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Depo-Provera: Costs eat up clinic contraceptive budgets

Few price concessions lead to hard choices for clinic administrators

Teen-age girls may consider Depo-Provera the dream method for birth control, but many publicly funded clinic administrators are finding the contraceptive injectable a purchasing nightmare as they try to balance fixed budgets with an upsurge in demand.

Since its U.S. introduction in 1993, increasing numbers of adolescents have moved to Depo-Provera, according to **Jacqueline Darroch**, PhD, senior vice president and vice president for research with the Alan Guttmacher Institute in New York City.

The upswing has been noted by *Contraceptive Technology Update* readers as well. Seventeen percent of adolescent patients chose Depo-Provera in 1997, jumping from an 11% increase in 1996, *CTU* readers noted in the newsletter's annual contraceptive survey. **(See the November 1997 issue, pp. 133-136, for full results.)**

During the 1980s, more sexually active teens began using birth control, primarily in the form of oral contraceptives (OCs), notes Darroch. However, between 1988 and 1995, while the overall level of contraceptive use remained stable, the use of such long-acting methods as Depo-Provera and the Norplant implant showed a steep increase, she explains.

EXECUTIVE SUMMARY

While the contraceptive injectable Depo-Provera has become a popular method of contraception among adolescents since its 1993 U.S. introduction, its costs have affected budgets of many publicly funded clinics.

- Manufacturer Pharmacia and Upjohn of Bridgewater, NJ, offers volume discounts for the injectable, but clinics, which receive significant discounts on oral contraceptives, still say the costs are beyond their funding capacities.
- In 1995, the first year Depo-Provera was tracked in national use, it was named by 19% of non-Hispanic blacks and slightly less than 10% of white and Hispanic adolescents as the primary choice of contraception among sexually active youths using birth control.

While the use of any form of effective birth control is a positive step, the switch to Depo-Provera has resulted in a serious budget crunch for those publicly funded family planning clinics struggling with the cost of the injections and climbing patient demand.

Depending on the negotiated price, OCs may cost a clinic $2 per cycle, for an annual per-patient cost of $24. Depo-Provera, in contrast, may cost a clinic $15 per quarterly shot for an annual per-patient cost of $60. For clinics such as Family Planning Services of Lorain County in Elyria, OH, the increase has "destroyed whatever concept I had of having a budget," says executive director **Ellen Bricmont**.

Family Planning Services' problems began in July 1997, when the clinic went from about 70 injections per month, to 90, 110, and then 120, notes Bricmont. The Title X-funded facility services an area outside Cincinnati with the ninth-highest level of teen pregnancy in the state.

"It happened in the last quarter of 1997, and by then I had already set my budget and the board had voted on it," says Bricmont. "We are already $5,000 over budget in our contraceptive account, and that is just through the end of September."

The Family Planning Council of Philadelphia, which serves as the federal Title X grantee for 70 clinics in southeastern Pennsylvania, spends 50% of its budget on the 15% of its patients who use Depo-Provera, confirms **Dorothy Mann**, executive director. "It is by far the most expensive method, and so we make it available within the confines of our financial resources," she says. "For the last two years, we have put a cap on the amount of money that we would spend on Depo, and the only way we will get through this year is if the price reduction holds."

Depo-Provera, manufactured by Pharmacia and Upjohn of Bridgewater, NJ, is the sole injectable method available in the United States. The company reports that the product recorded $62.2 million in global sales as of the third quarter of 1998, compared to $50.7 million in the same quarter of 1997. The company does offer what it terms "substantial" discounts to clinics, government programs, and Title X programs in the form of free goods based on purchases, confirms **Daniel Watts**, media relations manager. It also offers support through sales representatives and telemarketing techniques to check clinic stock and patient education and support material, he says. While public clinics are an important market segment for Depo-Provera, they do not represent the total market, he notes, adding that the company plans no further price reductions outside of its current pricing strategy.

That strategy is much the same as a "buy three, get one free" pyramid scheme, since clinics have to purchase more in order to get the discounted goods, contends **Jeffrey Zonis**, MBA, MPA, president and chief executive officer of the Family Health Council of Central Pennsylvania in Camp Hill, PA.

Initial subsidies dropped

When Depo-Provera was first introduced, Family Health Council offered a subsidy to its 47 family planning clinics to help boost use of the method. When the demand began to outstrip the council's resources, the organization turned to Pharmacia and Upjohn for relief in the form of reduced prices. The result was the current incentive program. Family Health Council since has ended its subsidies to its clinics.

"We did see then a dramatic drop-off — not actually a reduction, but the growth has stopped," Zonis says. "There are some new patients, but the method is not going to grow the way it has been, and it is a cost issue."

The first year Depo-Provera was listed as a contraceptive method in the National Survey of Family Growth was 1995. That survey is conducted by the National Center for Health Statistics in Hyattsville, MD, a division of the Atlanta-based Centers for Disease Control and Prevention, In 1995, Depo-Provera was named by 19% of non-Hispanic blacks and slightly less than 10% of white and Hispanic adolescent females as the method used by those who were sexually active and using a contraceptive method, says Darroch.

COMING IN FUTURE MONTHS

- Targeting young men in Title X programs
- Cyclo-Provera: Is 1999 the year for the U.S.?
- Tips on preventing condom breakage and slippage
- Dealing with adolescent gyn problems
- Advising your patients on osteoporosis

According to a 1998 analysis released by the Alan Guttmacher Institute, between 1991 and 1996, the teen-age birthrate in the United States declined from a 20-year high of 62.1 births per 1,000 females ages 15 to 19 to 54.4 per 1,000.[1] While such a drop cannot not be attributed to any one factor, family planners say that Depo-Provera definitely has made an impact.

While there are still too many sexually active adolescents who are not using a contraceptive method, Darroch says the net move has been to long-acting methods that don't require any action from the teen. Depo-Provera eliminates the need to remember a daily pill or hide contraceptive supplies, and its use results in absence of menstrual periods. These are all benefits teens like — and report to their friends.

"It is incredibly popular with adolescents," says Bricmont. "If I only had a dime for every time someone called and said, "I want the shot,' and when I ask how old they are, they say, 'I'm 15, and my friend has it.'"

Swaying teens from a mindset of "got to have the shot" is problematic for Family Planning Services providers, says Bricmont. Those first-time patients who request Depo-Provera are now counseled with, "We'd like to try you on the pill and see how you do on it."

The clinic operates a monthly waiting list for Depo-Provera, with patients instructed to call at a certain time of the month. Within minutes, the limited slots are filled, Bricmont reports. "The clinicians hate having to be restrictive. They understand it is a strictly financial decision."

Hard choices are facing all publicly funded clinics. With budget cuts looming for the family planning program for the San Antonio Metropolitan Health District, administrators are unsure whether resources will allow Depo-Provera to be provided to all who want it in the upcoming fiscal year, says **Janet Realini**, MD, MPH, medical director.

"If we need to limit the number of patients we supply with Depo-Provera in our clinics, we will give teens priority," Realini affirms. "San Antonio's teen birth rate is over 50% higher than the national rate for ages 15 to 17 and nearly twice the national rate for young adolescents ages 10 to 14."

Reference

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Filshie clip system gains U.S. acceptance

As American women continue to rely on sterilization as the leading method of birth control, U.S. physicians are adding another mechanical clip option to their techniques for tubal occlusion.

More than 35,000 U.S. women have been sterilized using the Filshie clip system in the two years since it received federal Food and Drug Administration (FDA) approval, says **Stuart Smyth**, chief executive officer of Avalon Medical Corp. of Williston, VT, distributor of the system. **[*Contraceptive Technology Update* covered the clip's introduction in November 1996 (p. 129) and reported on efficacy data presented to a FDA review panel in May 1996 (p. 58).]**

10-year data to come

Look for 10-year effectiveness data to be published this spring, says Smyth. **(*CTU* will offer an analysis of the data when the information is released.)** Family planners are indeed interested in such information, for in the 1996 landmark U.S. Collaborative Review of Sterilization (CREST) study (which did not include the Filshie clip), the probability of failure for laparoscopic spring clip applications was recorded at 36.5 pregnancies per 1,000 procedures, the highest among six sterilization methods.[1] **(See *CTU*, August 1996, pp. 93 and 99, for more on the CREST study findings.)**

Avalon Medical Corp. has quoted two-year failure rates at 2.7 per 1000 on the integral failure;

EXECUTIVE SUMMARY

The Filshie Clip system, a mechanical clip system used in tubal sterilization, has gained acceptance among providers since its 1996 U.S. introduction.

- Look for the 1999 publication of 10-year efficacy data on the Filshie Clip system. Family planners are interested in such data because the system was not included in a large, long-term review of U.S. sterilization methods.
- While the majority of American women continue to rely on sterilization as their chosen method of birth control, regret is still an important factor to consider in counseling for the method. Other long-acting methods, such as the intrauterine device and the Norplant implant, also should be offered as contraceptive options.

seven to nine per 1000 on the postpartum, says Smyth. Although he declined to reveal final rates from the 10-year data, he says the results "are not surprising."

Canadian providers and patients have been well satisfied with the Filshie clip system since it was introduced 15 years ago, reports **Albert Yuzpe**, MD, professor emeritus of OB/GYN at the University of Western Ontario in London and co-director of the Genesis Fertility Clinic in Vancouver, British Columbia. About 85% of interval female sterilizations in Canada now are performed using the clip system, says Yuzpe, who presented a paper on the method at the recent Emory University Quest for Excellence in Women's Health conference in Atlanta.

The clip, which features a titanium construction with an inner silicone rubber lining, has only one moving part, which locks into place upon application, notes Yuzpe. The silicone rubber expands as the clamped tube shrinks, giving full occlusion. The applicator is specifically designed for single- or dual-incision laparoscopy or mini-laparotomy.

A new provider training video will be released this year covering both single- and dual-incision methods, as well as local anesthesia conscious sedation, states Smyth. The company sponsors grand rounds teaching presentations and offers an extensive physician network so providers can get support and feedback on the method.

The clip system has found favor with U.S. managed care programs, with large preferred provider and health maintenance organizations purchasing from Avalon, Smyth reports.

Regret important factor

Between 1965 and 1988, the prevalence of surgical sterilization grew from 16 to 42% among U.S. married women ages 15 to 44, with the method the most popular form of birth control, states a new report on U.S. surgical sterilization from the National Survey of Family Growth, conducted by the National Center for Health Statistics in Hyattsville, MD, a division of the Atlanta-based Centers for Disease Control and Prevention.[2] In 1995, the prevalence remained at 41%. Since 1982, tubal ligation has become more common than vasectomy, occurring at a rate of 1.5 to two times as often among currently married and ever-married women ages 15 to 44. Among married women in 1995, 24% noted a tubal ligation, compared with 15% of husbands who underwent a vasectomy. In earlier years, tubal ligation and vasectomy were equally common among these women and their partners.

It is important for family planners to point out failure rates for tubal sterilizations along with those of other long-acting contraceptive methods, such as the intrauterine device, when counseling on long-term birth control decisions, says **Anita Nelson**, MD, medical director of the Women's Health Care Clinic at the Harbor-University of California in Los Angeles Medical Center in Torrance, CA. Remember that among younger women included in the CREST study, 10-year failure rates for clip systems were comparable to those for the IUD, she notes.

RESOURCE

For more on the Filshie Clip system, contact:
Avalon Medical Corp., 372 Hurricane Lane, Suite 201, Williston, VT 05495. Telephone: (888) 872-2547 or (802) 878-2900. Fax: (802) 878-3100.

Address regret when counseling

Regret following sterilization is an important factor to consider when counseling on the method. A 1998 survey conducted by Wirthlin Worldwide, a McLean, VA-based market research firm, and funded by Ortho-McNeil Pharmaceutical of Raritan, NJ, finds that one of five U.S. women who have undergone surgical sterilization later regretted their decision.[3] Ortho-McNeil manufactures the ParaGard T380A IUD.

About a third of the women who chose sterilization selected it due to its high level of effectiveness. Yet 53% of those women agreed that if an equally effective, nonsurgical option had been available, they would have chosen it.

Nearly 25% of women with an unreversed tubal ligation in 1995 expressed a desire for reversal of the operation, on the part of herself, her husband or partner, or both, states the National Center for Health Statistics report. Desire for tubal ligation reversal was more frequently reported by younger women, Hispanic women, and women with lower levels of education and income, the report notes.

Provide contraceptive choices, assess the patient's understanding of the procedure, and facilitate the decision-making process so the patient has sufficient time to make a thoughtful,

informed decision about sterilization, note the authors of *Contraceptive Technology*.[4] While reversal techniques do exist, be sure to emphasize that sterilization should be considered a permanent form of contraception.

References

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2. Public Health Service. *Surgical Sterilization in the United States: Prevalence and Characteristics, 1965-95.* 1996; 98:40.
3. Wirthlin Worldwide. Women report having second thoughts about surgical sterilization: New survey shows women should consider alternatives. Ortho-McNeil Pharmaceuticals survey. Raritan, NJ; Sept. 17, 1998.
4. Hatcher RA, Trussell J, Stewart F, et al. *Contraceptive Technology*. 17th ed. New York: Ardent Media; 1998. ■

Spermicides with N-9 focus of clinical trial

Research is now under way in getting up-to-date contraceptive efficacy information on over-the-counter (OTC) spermicidal products containing nonoxynol-9 (N-9), ending a reliance on decades-old data.

Family Health International (FHI), a reproductive health research firm in Research Triangle Park, NC, is overseeing the three-year multicenter clinical trial. Funding for the $4.7 million project comes from the National Institute of Child Health and Human Development in Bethesda, MD.

The main objective of the trial is to evaluate and compare the contraceptive effectiveness of five spermicidal preparations, says **Elizabeth Raymond**, MD, MPH, associate medical director of the biomedical affairs division at FHI. Researchers also will be looking at the safety, acceptability, and consistency of use of these preparations.

OTC spermicides, which rely on several formulations to deliver a chemical to kill sperm, have been in use in the United States for more than 40 years. These products were "grandfathered" into U.S. Food and Drug Administration (FDA) regulations under the monograph process. Most published clinical trials of spermicide used alone do not meet modern standards for study design and analysis; therefore clinicians must be cautious when comparing the efficacy of spermicides with the effectiveness of other contraceptive methods, warn the authors of *Contraceptive Technology*.[1]

The FDA, following a review of the spermicide drug class, determined in 1995 that the effectiveness of N-9 cannot be considered separately from its carrier, be it foam, pill, gel, cream, or suppository. The agency has stated that the active ingredients in marketed spermicides generally are safe, but their effectiveness in final product formulations is highly variable.[2]

Concern was raised following the 1995 ruling that OTC spermicide manufacturers may have to file new drug applications and submit clinical efficacy data to receive FDA approval. The costs of mounting such studies may convince many manufacturers of spermicide, which represents a small segment of the total contraceptive market, to withdraw their products. Such a move would leave women without a product that is easily available, does not require a provider's prescription, and is female-controlled**. *(See* Contraceptive Technology Update, *February 1997, p. 17, for more on the search for updated efficacy information.)***

The current trial has been designed to satisfy the FDA's request for information, says Raymond. The data may be used to define classes of spermicides so individual brands need not be tested, although this approach is still under consideration, she notes.

Five spermicidal preparations will be examined in the clinical trial. Women will be randomly assigned to one preparation and followed for seven months to obtain efficacy data. Three of the preparations are gel products with varying

EXECUTIVE SUMMARY

Patient enrollment is under way in a three-year multicenter study that finally will yield up-to-date efficacy information on formulations of over-the-counter spermicides with nonoxynol-9 (N-9).

- Such N-9 products have been in existence for more than 40 years, with their use "grandfathered" in under U.S. Food and Drug Administration regulations. With little research available on their efficacy, family planners have been unable to give a true comparison of such methods against other birth control options.
- Five formulations of N-9 products will be tested, with 1,800 women included in the 11-center trial.

amounts of N-9, which will allow researchers to determine if the amount of spermicide influences efficacy rates. A suppository tablet and a film preparation share the same N-9 level as one of the gels, which provides a mechanism to determine whether the method of delivery affects the efficacy rate.

"N-9 is in use in many different products and many different varieties of products, and we really don't know if there is an optimal dose or an optimal way of using it," says **Kurt Barnhart**, MD, MSCE, assistant professor of OB/GYN and human reproduction at the University of Pennsylvania Medical Center in Philadelphia, one of the centers for the clinical trial. "This comparison will not only help us to decide how good N-9 is overall, but if one product is actually superior to another."

Women now enrolling

The multicenter trial includes 11 study sites: Planned Parenthood of Central and Northern Arizona in Phoenix, University of Arizona Health Sciences Center in Tucson, Johns Hopkins Medical Services Corp. in Baltimore, Minneapolis Medical Research Foundation at Hennepin County Medical Center in Minneapolis, University of Pennsylvania Medical Center in Philadelphia, Magee-Women's Hospital in Pittsburgh, Medical University of South Carolina in Charleston, Baylor College of Medicine in Houston, University of Texas Health Sciences Center at San Antonio, Vermont Women's Health Center in Burlington, and Eastern Virginia Medical School in Norfolk.

Finding women who are interested in using spermicides as their sole contraceptive method can be challenging, says Raymond. Recruitment began in June, with some 200 women enrolled as of the first of November. A total of 1,800 women will be included in the trial.

Philadelphia has been successful in recruiting for the study because it is advertising spermicides as an alternative to hormonal contraception, Barnhart reports. "Many women prefer a nonhormonal method, as well as a method that is under their control," he notes.

References

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Test card is positive step in vaginitis diagnosis

What is your current procedure to diagnose vaginitis? Do you rely on laboratory pH paper to determine pH imbalance, potassium hydroxide to detect amines, and a wet mount slide under the microscope to make a definitive diagnosis? Or is the process so time-consuming that diagnosis is based on a visual exam, which may lead to improper treatment?

"In my experience, the inconvenience of using pH paper and the whiff test leads to most clinicians not bothering to do them," notes **David Soper**, MD, professor and director of the division of gynecology at the Medical University of South Carolina in Charleston. "Unfortunately, in making the diagnosis of vaginitis, knowing the results of the pH and amines test makes one a better microscopist, and diagnostic microscopy is the way we make the diagnosis of bacterial vaginosis [BV], vaginal yeast infections [candidiasis], and trichomoniasis vaginitis."

Clinicians now can use the FemExam pH and Amines TestCard from CooperSurgical of Shelton, CT, to eliminate the need for pH paper and potassium hydroxide. By placing a drop of vaginal fluid on the disposable, credit card-sized device, clinicians get a reading in two minutes whether the patient tests positive or negative for elevated pH and presence of volatile amines.

"I believe the FemExam card will make it easier for clinicians to do the tests and, therefore, make them better at the microscope," says Soper. "This translates into better diagnostic accuracy

EXECUTIVE SUMMARY

The three-step method of using pH laboratory paper, the potassium hydroxide "whiff" test, and the wet mount microscope slide to diagnose vaginitis may now be shortened with the use of the FemExam TestCard.

- The TestCard, a credit-card size disposable point-of-care test, allows clinicians to get accurate readings on pH imbalance and the presence of volatile amines. Cost of the method averages between $5.25 and $6.50 per patient.
- Interest is rising in the early detection and treatment of vaginitis, especially bacterial vaginosis, which has been linked to adverse outcomes in pregnancy.

and, therefore, better care for the patient."

The FemExam card originally was developed by Litmus Concepts of Santa Clara, CA. **(See *Contraceptive Technology Update*, September 1997, p. 115, for information on the Food and Drug Administration approval of the testing device.)** CooperSurgical, which has acquired the TestCard technology, has announced plans to introduce individual tests for BV, candidiasis, and trichomoniasis, the three most common forms of vaginitis.

When a swab containing unprocessed vaginal fluid is rubbed across the two test areas of the card, chemical changes will result in a positive or negative sign to appear in the test areas.

Two plus signs on the FemExam card suggest the diagnosis of BV, Soper explains. Two negative signs in the test areas suggest the diagnosis of yeast in a symptomatic patient. This knowledge can lead the clinician to look for either the "clue cells" associated with BV or the fungal elements of yeast infection.

Cost of a FemExam card averages between $5.25 and $6.50, depending on the purchased amount, according to company figures. The card technology features built-in controls to ensure accuracy and requires no added equipment, special storage, or disposal conditions.

Serious health risk link

Vaginitis, especially BV, has been the subject of increasing health concerns. BV has been linked with adverse outcomes in pregnancy, such as premature rupture of the membranes, preterm labor, and preterm birth, and the organisms found in BV also are frequently present in postpartum or post-cesarean endometritis, according to the Centers for Disease Control and Prevention (CDC) in Atlanta.[1] Annual estimated costs for BV-associated complications in pregnancy are estimated at $500 million to $1 billion annually.[2]

"We have had a lot of discussion in Maryland about the role of undiagnosed, untreated infections, especially BV in preterm pregnancy and infant mortality," says **Willa Brown**, MD, MPH, director of the Howard County Health Department's bureau of personal health in Columbia, MD. "An accurate, rapid, inexpensive test would help define this problem and, with early treatment, reduce the morbidity from these infections, especially in pregnant women."

In a study by researchers with the CDC's National Center for Infectious Disease and Emory University in Atlanta, 100 women presenting for initial prenatal visits were evaluated for BV using Gram stain of vaginal secretions, standard clinical criteria, and the FemExam card.

Gram stains were read by microbiologists, and BV was diagnosed using standard criteria. BV was diagnosed on the basis of Eschenbach's modification of Amsel's criteria if "clue cells" were present on wet mount and a positive amine odor was present upon testing with potassium hydroxide solution. BV was diagnosed using the card if both the pH icon and amine icon displayed a plus sign. Sensitivity, specificity, positive predictive value, and negative predictive values were calculated comparing the two methods with Gram-stain diagnosis as the "gold standard."

The prevalence of BV in the study population was 28% using Gram-stain criteria. When the Gram stain was used as the "gold standard" for diagnosis, results provided a sensitivity of 75%, a specificity of 94.4%, a positive predictive value of 84%, and a negative predictive value of 90.7%. The TestCard's numbers, in comparison, were 78.6%, 91.7%, 78.6%, and 91.7%, respectively.

The researchers, lead by Mark Newman, MD, a guest investigator with the National Center for Infectious Disease, concluded that the FemExam TestCard demonstrates "a diagnostic utility at least equal to the wet prep / vaginal pH / whiff-test criteria currently used to diagnose BV in an obstetric population."

Anita Nelson, MD, medical director of the Women's Health Care Clinic at the Harbor-University of California in Los Angeles Medical Center in Torrance, reminds clinicians that while the FemExam card does help diagnose vaginitis, a wet mount slide reading still is necessary to rule out a second, underlying infection. "It does give us a bridge as we move to the antigen test, which is what we really need to have if people are not going have a colposcope in their office."

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2. Oleen-Burkey MA, Hillier SL. Pregnancy complications associated with bacterial vaginosis and their estimated costs. *Infect Dis Obstet Gynecol* 1995; 3:149-157. ■

RESOURCE

For more on the FemExam TestCard, contact:
CooperSurgical, 15 Forest Parkway, Shelton, CT 06484. Telephone: (800) 848-0033.

Manual vacuum aspiration technique draws interest

(Editor's note: This is the second of a two-part series on abortion options. In the December 1998 issue, we provided information on mifepristone and methotrexate. The following article includes information on manual vacuum aspiration use in early abortions.)

Providers are looking at manual vacuum aspiration (MVA) with renewed interest for use in very early pregnancy termination, as well as for a backup method for mifepristone and methotrexate forms of medical abortion.

MVA is a nonelectric vacuum aspiration technique for removing uterine contents, using suction provided by a handheld syringe. It is indicated for use in endometrial sampling, first-trimester abortions, and incomplete abortions, says **Forrest Greenslade**, PhD, president of Ipas in Carrboro, NC. Ipas manufactures and distributes MVA instruments on an international basis and supplies an array of educational materials on reproductive health, including MVA and postabortion family planning.

MVA has been used as an abortion method for many years, so the technology is not unknown. However, a protocol for very early abortion, confirmed in research published by **Jerry Edwards**, MD, formerly with Planned Parenthood of Houston and Southeast Texas,[1] has led to a higher profile for MVA, Greenslade says.

Providers who are considering offering medical abortion, whether it be with off-label use of methotrexate or mifepristone, which still awaits its U.S. introduction, should consider MVA as a backup for method failures. Many providers who have participated in U.S. studies of mifepristone and methotrexate learned MVA as a backup method and now continue to offer it as an option, says **Ann Gerhardt**, MPH, U.S. marketing associate for Ipas.

"The message is that clinicians should have this in addition to medical abortion for accessible, confidential services," Greenslade says. "The issue isn't [just] medical abortion. It's moving to an array of services to make earlier abortion less centralized and to offer more choices to women."

EXECUTIVE SUMMARY

While vacuum suction has been used for many years in first-trimester abortions, the advent of ultrasensitive pregnancy tests and vaginal ultrasound now allow for the use of manual vacuum aspiration (MVA) in very early pregnancy terminations.

- MVA, which relies on use of a handheld syringe to remove uterine contents, is indicated in the use of endometrial sampling and incomplete abortions, as well as for first-trimester abortions.
- One benefit of using the MVA protocol is that it facilitates early detection of ectopic pregnancy, which can be treated before serious complications occur.

Look at the protocol

The MVA protocol researched by Edwards, now with Baylor College of Medicine in Houston, combines the use of the manual vacuum with vaginal ultrasound and modern human chorionic gonadotropin (HCG) quantitative analysis technology to safely perform abortion procedures as soon as the pregnancy test becomes positive, which is about eight days after conception.

Providers were concerned about performing very early suction procedures during the 1970s and 1980s because pregnancy tests at that time did not register positive results early, which delayed most abortions until seven weeks, says Edwards. Many providers performed early abortions under suspicion of pregnancy. Such early terminations were associated with more discomfort and pain, he notes.

With the development of ultrasensitive urine HCG tests, though, providers are able to determine pregnancy more accurately. The use of ultrasound before and after the MVA process allows the clinician to identify the gestational sac and ensure it has been removed for a complete abortion. It is important that the sac be identified and that women understand an additional visit may be required for serum HCG testing to make sure that the pregnancy has been successfully terminated, says **Nancy Meyers**, MA, SWA, study coordinator at Planned Parenthood of Houston and Southeast Texas.

The MVA protocol also allows for the identification of undetected ectopic pregnancies. By safely diagnosing the ectopic pregnancy, followed with medical abortion using methotrexate, women are spared the potential hazards associated with ectopic pregnancies. "We have detected ectopics, and we have referred, and a very minimal amount

of them have had to have surgery," notes Meyers. "That is a big advantage of doing it early."

Before providers consider implementing abortion services, they need to check with attorneys in understanding the state-by-state restrictions in abortion care, says **Susan Dudley**, deputy director of the National Abortion Federation in Washington, DC, a national association for abortion providers. Some states allow only providers at the MD level to perform abortions, while others sanction training for midlevel clinicians.

The MVA procedure has a slightly different feel than using electric suction, so even clinicians with plenty of first-trimester experience still need to do a few under supervision to gain competency, says **Carolyn Westhoff**, MD, DSc, medical director of family planning at Columbia Presbyterian Medical Center and associate professor of clinical OB/GYN and public health at Columbia University, both in New York City. **(See box, at right, for training information.)** "In general, one needs to be comfortable and competent emptying a pregnant uterus, plus be familiar with the equipment," she says. "Clinicians who do not have experience with doing abortions under totally local anesthesia also need that skill."

For any abortion procedure, counseling plays an important role in providing safe, legal, patient-centered care. Counseling for very early abortion using MVA must include the fact that patients may need to return for further HCG testing if the gestational sac cannot be identified following the procedure. Other issues covered in any abortion counseling include options (such as carrying the birth to term, keeping the baby, adoption placement), as well as birth control.

Women who discover that abortion can be offered so early in their pregnancies often choose MVA, says Meyers. Many appreciate the absence of noise associated with electric suction procedures.

"You can only imagine that people know that this is one of the toughest decisions they will ever have to make," says Meyers. "Anything that can be made easier, not hearing the noise, knowing it can be done very, very early, they are ecstatic about it."

Reference

1. Edwards J, Carson SA. New technologies permit safe abortion at less than six weeks' gestation and provide timely detection of ectopic gestation. *Am J Obstet Gynecol* 1997; 176:1,101-1,106. ■

TRAINING RESOURCES

For more on manual vacuum aspiration (MVA), contact:

❑ **Ipas**, P.O. Box 999, Carrboro, NC 27510. Phone: (800) 334-8446 or (919) 967-7052. Fax: (919) 929-0258. E-mail: ipas@ipas.org. Web: http://www.ipas.org. Ipas manufactures and distributes MVA instruments and pregnancy tests and supplies educational materials on reproductive health, including MVA and postabortion family planning. Get a complete overview of the MVA procedure through "Early Abortion Services: New Choices for Providers and Women" (*Advances in Abortion Care*, Vol. 5, No. 2), available in print at Ipas or in the archive section of the Ipas Web site.

❑ **National Abortion Federation** (NAF), 1755 Massachusetts Ave. NW, Suite 600, Washington, DC 20036. Phone: (202) 667-5881. Fax: (202) 667-5890. Web: http://www.prochoice.org. NAF offers accredited CME courses on reproductive health care, including early pregnancy termination services and counseling issues. A new training and resource manual on MVA, by Jerry Edwards, MD, and IPAS, is $8, including shipping and handling. A 22-minute MVA video is available to NAF members at $60 and to nonmembers at $75, shipping and handling included. The video also includes a monograph by Edwards and Mitchell Creinin, MD, assistant professor and director of family planning at the University of Pittsburgh. NAF offers provider and counselor training at its spring and fall conferences; the next session is scheduled for April 25 to 28. Contact NAF for details.

❑ **CAPS Project**, Planned Parenthood of Houston and Southeast Texas, 3601 Fannin, Houston, TX 77004. Phone: (713) 831-6559. CAPS provides resources, information, and assistance on abortion services primarily to Planned Parenthood affiliates. It offers a video on first trimester abortion, which covers traditional surgical abortion, and a video on early surgical abortion. Videos are $60 each, including shipping and handling.

❑ **Clinician Training Initiative of Planned Parenthood** of New York City, 26 Bleecker St., New York, NY 10012. Phone: (212) 274-7255. The Initiative offers teaching guides and educational resources to increase the number of providers who are willing and trained to perform abortions. Physicians and physician assistants who are licensed in the state of New York can receive provider training for medical and surgical abortion methods through the Initiative. ■

Monitoring the claims of consumer advertising

[Editor's note: This is the second of a two-part series on the impact of consumer-directed prescription drug advertising. In the December 1998 Contraceptive Technology Update, *p. 153, we offered information on changes in U.S. Food and Drug Administration (FDA) advertising regulations. The following article covers the role of the FDA's watchdog agency in monitoring such advertising and the contraceptive manufacturers who were cited in 1998 for violations of FDA advertising rules.]*

When it comes to advertising prescription drugs, the U.S. Food and Drug Administration regulates consumer-directed ads under the same rules as those it targets to health care providers.

Consumer ads, just like those aimed at providers, must make claims that are supported by scientific evidence and consistent with the FDA-approved product labeling. And just like provider advertising, consumer pitches must not present false or misleading information.

FDA guidance requires that consumers be able to understand the benefits and limitations of an advertised drug. The agency monitors ads to make sure they are easily understood and designed for their target audience. For example, ads may be considered misleading unless they clearly explain a drug's benefits and risks in everyday language.

EXECUTIVE SUMMARY

Since the U.S. Food and Drug Administration (FDA) announced changes in 1997 in direct-to-consumer advertising, pharmaceutical companies have made increased use of such advertising. The agency is keeping a close eye on such moves and cites companies for ads and promotional material that may present false or misleading information.

- FDA guidance requires that consumers be able to understand the benefits and limitations of an advertised drug. A "fair balance" of information must be presented for proper communication.
- The FDA's Division of Drug Marketing, Advertising, and Communications cited 125 companies for advertising violations in 1998. Six of those companies cited were contraceptive manufacturers.

The goal of any prescription drug ad is to promote what the FDA terms "fair balance." This balance is achieved by prominent presentation of the risks, with no overemphasis of the benefits.

The revision of broadcast direct-to-consumer advertising guidance has changed the way the FDA prioritizes its workload, says **Norman Drezin**, RPh, JD, deputy director of the FDA's division of drug marketing, advertising, and communications in Rockville, MD. The division, which operates within the FDA's center for drug enforcement and regulation, is charged with monitoring all prescription drug advertising materials.

"We get a lot of material coming to us, so to us, [broadcast advertising] is another piece," Drezin explains. "We do look at it with a little more priority because of its impact, its broad dissemination of information."

Monitoring violations

The division continues to keep a sharp eye out for violations of the federal Food, Drug, and Cosmetic Act, whether they are made in a press release, a consumer print ad, or a television commercial. According to information posted by the FDA center's freedom of electronic information office, 125 companies have been cited for violations in 1998.

Six of those companies were cited specifically for violations in connection with information disseminated regarding contraceptives:

- Pharmacia and Upjohn of Bridgewater, NJ (Depo-Provera);
- Organon of West Orange, NJ (Mircette, Desogen);
- Wyeth-Ayerst of Philadelphia (Alesse, Lo/Ovral, Nordette, Triphasil);
- Searle of Skokie, IL (Demulen, Tri-Norinyl);
- Watson Laboratories of Corona, CA (Trivora, Zovia, Necon, Levora, Nor-QD);
- Ortho-McNeil of Raritan, NJ, received a citation in 1997 for a consumer ad for Ortho Tri-Cyclen.

The contraceptive manufacturers' violations were addressed by the FDA in what are known as "untitled letters," used for the least serious violations of advertising regulations. (To review the letters on line, go to the FDA's center for drug enforcement and regulation World Wide Web site at http://www.fda.gov/cder/handbook/index.htm. Click on "Post Drug Approval Process," "Prescription Drug Advertising and Promotional

Labeling," "DDMAC Home Page," and "Information for Industry.")

The majority of violations stem from the manufacturers' claims that a particular oral contraceptive (OC) is unique or superior to another. Such claims must be backed up by adequate clinical comparative trials, states the FDA.

Other violations include failure to adequately disclose risks, especially the fact that no OC protects against HIV and other sexually transmitted infections.

Under this ruling, the following claims are misleading because they purport superiority or fail to provide adequate substantiation:

- **Alesse:** "a balanced combination that's just right for new starts."
- **Demulen:** superiority due to its low androgenic potential or low incidence of side effects.
- **Depo-Provera:** Two television ads ("Barbecue" and "Birthday") fail to adequately direct consumers to other sources of additional product information.
- **Desogen:** "My body knows the difference."
- **Levora:** having specific characteristics that make it clinically significantly different from another, or that it is specifically indicated for a particular patient or population.
- **Lo-Ovral:** "the physician's first choice when it comes to switching OCs."
- **Mircette:** "Uniqueness is based on the patented shortened hormone-free interval."
- **Necon:** "low risk of acne, oily skin, hirsuitism, weight gain."
- **Nordette:** "the patient acceptance of levonorgestrel."
- **Ortho Tri-Cyclen:** "announcing a birth control pill that's also a beauty aid."
- **Triphasil:** "No OC is better than Triphasil at reducing menstrual irregularities."
- **Tri-Norinyl:** "similar yet different."
- **Trivora:** "minimize[s] androgenic side effects such as hirsuitism, chronic anovulation, polycystic ovarian disease, acne, bloating and weight gain, reduced libido."
- **Zovia:** "low androgenic potential."

"In each letter, we articulate what we would like done," Drezin says. "Usually, it's to discontinue the dissemination of the material."

Drezin categorizes the relationship between the regulatory agency and the companies as "fairly cordial." In most instances, companies agree to stop releasing the material in question, he says. ■

CTUPDATES
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State women's health profiles

State statistics on women's health are available in *State Profiles on Women's Health* from the Jacobs Institute of Women's Health, based in Washington, DC. The Institute is an independent nonprofit organization. Each state section features four pages of charts that allow comparisons with national data on health status, insurance coverage, risk factors for illness, and health policy issues. Cost: $30, plus $3.50 shipping and handling. For details, contact the Institute at 409 12th St. SW, Washington, DC 20024-2188. Phone: (202) 863-4990. Fax: (202) 488-4229. Web: http://www.jiwh.org. ▼

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Editor: **Rebecca Bowers**.
Publisher: **Brenda Mooney**, (404) 262-5403, (brenda.mooney@medec.com).
Managing Editor: **Joy Daughtery Dickinson**, (912) 377-8044, (joy.daughtery@medec.com).
Production Editor: **Terri McIntosh**.

Editorial Questions

Questions or comments?
Call **Joy Daughtery Dickinson** (912) 377-8044.

Ortho launches Web sites

Two new World Wide Web sites by contraceptive manufacturer Ortho-McNeil Pharmaceutical of Raritan, NJ, provide information for family planners and their patients.

Http://www.ortho-mcneil.com carries prescribing information for all products made and marketed by the company. Http://www.womenintheknow.com offers information on birth control, sexually transmitted diseases, vaginal and urinary tract infections, reproductive health, an analysis of family planning options, and questions patients can ask providers. Selected questions are answered by a panel of women's health care experts. ■

CE objectives

[For details on our CE program, contact: Customer Service, American Health Consultants, P.O. Box 740056, Atlanta, GA 30374. Phone: (800) 688-2421. Fax: (800) 284-3291. E-mail: . Web:]

After reading this issue of *Contraceptive Technology Update,* the continuing education participant should be able to:

1. Cite the average clinic's annual per-patient cost for oral contraceptives and Depo-Provera.
2. Name the mechanical clip system approved in 1996 for use in female tubal sterilization.
3. State the importance of the multicenter study of spermicides now under way by Family Health International.
4. Name three medical indications for use of manual vacuum aspiration. ■

Correction

The November 1998 story on the Prentif cervical cap included two errors. The average cost of a Prentif cap (not including medical exam and fitting) ranges from $40 to $70. The address for Cervical Cap Ltd. is 430 Monterey Ave., Suite 1B, Los Gatos, CA 95030. We regret the errors.

U.S. distributor Cervical Cap Ltd. also reports this on its Prentif package insert: "The Prentif Cavity-Rim Cervical Cap has been found to range in effectiveness from 82.6% to 93.6%, depending on consistency of use." ■

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