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Women who want permanent birth control now have a second option

Essure procedure offers noninvasive alternative to tubal ligation

American women now have a choice when it comes to permanent birth control: They can opt to undergo tubal ligation or choose the Essure transcervical sterilization procedure.

Essure, developed by San Carlos, CA-based Conceptus, is the first alternative to tubal ligation for women seeking permanent birth control in the United States. It is marketed in Australia, Europe, Singapore, and Canada. Unlike tubal ligation, which requires an abdominal incision and is typically done under general anesthesia, Essure requires no incisions and can be performed without general anesthesia. Cost of the Essure procedure is expected to be about the same as traditional tubal ligation, about $2,500.

The Essure method involves the use of a proprietary microinsert device and catheter delivery system for minimally invasive transcervical tubal access. The Food and Drug Administration (FDA) approved the sterilization procedure in November 2002. The agency expedited its review because of the potential benefit to couples seeking alternative means of sterilization.[1] Conceptus, the manufacturer of Essure, expects to have the product available nationwide by March 2003. **(*Contraceptive Technology Update* reported on the method in the February 2002 article,**

EXECUTIVE SUMMARY

The Food and Drug Administration has approved Essure, the first alternative to tubal ligation for women seeking permanent birth control in the United States.

- Unlike tubal ligation, Essure requires no incisions and can be performed without general anesthesia.
- The method involves a proprietary microinsert device and catheter delivery system for minimally invasive transcervical tubal access. Women must use backup contraception for three months, when a hysterosalpingogram evaluation ensures that both of the microinserts are in the correct location and that both tubes are blocked.

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"Noninvasive female sterilization eyed," p. 15, and the October 2002 article, "Sterilization options may expand soon in U.S.," p. 111.)

Tubal sterilization is the most common method of contraception used in the United States; 11 million women ages 15-44 rely on the method for birth control.[2] Half of the 700,000 annual bilateral tubal sterilizations are performed postpartum, and half are performed as ambulatory interval (unrelated in time to a pregnancy) procedures.[2]

"The No. 1 method used for pregnancy prevention in the U.S. is tubal ligation, and that is a fairly cumbersome procedure that involves surgery," observes **Wayne Shields**, president and chief executive officer of the Washington, DC-based Association of Reproductive Health Professionals (ARHP). "We are really encouraged to see a new method that accomplishes the same thing, is as effective, is safe, and doesn't require surgery."

How does it work?

The Essure microinsert device measures 4 cm and consists of a stainless steel inner coil, a nickel titanium alloy outer coil, and polyethylene terephthalate (PET) fibers. The inner coil attaches the device to a guidewire used for placement in the fallopian tubes, while the outer coil anchors the microinsert in the fallopian tube. The PET fibers are a mesh between the two coils. **(See the box on p. 3 for information on who may not use Essure.)**

During the Essure procedure, the device is inserted through the cervix into the fallopian tubes through a catheter that covers the guidewire, from which the device is then released. The device promotes tissue growth in the fallopian tubes, that over a three-month period, provides tubal occlusion.

In clinical testing, the total procedure lasted about 35 minutes, with 15 minutes required to place the microinserts into the fallopian tubes. Most women were able to leave the treatment facility 45 minutes after the procedure. About 90% of women were able to resume work in 24 hours or less after the day of the procedure, with many women resuming normal physical activities the same day of the procedure.

Women must use another method of birth control for at least three months after the procedure is performed. At that time, a hysterosalpingogram evaluation is performed to make sure that both of the Essure microinserts are in the correct location and that both tubes have been blocked.

The FDA approval was based on data from two clinical trials involving more than 600 women who

Who should not use Essure?

Any woman who:

- is uncertain about her desire to end fertility;
- is pregnant or suspects she is pregnant;
- has delivered a baby, had a miscarriage, or had an abortion within six weeks before the Essure microinsert placement procedure;
- has an active or recent pelvic infection;
- has an unusual uterine shape (for example, a uterus with only one tube or a divided uterus);
- has a known allergy to dye (contrast media);
- has a known hypersensitivity or allergy to nickel confirmed by skin test;
- is unwilling to use another method of contraception for at least three months after the Essure microinsert placement procedure;
- is unwilling to undergo a hysterosalpingogram approximately three months after the Essure placement procedure to make sure the tubes are blocked and the devices are in the correct position;
- has had a prior tubal ligation.

Source: Adapted from Essure Patient Information Booklet, Conceptus. Web: www.essure.com.

relied on the current Essure design for one to two years. Look for the U.S. data to be published in the first or second quarter of 2003, says **Stan Van Gent**, vice president of marketing for Conceptus.

In one clinical study, placement of the Essure implants in both fallopian tubes (bilateral placement) was achieved in 200 of 227 women. Following confirmation of placement after three months, 194 women began relying exclusively on the device to prevent pregnancy. Of those, 181 women have relied on the device for at least 24 months, and another 12 women have relied on the device for at least 12 months. To date, none of the women have reported pregnancy.[1]

In the second study, bilateral placement of the Essure implants was attempted in 518 women between ages 21 and 40. All women used an alternate form of contraception for the first three months. Following confirmation of proper placement, 449 women began relying on the device alone to prevent pregnancy. These women were then followed to see if any became pregnant or had any other adverse events. In this study, the FDA considered one-year data on 439 women and two-year data on 16 women. To date, none of these women have reported pregnancy.[1]

In the second study, physicians failed to achieve bilateral placement of the Essure implants at first attempt with 14% of patients in the study.[1] According to the FDA, Conceptus will conduct a post-approval study to document the placement failure rate with newly trained physicians and to identify factors associated with placement failure.

Because women will rely on the Essure device for permanent sterilization for many years after placement, Conceptus also is required to follow all study participants from both clinical studies for at least five years to evaluate long-term contraceptive effectiveness.

RESOURCES

For more information on Essure, contact Conceptus, 1021 Howard Ave., San Carlos, CA 94070. Telephone: (650) 802-7240. Fax: (650) 610-8363. Web: www.essure.com or www.conceptus.com.

The Washington, DC-based **Association of Reproductive Health Professionals** (ARHP) has released an accredited issue of its monograph, *Clinical Proceedings*, on the topic of transcervical sterilization. The monograph is based on a December 2001 ARHP conference, *Clinical Update on Transcervical Sterilization*. Review the monograph on-line at ARHP's web site, www.arhp.org. Click on "healthcare providers," and "online publications." Then click on "*Clinical Proceedings*," then the publication title, *Clinical Update on Transcervical Sterilization*. Up to 2.4 continuing medical education credits are available.

Check training options

A variety of training options will be available to help physicians receive education about the Essure procedure, says Van Gent. Conceptus will conduct one-day training sessions at multiple sites around the country; information about the training schedules will be available on the company's web site, www.essure.com.

The sessions will cover indications, contraindications, risks, benefits, counseling, and the steps of the procedure. Physicians will be able to test their hysteroscopy skills and placement techniques on specially designed models, says Van Gent. Following the training session, company representatives will attend, on average, the physician's first

five placements and monitor the results of the first 10 cases via a voluntary fax reporting system.

Information about the Essure procedure will be included in ARHP's accredited visiting faculty program in 2003 and 2004, says Shields. The sessions will include education about new contraceptive options, including the Essure method, and also will involve a nonaccredited hands-on practicum training session, he notes. ARHP will be developing centrally located centers of excellence for the visiting faculty program; check the ARHP web site, www.arhp.org, for specific sites. **(ARHP has developed a monograph on transcervical sterilization; check the resource box on p. 3 for more information.)**

While the Essure method may be different from tubal ligation, both are permanent forms of contraception, says Shields. Providers must follow the same steps of informed consent when counseling women on the Essure method.

"I think it is important for women to understand all of their options and to understand this new option, and how it works, and that it is permanent," he notes . "If women aren't clear that it is permanent, then this is not the method for them."

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Will 'Quick Start' give women jump on pill use?

EXECUTIVE SUMMARY

The Quick Start method of initiating oral contraceptives (OC) represents an alternative to the traditional approach of starting pills around the menstrual period.

- The woman takes her first pill on the day of her first visit to a family planning provider. It may improve OC acceptability and use by eliminating the time in which women wait for their menstrual periods.
- Two small observational studies in the United States have found improved continuation rates with Quick Start. The method is under investigation in a larger randomized clinical trial.

You reviewed the instructions for initiating the first pack of oral contraceptives (OCs) with your patient. She elects to use the "Sunday start," beginning pills on the first Sunday after her next period. When she returns for a follow-up visit in a few months, though, you discover she never started the pills and now is pregnant.

How can you combat this problem?

Researchers are evaluating the effectiveness of the "Quick Start" method of initiating pill use, which entails the patient taking the first pill in the office following counseling by the clinician. The rationale for this approach is to improve acceptability and use by eliminating the time period women wait for their menstrual periods.

Results from two small observational studies have found improved pill continuation rates with Quick Start users.[1,2] A second paper, scheduled for upcoming publication, shows no adverse impact on bleeding patterns in women using the initiation method.

Researchers at New York City's Columbia University are following up their initial work and spearheading a randomized clinical trial funded by the Bethesda, MD-based National Institute of Child Health and Human Development. The investigation will evaluate continuation and pregnancy outcomes at six months among 2,000 urban U.S. women younger than age 25 who receive pills at clinics at Mount Sinai Adolescent Health Center and Columbia University in New York City, University of Texas Southwestern Medical Center in Dallas, and Emory University in Atlanta, reports **Carolyn Westhoff**, MD, MSc, associate professor of OB/GYN and public health at Columbia University.

OCs work — when taken

Oral contraceptives are one of the most effective methods of birth control, but they must be taken consistently and correctly to achieve efficacy. According to *A Pocket Guide to Managing Contraception,* OCs may be initiated in one of three ways:

- first day of next menstrual period (generally preferred because no routine backup method is needed);
- first Sunday after menstrual bleeding begins;
- immediately, if pregnancy is excluded.[3]

If the woman is not switching from another

hormonal method, instruct her to use backup contraception for seven days for options 2 and 3.[3]

How does Quick Start differ from the third option?

"Our concept of Quick Start includes directly observed therapy, not simply any-day start, for the positive impact of taking the first pill right there with the encouragement of the provider," offers Westhoff. "'Any-day start' obviously can have benefits too, but isn't really what we mean by Quick Start."

Why do patients often return to the clinic having failed to begin their first pack of pills? Some women may become pregnant while waiting for their period and the initiation of the pill pack, while others may encounter confusion about starting instructions when their period finally arrives, she says. Some women have ambivalence over the pill after they leave the clinic, due to discussion with friends and family who emphasize disadvantages and myths about pill use, she notes.

The Quick Start method alleviates these problems, Westhoff notes. By taking the first pill in the office, all the woman has to remember after she leaves is to follow her daily pill schedule. By being on hand when the first pill is taken, the clinician is on hand to answer any questions involving pill use, she notes.

Since pills are initiated during the clinic's work week, the odds are that office staff will be on hand when patients call in for refills, rather than when women opt for a "Sunday start."[2] This availability keeps women from discontinuing the method when they are unable to access health care during the weekend.

Improve OC compliance

In its observational study, Columbia University investigators prospectively evaluated predictors of short-term OC continuation among 250 OC women who requested pill use.[1] Telephone follow-up of participants showed that women who swallowed the first OC in the clinic were more likely to continue on their pill schedule until the second package than women who planned to start the pills later.

Staying on schedule with pills is a particular problem with adolescents. While pills are the most popular form of contraception for teens, compliance rates range from 44%-55%.[2] A small-scale study suggests better compliance in adolescents at three months with the Quick Start approach while maintaining side effect profile.[2]

Evaluation of this method of pill initiation is welcomed by family planning providers such as **David Archer**, MD, professor of obstetrics and gynecology and director of the Clinical Research Center at the Eastern Virginia Medical Center in Norfolk.

"I cannot understand why it takes us so long to do a clinical trial to show efficacy for initiating oral contraceptives immediately in women," comments Archer. "It is important that we think outside of the box more often with such simple, but important, innovations."

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Check STD screening: Room for improvement?

Review the number of patients who came through your examination room today, and count how many were screened for one or more sexually transmitted diseases (STDs). If the answer is "zero," then perhaps it is time to review your practice guidelines.

According to a national survey of U.S. physicians that assessed screening, case reporting, partner management, and clinical practices for syphilis, gonorrhea, chlamydia, and HIV infection, STD screening levels are well below national guidelines for women and virtually nonexistent for men.[1] While obstetrician-gynecologists (OB/GYNs) were found to screen women for STDs at a higher rate than physicians in several other specialties, companion research notes that they are more likely to screen pregnant than nonpregnant women, and thus they are missing many opportunities to stem what has been called "the hidden epidemic" of STDs in the United States.[2]

Why are so many providers failing to screen? There are a number of factors coming into play, says **Matthew Hogben**, PhD, of the Division of STD Prevention at the Atlanta-based Centers for Disease Control and Prevention (CDC).

EXECUTIVE SUMMARY

While national guidelines are calling for increased screening for sexually transmitted diseases (STDs), a national survey of physicians reveals that rates for screening of pregnant and nonpregnant women still are below optimal levels.

- While obstetrician-gynecologists were found to screen women for STDs at a higher rate than physicians in several other specialties, they are more likely to screen pregnant than nonpregnant women.
- Women receiving contraceptive or related services at family planning clinics are one-third more likely than those receiving such services from private physicians to obtain an STD service. However, providers face challenges in incorporating new STD diagnostic and treatment options within budget constraints.

Some providers may not be familiar with national screening guidelines, notes Hogben. **(Review the highlights of the recently released *2002 Guidelines for the Treatment of Sexually Transmitted Diseases*; see the article, "Take your STD skills to the next level with new guidelines," in the *STD Quarterly* inserted in the August 2002 issue of *Contraceptive Technology Update.)***

Some physicians report that they are uncomfortable talking about sexual behavior with their patients, observes Hogben. Also, if STD screening is not reimbursable under the patient's health coverage, such tests may be less likely to be ordered, he notes.

Where is the care?

The physician survey, mailed to a random sample of 7,300 physicians, was conducted by the CDC with the Seattle-based Battelle Centers for Public Health Research and Evaluation. Results indicate that a substantial proportion of STD care is provided outside of dedicated STD clinics. With more people seeking care outside of STD clinic walls, providers who work in community-based practices are "essential links" in STD partner management and public health surveillance, researchers note.[1]

When looking at all physicians surveyed, fewer than one-third reported routinely screening men or women (regardless of pregnancy status) for STDs. When STDs were diagnosed, many providers failed to report to public health officials: Case reporting was lowest for chlamydia (37%), intermediate for gonorrhea (44%), and higher for syphilis, HIV, and AIDS (53%-57%). And when it came to partner notification, the majority of physicians said they instructed patients to notify their partners or the health department, rather than doing so themselves.

Researchers found that OB/GYNs were more likely to screen women for syphilis, gonorrhea, and chlamydia than other surveyed physicians. Depending on the STD, 23%-55% of OB/GYNs screened nonpregnant patients for STDs, compared to the 19%-31% of other specialists screening nonpregnant women. However, OB/GYNs screened nonpregnant women at significantly lower rates than they screened their pregnant patients. Approximately four-fifths of OB/GYNs screened pregnant women for chlamydia and gonorrhea, and 85.6% screened pregnant women for syphilis.

Such low rates of screening are troublesome, particularly in the case of chlamydia, the most common of all bacterial STDs. The CDC estimates there are 3 million new cases of the STD each year, and many women who become infected do not present with symptoms. In an effort to stem the spread of the disease, the U.S. Preventive Services Task Force in 2001 called for all primary care clinicians to perform chlamydia screening for all sexually active women ages 25 and younger, as well as older women at risk, as part of their regular health care visits. **(Review the guidelines in the *CTU* July 2001 article, "Task force calls for chlamydia screening," p. 81.)**

Finances constrain care

Family planning providers are doing their part in delivering STD services to low-income women and teens, according to research published by the New York City-based Alan Guttmacher Institute. Findings indicate that women receiving contraceptive or other related services at family planning clinics are one-third more likely than those receiving such services from private physicians to report that they obtained an STD service.[3]

However, budget constraints often keep many family planning facilities from offering new STD diagnostic or treatment modalities. New nucleic acid amplification tests offer a noninvasive way to test for chlamydia; however, facilities such as Tapestry Health, an independent family planning agency serving western Massachusetts, are unable to institute their use due to price constraints. **(Read**

about the tests in the *STD Quarterly* article, "How to stem chlamydia's silent spread?" inserted in the February 2001 issue of *CTU.)*

While laboratory costs and pricing are variable due to negotiated rates and test volume, nuceic acid amplification tests can have a two- to three-fold higher per test cost. State subsidies have helped in allowing Tapestry Health to offer one-dose chlamydia treatment to qualified patients; however, self-paying patients are offered the option of the one-dose therapy, or a multi-day treatment, which is less expensive, says **Lucy Hartry**, director of administrative services.

One way the agency has been able to check out new STD screening and treatment methods is through participation in research trials, says Hartry. However, when it comes to implementing daily use of technologies, funding keeps the facility from moving forward, she notes.

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New data address impact of sterilization

Since about one-fourth of all U.S. women ages 15-44 who have ever married have undergone tubal sterilization,[1] chances are that you have counseled women about their permanent contraceptive options.

Family planning providers now have new information on incidence of regret following sterilization. Findings from a large-scale prospective cohort study indicate that the probability of regret is similar for women whose husbands undergo vasectomy to those of sterilized women. However, providers will need to check for conflict between partners; researchers note that when there was substantial conflict between a woman and her husband before vasectomy or tubal sterilization, the probability of subsequent request for reversal was increased.[2]

In a separate report, researchers found that a majority of women indicated no change in sexual interest (80%) or pleasure (81.7%) after tubal sterilization — but in those who did, women were 10-15 times more likely to report increased rather than decreased sexual interest or pleasure.[3]

EXECUTIVE SUMMARY

New publications from the US Collaborative Review of Sterilization (CREST) offer new evidence about the impact of female sterilization.

- The probability of regret is similar for women whose husbands undergo vasectomy to those of sterilized women. However, when there was substantial conflict between spouses before vasectomy or tubal sterilization, the probability of a subsequent request for reversal was increased.
- Most women indicated no change in sexual interest or pleasure after tubal sterilization. However, in those who did, women were 10-15 times more likely to report increased rather than decreased sexual interest or pleasure.

CREST yields new reports

Both publications draw their findings from the U.S. Collaborative Review of Sterilization (CREST), a large-scale U.S. trial encompassing 15 participating medical centers. Women ages 18-44 undergoing tubal sterilization were enrolled in the prospective, multicenter cohort study. **(Review the following *Contraceptive Technology Update* articles for analysis of CREST data: "Sterilization note the cause of menstrual problems," March 2001, p. 30; "Young age a factor in sterilization regret," October 1999, p. 116; "Tubal sterilizations don't rule out ectopic pregnancy," June 1997, p. 67; "Include new failure rates in reviewing sterilization," August 1996, p. 93.)**

In the new report comparing women's regret after vasectomy versus tubal sterilization, 6.1% of the 525 women whose husbands underwent vasectomy regretted the decision five years later, compared to 7% of the 3,672 women who had a tubal ligation. In addition, the overall cumulative probability that a woman would request to have a tubal ligation reversed was 2.2%, compared with 2.0% of women who requested that their husbands' vasectomies be reversed.[2]

Women who reported substantial conflict with their husbands or partners before tubal sterilization were more then three times as likely to

regret their decision and more than five times as likely to request a reversal than women who did not report such conflict, report the investigators.[2]

Investigators asked each woman "When it was decided that your husband would have a vasectomy or you would have a tubal ligation, was there any conflict between you and your husband?" If the woman responded, "yes, some," or "yes, a lot," substantial conflict was determined. The study didn't ask women to specify the nature of the conflict, so the authors don't know whether the conflicts were about the sterilization procedures or other matters.

Encourage participation of the male partner in making decisions about sterilization, advises **Denise Jamieson** MD, MPH with the Division of Reproductive Health of the National Center for Chronic Disease Prevention and Health Promotion in the Atlanta-based Centers for Disease Control and Prevention (CDC). In these counseling sessions, potential areas of conflict regarding decisions about sterilization may be identified, she says.

During the counseling process, talk with patients and their partners regarding marital stability, spousal health, and children's health.[4] To assess these areas, ask, "Are you sure you will want no more children? Is your partner?" and "Are you having any marriage problems?"[5] Ask the man or woman if either would regret the loss of fertility if their marriage failed or if their spouse or child should die.[4] Identifying such risks should not be a reason for denying sterilization; it indicates that more counseling and discussion of long-term reversible methods are necessary.[4]

Is sex better?

In the second CREST report, researchers concluded that tubal ligation is unlikely to result in changed sexual interest or pleasure.[3] Among those women with change, though, the majority experienced positive sexual effects.

Why do some women experience increased sexual interest or pleasure after sterilization? The removal of fear of unwanted pregnancy or the discontinuation of a birth control method with uncomfortable side effects may be the cause, researchers surmise.

Women with post-sterilization regret were the subgroup most likely to have a negative effect; similarly, women reporting regret were significantly less likely to report increased interest or pleasure. Whether the regret or the decreased sexual interest or pleasure occurred first is unclear, say researchers.

How can family planning providers reduce the risk of regret associated with sterilization?

"Most women who choose tubal sterilization are satisfied with their decision and do not experience regret," says **Caroline Costello**, MPH, with the CDC's Division of Reproductive Health of the National Center for Chronic Disease Prevention and Health Promotion. "However, previous CREST study analyses have identified some characteristics that may help practitioners identify women who may be at increased risk for experiencing regret: age younger than 30 years, less than one year since the birth of the youngest child, and spousal/partner conflict over the decision to have tubal sterilization."

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Douching linked to vaginal infection

Your next patient, a 19-year-old woman who is sexually active, says she douches on a weekly basis for hygiene purposes. She has been previously treated for a sexually transmitted disease (STD). What should you tell her?

Share the results of a just-released study: Women who douche at least once a month have higher rates of bacterial vaginosis (BV) infections than do women who don't douche.[1]

Bacterial vaginosis is the most common vaginal infection in women of childbearing age, according to the Atlanta-based Centers for Disease Control and Prevention. About half of women with BV may be asymptomatic; those who do have symptoms may notice a fish-like odor or a

EXECUTIVE SUMMARY

Findings from a just-released study indicate that women who douche at least once a month have higher rates of bacterial vaginosis (BV) infections than do women who don't douche.

- Researchers studied 1,200 women at high risk for sexually transmitted diseases at five U.S. clinical sites. Out of approximately 40% of women who reported douching regularly for hygiene reasons or to treat bothersome vaginal symptoms, two out of every five had BV.
- Bacterial vaginosis has been linked to acquisition of HIV, preterm birth, and pelvic inflammatory disease.

thin white or gray vaginal discharge.[2] Since bacterial vaginosis has been linked to acquisition of HIV, preterm birth, and pelvic inflammatory disease (PID),[3-7] the new research adds to growing concerns about the adverse health effects from douching. **(Review BV screening and treatment information in the *Contraceptive Technology Update* March 2002 article, "New guidelines are up for bacterial vaginosis," p. 31.)**

To date, there has been no prospective data linking BV to douching, notes **Roberta Ness**, MD, MPH, associate professor of epidemiology, medicine and OB/GYN at the University of Pittsburgh, lead author of the new paper. The just-published information, however, is baseline data from a prospective cohort study on douching, BV, and incident PID; researchers will be publishing the prospective data in about a year, she reports.

Douching may disrupt the normal vaginal microbiology and lead to vulnerability to BV, concludes the new report.

Researchers studied 1,200 women at high risk for STDs at five clinical sites around the United States. They found that of the approximately 40% of women who reported douching regularly for hygiene reasons or to treat bothersome vaginal symptoms, two out of every five women had BV. The women with BV were much more likely to lack hydrogen peroxide (H_2O_2)+ lactobacilli, a specific kind of naturally occurring bacteria necessary to fight off BV-causing bacteria.

In the 1995 National Survey of Family Growth, regular douching was reported by 15.5% of adolescent girls and young women ages 15-19, and by 28% of those ages 20 to 24 years.[8] In the 1995 report, regular douching was reported by 37% of African-American and 11% of white 15- to 19-year-old females; for those ages 20-24, 60% of African-Americans reported regular douching, while 20% of whites noted similar practices.

Women may believe that douching is good hygiene, similar to brushing their teeth, suggests **David Soper**, MD, vice chairman of business and clinical affairs and director of the division of gynecology at the Charleston-based Medical University of South Carolina. Some women may practice douching as a response to vaginal odor, and some are taught to douche by their mother or grandmother.

Douching is a cultural hygiene habit passed down through the generations, agrees Ness.

"It is not clear how hard it will be to get women to stop," she observes. "However, we have another publication coming out soon which suggests that health provider advice to stop may be important."

What can you do?

Here are some counseling tips you can use in talking with women about douching:

Emphasize the need to maintain normal vaginal flora as a way of maintaining vaginal health, says Soper. Because routine douching changes the delicate chemical balance in the vagina, it can make a woman more susceptible to bacterial infections and introduce new bacteria into the vagina and cervix.

Soper suggests contrasting the vagina with the mouth: The mouth with its teeth needs brushing, while the vagina is cleaner and doesn't need similar hygiene techniques.

Some women believe that menstrual blood is "dirty," says Soper. Explain to them that menstruation is a normal process, and they do not need to be "cleansed" by douching.

Because the chemical balance of the vagina is very sensitive, direct women to let the vagina clean itself, according to information from the Washington, DC-based National Women's Health Information Center (NWHIC).[9] Warm water and gentle, unscented soap during the bath or shower is the best way to clean the sensitive outside areas of the vagina; products such as feminine hygiene soaps, powders, and sprays are not necessary, according to the NWHIC.

Remind women to return to your office if they experience symptoms such as vaginal pain, itching, burning, pain when urinating, or a vaginal discharge that is different from normal. Such symptoms may indicate a yeast infection, urinary tract infection, or bacterial infection that can be treated with medication.[9]

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Check your options to expand IUD access

Your patient is a young mother in a mutually monogamous relationship who cannot tolerate oral contraceptives, has heavy menses, and says she doesn't want to use an injectable birth control method. She has no medical insurance coverage. What options can you offer her?

EXECUTIVE SUMMARY

Two new avenues of access to intrauterine contraception are available: a multi-payment plan for women who are self-paying, and assistance through a not-for-profit foundation.

- Women who wish to pay for the Mirena intrauterine system (IUS) can spread payments over months, rather than paying in full at time of insertion.
- The Access and Resources in Contraceptive Health Foundation provides assistance for obtaining the Mirena IUS on a patient-specific basis according to predetermined eligibility criteria. Financial criteria are based on federal poverty level guidelines.

RESOURCES

For information on the **Mirena payment plan**, contact Berlex Laboratories' reimbursement hotline, (866) 647-3646. The hotline also offers advice on insurance information and reimbursement issues.

For information on the **Access and Resources in Contraceptive Health (ARCH) Foundation**, contact ARCH Foundation, P.O. Box 220908, Charlotte, NC 28222-0908. Telephone: (877) 393-9071. Fax: (704) 357-0036. Web: www.archfoundation.com.

If one of your options includes the Mirena intrauterine system (IUS), two avenues of access may be open. The ARCH (Access and Resources in Contraceptive Health) Foundation, a not-for-profit organization with operations in Charlotte, NC, operates a patient assistance program that is designed to assist low-income patients who do not have insurance coverage for the device. The Foundation is funded by Berlex Laboratories of Montville, NJ, which markets the Mirena device.

Berlex Laboratories also has just established a payment plan for the Mirena IUS for those women who are self-paying for the device, says **Kim Schillace**, Berlex Laboratories' manager of public relations for female health care. Through an arrangement with TheraCom of Bethesda, MD, which distributes the Mirena IUS to physicians' offices, women can set up an interest-free plan for the device. The new plan will allow women to pay for the IUS in four payments, which will spread the cost over several months, notes Schillace. **(See resource box, above, for contact information.)**

According to *A Pocket Guide to Managing Contraception*, average wholesale price for the Mirena IUS is $395.[1] While Medicaid in 47 states covers IUD insertion and removal, the device's price tag may be prohibitive for family planning facilities who serve lower-income women who may not be covered by Medicaid.[2]

The device relies on a slow daily 20-mcg release of the progestin levonorgestrel for its contraceptive efficacy. It has been approved in the United States for five years' use as a contraceptive. **(For more information, see "FDA gives green light to Berlex's Mirena intrauterine system," *Contraceptive Technology* Update, February 2001, p. 13, as well as "The Levonorgestrel Intrauterine System: An Effective New Contraceptive Option," *Contraceptive Technology Report*, May 2001, insert.)**

The ARCH Foundation provides assistance on

a patient-specific basis according to predetermined eligibility criteria. Financial criteria are based on federal poverty level guidelines.

Patients and providers can talk via telephone with a patient case coordinator, and then patients must fill out a one-page application form to be considered for assistance. **(See resources box, p. 10, for contact information.)**

The application is reviewed and eligibility is determined within approximately two business days, provided that a complete application is received with patient income information. If the patient qualifies for assistance, the Mirena IUS is shipped to the patient's health care provider or clinic. If patients do not have insurance coverage, the foundation encourages health care providers to provide insertion of donated Mirena devices free of charge.

Ortho-McNeil Pharmaceutical of Raritan, NJ, offers a variety of options to increase access to its ParaGard IUD, says Kellie McLaughlin, director of global pharmaceutical communications for New Brunswick, NJ-based Johnson & Johnson, Ortho-McNeil's parent company. However, ParaGard is no longer covered under Ortho-McNeil's patient assistance program, which provides assistance for qualified patients. The company has opted to offer clinics a discounted price on the IUD, and it also supports Title X pricing, she notes.

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New on-line program details mifepristone

The Washington, DC-based National Abortion Federation (NAF) has launched the first interactive on-line continuing medical education (CME) program to allow health care providers to learn more about mifepristone.

The new program contains five modules that focus on medical abortion regimens, management of side effects and complications, counseling, ultrasound, and service delivery issues. It also includes interactive questions and video clips from NAF's Early Options video education series.

Available at www.earlyoptions.org, the program will allow providers to earn up to five hours in Category I credit toward the American Medical Association's Physician Recognition Award. The program may be reviewed free of charge; to earn CME credit, cost is $17 for NAF members and $20 for nonmembers.

Since mifepristone was approved by the Food and Drug Administration in 2000, NAF has educated nearly 4,400 health care providers about the safe and effective use of medical abortion. ■

Conferences coming for *Contraceptive Technology*

Circle your calendar for the upcoming annual *Contraceptive Technology* Conferences. The San Francisco conference is scheduled for March 12-15, with the Washington, DC, conference set for March 26-29.

Pre-conferences include sessions on evaluating genital lesions, fine-tuning pelvic examination skills, fundamentals of contraception, and effective coding for women's health services. Conference sessions will address such issues as advances in contraception, developments in sexually transmitted disease diagnosis and treatment, and other women's health issues.

To receive a brochure on the conference programs, go to Contemporary Forums' web site, www.contemporaryforums.com, click where indicated to obtain information on "current conferences," then click on the conference of your choice. Registrants also may call Contemporary Forums at (800) 377-7707, fax requests to (800) 329-9923, e-mail info@cforums.com, or write to 11900 Silvergate Drive, Dublin, CA 94568-2257. ■

COMING IN FUTURE MONTHS

- Syphilis cases report first rise in decade
- Clinician tips for breaking bad news to patients
- New OC options on the way
- Examine the role of testosterone in women
- Does the Pill boost future futility?

CE/CME Questions

[For details on Contraceptive Technology Update's continuing education program, contact: Customer Service, American Health Consultants, P.O. Box 740056, Atlanta, GA 30374. Telephone: (800) 688-2421. Fax: (800) 284-3291. E-mail: customerservice@ahcpub.com. Web: www.ahcpub.com.]

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

- Define the time period for backup contraception following placement of the Essure microinserts. **(See "Women who want permanent birth control now have a second option" in this issue.)**
- Identify the most common bacterial STD in the U.S. **(See 'Check STD screening: Room for improvement?")**
- Give the estimate of U.S. women who have undergone tubal sterilization. **(See "New data address impact of sterilization.")**
- State the most common vaginal infection in women of childbearing age. **(See "Douching linked to vaginal infection.")**

1. How long should women use backup contraception following placement of the Essure microinserts?

A. Seven days
B. One month
C. Three months
D. Six months

2. What is the most common bacterial STD?

A. Gonorrhea
B. Syphilis
C. Chlamydia
D. Genital herpes

3. About how many U.S. women ages 15-44 who have ever married have undergone tubal sterilization?

A. Less than one-tenth
B. One-fourth
C. One-third
D. One-half

4. What is the most common vaginal infection in women of childbearing age?

A. Bacterial vaginosis
B. Trichomoniasis
C. Granuloma inguinale
D. Chancroid

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