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IN THIS ISSUE

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New methods make inroads on Pill's position, but OCs remain popular

Patch use edges down, ring use increases, and over half offer implant

As 2007 draws to a close, review the changes at your family planning facility. How has the mix of contraceptive options changed throughout the year?

For more than half (53%) of the 2007 *Contraceptive Technology Update* Contraception Survey respondents, 2007 marked the first year of availability of the contraceptive implant (Implanon, Organon; Roseland, NJ).

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.

Implanon represents an extremely effective, convenient, and safe method of contraception, observes **Andrew Kaunitz**, MD, professor and

EXECUTIVE SUMMARY

New methods continue to be added to U.S. family planning clinics, according to results of the 2007 Contraception Survey.

- More than 90% of responses indicate the availability of NuvaRing, the contraceptive vaginal ring. The number reflects an almost 10% increase from the previous year.
- About 84% of survey participants said their facility offered the Evra contraceptive patch, compared to about 88% in 2006. About 93% of participants indicated the method was in use in 2005.
- More than half (53%) of survey participants say they now offer Implanon, the contraceptive implant.

associate chair in the Obstetrics and Gynecology Department at the University of Florida College of Medicine — Jacksonville. "The insertions I have performed have proceeded quickly and smoothly, and all recipients are continuing to use their implants," he notes. "Unfortunately, few women seem to be aware of this method currently, and insurance coverage is iffy."

Kaunitz says he is looking forward to the manufacturer sponsoring direct-to-consumer (DTC) advertising regarding implantable contraception to increase awareness among women. Organon is now evaluating a DTC campaign for Implanon, but has not yet set a timeline for implementation, says **Jake Knorr**, company spokesman. Kaunitz also looks to more health plans to cover the birth control method. (Implanon training will be offered at the 2008 *Contraceptive Technology* conference in Boston March 6-8 and in San Francisco April 3-5. Registration information is available at the Contemporary Forums web site, www.contemporaryforums.com.)

More women select ring

The contraceptive vaginal ring (NuvaRing, Organon; West Orange, NJ) continues to gain ground among women since its FDA approval in 2001. More than 90% of 2007 survey participants say they now offer NuvaRing, up from 80% in 2005.

The NuvaRing is popular with college-age and older women, reports **Lynn Fair**, WHNP, a nurse practitioner at Columbia/Boone (MO) County Health Department.

Some survey participants say the need for vaginal insertion makes some women shy away from NuvaRing use. Reassurance is needed to help women understand the ease of NuvaRing, says **Bryna Harwood**, MD, assistant professor of obstetrics and gynecology and director of family planning at the University of Illinois at Chicago. Harwood reviewed patient guidelines for use of the contraceptive ring and patch at the 2007 *Contraceptive Technology* conference in Washington, DC.[1]

When counseling women, instruct women to insert the ring into the vagina as far as possible, she says. Reassure women that the ring can't get lost or "misplaced," Harwood notes.

Patch use declines

Use of the contraceptive patch (Ortho Evra, Ortho-McNeil Pharmaceutical; Raritan, NJ) dropped in 2007. About 84% of survey participants said their facility offered the method, compared to about 88% in 2006. About 93% of participants indicated the method was in use in 2005. What has led to the decrease?

The FDA revised Ortho Evra's labeling in November 2005 with a bolded warning that the patch exposes women to higher total amounts of

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Editorial Questions

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

Editor: **Rebecca Bowers**.
Senior Vice President/Group Publisher: **Brenda Mooney** (404) 262-5403 (brenda.mooney@ahcmedia.com).
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**.

estrogen than a typical birth control pill containing 35 mcg estrogen. **(Review the *CTU* article, "FDA revises Evra safety labeling due to increased estrogen levels," January 2006, p. 1.)**

While there has been positive response to the patch and ring, neither method is used as much as pills. Cost is an important factor, says **Tia Hansuld**, clinic director and nurse practitioner at the Casper-Natrona County Health Department in Casper, WY.

Quick Start an option?

How do you initiate use of the contraceptive ring and patch? Research has looked at immediate initiation of combined hormonal methods.

For the vaginal ring, researchers looked at 201 women who used immediate start of the ring or low-dose oral contraceptives. Researchers charted user satisfaction and method continuation three months after ring or pill initiation. Among the study participants with follow-up data, 61% of ring users and 34% of pill users were very satisfied with their methods. About 80% of women using the ring chose to continue with the ring following the trial, while 59% of pill users chose to continue with the Pill.[2] **(See "New research emerges on NuvaRing contraceptive," *CTU*, August 2006, p. 88.)**

In a different study with the contraceptive patch, 60 women were evenly randomized to initiate use of the method by Quick Start (Group 1) or on the first day of their next menses (Group 2). Investigators used telephone contact at six weeks to ensure that the second cycle had been initiated. A single follow-up visit was scheduled after completion of the third patch cycle. Continuation rates for Groups 1 and 2 were 97% and 93%, respectively, into the second cycle, and 93% and 90%, respectively, into the third cycle. About half of the subjects planned to continue using the patch after the study.[3] **(See "'Quick Start' approach eyed for DMPA and patch," *CTU*, May 2006, p. 53.)**

Anita Nelson, MD, professor in the Obstetrics and Gynecology Department at the University of California in Los Angeles (UCLA) and medical director of the women's health care programs at Harbor — UCLA Medical Center in Torrance, describes the Quick Start method for pill initiation in *Contraceptive Technology*.[4] She also is an advocate of the approach for initiating the contraceptive ring, patch, and injection. Nelson advises nine days of backup contraception when the Quick Start method is used for the patch, and seven days of backup contraception for the ring.

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What pills do you offer? Readers share options

A quick check of the charts shows the next patient is a 21-year-old nonsmoking women. If she is a candidate for oral contraceptives (OCs),

Survey Profile

A total of 166 providers participated in the 2007 *Contraceptive Technology Update* Contraception Survey, which monitors contraceptive trends and family planning issues among readers. Results were tallied and analyzed by AHC Media in Atlanta, which publishes *CTU* and more than 60 other medical newsletters and sourcebooks, as well as produces audio conferences.

About 54% of responses came from nurse practitioners or registered nurses. Physicians represented about 41% of the responses, with health educators/counselors representing about 1% of the response group. About 4% listed other professions. About 85% of respondents identified themselves as care providers, with nearly 10% involved in administration.

Some 38% of the respondents said they were employed at public health facilities, with about 32% working in private practice settings. About 13% listed student health centers as their place of employment, with some 7% working in hospitals. The remaining 10% reported employment in other settings.

When it comes to location of their employment, about 40% said they worked in an urban setting. About 33% said they were employed in a rural facility, while about 24% listed a suburban location. ■

EXECUTIVE SUMMARY

The leading nonformulary pill choice for young women in the 2007 Contraception Survey is Yasmin, a monophasic pill containing 3 mg drospirenone and 0.030 mg ethinyl estradiol. The pill held the leading spot for the second year in a row.

- Almost 65% of survey participants say their facilities have increased the use of generic oral contraceptives due to budget constraints.
- While the contraceptive patch and vaginal ring have gained popularity with family planning patients, the Pill still holds a top spot. About 42% of 2007 survey participants report more than half of their patients leave the office with an oral contraceptive prescription in hand.

which one will you choose? Participants in the 2007 *Contraceptive Technology Update* Contraception Survey say their No. 1 oral contraceptive (OC) of choice is Yasmin, a monophasic pill containing 3 mg drospirenone and 0.030 mg ethinyl estradiol from Berlex, the U.S. affiliate of Bayer HealthCare Pharmaceuticals in Wayne, NJ.

Yasmin leads the nonformulary category for the second year in a row. It is followed by Ortho Tri-Cyclen Lo (Ortho-McNeil Pharmaceutical; Raritan, NJ) and Alesse, from Wyeth Pharmaceuticals; Collegeville, PA. **(See the graphic, below, on top nonformulary pills.)** Ortho Tri-Cyclen Lo is a triphasic pill that 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). Alesse is a monophasic 20-mcg pill.

Joe Childress, MD, a physician at the Institute for Women's Health in San Antonio, likes the progestin in Yasmin. The progestin, drospirenone, is a spironolactone analogue with antimineralocorticoid properties.

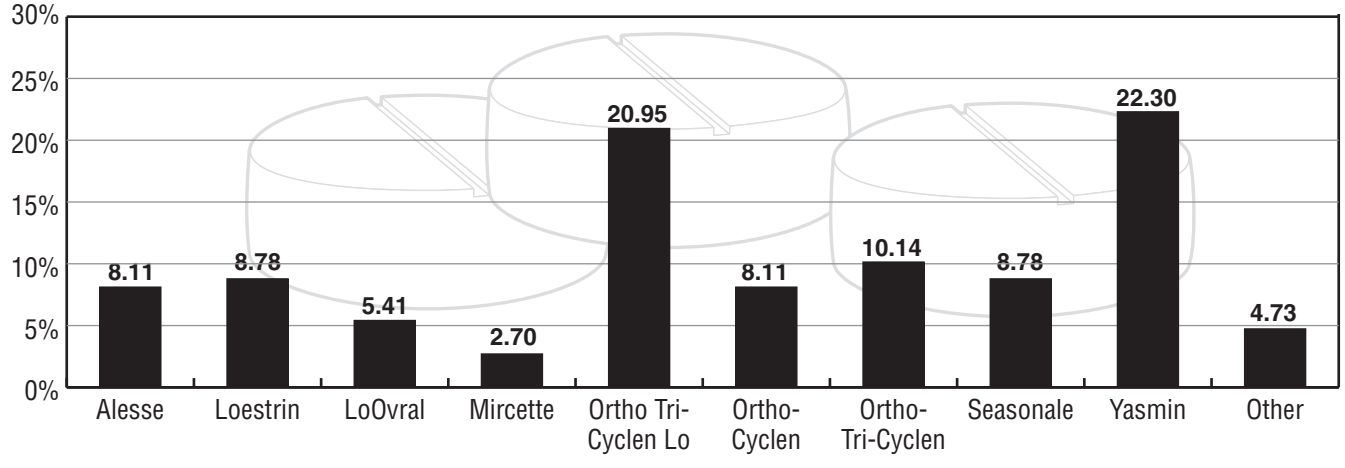
When bound by formulary, about 32% of 2006 survey participants say they write prescriptions for Ortho Tri-Cyclen Lo for young nonsmoking women. Alesse and Yasmin were other leading choices in the 2007 formulary category.

More generics in use

The year 2007 saw the addition of the first combination contraceptive pill, Lybrel from Wyeth Pharmaceuticals of Collegeville, PA. The drug is designed to be taken 365 days a year, without a placebo phase or pill-free interval. **(Read more about the drug approval; see the article "Continuous use oral contraceptive receives FDA regulatory approval," July 2007, p. 73.)** Also, the Food and Drug Administration gave approval to a separate indication for the treatment of acne to Yaz, a 20 mcg ethinyl estradiol/3 mg drospirenone pill from Berlex. ***(CTU* reported on the news in "Add another 'acne pill' to list of current OCs," April 2007, p. 41.)**

However, the addition of new pills to the market may not signal the expansion of your family planning facility's formulary. Almost 65% of participants in the 2007 *CTU* Contraception Survey say their facilities have increased the use

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?



of generic oral contraceptives due to budget constraints. While U.S. clinicians have been able to choose from a variety of generic OCs for a number of years, Canadian clinicians have just seen approval of the first generic birth control pill in the form of Portia, a pill with 0.15 mg levonorgestrel and 0.03 mg ethinyl estradiol from Barr Laboratories of Pomona, NY.

Affordable options are a must

Affordable options are a must, says **Tricia Trow Weaver**, PA-C, a physician's assistant at the University of South Florida Student Health Services Women's Clinic in Tampa. When possible, Weaver writes a prescription for a branded product when the patient has insurance with an affordable copay. Students often prefer to purchase what the student center has on formulary, she notes.

While the contraceptive patch and vaginal ring have gained popularity with family planning patients, the Pill still holds a top spot, say participants in the 2007 *CTU* survey. Case in point: **Ruth Miner**, RN, CNP, a nurse practitioner at the Jackson County Health Department in Murphysboro, IL, says at least 75% of women who seek care at the facility use pills, and that number has been increasing.

About 42% of 2007 survey participants report that more than half of their patients leave the office with an OC prescription in hand. This number reflects an increase from 2006's 37% figure. ■

How do you use pills? Check these strategies

When counseling a woman on when to start her first pack of oral contraceptives (OCs), what is your strategy for pill initiation? Most participants in the 2007 *Contraceptive Technology Update Contraception Survey* say they are using the Quick Start method.

Recent research indicates that immediate initiation of pills before start of the next menses improves continuation of pill use.[1-3] **(See the *CTU* articles "Quick Start, Same Day: Jump-start pills, shot," August 2007, p. 88, and "Will 'Quick Start' give women jump on pill use?" January 2003, p. 4.)** Prescribers once instructed on one of two approaches: the "first-day start," which initiates pill use on the first day of the woman's next period, or the "Sunday start," when pill use begins on the Sunday after the menstrual cycle begins. Now Quick Start is listed as the preferred method of pill initiation in *Contraceptive Technology*.[4]

"I feel especially in teenage girls who are sexually active, it is a good way to protect them from pregnancy rather than waiting for menses," says **Eileen Britton**, RNC, WHNP, a physician extender at Beaufort County Health Department in Washington, NC. Using Quick Start cuts down on the chance of unintended pregnancy by getting patients started on a method in a timely manner, agrees **Wendy Hearn**, MSN, FNP-C, a nurse practitioner at the Jefferson County Department of Health and Environment in Lakewood, CO. Clinicians at the facility used to require women to abstain for two weeks and return for a pregnancy test and then start them on pills if the test was negative. Quick Start cuts out this unnecessary delay, says Hearn. **(Research also has looked at Quick Start of two other combined hormonal methods, the contraceptive vaginal ring and patch. See "New research emerges on NuvaRing contraceptive," *CTU*, August 2006, p. 88, and "'Quick Start' approach eyed for DMPA and patch," *CTU*, May 2006, p. 53.)**

Smoking, OCs don't mix

When it comes to women who smoke and the Pill, about 79% 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, about 90% say they will not prescribe OCs.

How can you help women to stop smoking?

EXECUTIVE SUMMARY

Most participants (64.5%) in the 2007 Contraception Survey say they are using the Quick Start method to initiate combined pill use.

- When it comes to women who smoke and the Pill, about 79% 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, about 90% say they will not prescribe OCs.
- Most survey participants say they prescribe Alesse, a monophasic 20 mcg pill, for women who have experienced nausea on previous combined pills. The brand also garnered the most votes as pill of choice for older nonsmoking women.

Try the "Five A's" approach developed by the federal Public Health Service[5]:

- **Ask.** Check tobacco use at every visit. When discussing tobacco use, avoid yes/no questions such as, "Do you smoke?" Opt for multiple-choice questions that will yield more information.
- **Advise.** Use clear, strong, and personal recommendations to help women quit. Statements such as, "Your hair and breath will smell better," may help patients respond to the smoking cessation message.
- **Assess.** Where is your patient in her path to smoking cessation? If she isn't ready to stop now, review the benefits that will be achieved when she is, such as saving money and improving health. Repetition is crucial for patients who are struggling to stop smoking. Keep delivering the message.
- **Assist.** Help your patient devise a plan to stop smoking. Look at options such as nicotine patches, gum, inhalers, and other nicotine replacement products, because only 5% of women who go "cold turkey" are successful.[6]
- **Arrange for follow-up.** The first attempt may not be successful; on average, it takes five attempts before a woman actually quits smoking.

What pill for nausea?

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

Alesse, a monophasic 20 mcg pill from Wyeth Pharmaceuticals, Collegeville, PA, continues to lead in this category. About 56% of 2007 participants named the pill as top choice, compared to 44% in 2006. Alesse was followed by Loestrin, a 20 mcg pill from Warner-Chilcott of Rockaway, NJ, and Ortho Tri-Cyclen Lo, a multiphasic 25 mcg pill from Ortho-McNeil Pharmaceutical in Raritan, NJ. The two were named by 19% and 20% of respondents, respectively.

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, 2007 survey participants again named Alesse (44%) as their preferred choice, followed by Loestrin (19%) and Ortho Tri-Cyclen Lo (11%).

When do you use pills?

While oral contraceptives provide reliable birth control, they also offer noncontraceptive benefits. Use of combined OCs can lead to reduced risk of ovarian cancer and endometrial cancer.[4] About 40% of 2007 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 46% of 2007 survey participants say they will begin pill use four to six weeks after delivery. About 22% say they start pills one to three weeks postpartum, while about 11% begin OC use upon hospital discharge.

For breast-feeding women who wish to use progestin-only pills, about 42% indicate they will initiate pill use four to six weeks postpartum, while about 24% say they begin pill use one to three weeks following delivery. About 23% state they start minipills upon hospital discharge.

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EC: Family planners still advocate access

August 2007 marked the first anniversary of the Food and Drug Administration's (FDA) approval of over-the-counter (OTC) status for the emergency contraceptive Plan B (Barr Pharmaceuticals; Pomona, NY). How has the change affected how family planning clinicians work with emergency contraception (EC)?

Not much, according to the results of the 2007 *Contraceptive Technology Update* survey. About 83% report their facilities prescribe EC onsite and provide EC pills at any time, slightly lower than

EXECUTIVE SUMMARY

Family planners continue to support access to emergency contraception (EC) following the 2006 approval of over-the-counter status (OTC) for Plan B. About 83% of 2007 *Contraception Survey* participants report their facilities prescribe EC onsite and provide EC pills at any time, slightly lower than 2006's 88% figure.

- About 70% say they prescribe advance provision of EC, up from 2006's 66% statistic.
- Advocacy organizations are working together to tackle Medicaid coverage for over-the-counter emergency contraception. Medicaid covers no OTC product in about one-third of states. About one-third of states have Medicaid coverage for some OTC products, while the remaining one-third have coverage of many products.

2006's 88% figure. However, 69% say they prescribe advance provision of EC, up from 2006's 66% statistic.

While women and men ages 18 and older are now able to buy the drug without a prescription at participating pharmacies, Plan B remains prescription-only for women younger than 18. The nonprescription version of the drug is kept behind pharmacy counters, and proof of age must be shown prior to purchase. Duramed, Barr Pharmaceutical's subsidiary, began shipping the dual-label EC product in November 2006. **(See the articles "Finally! Emergency contraception given approval by FDA for nonprescription sale," *CTU,* October 2006, p. 109, and "Shipment of dual-label EC now reaching stores," *CTU,* January 2007, p. 5.)**

Consumers are watching ads

Consumer advertising for the new form of Plan B may have raised awareness about emergency contraception, report respondents to the *CTU* annual survey. Use of Plan B has almost doubled in the last year at Hill County Family Planning in Havre, MT, says director **Karen Sloan**, RNCNP. "All our new clients see a video that I made that discusses all forms of birth control and talks about Plan B," she says. These people tell their friends, she adds. "We advertise in the local paper and the college phone book and, on our answering machine, we have a message about the 'morning-after pill,'" Sloan says.

Numbers for EC requests also have increased at Virginia Commonwealth University Student Health Service in Richmond, says **Nancy Harris**, NP, a nurse practitioner at the facility. Center clinicians inform students about the availability of EC when they come in for health visits, as well as provide information in the waiting room and on its web page. The center also provides an EC "blackboard in a bag" — a blackboard presentation that residence advisors (RAs) can access to put up on their dorm floors. The "blackboard in a bag" is in a computerized graphic format and allows RAs to print it out to be displayed on dorm bulletin boards, explains Harris. The presentation, developed by the health center at minimal cost, covers basic information on EC and reminds women to seek sexually transmitted disease (STD) testing as well if they have had sex with a new partner. It also includes counseling contact information for women who may have been sexually assaulted.

Who pays for OTC?

Continuing to write prescriptions for emergency contraception makes sense for two reasons. For example, **Martha Cole**, MD, a private practice

RESOURCES

The National Health Law Program, a public interest law firm that seeks to improve health care for the working and unemployed poor, children, people with disabilities, and people of color, has published *Over the Counter or Out of Reach? A Report on Evolving State Medicaid Policies for Covering Emergency Contraception*. The publication offers a chart that maps policies in all 50 states, as well as a resource list for each state. An online version of the document is available on the agency's web site, www.healthlaw.org. Click on the publication's title under the subheading, "NHeLP Publication."

The National Institute for Reproductive Health/ NARAL Pro-Choice New York offers a publication, *Expanding Medicaid Coverage for EC on the State Level*, which outlines how eight states have changed their Medicaid policies to cover OTC EC. The publication also includes a set of recommendations to help advocates ensure that low-income women have access to EC. An online version of the publication is available at NARAL Pro-Choice New York's web site, www.prochoiceny.org. Click on "Medicaid and EC," then "Learn More." Click on the publication title to download it.

obstetrician/gynecologist in Bethesda, MD, says she writes advance prescriptions for EC because patients tell her that paying for OTC EC out of pocket is more expensive than having the prescription filled, with insurance picking up the cost.

Secondly, some women with Medicaid coverage may not be getting coverage for OTC emergency contraception. According to the Emergency Contraception web site (www.not-2-late.com), Medicaid currently covers no OTC product in about one-third of states. Nearly another third of states have Medicaid coverage for some OTC products, while the remaining one-third have coverage of many products. A group of advocacy organizations is working to tackle this and other access issues for low-income women, reports the web site.

Most state Medicaid programs still require a prescription for drug reimbursement, according to the National Institute for Reproductive Health/NARAL Pro-Choice New York. Women on Medicaid have to pay out of pocket for the drug, which averages about $50, or obtain a provider prescription to obtain coverage.[1]

Eight states (Hawaii, Illinois, Maryland, New Jersey, New York, Oklahoma, Oregon, and Washington) have revised their Medicaid legislation to cover OTC emergency contraception. Other states are looking at revising statutes to include coverage**. (See the resource box on p. 123 to check your state's position.)**

Reference

1. National Institute for Reproductive Health/NARAL Pro-Choice New York. *Expanding Medicaid Coverage for EC on the State Level*. Accessed at: www.prochoiceny.org/assets/files/ecreport.pdf. ■

Snapshot: Shot remains as long-acting option

The next patient in your examination room is an 18-year-old female who is seeking effective contraception. She has tried oral contraceptives (OCs), but she hasn't been successful in sticking with the dosing regimen. What options can you offer her?

Consider the contraceptive injection (DMPA, Depo-Provera; Pfizer, New York City; or Medroxyprogesterone Acetate Injection, Teva Pharmaceuticals USA, North Wales, PA).

EXECUTIVE SUMMARY

In spite of concerns about bone health, many family planning providers continue to prescribe the contraceptive injection depot medroxyprogesterone acetate (DMPA) 15 years after its debut on the U.S. market.

- The shot remains a popular option for younger women. About 86% of 2007 Contraception Survey participants say they are in favor of prescribing the drug for teens, similar to 2006's survey results.
- More clinicians are now eyeing the use of same-day start of the injection. Recent research indicates that introduction of DMPA as a Same Day injection policy is a safe and efficient way of providing women needed effective contraception.

According to results of the 2007 *Contraceptive Technology Update* Contraception Survey, many family planning providers continue to prescribe the drug, 15 years after it debuted on the U.S. market. The shot remains a popular option for younger women: About 86% say they are in favor of prescribing the drug for teens, similar to 2006's survey results.

Not only is Depo-Provera a popular choice, it is a wise choice for young teens, says **Beth Sperring**, ARNP, a nurse practitioner at Suwannee County Health Department in Live Oak, FL. When the teen's parents are involved in the birth control process, they often express preference to Depo-Provera over the pill, she says. "I still deliver the message about sexually transmitted disease [STD] risks, cervical cancer risks, and encourage abstinence and safe sex," says Sperring. "The dosing schedule of Depo allows elimination of one more topic of contention between the parent and adolescent that will often occur with daily reminders about taking the pill."

Check Same Day Start

If your clinic offers DMPA, consider the use of same-day start of the injection. More clinicians are now eyeing this form of contraceptive initiation, says **Anita Nelson**, MD, professor in the Obstetrics and Gynecology Department at the University of California in Los Angeles (UCLA) and medical director of the women's health care programs at Harbor — UCLA Medical Center in Torrance.

Recent research indicates that introduction of DMPA as a Same Day injection policy is a safe and

efficient way of providing women needed effective contraception within seven days of the office visit.[1] Immediate administration of DMPA is associated with improved adherence to DMPA continuation and fewer pregnancies.[2] **(See the articles "Quick Start, Same Day: Jump-start pills, shot," August 2007 *CTU*, p. 88, and "'Quick Start' approach eyed for DMPA and patch," May 2006, *CTU*, p. 53.)**

To offer DMPA in the Same Day start manner, clinicians need to obtain a thorough history of unprotected intercourse since the last menstrual period to determine the need for pregnancy testing. Women who have had unprotected intercourse in that time frame should have a sensitive urine pregnancy test to determine their status. If patients have had unprotected intercourse in the last five days, they should be provided emergency contraception. If DMPA is given in the Same Day start manner, condoms must be used for the next seven days. Patients will need to repeat the pregnancy test two to three weeks after the injection if they have had any recent unprotected intercourse, says Nelson.

Impact on bone health?

Clinicians and patients continue to be mindful of DMPA's potential impact on bone health, following the 2004 "black box" warning added to DMPA labeling. The warning states that prolonged use of the drug may result in the loss of bone mineral density (BMD). The labeling now advises that DMPA should be used as a long-term birth control method (longer than two years) only if other birth control methods are inadequate. Women who continue to use the drug past the two-year mark should have their BMD evaluated. **(Review *CTU*'s coverage of the DMPA labeling; see "Be prepared to counsel on use of DMPA and bone health issues," February 2005, p. 17.)**

The Association of Reproductive Health Professionals (ARHP) offers the following information for health care providers to help them discuss the revised labeling.[3]

- DMPA is a safe and effective contraceptive for adolescent females as well as adult women.
- Use of DMPA should not be restricted routinely based on skeletal health concerns, because there is no evidence of increased fracture risk from the reversible and transient decreased BMD evident in current DMPA users.
- The black box label does not mandate serial BMD testing or the provision of "add-back" estrogen supplementation.
- The current Food and Drug Administration (FDA) guidance does not prohibit use of DMPA for more than two years. Existing data do not suggest the need to place any time limit on DMPA use for adolescents or women in general.

For women who have additional risk factors for low BMD, such as cigarette smokers and women on chronic corticosteroids, clinicians can consider supplemental use of menopausal doses of estrogen along with ongoing DMPA use. Examples of menopausal doses of estrogen include conjugated equine oral estrogen 0.625 mg daily, micronized oral estradiol 1 mg daily, and transdermal estradiol 0.05 mg patches. All women should consume age-based, appropriate amounts of calcium and vitamin D, advises the ARHP.[3] (ARHP offers a handout on the revised DMPA labeling at www.arhp.org/factsheets/ dmpa.cfm.)

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Clinics look to provide HPV vaccine, education

By **Adam Sonfield**
Senior Public Policy Associate
Guttmacher Institute
Washington, DC

A year ago, the introduction of the human papillomavirus (HPV) vaccine was being hailed as a major public health success story. Merck's Gardasil, shown to prevent two HPV strains responsible for 70% of cervical cancer cases (as well as two other

strains tied to nearly all cases of genital warts), was approved by the Food and Drug Administration (FDA) in June 2006. It soon was recommended by the government for all girls ages 11-12. A "catch-up" campaign also was advised for young women aged 13-26.

A second vaccine, Cervarix, was submitted to the FDA in April 2007 by GlaxoSmithKline and could be approved early in 2008.

At the start of 2007, legislators in half the states introduced proposals to require HPV immunization for school attendance,[1] a tactic that has been widely credited for achieving near-universal use of other vaccines. Yet, these proposals were derailed by opposition from an unlikely combination of supporters of parental rights, opponents of vaccines in general, drug company critics, communities of color, and public health advocates. Many in the latter group argued for a slower approach and support voluntary vaccination while educating the public and monitoring the vaccine's safety as it is rolled out to millions of Americans.

The nation's 7,500 family planning clinics are well positioned to help under this new scenario in terms of providing HPV vaccination — particularly the older, catch-up population. . .

The nation's 7,500 family planning clinics are well positioned to help under this new scenario in terms of providing voluntary HPV vaccination — particularly to the older, catch-up population — and educating women about HPV, cervical cancer, and the benefits of the vaccine. Nearly four in 10 of women ages 15-24 who obtain sexually transmitted disease testing or treatment services do so at one of these clinics.[2] Many of these young women have no interaction with the health care system apart from their clinic visits.

More specifically, family planning clinics are a key source of care for black and Latina women, groups that have particularly high rates of cervical cancer mortality.[3] And because almost six in 10 of their clients are parents,[2] clinics' educational efforts can help not only to inform a client's own vaccine choice but also to equip her decision about vaccinating her children.

At about $300 per patient, even with Merck's discount for clinics, the HPV vaccine is extraordinarily expensive for a vaccine. To meet this cost, clinics will have to cobble together money from a range of public and private funding sources. The Vaccines for Children (VFC) program provides free vaccines to children through age 18 who are uninsured, underinsured, or have public coverage such as Medicaid. Medicaid itself covers the vaccine for women ages 19-20 and through age 26 in roughly half the states (at the state's option). Several states also have allocated millions of their own dollars to cover vaccine provision and education. (Ironically, the Title X family planning program may not play a major role because its funding is limited and because in some states, laws requiring parental consent for vaccination will interfere. Title X-supported services must be provided confidentially to all clients, including minors.)

In the private sector, a major source of funding will be private health insurance. Merck estimates that 94% of individuals with private coverage are in plans covering the vaccine,[4] and three states — Colorado, Nevada, and New Mexico — already have enacted laws mandating such coverage.[1] Yet, reimbursement by private plans has been reportedly low compared to high upfront costs for providers.

Merck itself has established a patient assistance program to reimburse providers for that upfront cost for vaccines provided to uninsured, low-income adults. However, health department clinics and other government-run agencies are not eligible, and providers that are eligible are reimbursed quarterly, which requires another source of funding to tide them over.

What lies ahead?

Beyond the financial challenges, clinics wishing to provide the vaccine must decide which populations to target, secure quality training for their staff, design appropriate counseling and service protocols, explore reconfiguring their hours and

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venues, and find ways to bring in potential clients.

In some states, VFC participation requires providers to offer all of the vaccines required for adolescents and young adults, not merely the HPV vaccine, and it entails costly procedures related to vaccine refrigeration. The vaccine's unusual regimen, which is three shots in six months, means that clinics must ensure that women return for subsequent shots when they would not otherwise visit. And with continuing controversy, whatever its validity, over the HPV vaccine's safety, efficacy, and link to sexual behavior, rigorous informed consent protocols will be especially salient.

These are serious challenges, but if they can be overcome, family planning clinics can prove themselves anew to be a central cog in the nation's public health system and help reduce long-standing racial, ethnic, and socioeconomic disparities in cervical cancer incidence and mortality.

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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 **December** issue, you must complete the evaluation form provided and return it in the reply envelope provided in that issue to receive a certificate of completion. When your evaluation is received, a certificate will be mailed to you. ■

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.

17. What is the hormone dosage in the contraceptive implant Implanon?
A. 68 mg of the progestin etonogestrel
B. 50 mg of the progestin etonogestrel
C. 35 mg of the progestin etonogestrel
D. 25 mg of the progestin etonogestrel

18. Drospirenone, the progestin found in the oral contraceptive Yasmin, is an analogue of:
A. norgestimate.
B. spironolactone.
C. norelgestromin.
D. ethynodiol diacetate.

19. The emergency contraceptive Plan B remains prescription-only for women:
A. younger than 25.
B. younger than age 21.
C. younger than age 18.
D. younger than age 16.

20. If DMPA is given in the Same Day start manner, condoms must be used:
A. until the next menses.
B. for the next month.
C. for the next two weeks.
D. for the next seven days.

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

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.*

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