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Consulting Editor **Robert A. Hatcher**, MD, MPH, Author **Rebecca Bowers**, Executive Editor **Joy Dickinson**, 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. **Melanie Gold**, guest columnist, discloses that she is on the speaker's bureau for teh Susan Keller Program at Novartis Pharmaceuticals Corp. **Anita Brakman**, guest columnist, has no relationships to disclose.

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New develoment: More women report making the move to LARC

Over 80% report increase in LARC method use

While pills remain a popular birth control choice, more women are selecting long-acting reversible contraception (LARC), say respondents to the 2011 *Contraceptive Technology Update* Contraception Survey. More than 80% of respondents say they have seen an increase in LARC methods.

LARC, or "get it and forget it" methods, include the contraceptive implant (Implanon, now followed by Nexplanon, Merck & Co. of Whitehouse Station, NJ), and the two intrauterine devices (IUDs), the copper T380A (ParaGard IUD, Teva North America, North Wales, PA) and the levonorgestrel intrauterine contraceptive (Mirena, Bayer HealthCare Pharmaceuticals, Wayne, NJ).

Patricia McKenzie, NP, director of women's health at Waianae Comprehensive Health Center, Waianae, HI, reports a "huge" increase in LARC method use following Title X funding specifically for IUD and contraceptive implant purchase. "More

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Set to change: Patch, drospirenone OC labels

Focus to be on increased risks

New labeling is being eyed regarding increased risks for blood clots for the contraceptive patch and combined oral contraceptives (COCs) containing the progestin drospirenone (DRSP) following recommendations from joint votes from two Food and Drug Administration (FDA) committees.

The FDA's Reproductive Health Drugs Advisory Committee and the FDA's Drug Safety and Risk Management Advisory Committee Meeting met together on two consecutive days in December 2011 to consider data on drospirenone pills, then the contraceptive patch. At both meetings, the committees evaluated available safety data on both sets of products and voted on the same two questions:

1. Do you believe that, in the general population of women who desire contra-

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importantly, all providers were precepted in insertion, removal, and problems with LARC, so provider comfort was great," she notes.

The initial results from the St. Louis Contraceptive Choice Program might be inspiring clinicians to do more with LARC methods. The project enrolled 9,256 women in four years, with the last woman enrolled in September 2011. Three-quarters of all women enrolled chose a LARC method; more than 40% of young women ages 14-17 (93 out 148) chose the implant, and more than 40% of young women ages 18-20 (364 out of 510) chose an IUD. Among those who chose a LARC method, 86% were still using their method at one year, compared to 55% of women who chose non-long-acting methods.[1]

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Editor: **Rebecca Bowers.**
Executive Editor: **Joy Daughtery Dickinson** (229) 551-9195 (joy.dickinson@ahcmedia.com).
Production Editor: **Kristen Ramsey.**

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Editorial Questions

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

EXECUTIVE SUMMARY

While pills remain a popular birth control choice, more women are selecting long-acting reversible contraception (LARC), say respondents to the 2011 *Contraceptive Technology Update* Contraception Survey. More than 80% of respondents say they have seen an increase in LARC methods.

- LARC methods include the Implanon contraceptive implant and the two intrauterine devices, the ParaGard copper T380A IUD and the Mirena levonorgestrel intrauterine contraceptive.
- The World Health Organization and the Centers for Disease Control and Prevention consider the IUD an acceptable choice for women who have not had a baby.

Word of mouth ups use

What is leading to the increase in LARC method use? Some clinicians say it's coming from recommendations from current users of such options.

Donna Gray, NP, a nurse practitioner at Wyoming County Health Department in Silver Springs, NY, says, "A lot of clients are hearing from other friends that are using these long-term methods and love them, so now they come in to get one of them. They find out how convenient they are — not to have to do anything on a daily basis or a schedule."

Clinicians at the STD/Family Planning Clinic at the Skagit County Health Department in Mount Vernon, WA, talk about all methods at the initial visit, notes **Cathy Smith**, ARNP, a family nurse practitioner and clinician at the facility. Many patients who hear about LARC methods for the first time are attracted by the idea of three or five years of contraception with minimal effort, she states.

Marlene Carver, NP-C, a nurse practitioner at Graham County Department of Public Health in Robbinsville, NC, agrees. "I think our clients are more educated about all the methods that are available to them now," Carver says. Education, availability, the introduction of Implanon, and decreased fears about IUDs have contributed to the uptick in use at Carver's facility, she states.

Jacquelyne Bodden, RN, MS, WHNP-BC, program director and nurse practitioner at SWCAP (Southwest Wisconsin Community Action Program) Reproductive Health Care Center in Platteville, WI, says, "When you have a couple of patients satisfied with a method, they tell their friends, and then their friends will want to try the method. That is how we finally got women trying Implanon, and now it is our most popular long-term

method."

Smith agrees. Implanon insertion rates at her facility are going up, and most women requesting it have a friend or know someone who has the method and is happy with it, she reports.

Comfort level rises

The myth that nulliparous women cannot use intrauterine contraception might finally be banished. Both the World Health Organization and the Centers for Disease Control and Prevention consider the IUD an acceptable choice for women who have not had a baby.[2,3]

Sharon Carlisle, CNM, lead clinician at Planned Parenthood of Southwest and Central Florida in Tampa, FL, sees her own increased comfort level with insertion in nulliparous women as one of the reasons use of LARC methods has moved up in her practice. Another factor? The realization that IUD insertion takes only slightly more time than an annual well-woman exam and easily can be worked into an already busy schedule, she states.

Celest Horst, LPN, clinic manager at Hastings Family Planning in Hastings, NE, says, "I think what has led to the increase is that now we talk to patients who are nulliparous more about using IUDs. Before, we were only offering it to women who have had children."

Clinicians at Comprecare Clinic in San Jose, CA, have seen an increase in long-term methods such as the IUD with some patients, especially after pregnancy when contraception is desired for a longer length of time, notes **Lisa Friedrichs-Sherard**, NP, an obstetrics and gynecology nurse practitioner at the San Jose facility. A small portion of patients also is interested in trying Implanon, she notes.

Note cost-effectiveness

While LARC methods might have higher initiation costs than pills, they are tops in cost-effectiveness. By five years of use, IUDs and the contraceptive implant are the two most cost-effective methods of reversible contraception.[4]

The Charlotte, NC-based Arch Foundation (www.archfoundation.com) is a not-for-profit foundation established to assist low-income patients who do not have insurance coverage for the Mirena IUD. Patients who meet specific eligibility criteria might be able to receive the Mirena device free of charge. The ParaGard Patient Assistance Program also offers assistance to patients who meet certain eligibility criteria to receive the Copper T IUD free of charge. *(To download a brochure on the program, go to www.paragard.com, and click on "Healthcare Providers," "HCP Resources," and "Patient Assistance Program Brochure.")*

Eighty-five percent of patients at Planned Parenthood of Southwest and Central Florida pay full price for intrauterine contraception, says Carlisle. Thanks to the generosity of the Arch Foundation and the ParaGard Assistance Program, the remaining percentage who cannot afford them are recipients of free Mirenas or ParaGards, she states.

Some women who are losing insurance coverage come in to Wyoming County Health Department in Silver Springs, NY, to have Mirenas inserted so they don't have to worry about getting any birth control when their insurance runs out, says Gray. Most insurance policies will cover long-term methods, says Gray. Patients also like that a LARC method saves them from going to the drug store every month or worrying about refills should they be out of the country.

"Several younger clients have more serious plans for the future, like college, and don't want a child for a while, so they are using these methods," observes Gray.

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OTC access to EC blocked — What's next?

Almost 75% of respondents to the *Contraceptive Technology Update* 2011 Contraception Survey say they provide advance provision of emergency contraception (EC). Such practice might become even more important following Health and Human Services Secretary **Kathleen Sebelius**' decision to overrule the Food and Drug Administration's (FDA) decision to make Plan B One-Step (Teva Pharmaceuticals, Woodcliff Lake, NJ) emergency contraceptive available over the counter for all women of reproductive age. *(See story, p. 17, on readers' views on the importance of advance provision.)*

Plan B One-Step originally was approved in 2009 for use without a prescription for females age 17 and older, and as a prescription-only option for females younger than age 17. Teva Pharmaceuticals submitted a supplemental application in February 2011 to remove the prescription-only status for females younger than age 17, which would

have made the drug nonprescription for all females of child-bearing age.

The FDA's Center for Drug Evaluation and Research reviewed Teva's application. It determined that Plan B One-Step was safe and effective for use in adolescent females and that adolescent females understood the product was not for routine use and would not protect them against sexually transmitted diseases, according to a statement issued by FDA Commissioner **Margaret Hamburg**, MD. The data also supported that adolescent females could use the drug properly without the intervention of a healthcare provider. Based on the agency's review of the data, Hamburg was set to move forward with the agency's approval of the nonprescription status.[1]

However, Sebelius issued a letter on Dec. 7, 2011, registering her disagreement with the FDA's decision, and she stated her authority to execute such a provision under the Federal Food, Drug, and Cosmetic Act. In Sebelius' statement, she said she did not believe enough data were presented to support the application to make Plan B One-Step available over the counter for all girls of reproductive age.[2] Sebelius has since said Teva can submit another application with more testing for label comprehension and use among the girls at younger reproductive ages.[3]

"Because of her disagreement with FDA's determination, the Secretary has directed me to issue a complete response letter, which means that the supplement for nonprescription use in females under the age of 17 is not approved," reads Hamburg's statement.[1]

Advocates on the move

Women's health advocates have voiced displeasure with the action and questioned the rationale for Sebelius' decision.

"Emergency contraception is more effective the sooner it is used, so it is critical that women of all ages are able to get it quickly and easily, without having to jump through unnecessary hoops," said **Sharon Camp**, PhD, president and chief executive officer of the Guttmacher Institute in New York City in a statement following the announcement. "Secretary Sebelius' decision to ignore the scientific evidence and keep Plan B One-Step off the shelves of local grocery stores and pharmacies is a huge disappointment."

The American Academy of Pediatrics in Elk Grove Village, IL, the American College of Obstetricians and Gynecologists in Washington, DC, and the Society of Adolescent Health and Medicine in Deerfield, IL issued a joint statement to denounce the action, and the Washington, DC-based Association of Reproductive Health Professionals (ARHP) called it an "unfortunate case of politics trumping science."[4]

"Emergency contraception is a safe product that is by its nature very time-sensitive," said **Michael Thomas**, MD, ARHP board chair. "ARHP members support removing barriers that limit access to contraceptive methods that can prevent unintended pregnancies and are adamant that policymakers make their policy decisions transparent and based on the best possible science."

Survey profile

The 2011 *Contraceptive Technology Update (CTU)* Contraception Survey monitors contraceptive trends and family planning issues among readers. Results were tallied and analyzed by AHC Media in Atlanta, publisher of *CTU* and more than 60 other medical newsletters and sourcebooks. The survey was mailed in October 2011 to 849 subscribers with 55 responses, for a response rate of 6.4%.

Eighty percent of responses came from nurse practitioners or registered nurses. Physicians represented about 5% of the responses; with health educators/counselors comprising about 2% of the response group. About 13% listed other professions. About 82% of respondents identified themselves as care providers, with some 16% involved in administration, and 2% in other professions.

Almost 70% said they worked in public health facilities, with about 9% listing student health centers or academic institutions as their place of employment, 2% working in hospitals, and 2% in private practice. The remaining percentage reported employment in other settings.

When it comes to location of their employment, about 57% said they worked in a rural area location. About 25% said they were employed in an urban area, while about 19% listed a suburban setting. ■

EXECUTIVE SUMMARY

The emergency contraceptive Plan B One-Step remains a prescription-only product for women under age 17 following Health and Human Services Secretary Kathleen Sebelius' decision to overrule the Food and Drug Administration's (FDA's) decision to make the product available over the counter for all reproductive-age women.

- The FDA had determined that Plan B One-Step was safe and effective for use in adolescent females. The data supported that adolescent females could use the drug properly without the intervention of a healthcare provider, FDA officials said.
- Sebelius registered her disagreement with the FDA decision in a December 2011 letter. In her letter, Sebelius said she did not believe enough data were presented to support the move.

Next stop: courts?

The New York City-based Center for Reproductive Rights is moving to reopen its 2005 lawsuit against the FDA for imposing unnecessary age restrictions on emergency contraceptives. It will seek immediate relief to allow broader access to available drugs. The center also will add Sebelius as a defendant in the reopened case for her role in overruling the FDA's approval of Plan B One-Step.[5]

The center filed its original petition in 2001 on behalf of more than 70 medical and public health organizations. It asked the FDA to grant over-the-counter status to the original two-pill version of Plan B. When the FDA refused to rule on the petition, the center filed a lawsuit in 2005 in federal court. In 2009, the federal court ordered the FDA to reconsider its decision to limit over-the-counter access, The center filed a motion for contempt against the FDA in November 2010 for failing to follow that order. On Dec. 12, 2011, U.S. District Court Judge **Edward Korman** found the contempt motion moot; however, he invited the center to reopen its 2005 lawsuit and agreed that the center could add Secretary Sebelius as a defendant.[5]

"Six years ago, we sued the Bush administration for rejecting science and playing politics with women's health by denying emergency contraception for over-the-counter sale," said **Nancy Northup**, center president in a statement. "We are stunned to see the same behavior from the Obama administration."[6]

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What do clinicians say about advance provision?

In 2004, 54% of respondents to the *Contraceptive Technology Update* Contraception Survey said they provided advance provision of emergency contraception (EC), the first year readers were polled on the subject. Seven years later, that percentage has moved up to 74%.

Now that women age 17 and older can obtain EC pills from pharmacies without a prescription, why are clinicians continuing to write advance prescriptions? In today's challenging economy, many women cannot afford them, say readers.

"We are still prescribing Plan B because our patients cannot afford to buy themselves over the counter," says **Lisa Friedrichs-Sherard**, NP, obstetrics and gynecology nurse practitioner at Comprecare Clinic in San Jose, CA. "The Family PACT (Planning, Access, Care, Treatment) program covers this prescription if we prescribe it."

Jacquelyne Bodden, RN, MS, WHNP-BC, program director and nurse practitioner at SWCAP (Southwest Wisconsin Community Action Program) Reproductive Health Care Center in Platteville, notes a similar circumstance. "We provide EC in our office, and as long as a script is written, it can be covered under Medicaid and some private insurances at lower cost to a patient than buying it over the counter," Bodden explains.

While research indicates that at the population level, advance provision of ECPs has not been demonstrated to be cost-effective,[1] many providers see it as a way to help women guard against unintended pregnancy. "I continue to give patients advance boxes of Plan B in the office and write prescriptions for anyone who needs it," states **Cathy Smith**, ARNP, a family nurse practitioner and clinician in the STD/ Family Planning Clinic at the Skagit County Health Department in Mount Vernon, WA. "It is automatic to supply patients with Plan B as back-up to their chosen method of contraception, unless they decline."

When discussing emergency contraception with patients, remember to counsel on placement of the Copper T380A intrauterine device (ParaGard IUD, Teva North America, North Wales, PA) the most effective way to provide EC. Placement of the IUD within several days of unprotected sex reduces a woman's risk of pregnancy to about 1 in 1,000 and provides her with 10 to 12 years of highly effective, fully reversible contraception if she tolerates her IUD well and wants to continue contraception.[2]

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EXECUTIVE SUMMARY

While combined oral contraceptives remain a leading choice for contraception, other methods are making their mark. About 38% of respondents to the 2011 *Contraceptive Technology Update* Contraception Survey said more than half of their patients use pills, a drop from 2010's 42% level.

- About 42% of respondents say their prescription of extended or continuous regimen pills has increased, while about 49% say their practice has remained steady.
- Three-quarters of 2011 survey respondents say their facilities have stepped up use of generic oral contraceptives in the past year due to tightened budgets.

Readers speak out on status of the Pill

While combined oral contraceptives (OCs) remain a leading choice for contraception, other methods are making their mark. About 38% of respondents to the 2011 *Contraceptive Technology Update* Contraception Survey said more than half of their patients use OCs, a drop from 2010's 42% level.

Sharon Carlisle, CNM, lead clinician at Planned Parenthood of Southwest and Central Florida in Tampa, FL, says the number of patients leaving her office using birth control pills has definitely changed in the last year. More women are choosing the vaginal contraceptive ring (NuvaRing, Merck & Co., Whitehouse Station, NJ), and many more women are selecting intrauterine contraception, Carlisle reports. Results of the 2011 *CTU* survey show that 91% of respondents say their facility is offering NuvaRing, with 78% carrying the contraceptive patch (Ortho Evra, Ortho Women's Health & Urology, Raritan, NJ).

About 42% of respondents say their prescription of extended or continuous regimen pills has increased, while about 49% say their practice has remained steady.

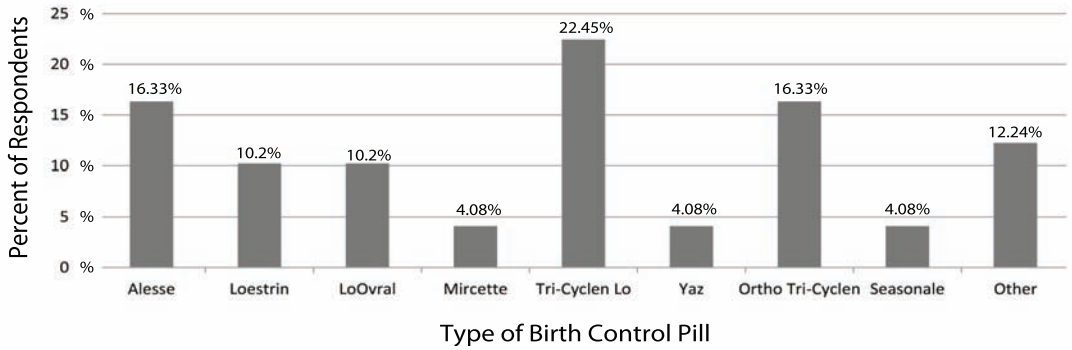
Patricia McKenzie, NP, director of women's health at Waianae Comprehensive Health Center in Waianae, HI, says her prescribing of such regimen pills has increased only slightly as most insurance companies and Medicaid do not cover continuous use. Medicaid patients can only pick up one pack of pills per 28 days, she states.

There are five 30-mcg dedicated extended regimen pills: Seasonale, Seasonique, and Jolessa, all from Teva Pharmaceuticals, North Wales, PA, and Quasense and Amethia from Watson Pharmaceuticals, Morristown, NJ. LoSeasonique from Teva Pharmaceuticals is a 20-mcg extended regimen pill. The Food and Drug Administration issued approval in December 2011 to Watson's Amethia Lo as a generic equivalent of LoSeasonique, with approval given in October 2011 to Baltimore-based Lupin Pharmaceuticals' generic version of the same pill. Two options are available in dedicated continuous pills: Lybrel, a 20-mcg pill from Wyeth Pharmaceuticals of Philadelphia, and Amethyst, its generic equivalent from Watson, launched in 2011.

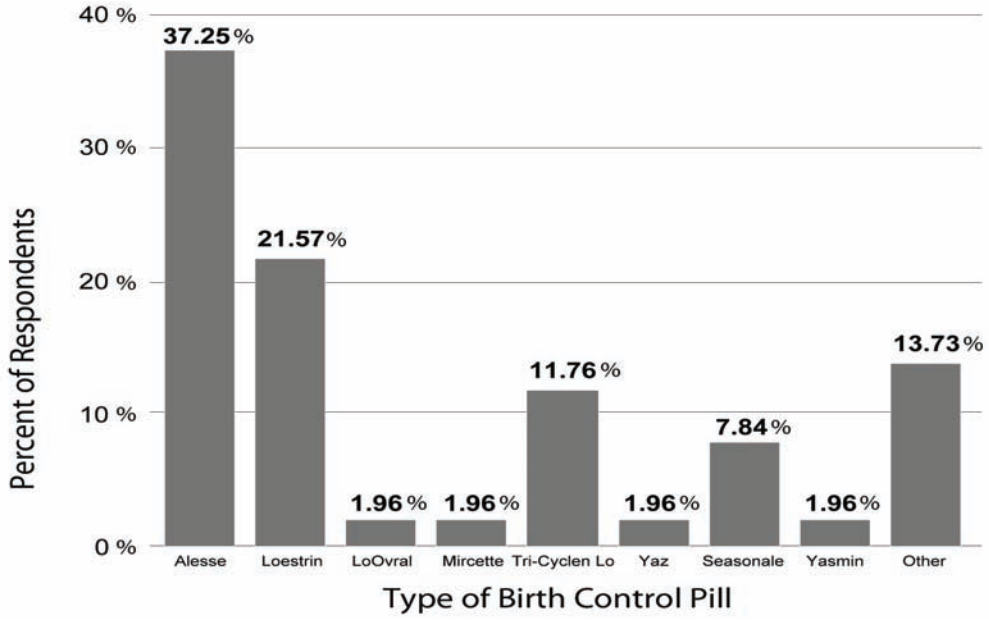
Which pill to use?

Ortho Tri-Cyclen Lo (Ortho-McNeil Pharmaceutical; Raritan, NJ) continues as the no. 1 choice as the top nonformulary pill for young women, a spot it has maintained since 2008. *(See graphic on p. 18.)* However, when formulary rules dictate which pill to use for this age category, respondents to the 2011 survey named Loestrin from

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 non-smoking woman who wants to use combined pills?



Teva Pharmaceuticals. Ortho Tri-Cyclen, a 35-micg phasic pill from Ortho-McNeil Pharmaceutical, was the 2010 formulary leader. Alesse (37%) remains in its top spot as the pill of choice for older women, followed by last year's leader, Loestrin (22%).

Which pill do clinicians choose when it comes to prescribing an OC for a 42-year-old patient? About 40% of patients named Alesse, a 20-mcg pill from Wyeth, which kept it in its top spot from last year. *(See graphic above.)*

Alesse also continues as the leading option for women who have experienced nausea when using previous pills, with 49% naming it as the top pill in the 2011 survey. The pill has been named the top choice in this category since 1999.

Generics gain ground

Budget constraints are pinching the pocketbooks at many family planning facilities. Three-quarters of 2011 survey respondents say their facilities have stepped up use of generic oral contraceptives in the past year due to tightened budgets. No doubt use of generics has risen; the price differential between generic and brand-name products can be as much as 70%.[1]

"Generics have helped to keep our costs down and still be able to provide on-site OCs for our most common types of pills" says **Donna Gray**, NP, a nurse practitioner at Wyoming County Health Department in Silver Springs, NY. "It does make it hard to keep updating our inventory with different pills every time I order."

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How do you use OCs? Clinicians share tips

A woman comes into your office and says she wants to use an oral contraceptive (OC) for birth control. After confirming that she is a good candidate for the method, when do you start her on her first pack of pills?

Almost all (93%) of respondents to the 2011 *Contraceptive Technology Update* Contraception Survey say they use the Quick Start method of pill initiation, up from 2010's 87% figure. Also known as the Same-Day Start, the practice entails having the woman take the first pill in her pill pack on the day of her visit as long as it is reasonably certain that she is not pregnant and not in need of emergency contraception.[1]

Quick Start is preferred because other combined oral contraceptive initial protocols generally have a time gap between the time of prescription and the time the patient begins taking it. Research indicates as many as 25% of women who use other protocols fail to take the pills as instructed because they conceive in the interim, fail to fill the prescription, or worry about taking the Pill.[2,3]

Quick Start was accepted easily by staff at the Graham

EXECUTIVE SUMMARY

Almost all (93%) of respondents to the 2011 *Contraceptive Technology Update* Contraception Survey say they use the Quick Start method of pill initiation, up from 2010's 87% figure. Quick Start entails having the woman take the first pill in her pill pack on the day of her visit as long as it is reasonably certain that she is not pregnant and not in need of emergency contraception.

- Clinicians continue to hold the line when it comes to prescribing combined pills to older women (40 and above) who smoke 10 cigarettes a day.
- Almost 98% said they would withhold pills from such patients, moving up from 2010's 96% statistic.

County Department of Public Health in Robbinsville, NC, says **Marlene Carver**, NP-C, a nurse practitioner at the facility. "We had a nursing staff meeting and reviewed all the methods using Quick Start and rewrote our policies and attached them to our standing orders," says Carver. "Staff are more knowledgeable about how to use the Quick Start protocol."

Donna Gray, NP, a nurse practitioner at Wyoming County Health Department in Silver Springs, NY, says she hopes that Quick Start is decreasing unwanted pregnancies. "If someone comes in for a pregnancy test and it is negative, I can then start them on a method, and they will return for preventative care and continue on their method," notes Gray. "If a new client comes in, I have been starting them on their method at that appointment after I try and make sure they couldn't be pregnant already, and I also instruct them that even if they are pregnant, the method they start will not hurt a pregnancy."

This practice also gives patients time to bring in their information to get started on insurance to cover their method at the drug store, which saves the health department's inventory for those who need it, says Gray.

No OCs for older smokers

Clinicians continue to hold the line when it comes to prescribing combined pills to older women (40 and above) who smoke 10 cigarettes a day. Almost 98% said they would withhold OCs from such patients, moving up from 2010's 96% statistic. Readers were almost as emphatic when it comes to women smokers ages 35-39; about 90% said they would not prescribe combined pills to those who smoke 10 cigarettes a day.

The U.S. Medical Eligibility Guidelines For Contraceptive Use rank combined hormonal contraceptive use for women age 35 or older who smoke less than 15 cigarettes per day as a "3" — a condition for which the theoretical or proven risks usually outweigh the advantages of using the method. For women in the same age range who smoke 15 cigarettes or more per day, the guidelines rank combined hormonal contraceptive use as a "4" — where the condition represents an unacceptable health risk if the method is used. Use of combined hormonal contraceptives for smokers under age 35 is listed as a "2" — a condition for which the advantages of using the method generally outweigh the theoretical or proven risks.[4]

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Set to change

Continued from cover

ception, the benefits of the [product] for prevention of pregnancy outweigh the risks?

2. Do you believe the current [product] label adequately reflects the risk/benefit profile for the product?

In voting on whether the current drospirenone labels adequately reflect the risk/benefit profile for these products, 21 of the committee members voted "no," with five voting "yes." The two committees voted 15-11 that the benefits of drospirenone pills outweigh the risks.

In a 20 to 3 vote, with one abstention, the two committees found the current label for Ortho Evra inadequately reflects the risks women face by using it. The two committees voted 19 to 5 that the benefits of the contraceptive patch outweigh the risks.

Recommendations from the advisory committees will be considered by the FDA agency in making its final decisions.

Drospirenone is the progestin contained in the Yaz/Yasmin line of oral contraceptives from Bayer HealthCare Pharmaceuticals of Wayne, NJ, Two other Bayer products also contain drospirenone: Beyaz and Safyral. Drospirenone also is found in generic equivalents: North Wales, PA-based Teva Pharmaceuticals' Ocella and Gianvi; Princeton, NJ-based Sandoz's Loryna and Syeda; and Morristown, NJ-based Watson Pharmaceuticals' Zarah. Watson received FDA approval in November 2011 for Vestura, a generic equivalent to Yaz.

EXECUTIVE SUMMARY

New labeling is being eyed regarding increased risks for blood clots for the contraceptive patch and combined oral contraceptives containing the progestin drospirenone following recommendations from joint votes from two Food and Drug Administration (FDA) committees.

- After reviewing safety data for both product classes, the FDA's Reproductive Health Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee Meeting voted that the benefits outweighed the risks for both product classes.
- The groups said that both sets need new labeling to adequately reflect their risk/benefit profiles.

In the Dec. 8 hearing, the committees reviewed all available data regarding use of drospirenone pills, including three studies published in 2011, as well as an FDA-funded study.[1-3] "None of the studies to date provides a definitive answer as to the safety of DRSP-containing COCs with regard to the risks of venous thrombotic events [VTE] and arterial thrombotic event [ATE]," states background material prepared by the FDA and presented at the Dec. 8 meeting.[4] "The entire body of studies provides conflicting evidence that cannot easily be reconciled by consideration of any single difference among studies."

The FDA in April 2010 approved labeling changes in Yasmin and Yaz to discuss VTE risk in light of two prospective studies[5-6] and two epidemiologic studies.[7-8] In March 2011, the agency approved a labeling change for Yaz stating that the risk for VTE is greatest in the first six months of use and is present after initially starting a COC or restarting (following a four-week or greater pill-free interval) the same or a different COC.

How should clinicians interpret the data? Keep in mind that retrospective studies that look for rare events have many limitations, says **Susan Wysocki**, WHNP-BC, FAANP, a Washington, DC-based women's health expert and former president of National Association of Nurse Practitioners in Women's Health. Even though there is an increasing number of studies that have shown a heightened risk of VTE with drospirenone over levonorgestrel OCs, that does not speak to the quality of the studies, she notes.

"We know that events such as VTE tend to occur in the first year of use," says Wysocki. "Therefore, it is particularly important for women who have been doing well on these pills not to panic and stop taking these pills."

According to the chapter on combined oral contraceptives in the newly released 20th revised edition of *Contraceptive Technology*, "though the relative risk of thrombosis is increased with COC use, most COC users face a low absolute risk of thrombosis because VTE is a rare event in healthy young women."[9]

Label change for Evra

Since the contraceptive patch (Ortho Evra, Ortho Women's Health & Urology, Raritan, NJ) was approved in 2001, its labeling has been edited to address issues relating to the risk of VTE and exposure to contraceptive hormones seen with Ortho Evra as compared to certain COCs. In March 2011, the boxed warning was edited to include information about the potential risk of VTE and the pharmacokinetics profile of ethinyl estradiol associated with the use of Ortho Evra, which made it more prominent to healthcare providers.

Background material prepared for the Dec. 9, 2011, joint committee meeting offers a similar conclusion as stated in material for DRSP pills.[10]

"None of the studies to date provides a definitive answer as to the safety of Ortho Evra [patch] with regard to thrombotic and thromboembolic events," the material states. "The entire body of studies provides conflicting evidence that cannot be easily reconciled by considering any single difference among studies."

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Teen TOPICS

Teen OC use is more than contraception

By **Anita Brakman**, MS
Director of Education, Research & Training
Physicians for Reproductive Choice and Health
New York City

Melanie Gold, DO, FAAP, FACOP
Clinical Professor of Pediatrics
University of Pittsburgh School of Medicine
Staff Physician
University of Pittsburgh Student Health Service

Combination oral contraceptives (OCs) are the most common form of hormonal contraception used by sexually active females ages 15-19, with 56% of this group reporting ever having used OCs, and 30% reporting use at last intercourse.[1] New research from the Guttmacher Institute in New York City found that a significant percentage of women report they use OCs for their noncontraceptive benefits rather than for pregnancy prevention. This group includes many young women and adolescents, some of whom have never had sexual intercourse and some of whom are not currently sexually active.

While pregnancy prevention remains the primary reason for taking OCs among the 18% of women who report current use, 14% of current users (1.5 million women) report they take the medications solely for noncontraceptive reasons. More than half (58%) of OC current users report using them for more than one reason, indicating most users consider the noncontraceptive benefits of OCs to be at least part of the reason for use. Additionally, 9% of all OC current users report they are not currently sexually active (within the past three months). Most (86%) of this group report noncontraceptive reasons for using OCs.[2]

Nine percent of virginal women report using OCs in the past three months. Of this group, 95% do so for noncontraceptive reasons. Most virginal women are teens, and 8% of virginal 15- to 19-year-old female adolescents report that they have taken OCs in the past three months. The Guttmacher study found the following noncontraceptive reasons for using OCs: 54% use OCs for menstrual pain, 33% for menstrual regulation, 30% for reducing acne, and nearly 20% for other reasons.[2]

Menstrual issues are key

Early and middle female adolescents are a population that is more likely to use OCs for noncontraceptive reasons because they experience high rates of menstrual-related health issues and might be less likely to be sexually active compared to older women. Eighty-two percent of 15- to 19-year-old current OC users report using OCs for reasons beyond contraception, and 33% report using OCs solely for noncontraceptive reasons. This number is in contrast to the pattern of use reported by older women; 90% of current OC users over age 20 report pregnancy prevention as the primary motivation for use.[2]

Because menstrual irregularities and disorders are more common during adolescence, it follows that many female adolescents use OCs to provide relief for dysmenorrhea, menorrhagia, oligomenorrhea, dysfunctional uterine bleeding, or other menstrual-related conditions. In some studies, up to 91% of female adolescents report painful periods.[3,4]

Women who wish to avoid menstrual-related health problems can eliminate the hormone-free interval of OCs to achieve continuous or extended cycling through a dedicated product or by altering the 21/7 or 24/4 regimens of regular OCs to provide relief from painful periods, cramping, heavy bleeding, or other symptoms that accompany periods such as migraines.[5]

OCs also protect against ectopic pregnancy; pelvic inflammatory disease; and ovarian, endometrial and colorectal cancer; and they might improve bone health in some women.[6] High-dose OCs might protect against benign breast disease. OCs can also reduce anemia and treat dysfunctional uterine bleeding.[6] Some OCs can also decrease premenstrual syndrome.[7]

The contraceptive patch and vaginal ring have similar components, properties, and side effects to OCs. Thus, women who desire relief from menstrual disorders or

irregularities but prefer a method without a daily regimen might prefer to obtain noncontraceptive benefits from these hormonal methods.

The levonorgestrel intrauterine system reduces blood loss and anemia as well as cramping. It can be used to treat endometriosis or menorrhagia.[7] Progestin-only methods can be used while breastfeeding, which may be beneficial for adolescent mothers wishing to delay subsequent pregnancies.[8] The injectable contraceptive depot medroxyprogesterone acetate can reduce seizure risk in women with epilepsy, reduces sickle cell crises in women with sickle cell anemia, and might protect against ovarian and endometrial cancers.[8]

Noncontraceptive benefits such as cancer prevention or even diminished menstrual symptoms also might provide additional motivation for female adolescents to continue and adhere to a method. This motivation can be especially useful for teens who might have difficulty tolerating side effects and adhering to a method requiring daily maintenance.

All of this data provides insight into the noncontraceptive benefits that young women seek from contraceptives even when they are have never been or are not currently sexually active. In caring for female adolescents who use OCs or request to start any contraceptive method, this information highlights the necessity of taking a family, medical, dermatologic, menstrual, and sexual history to fully understand a patient's needs. This data also might be helpful for alternative coding when a religious insurance plan will not cover contraception for pregnancy prevention, but it might allow coverage for medical indications.

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COMING IN FUTURE MONTHS

- Contraceptive counseling tips for women with comorbidities
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CNE/CME QUESTIONS

1. By five years of use, which two methods are the most cost-effective methods of reversible contraception?
   A. Intrauterine contraceptives and the contraceptive implant
   B. Intrauterine contraceptives and combined oral contraceptives
   C. Intrauterine contraceptives and the contraceptive injection
   D. Intrauterine contraceptives and progestin-only pills

2. What did two Food and Drug Administration committees vote in December 2011 regarding combined oral contraceptives containing drospirenone and the contraceptive patch?
   A. Recommendation to remove both classes of product from the market
   B. Recommendation to remove drospirenone pills from the market
   C. Recommendation to remove the contraceptive patch from the market
   D. Recommendation for new labeling to adequately reflect both classes of product risk/benefit profiles

3. What is the most effective way to provide emergency contraception?
   A. Levonorgestrel pills
   B. Copper T 380A intrauterine device
   C. Ulipristal acetate
   D. Danazol

4. The U.S. Medical Eligibility Guidelines For Contraceptive Use rank combined hormonal contraceptive use for women age 35 or older who smoke less than 15 cigarettes per day as
   A. "1" — a condition for which there is no restriction for use of the method.
   B. "2" — a condition for which the advantages of using the method usually outweigh the theoretical or proven risks.
   C. "3" — a condition for which the theoretical or proven risks usually outweigh the advantages of using the method.
   D. "4" — a condition that represents an unacceptable health risk if the method is used.

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CNE/CME OBJECTIVES

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. ■

CNE/CME INSTRUCTIONS

To earn credit for this activity, please follow these instructions.

1. Read and study the activity, using the provided references for further research.
2. Log on to www.cmecity.com to take a post-test; tests can be taken after each issue or collectively at the end of the semester. First-time users will have to register on the site using the 8-digit subscriber number printed on their mailing label, invoice or renewal notice.
3. Pass the online tests with a score of 100%; you will be allowed to answer the questions as many times as needed to achieve a score of 100%.
4. After successfully completing the last test of the semester, your browser will be automatically directed to the activity evaluation form, which you will submit online.
5. Once the completed evaluation is received, a credit letter will be e-mailed to you instantly. ■

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 healthcare professionals.