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IN THIS ISSUE

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What is next for over-the-counter access to emergency contraception?

Advocates push on after FDA refusal, continue to affirm drug's safety

While the avenue to broader access to emergency contraception (EC) has hit a roadblock with the Food and Drug Administration (FDA)'s initial rejection of over-the-counter (OTC) status for the levonorgestrel-only drug Plan B, the drug's manufacturer is eyeing two alternative approaches for seeking OTC approval of the drug.

In the May 6, 2004, agency letter, signed by Steven Galson, MD, MPH, acting director of the agency's Center for Drug Evaluation and Research, the FDA outlined two possible avenues for approval for Plan B's Pomona, NY-based manufacturer. Barr Laboratories either can:

- Provide additional data demonstrating that Plan B can be used safely by women younger than 16 years of age without professional supervision; or
- Supply additional information in support of a submission to allow for the marketing of Plan B as a prescription-only product for women younger than 16 and a nonprescription product for women 16 years and older.[1]

"While we are disappointed that FDA did not approve our application

EXECUTIVE SUMMARY

The Food and Drug Administration (FDA) has issued a nonapprovable letter in response to the request for over-the-counter (OTC) status for Plan B, an emergency contraception drug manufactured by Barr Laboratories.

- In issuing the nonapprovable letter, the agency stated there was a lack of data surrounding OTC use of Plan B among teens younger than age 16.
- According to the FDA, Barr Labs can provide additional data demonstrating that Plan B can be used safely by women younger than 16 years of age without professional supervision, or supply more data to allow the drug to be marketed as a prescription-only product for women younger than 16 and as a nonprescription product for women ages 16 and older.

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at this time, we are encouraged by FDA's suggestions and look forward to working with the agency toward approval of Plan B for over-the-counter use," says **Bruce Downey**, chairman and CEO of Woodcliff Lake, NJ-based Barr Pharmaceuticals, the parent company of Barr Laboratories. "In the meantime, we remain committed to providing Plan B as a prescription-only product and to increasing awareness among the health care provider community and women of this safe and effective option."

While the company is maintaining a low-key approach while it works with the regulatory agency, the FDA has drawn sharp criticism from a broad cross-section of Congressional members, medical and public health organizations, scientists, and women's advocacy, health, and religious groups for issuing the nonapprovable decision.

Groups have registered surprise and outrage at the FDA's decision and pointed to the December 2003 recommendation by two FDA expert advisory panels for approval of OTC status. Members then voted 23-4 to recommend OTC sales of the drug. The FDA typically follows the recommendations of its scientific committees.

In a press statement issued by the Washington, DC-based American College of Obstetricians and Gynecologists (ACOG), president **Vivian Dickerson**, MD, said, "This decision to ignore an advisory panel's assessment of the scientific evidence is not only rare, but it gives credence to recent criticisms that political interference is hampering scientific review within federal agencies today."[2]

"The FDA let politics trump science when it refused to approve Plan B for over-the-counter use," agrees **James Trussell**, PhD, professor of economics and public affairs and director of the Office of Population Research at Princeton (NJ) University and member of the FDA's joint committee. "Despite the scientific evidence and findings of independent medical experts, the Bush administration has denied American women timely access to a safe, effective second chance to prevent pregnancy."

In a press release issued by the regulatory agency, the FDA says it based its action on the lack of data surrounding OTC use of Plan B among teens younger than 16.[3] According to the FDA, Barr Labs' application "contained no data in subjects under 14 years of age and very limited data in adolescents 14 to 16 years old."

What if Plan B is made available over the

counter to women 16 and older, but remains as a prescription-only drug to those younger than age 16?

"This is probably an unworkable scheme as it has never been done in the United States; therefore, it might take years to establish this two-tiered system," reflects **Susan Wysocki**, RNC, NP, president and chief executive officer of the Washington, DC-based National Association of Nurse Practitioners in Women's Health.

What if the drug is made available "behind the counter" — where patients must discuss the drug's purchase with a pharmacist but need not get a provider's prescription?

"Although I would prefer neither limitation [prescriptions for under-16-year-old girls or 'behind the counter'], I would happily give up for the time being and proclaim the OTC, or behind the counter, availability of Plan B for women 16 and older a major step ahead," says **Robert Hatcher**, MD, MPH, professor of gynecology and obstetrics at Emory University School of Medicine in Atlanta.

Wysocki sees drawbacks in the behind-the-counter approach to the drug, and she cites the lack of confidentiality in most pharmacies.

"It would be very intimidating not only for adult women, but particularly for teens," she says. "Pharmacists for the most part are not trained to handle this type of sensitive counseling."

In California, Plan B is offered behind the pharmacist's counter, reports **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 clinic and nurse practitioner training program at Harbor-UCLA Medical Center in Torrance.

Nelson sees financial problems with the "behind-the-counter" approach. While the cost of EC is covered by the state's MediCal and clinical services program, Family Planning, Access, Care and Treatment (PACT), the charge the pharmacist makes for the required counseling is not, which leaves even women who have insurance with a costly solution, says Nelson. Women who don't have insurance pay more than $50 for behind-the-counter Plan B, she states.

The California program has yet to reach its full audience; a new survey conducted by the Menlo Park, CA-based Kaiser Family Foundation shows that only one in 10 California women ages 15-44 know about the EC program.[4]

While the regulatory wheels grind onward, what can providers do to broaden access to EC now?

RESOURCE

The Washington, DC-based Association of Reproductive Health Professionals has developed an Emergency Contraception Resource Center at its web site, www.arhp.org. To access the resource center, click on "Emergency Contraception Over the Counter — Rejected" on the home page of the web site. The resource center has links to the Food and Drug Administration (FDA) letter to Barr Pharmaceuticals announcing the rejection of the over-the-counter (OTC) request, a summary of the December 2003 FDA hearing on the OTC request, and other helpful information, as well as links to sites such as the Emergency Contraception Hotline and Back Up Your Birth Control.

"It is especially important for clinicians to address safety explicitly," says **Felicia Stewart**, MD, adjunct professor in the department of obstetrics, gynecology and reproductive sciences at the University of California San Francisco and co-director of the Center for Reproductive Health Research & Policy. "Many people may have gotten the incorrect idea that medication safety is an issue with Plan B." **(Use the resources listed on the Washington, DC-based Association of Reproductive Health Professional's EC Resource Center web site; contact information is listed above.)**

Nelson agrees about raising the awareness level when it comes to safe and effective use of EC. Information geared for adolescent awareness would help in teens' understanding of the drug, she notes.

"Articles in teen and pre-teen magazines about the FDA decision would be great. Maybe teens would become more aware of Plan B and EC in general," says Nelson. "I have found no more effective method to spin adolescent interest in something than to tell them that they are too young and need to be adults to do it."

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New programs broaden contraceptive access

Women in two Western states are finding the doors are swinging open to wider contraceptive access, thanks to two innovative programs.

Planned Parenthood of the Columbia/Willamette (PPCW) in Portland, OR, is using its Internet site, www.ppcw.org, to provide birth control pills, the Ortho Evra contraceptive patch (Ortho-McNeil Pharmaceutical, Raritan, NJ), and the NuvaRing contraceptive vaginal ring (Organon, West Orange, NJ) to women across the state. The pilot Contraception Online program, the first of its kind among Planned Parenthood of America affiliates, is allowing women to undergo an on-line assessment and place orders for these three forms of birth control without having to visit a provider's office. The methods can be mailed by overnight express mail or standard mail, picked up at a local pharmacy, or obtained at one of PPCW's eight health centers. About 80 requests had been filled or were being processed within the first few weeks of the program, reports **David Greenberg**, the affiliate's president and chief operating officer.

A second program, based in Washington state, is the basis of the Direct Access study, which is determining the feasibility of screening and prescribing oral contraceptives (OCs), the patch, and the ring through specially trained pharmacists, rather than through visits to a doctor or clinic. More than 150 Washington state women have enrolled in the study, conducted by the Seattle-based University of Washington School of Pharmacy and the Department of Obstetrics and Gynecology, reports **Jacqueline Gardner**, MPH, PhD, professor in the School of Pharmacy and the study's principal investigator.

Oregon women who wish to use the Contraception Online service can obtain birth control after they review on-line information about hormonal methods of contraception; read and accept a medical consent form and Health Insurance Portability and Accountability Act privacy form; and complete a detailed medical history questionnaire. Once the forms have been submitted, a registered nurse or nurse practitioner contacts the patient by phone to review the information and answer questions. If the patient meets the necessary health requirements, she may opt to obtain a two-month supply of contraception by mail, pick up her prescription at her local pharmacy, or visit a PPCW health center. The affiliate charges a $35 fee to cover the medical assessment.

In order to get refills after two months, patients must submit a blood pressure reading obtained from a licensed medical provider at a local physician's office, public health department, pharmacy, or a PPCW center. The blood pressure reading can be faxed or mailed to the PPCW on-line services center.

What led the Oregon affiliate to pursue this avenue of family planning delivery? The success of its emergency contraceptive (EC) service was the impetus, says Greenberg. Since the program was launched in 2002, 588 women have received an ECP prescription. The affiliate also uses the Internet to schedule appointments; since 2002, 5,740 people have made appointments on-line at PPCW clinics.

Establishing the new service was not difficult, since the affiliate already had a nurse practitioner and an assistant already assigned to the emergency contraception on-line program and a telephone nurse advice line, says Greenberg. Computer programmers designed the module for the new program. The affiliate will add part-time nurse practitioner hours as demand for the on-line service increases, he notes.

The on-line program is touching a number of needs, Greenberg explains. It provides an avenue of service for women who live far away from health care providers and offers women with active lifestyles an opportunity to take care of

EXECUTIVE SUMMARY

Contraceptive access is broadening in two Western states through innovative public health efforts.

- Planned Parenthood of the Columbia/Willamette in Portland, OR, is using its Internet site to provide birth control pills, the contraceptive patch, and the contraceptive vaginal ring to Oregon women through its pilot Contraception Online program.
- Researchers at the University of Washington in Seattle are using the Direct Access study to determine the feasibility of screening and prescribing birth control pills, the patch, and the ring through specially trained pharmacists, rather than through visits to a doctor or clinic.

their contraceptive needs in a convenient manner.

Other Planned Parenthood affiliates already have expressed interest in the program; however, some see obstacles within their state laws in providing this delivery of service, says Greenberg.

"I think that if this service really becomes as successful as I think it could become, then our public policy folks need to begin to work in those states to get those laws changed, " he notes.

Look at WA program

What led researchers to design the Washington state Direct Access program? Providing contraception is a natural progression for the state's pharmacists, explains Gardner; they have been prescribing emergency contraception for seven years through collaborative drug therapy agreements.

Funded by the Bethesda-based National Institutes of Health, the Washington study will monitor whether women can answer self-test questions to see if they can safely use OCs, the ring, or the patch with the help of specially trained pharmacists. Pharmacists at eight Bartell Drug Stores and Fred Meyer stores in King and Pierce counties are participating in the study. All have entered collaborative drug therapy agreements with physician prescribers and have received training in contraceptive provision.

Women in the study must be between ages 18 and 45, weigh less than 200 pounds, and be able to pay for the birth control method and the pharmacist consultation, which costs about $50. Women may go through the pharmacy process or opt to become comparators, whereby they receive family planning care from another medical provider. Pharmacists can provide an initial three-month prescription, followed by a nine-month prescription if blood pressure is normal at the time of a return visit to the pharmacy at the end of the first three months. Pharmacists also encourage women to visit a primary care practitioner or family planning clinic for cervical exams and infection screenings.

The study currently allows the pharmacists to prescribe OCs, the patch, and the ring. If safety is documented after preliminary analysis, injectable contraceptive methods will be added to the study, according to the Direct Access web site, www.directaccessstudy.info.

All women in the study will be contacted by telephone at one, three, six, and 12 months for a 10-minute telephone interview. The study is expected to be completed in April 2006, says Gardner. ■

New study to examine the role of estrogen

What is the role of estrogen in protecting postmenopausal women's hearts? While recent research indicates that the hormone may not benefit cardiovascular health in older women,[1-3] a group of privately funded researchers is re-examining the role of the hormone in women ages 40-55.

The Kronos Early Estrogen Prevention Study (KEEPS) trial will address whether estrogen therapy delays atherosclerosis in recently menopausal women, the group most likely to initiate hormone therapy, explains **JoAnn Manson**, MD, DrPH, chief of the division of preventive medicine at Brigham and Women's Hospital and professor of medicine at Harvard Medical School, both in Boston. Manson will serve as principal investigator of the new trial.

"Previous randomized trials have not focused on younger, recently menopausal women; most participants have been 10-15 years past menopause," states Manson. "Additionally, KEEPS will address the role of estrogen formulation and route of delivery by comparing transdermal estrogen to low-dose oral estrogen to placebo."

What prompted the Phoenix-based Kronos Longevity Research Institute (KLRI), a facility that focuses its clinical research on aging and age-related diseases, to undertake the KEEPS project?

"The stimulus was the sense that 'someone ought to do something' to clear up the overinterpretation of the Women's Health Institute data, which left the impression with both professional and lay public that it is now incontrovertibly clear that

EXECUTIVE SUMMARY

Researchers are taking another look at use of estrogen therapy with the launch of the Kronos Early Estrogen Prevention Study (KEEPS).

- KEEPS, a privately funded study, is a randomized, controlled, double-blinded trial of some 720 women that will provide prospective data on the risks and benefits of early menopausal hormone therapy with a special focus on the hormone's impact on the progression of atherosclerosis.
- Eight centers will participate in the prospective trial. Final data may be published in 2010; however, researchers will take an interim look at the data in 2008.

the risk/benefit ratio for long-term menopausal hormone therapy [MHT] is unfavorable for all women," states **Mitchell Harman**, MD, PhD, the institute's director and president.

According to Harman, the WHI data only addressed the issue for women initiating estrogen relatively long after the menopause (average about 12 years); however, women decide to use MHT between ages 40-55, within six months or a year of their last period, he points out.

Results from earlier observational studies suggest that hormone therapy protects against heart disease,[4] and the latest analysis from the WHI's estrogen-only arm indicates that women ages 50 to 59 had a 44% lower risk of heart disease compared with the placebo group.[2] With those findings in hand, the institute is moving forward with the KEEPS trial in an effort to settle the question of MHT use.

"The fact is that, over the next 30 years or so, many millions of women may suffer needless heart attacks and bone fractures through eschewing MHT, if, as we hypothesize, hormones initiated early do really retard development of atherosclerosis," says Harman.

Funding for the five-year KEEPS trial, which is expected to cost more than $14 million, is being underwritten by the Phoenix-based Aurora Foundation, headed by billionaire John Sperling.[5] KLRI is seeking additional funding sources for additional research as part of KEEPS.

Eight centers join in

Eight centers will participate in the randomized, placebo-controlled double-blinded, prospective trial: Albert Einstein College of Medicine of Yeshiva University/Montefiore Medical Center and Columbia University College of Physicians and Surgeons, both based in New York City; Harvard Medical School/ Brigham and Women's Hospital in Boston; Mayo Clinic College of Medicine in Rochester, MN; University of California-San Francisco/ Center for Reproductive Health, San Francisco; University of Utah School of Medicine in Salt Lake City; University of Washington School of Medicine in Seattle; and Yale University College of Medicine in New Haven, CT.

Approximately 720 perimenopausal women will be recruited for the study. They will receive transdermal estrogen, oral estrogen, or placebo. The study drug regimens include:

- a daily oral tablet containing 0.45 mg conjugated estrogens (Premarin, Wyeth, Philadelphia) and a placebo skin patch;
- an oral placebo tablet and a skin patch delivering 50 mcg estradiol daily for 3.5 days and applied twice weekly (Vivelle-Dot, Novartis Corp., New York City);
- a placebo tablet and a placebo skin patch.

Progestin will be administered as a transvaginal progesterone gel (Prochieve, Columbia Laboratories, Livingston, NJ) every day for the last 10 days of the artificial cycle to women receiving active estrogens. Women not receiving active estrogens will apply a placebo gel.

When will you see results?

What can clinicians and women expect to see results from the KEEPS trial? Harman offers the following timeline:

"If we can stay on schedule, women will be randomized beginning in September 2004, and with any luck, the study will fill [to] 720 women before Aug. 31, 2005," he explains. "That means the last subject will complete the study in August 2010."

Researchers will need an additional two to three months to evaluate data and prepare initial reports, so first publication of final KEEPS results may arrive in late 2010, estimates Harman.

"However, we tentatively plan to have a peek at the data after all women have completed three years, [about] August 2008," states Harman. "What, if anything, will be published at that point depends on the decision of the principal investigators."

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Sterilization: Is your practice up to date?

With the growing popularity of a new approach to sterilization in the form of the Essure device (Conceptus, San Carlos, CA), family planning providers need to update their counseling information in presenting the option to women considering permanent contraception.

Three presentations at the recent annual meeting of the Washington, DC-based American College of Obstetricians and Gynecologists (ACOG) focused on use of the device in current practice.[1-3] Understanding how Essure fits into the contraceptive picture is important for providers and patients, says **Amy Pollack**, MD, MPH, president of EngenderHealth in New York City.

According to Pollack, the Essure device represents a "completely new paradigm" since it is the first new sterilization method of its kind.

"It is the first time since 1970 that we are introducing a completely different method," says Pollack, who presented at the ACOG meeting. "We have introduced methods of occlusion, from Hulka, bipolar, unipolar, the ring, and then the Filshie clip; we are now looking at something completely different, so we have to step back and reevaluate."

EXECUTIVE SUMMARY

More providers are taking a look at integrating the recently introduced Essure micro-insert tubal occlusion procedure for female sterilization into their practices.

- Recent research indicates that more women are seeking reversal of sterilization procedures. The Essure method is nonreversible; providers should factor that information into their counseling on sterilization options.
- Women who are not candidates for tubal sterilizations, such as obese women or women with severe medical disease, are eligible for using the Essure device for permanent contraception. Since there is no incision required, the procedure is less invasive that tubal sterilization, and general anesthesia is not needed.

Know the population

Eleven million U.S. women ages 15-44 years of age now rely on tubal sterilization for contraception.[4] Of the estimated 750,000 tubal sterilization procedures performed each year in the United States, half are performed postpartum and half as ambulatory interval procedures.[4] The average age of sterilization in the United States is about 30, says Pollack.[1]

Women now are having their first child later in life: the mean age of women bearing their first child in the United States now is about age 27, and about 20% of women are having their first child at the age of 35 or older, says Pollack.[1]

Much data have been collected on various forms of sterilization through the United States Collaborative Review of Sterilization (CREST), which analyzed the experiences of 11,232 women ages 18-44 who had tubal sterilizations between 1978 and 1987.[5] CREST data show that while most women express no regret after tubal sterilization, women 30 years of age and younger at the time of sterilization have an increased probability of expressing regret.[6] In another analysis of CREST data, women who were sterilized at a young age had a high chance of later requesting information about reversal, regardless of their number of living children.[7]

A recent analysis of Quebec women shows that sterilization reversal and pregnancy after sterilization are not rare.[8] Relatively high rates of reversal among the youngest age groups suggest a need for better counseling about alternative contraceptive strategies, researchers conclude.[8]

Providers need to understand that the Essure method is "completely irreversible," states Pollack. Unlike tubal interruption procedures where tubal segments may be reconnected with a measure of success, tissue in growth in the interstitial portion of the tube has not been shown to be surgically reversible.[9] Research indicates that use of mechanical devices such as the Hulka clip and the Filshie clip offer minimal degree of tubal destruction, increasing the chance for reversibility.[10]

The design of the Essure device may make it difficult for women to undergo in vitro fertilization (IVF) if they should wish to reverse the sterilization process, says Pollack. With more women considering Essure as an option, providers should keep this fact in mind when discussing the method, she adds.

While providers should continue to counsel women that sterilization should be considered a permanent procedure, they should look at the ages of their patient population, understand that

the risk of regret and the desire for reversal is real, and decide whether the addition of Essure is appropriate to their practice, says Pollack.

Who is a candidate?

Women who are not candidates for tubal sterilizations, such as obese women or women with severe medical disease, are eligible for using the Essure device for permanent contraception, says **John Nichols**, MD, reproductive endocrinologist and director of the Piedmont Reproductive Endocrinology Group in Greer, SC. Women who have large fibroids or polyps in the uterus may not be good candidates because a hysteroscopy is needed to visualize the tubes, he points out.

Since there is no incision required, the procedure is less invasive that tubal sterilization, and general anesthesia is not needed, says Nichols, who presented at the ACOG conference as part of the Washington, DC-based Association of Reproductive Health Professionals' set of special family planning presentations. Women have less discomfort and are able to return to work within one to two days, he notes.

Efficacy with the Essure device is good, Nichols notes. As of 2001, women had accumulated more than 4,800 and 5,200 months wearing the device in the phase II and pivotal trials, respectively; no pregnancies have been reported in either group.[11]

Nichols, who served as an investigator in the clinical trial of the device, sees the procedure as one that can be scheduled in the office, much as a vasectomy is handled for men. Training for Essure placement includes a one-day didactic training session, training on an Essure simulator, three to five proctored cases, and five cases assisted by Conceptus product specialists.[11] **(See the resource listing above for information on Essure and transcervical sterilization.)**

"It's quick, it's simple, and patients do very well," states Nichols.

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RESOURCES

- **For more information on Essure**, contact Conceptus, 1021 Howard Ave., San Carlos, CA 94070. Telephone: (877) 377-8732 or (650) 628-4700. Fax: (650) 610-8363. Web: www.conceptus.com.
- **Learn more about Essure** by reviewing the Washington, DC-based Association of Reproductive Health's *Clinical Proceedings* publication, part of its continuing medical education program, "New Developments in Contraception: Permanent Options for Women." Go to www.arhp.org and click on "Health Care Providers," "CME/CEU," "Monographs," and "Clinical Update on Transcervical Sterilization."

Research eyes vasectomy impact on sperm production

While family planning clinicians counsel on the permanency of vasectomy, more men are seeking reversals of the sterilization method. In the United States, approximately 500,000 vasectomies are performed each year.[1] It is estimated that up to 6% of men who undergo voluntary sterilization eventually will request reversal.[2]

EXECUTIVE SUMMARY

Results from a small study indicate that men who had a vasectomy more than 10 years ago have a much lower sperm count than nonvasectomized fertile men do, which suggests that vasectomy may have a lasting impact on sperm production.

- Men should continue to be counseled that the intention of vasectomy is to provide permanent protection against pregnancy.
- Also continue to counsel men that there is no guarantee of returned fertility after vasectomy reversal or fertility treatment.

Research from a small study indicates that men who have had a vasectomy, even if it has been reversed, produce less sperm and have poorer success rates when their partners have fertility treatments.[3]

"Men should consider having a vasectomy carefully, as it can be very difficult to have a child again, even with reversal or fertility treatment," says **Carmel McVicar**, PhD, lead author and a research fellow in the department of obstetrics and gynecology at Queen's University in Belfast, Northern Ireland.

Scientists at Queen's University decided to examine vasectomized men following two studies indicating a decrease in the pregnancy rate of the partners of men who have had a vasectomy, McVicar reports.[4,5] The researchers tested 21 men who had vasectomies and found their sperm count was about three times lower than that of the 39 nonvasectomized fertile men assessed. A further analysis of Sertoli cells, which nourish sperm development in the testis, revealed normal numbers in the vasectomized individuals; however, the amount of spermatids (developing sperm) were reduced. Success rate after intracytoplasmic sperm injection (ICSI), an assisted reproductive technology procedure for achieving pregnancy, was about 50% lower in the vasectomized men.

Findings from the small study suggest that one long-term outcome of vasectomy may be a significant reduction in sperm production, which could lower the chances of fertility following reversal or assisted reproductive technology (such as ICSI), says **Amy Pollack**, MD, MPH, president of EngenderHealth in New York City. This study alone, given the small size and design limitations, does not warrant a change in practice, she contends.

Other studies have shown that pregnancy rates decrease as the interval between vasectomy and reversal increases[6]; reduced sperm production could be a contributing factor, Pollack notes. High levels of antisperm antibodies following reversal also have been shown to negatively affect fertility, she observes.[7]

Counsel on permanency

A vasectomy reversal involves a surgical procedure that restores the flow of sperm through the vas deferens, the tubular structures that allow sperm to travel from the testicles. It usually is performed by an experienced microsurgeon using specialized instruments, including an operating microscope.[8]

Vasectomy reversal costs, including the surgeon's fee, the hospital's charge for use of the operating room and ambulatory care facility, and the anesthesia fee, can range from approximately $5,000 to $15,000.[8]

In comparison, ICSI adds about $2,500 to the cost of in vitro fertilization, which can range from $8,000 to $10,000.[9] "Men should continue to be counseled that the intention of vasectomy is to provide permanent protection against pregnancy and that there is no guarantee of returned fertility after vasectomy reversal or fertility treatment," states Pollack.

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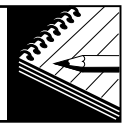
GUEST COLUMN



Latest edition of *CT* book targets dramatic changes

By **Deborah Kowal**, MA, PA
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Readers looking for the latest reference on family planning methods and practice can obtain the 18th edition of *Contraceptive Technology,* to be published this summer.

Since the last edition, family planning has undergone a marked transition. The menu of contraceptive options has expanded and offers women effective methods for short-term or long-term protection, as well as for coverage for unprotected intercourse. New data clarify the relationship between hormonal contraceptive use and the risks for breast cancer and cardiovascular problems. New findings about hormone therapy shift the risk/benefit equation for many women.

One of the pivotal chapters covers combined hormonal contraceptives. New sections on the patch and the vaginal ring are written by Robert Hatcher, MD, MPH, professor of gynecology and obstetrics and the Emory University School and Medicine, and Anita Nelson, MD, professor and medical director of Women's Health Care Clinic at Harbor-University of California at Los Angeles (UCLA) Medical Center. They include information about counseling women whose patches have come off or who forgot to insert a ring when scheduled. Instructions for missed pills have been updated and streamlined. Hatcher and Nelson describe the new formulations and the management guidance for extended pill regiments. The chapter describes the three methods for initiating pills, included the recommended Quick Start method.

Two chapters are completely rewritten: intrauterine devices (IUDs) and impaired fertility. David Grimes, MD, MPH, vice president of biomedical affairs at Family Health International and clinical professor of obstetrics and gynecology at the University of North Carolina School of Medicine, reassures providers and users on the safety of the IUD. He examines the research on infection and fertility and bleeding. The chapter covers the indications and precautions, insertion instructions, and management guidance for the new levonorgestrel intrauterine system (IUS), in addition to the progesterone IUD. The chapter on impaired fertility, written by John Marshall, MD, clinical professor of obstetrics and gynecology at the UCLA School and of Medicine, and Nelson, gives a straightforward approach to the office-based work-up of the infertile couple. The team gives an overview of more advanced assisted reproductive technology so clinicians can counsel those patients who may need referrals.

The most widely cited and reprinted information in the book comes from the table on contraceptive failure rates during the first year of use. James Trussell, PhD, professor of economics and public affairs and director of the Office of Population Research at Princeton (NJ) University, reviewed the published literature to calculate the probability of failure among typical and perfect users. The difference between these two probabilities reveals the consequences of imperfect use. It depends on how much a method will forgive imperfect use and how hard it is to use that method perfectly. Trussell gives rates for new methods, including the Evra patch (Ortho-McNeil Pharmaceuticals, Raritan NJ) and NuvaRing (Organon USA, Roseland NJ). The Women's Health Initiative study prompted many

COMING IN FUTURE MONTHS

- Clinical update coming for intrauterine contraception
- Chlamydia — Are adolescents at risk?
- Transdermal delivery of hormones — What's next?
- Research eyes new sterilization methods
- Review data on injectable contraception

experts to reconsider conventional menopause management. Sorting out the reports and the therapeutic and non-therapeutic alternatives, Nelson and Felicia Stewart, MD, co-director of the Center for Reproductive Health Research and Policy at the University of California, San Francisco, present prudent approaches for symptomatic women. The authors also review the available research on herbal regimens.

Willard Cates Jr., MD, MPH, president and chief executive officer of the Institute for Family Health, Family Health International, Durham, NC, updated the chapter on reproductive track infections with the new treatment guidelines for sexually transmitted diseases and new amplification tests that increase screening sensitivity. In the spermicide chapter, Cates reports the latest research on nonoxynol-9 (N-9) showing the lack of HIV and sexually transmitted infection (STI) protection. In the barrier methods chapter, he brings in the new Lea's Shield (Yama, Millburn NJ) and the FemCap (FemCap Inc., Del Mar, CA).

Advances in rapid test technology add to the HIV prevention and control armament. Felicia Guest, MPH, CHES, director of training at the Southeast AIDS Training and Education Center of Emory University School of Medicine, describes these technologies and suggests appropriate counseling points. She re-examines the issues for HIV-infected men and women who need to select suitable contraceptive methods.

The nearly 900-page reference book covers the latest research and practice guidance for all the contraceptive methods and for the many issues related to family planning and women's health. Here is just a short listing:

• Providers counseling about or providing abortion can benefit from comprehensive new information on early abortion options, including new medication methods (Mifeprex, Danco Laboratories, New York City) that, in many states, can be provided by advance practice clinicians.

• Emergency contraception has become mainstream, especially with the ease of Plan B (Barr Laboratories, Pomona, NY). The chapter outlines new and simplified rules for emergency contraceptive use and promotes advance provision.

• The Implanon implant (Organon USA, Roseland NJ), expected to be approved soon, has extensive coverage in the progestin-only methods chapter, which also covers the latest on Depo-Provera (Pharmacia Corp., Peapack, NJ).

• Do condoms work? Lee Warner, PhD, epidemiologist at the Centers for Disease Control and Prevention, Marcus Steiner, PhD, senior epidemiologist with Family Health International, and Hatcher thoroughly assess the data. With the concern about N-9 and STI risk, they also discuss whether there is any place for the spermicidal condom.

• The chapter on education and counseling presents patients with pointers on "how to pick a partner."

• Some of the trickiest dilemmas a clinician needs to sort through include dysfunctional uterine bleeding, polycystic ovarian syndrome (PCOS), and pelvic masses, which are covered in the chapter on menstrual problems and common gynecological concerns.

• The new Standard Days method streamlines fertility awareness techniques, which makes the rules simpler to follow and interpret while at the same time enhancing efficacy. The various fertility awareness-based methods are compared, and easy-to-understand instructions are provided for users.

• The new interpretative readings of Pap smears and the new recommendations for mammography are detailed.

[Editor's note: Contraceptive Technology *is available at a cost of $59.95 plus $9.99 for shipping/handling (total $69.94) by calling Bridging the Gap at (706) 265-7435 or through www. managingcontraception.com.]* ■

CE/CME Instructions

Physicians and nurses participate in this continuing medical education/continuing education program by reading the articles, using the provided references for further research, and studying the questions at the end of the issue. Participants should select what they believe to be the correct answers and refer to the list of correct answers to test their knowledge. To clarify confusion surrounding any questions answered incorrectly, please consult the source material. After completing this activity with the **December** issue, you must complete the evaluation form provided and return it in the reply envelope provided in that issue to receive a certificate of completion. When your evaluation is received, a certificate will be mailed to you. ■

CE/CME Questions

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

- **Identify** clinical, legal, or scientific issues related to development and provisions of contraceptive technology or other reproductive services. (See **"New study to examine the role of estrogen" and "Research eyes vasectomy impact on sperm production.")**
- **Describe** how those issues affect service delivery and note the benefits or problems created in patient care in the participant's practice area.
- **Cite** practical solutions to problems and integrate information into daily practices, according to advice from nationally recognized family planning experts. (See "**What is next for over-the-counter access to emergency contraception?"** and **"Sterilization: Is your practice up to date?")**

1. What reason did the Food and Drug Administration give in issuing nonapproval of the request from Barr Laboratories for over-the-counter (OTC) status for its emergency contraception drug, Plan B?

A. OTC use would be dangerous for women of all ages.
B. There was a lack of data surrounding OTC use of Plan B among teens younger than age 16.
C. Research indicated that women could not comprehend the OTC label.
D. Research indicated that women would use less effective forms of contraception following use of emergency contraception.

2. What is the name of the estradiol transdermal system being used in the Kronos Early Estrogen Prevention Study?

A. Vivelle-Dot
B. Esclim
C. Estraderm
D. Climara

3. What age group of women are most at risk for expressing regret following sterilization, according to research from the U.S. Collaborative Review on Sterilization?

A. Those women 25 years of age and younger at the time of sterilization
B. Those women 30 years of age and younger at the time of sterilization
C. Those women 35 years of age and younger at the time of sterilization
D. Those women 40 years of age and younger at the time of sterilization

4. What estimated percentage of men who undergo voluntary sterilization eventually will request reversal?

A. 2%
B. 5%
C. 6%
D. 20%

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

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