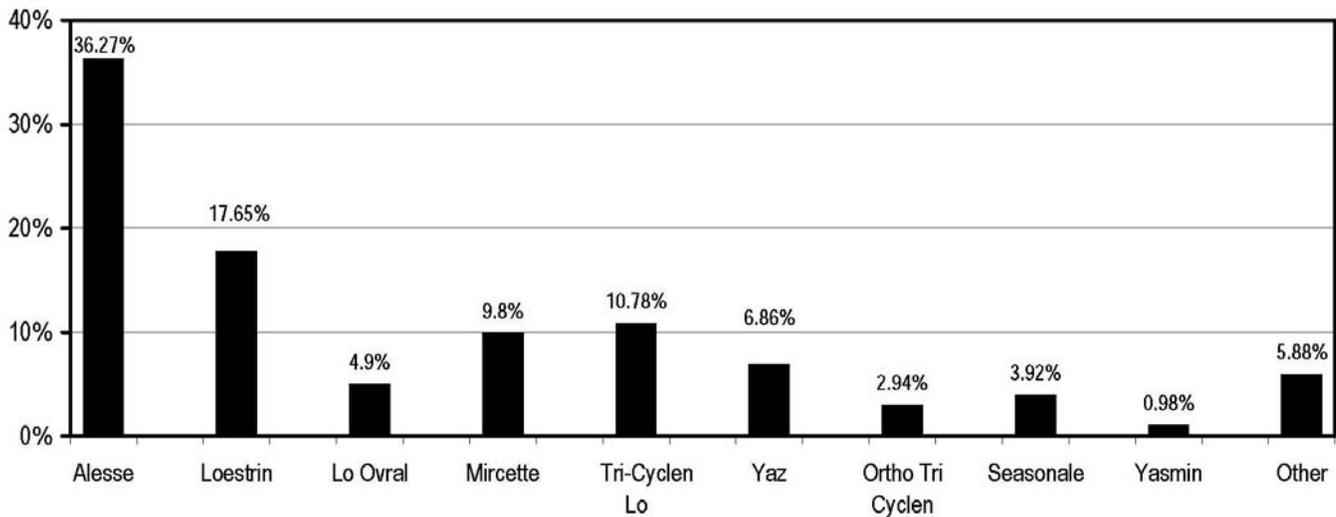
Which pill do clinicians choose for a 42-year-old nonsmoking woman? Alesse (Wyeth Pharmaceuticals; Collegeville, PA) returns to its top spot as the pill of choice (36%) for older women, followed by last year's leader, Loestrin (Teva Pharmaceuticals USA; North Wales, PA). Loestrin captured 18% of the 2009 vote. (See graphic, p. 20.) Alesse, a 20 mcg pill, remains the top selection for women with nausea (43%); its numbers increased from 2008's 33% in this category.

Are your formularies now listing more generic equivalents to traditional branded contraceptives? Use of generic oral contraceptives remain strong

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?



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



among family planners; about 68% say they have increased use of generic brands due to budget constraints, down from 2008's 77% statistic.

As brand-name pill costs have increased, offering generics has allowed providers at Six Rivers Planned Parenthood in Eureka, CA, to keep a broad range of birth control pills available to its clients, says **Karen Albright**, BSN, WHNP-C, lead clinician. Working with varied funders and formularies has been difficult, but clinicians are committed to finding a contraceptive that each client will be happy taking, she says.

"The discontinuation rate is already high in some client populations," notes Albright. "We need to keep [clients] happy."

Tracking the options in branded and generic contraceptives can be challenging, says **Donna Gray**, CNM, NP, a nurse practitioner and certified nurse midwife at Wyoming County Health Department in Silver Springs NY. "It makes it harder for me to be able to identify with the brand the patient is on," she notes. "A lot of times, the pharmacy gives them whatever they have on the shelves, so the patients get confused if they are taking the same pills." (See resource box, p. 19, for a poster that identifies contraceptive options.)

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How to use OCs? Check clinicians' strategies

The next woman in your exam room says she has had cramping, breast tenderness, and headaches during the pill-free placebo week of her oral contraceptive (OC). She is open to having less frequent withdrawal bleeding. What's your next move?

If you are considering extended cycle use of the Pill, you are not alone. About 59% of respondents to the 2009 *Contraceptive Technology Update*

EXECUTIVE SUMMARY

About 59% of respondents to the 2009 *Contraceptive Technology Update* Contraception Survey say they increased use of extended or continuous pill regimens in the last year, down slightly from 2008's 62% percentage.

- The Quick Start method of pill initiation is now gaining hold in family planning clinics. About 87% of respondents say they are using the method for beginning pill users, a jump from 2008's 65% level.
- About 38% of respondents say they would start combined pills in new moms who are not breastfeeding from three weeks to three weeks and six days postpartum. About 14% indicated initiation from one week to two weeks and six days postpartum, and 17% stated pill starts upon hospital discharge.

Contraception Survey say they increased use of extended or continuous pill regimens in the last year, down slightly from 2008's 62% percentage.

Women enjoy having fewer withdrawal bleeds each year and are beginning to understand that it is not biologically natural to have one every month, says **Crystal Wilmhoff**, CNP, a nurse practitioner at Planned Parenthood Southwest Ohio Region in Cincinnati. **(See resource box, right, for information on a patient handout on menstrual suppression.)**

Patients are becoming more knowledgeable about contraceptive options, says **Rakiiba Jackson**, CNM, a certified nurse midwife at the U.S. Virgin Islands Department of Health Family Planning Program in St. Thomas. "I see more interest in the extended regimens, especially as women understand that monthly menses is not necessary for the health of the uterus," says Jackson. "We use available monophasics when patients choose a continuous cycling option."

Extended regimens for OCs is proving popular among service women, reports **Michele Rounds**, CNM, a certified nurse midwife at Womack Army Medical Center at Fort Bragg, NC. "A lot has to do with marketing, but also, our population of active duty service women doesn't want to have periods when they are deployed," says Rounds.

The Quick Start method of pill initiation is now gaining hold in family planning clinics. About 87% of 2009 survey respondents say they are using the method for beginning pill users, a jump from 2008's 65% level.

Quick Start is defined as immediate initiation of

oral contraceptives, the same day as the office visit. Pills may be provided if clinicians are reasonably certain the woman is not pregnant and not in need of emergency contraception. Backup contraception should be advised for seven days.¹ Why prescribe in this manner? It eliminates the gap between decision and implementation, and it results in higher initiation rates, higher continuation rates (short-term), and lower pregnancy rates.¹

Colleen Taylor, NP, a nurse practitioner at Kennebec Valley Community Action Program Family Planning in Waterville, ME, says, "We have been utilizing this for a long time with great success. We always try to start our clients on a method as soon as possible, when there is no contraindication. I believe this averts many unwanted/unintended pregnancies."

Quick Start isn't only for pills. It is being used with the contraceptive injection, depot medroxyprogesterone acetate (Depo-Provera, Pfizer, New York City; Medroxyprogesterone Acetate Injectable Suspension, USP, Teva Pharmaceuticals USA, North Wales, PA).

Depo Quick Start use results in fewer women lost to follow up, and it serves the patients' needs more readily, says **Pat Jewell**, CNM, a certified nurse midwife at Kalihi-Palama Health Center in Honolulu.

After what period of time postpartum do most clinicians recommend pill initiation? About 38% of 2009 survey respondents say they would start combined pills in new moms who are not breastfeeding from three weeks to three weeks and six days postpartum. About 14% indicated initiation from one week to two weeks and six days postpartum, and 17% stated pill starts upon hospital discharge.

When it comes to use of progestin-only pills in breast-feeding women, 29% said they would issue the pills on hospital discharge. A total of 28% said

RESOURCE

The Association of Reproductive Health

Professionals (ARHP) offers several resources on menstrual suppression, including a free clinical fact sheet, "Menstrual Suppression," and a free patient handout in English and Spanish, "Understanding Menstrual Suppression." To access the publications, visit ARHP's web site, www.arhp.org. Click on "Publications & Resources." For the fact sheet, click on "Clinical Fact Sheets" on the left side of the page, and then the title. For the patient handout, click on "Patient Resources" and the title under "Fact Sheets."

they would start progestin-only pills from three weeks to three weeks and six days postpartum, and 14% indicated start dates from one week to two weeks and six days postpartum.

If a woman is breast-feeding, World Health Organization (WHO) criteria indicate that combined oral contraceptives should not be used during the first six to eight weeks postpartum (Category 4) and should be avoided from six weeks to six months postpartum unless other more appropriate methods are not available or acceptable (WHO Category 3).² If a woman is not breast-feeding, WHO criteria rank use of combined pills as a Category 3 before 21 days postpartum, and a Category 1 (use method in any circumstances) 21 days and beyond.

In the case of progestin-only pills, before six

weeks postpartum, breast-feeding women should avoid using such pills unless other more appropriate methods are not available or acceptable (WHO Category 3).² From six weeks to less than six months postpartum in women who are primarily breast-feeding, progestin-only pills are rated as Category 1.² If a woman is not breast-feeding, progestin-only pills can be started immediately.²

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Review ACOG guidance for adolescent screening

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In December 2009, the American College of Obstetricians and Gynecologists (ACOG) released a clinical management guideline recommending changes to cervical cancer screening guidelines.¹ This column will provide some background on human papillomavirus (HPV), the cause of cervical cancer, and ACOG's rationale for their shift in recommendations, with a focus on how this will impact adolescent and young women.

Human papillomavirus (HPV) is estimated to be the most common sexually transmitted disease in

the United States², infecting 50% of sexually active people at some point in their lives.³ Of the 30-40 sexually transmitted strains of HPV, 23 infect the cervix, and half of those are associated with invasive cervical cancer. Though in most cases HPV infection results in benign epithelial proliferations, oncogenic strains may cause malignancy in the presence of cofactors. Research indicates that HPV is the primary cause of cervical cancer and is present in more than 99% of cervical carcinomas.⁴

Like other sexually transmitted infections, HPV disproportionately affects adolescent and young adult women. Though prevalence rates are difficult to determine, 2007 research indicates that 24.5% of females ages 14-19 and 44.8% of women ages 20-24 had HPV.⁵ Among sexually active adolescents, the prevalence was 39.6% and 49.3%, respectively. A 2009 study reported lower prevalence rates of HPV among all young women ages 14-19 (18.3%) and among those who report being sexually active (29.5%).⁶

HPV commonly infects young women shortly after the initiation of sexual activity.^{6,7} Although 90% of HPV infections clear on their own within one to two years, some cases of HPV progress and eventually produce neoplastic changes.⁸ The American Cancer Society⁹, the American College of Obstetricians and Gynecologists (ACOG)¹⁰, and the U.S. Preventive Services Task Force¹¹ issued recommendations to begin cervical cytology screening within three years of coitarche or by age 21.

However, the December 2009 ACOG practice bulletin and clinical management guideline recommends changes to the previous guidance. The new guidelines suggest initiating cervical cancer screening at age 21, regardless of the age of onset of sexual

intercourse. To support this shift, ACOG refers to the low incidence of cervical cancer in younger women and possible adverse effects associated with the follow-up of abnormal cervical cytology results.

The bulletin contends that an average of 14 cases of invasive cancer are identified annually among females ages 15-19, making the incidence rate one to two cases per 1 million female adolescents. Because most HPV infections clear on their own, routine screening increases "anxiety, morbidity, and expense for the test itself and overuse of follow-up procedures."¹

Though recommending a delay in cervical cancer screening, the ACOG practice bulletin underscores the need for counseling all sexually active adolescents about safe sex practices and for testing for sexually transmitted infections annually. In an asymptomatic female adolescent, this testing can be accomplished without the use of a speculum.

In addition to changing when to initiate screening, the new guidelines recommend those women ages 21-29 undergo a Pap smear every two years (revised from previous recommendations that it to be done annually).¹

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(Continued on page 24)

CNE/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 services and patient care;
 - **integrate** practical solutions to problems and information into daily practices, according to advice from nationally recognized family planning experts;
 - **provide** practical information that is evidence-based to help clinicians deliver contraceptives sensitively and effectively.
5. What is the drug in the emergency contraceptive marketed in Europe as ellaOne?
 - A. Ulipristal acetate
 - B. Dienogest
 - C. Levonorgestrel
 - D. Nestorone
 6. According to national statistics, what is the leading method of birth control for women younger than 30?
 - A. Contraceptive vaginal ring
 - B. Combined oral contraceptives
 - C. Transdermal contraceptive
 - D. Contraceptive injection
 7. The World Health Organization medical eligibility criteria uses which category for the Copper-T intrauterine device and the levonorgestrel intrauterine system in women age 20 and younger, as well as for nulliparous women?
 - A. 1. No restriction for the use of the contraceptive method.
 - B. 2. The advantages of using the method generally outweigh the theoretical or proven risks.
 - C. 3. The theoretical or proven risks usually outweigh the advantages of using the method.
 - D. 4. An unacceptable health risk if the contraceptive method is used.
 8. What is the definition of Quick Start for oral contraceptives?
 - A. Women begin taking pills the day following an in-office urine pregnancy test.
 - B. Women begin taking pills on the first day of menses.
 - C. Women begin taking pills the first Sunday of menses.
 - D. Women begin taking pills the same day as the office visit.

Answers: 5. A; 6. B; 7. B; 8. D.

COMING IN FUTURE MONTHS

- Vaccines eyed for women's health issues
- Check point-of-care tests for STD detection
- How to overcome barriers to HPV vaccination
- Do bone drugs lower breast cancer risk?
- Science focuses on barrier contraception

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CNE/CME Instructions

Physicians and nurses participate in this continuing nursing 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. ■

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