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IN THIS ISSUE

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Men are missing in action when it comes to post-vasectomy testing

New at-home test eyed to help men check sperm post-vasectomy

Check the statistics for post-vasectomy follow-up tests at your family planning clinic. How many men are returning for semen analysis following their sterilization procedures?

A new study indicates that 25% of men who had vasectomies at the Glickman Urological Institute at Cleveland Clinic provided no follow-up semen specimens, and only 21% followed the full instructions to provide two consecutive negative semen analyses.[1] An earlier study indicates similar results and shows that 34% of men never returned to a Michigan private urological practice following their sterilization procedures.[2]

About 500,000 men receive a vasectomy in the United States each year; in contrast, 700,000 women receive a tubal sterilization.[3] Protocols for ensuring azoospermia vary among providers. In a national survey, 56% of physicians said they require one post-vasectomy semen specimen, while 39% require two, and 5% ask for three or more.[3]

Physicians participating in the Cleveland Clinic study typically recommend that patients have their semen tested for sperm at least twice, at eight and 12 weeks, following their procedures.[1] The current study included 436 men who got vasectomies at the Cleveland facility and were told to submit

EXECUTIVE SUMMARY

While about 500,000 men receive a vasectomy in the United States each year, research indicates many do not return post-procedure for a semen analysis.

- In a national survey, 56% of physicians said they require one post-vasectomy semen specimen, while 39% require two, and 5% ask for three or more.
- Researchers are examining the SpermCheck Vasectomy test as a possible at-home diagnostic for men who have received a vasectomy. SpermCheck features an immunological assay that identifies the antigen SP-10 in the head of sperm.

two semen samples two months after vasectomy and again a month later. If the samples contained sperm, the men were instructed to submit monthly semen samples until two consecutive negative tests were achieved.

Three-quarters of the patients provided a semen specimen at eight weeks after vasectomy; of these, 75% were azoospermic and 25% contained sperm. At 12 weeks after vasectomy, half the patients provided a semen specimen; of these, 91% were azoospermic and 9% contained sperm.[1]

J. Stephen Jones, MD, vice chairman of the Glickman Urological Institute and director of the study, says his facility now has found success by asking for just one specimen at three months post-procedure. Patients are scheduled for a three-month appointment, rather than being told simply to come in at three months and bring a specimen. Patients like the change because it calls for just one visit, and in turn, providers are seeing increased compliance, says Jones.

"If we don't confirm patients are sterile and especially if they don't follow up on that, then we fail to serve them well," says Jones.

Although vasectomy is the most effective type of all contraceptive approaches, it is not 100% effective. Commonly quoted failure rates range from 0.1% to 0.4%.[4] In a vasectomy, a small portion of the tubes that carry sperm from the testicles, known as the vasa deferentia, are cut and sealed. This prevents pregnancy because no sperm can get into the ejaculate. Rare failures occur because the initial procedure is not done properly or because recanalization occurs. Instructions for patients in A *Pocket Guide to Managing Contraception* suggest that other forms of contraception be used until two consecutive sperm samples show no motile sperm. Furthermore, to avoid failure due to late recanalization, "repeating semen analysis every few years makes sense," the book states.[5]

About 30% of the vasectomy procedures performed in the United States are no-scalpel vasectomies. This technique, developed in China, has been in use in the United States since 1988. The no-scalpel approach does not make a cut in the skin; it uses a special instrument to make one small puncture. Providers have found the technique is less traumatic, causes less pain and swelling, and results in a shorter recovery time. In the United States, about 30% of vasectomies are the no-scalpel type. **(Review information on the no-scalpel method in the April 1999 *Contraceptive Technology Update* article, "Expanding the use of no-scalpel vasectomies," p. 46.)**

No matter which technique is used to perform a vasectomy, success of the procedure can be determined only by a semen analysis that is negative for sperm.[6]

During patient counseling, providers should emphasize that pregnancy prevention is not assured until at least one semen analysis is

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

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RESOURCE

For more information on SpermCheck Vasectomy, contact:

- **Ed Leary**, ContraVac, P.O. Box 4608, Charlottesville, VA 22905. Telephone: (434) 243-9205. Fax: (434) 243-9206. E-mail: eleary1@adelphia.net. Web: www.contravac.com.

negative. *[Editor's note: A vasectomy handout is available with the on-line version of* Contraceptive Technology Update. *If you're accessing your on-line account for the first time, go to www.ahcpub.com. Click on the "Activate Your Subscription" tab in the left-hand column. Then follow the easy steps under "Account Activation." If you already have an on-line subscription, go to www.ahcpub.com. Select the tab labeled "Subscriber Direct Connect to Online Newsletters. Please select an archive." Choose* "Contraceptive Technology Update," *and then click "Sign on" from the left-hand column to log in. Once you're signed in, select "2006" and then select the July 2006 issue. For assistance, call Customer Service at (800) 688-2421.]* Until the negative analysis is obtained, another contraceptive method must be used.[6] When providing an outline of preoperative and postoperative instructions, providers should include the protocol and schedule for postoperative semen analysis in the postoperative instructions.[6]

Use of informed consent is key in any sterilization procedure.[5] Review your consent form to see that it contains language documenting the patient's knowledge of the following points:

- Temporary contraception is available.
- Vasectomy should be considered permanent. If the vasectomy is successful, the patient will be unable to father children.
- Vasectomy is surgery.
- Vasectomy has risks and benefits. Among the risks are possible complications resulting from the procedure. (Optional: List possible complications.)
- Vasectomy has a risk of failure. Sterility cannot be guaranteed. (Optional: List risk of failure.)
- The patient must use another method of contraception during the postoperative period until a negative semen analysis has been obtained. (Optional: Give schedule for postoperative semen analysis.)[6]

Despite the importance of the semen analysis, many men don't return for the follow-up visit. Reasons for noncompliance include inconvenience, embarrassment, and forgetfulness.[7]

What if men could check their sperm with an at-home test? ContraVac, a firm in Charlottesville, VA, is developing just such a test. Clinical trial studies to determine the effectiveness of the SpermCheck Vasectomy test compared to microscopic counts have recently begun, says **Ed Leary**, ContraVac president. Clinical studies are expected to be completed by the end of August, and the company expects to file an application with the Food and Drug Administration (FDA) in September to market the test as an over-the-counter device, he reports. Publication of the results of the clinical studies is planned in late 2006, Leary adds.

ContraVac was formed to commercialize technology resulting from work under way at the Charlottesville-based University of Virginia's Center for Research in Contraceptive and Reproductive Health, which is directed by John Herr, PhD, professor of cell biology and urology at the university. Products under development at ContraVac use the SP-10 antigen unique to sperm. SpermCheck features an immunological assay that identifies SP-10 in the head of sperm.

If approved, SpermCheck Vasectomy will offer an inexpensive, convenient, and private option for men, Leary states. The company is aiming to market the test for about $30 at pharmacies and mass merchandisers, as well as via the Internet. **(See contact information in the resource listing, this page.)**

"We expect SpermCheck Vasectomy to be rapidly accepted and endorsed by the medical community as the ideal test for the second post-vasectomy sperm test and all subsequent testing for recanalization," Leary says. Increased patient compliance will be the primary reason for this endorsement, he says. "Ultimately, we envision SpermCheck Vasectomy being the standard for all post-vasectomy sperm testing once it has demonstrated its utility as a simple, accurate, economical, and private sperm test device," Leary says.

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EC has limited effect on bleeding patterns

EXECUTIVE SUMMARY

Data for a just-released study indicate emergency contraception (EC) has limited effect on bleeding patterns.

- Researchers found that the single-dose regimen alters the timing and duration of the menstrual period that immediately follows ED. If taken early in the cycle, EC use causes the menstrual period to begin earlier than usual, and if taken late in the cycle, it prolongs the next menstrual period. Menstrual timing resumes in a normal pattern by the second cycle.
- Women should be informed that after using EC, their next ovulation may come earlier than expected and, therefore, prompt initiation of regular contraception is advisable. A pregnancy test should be considered if menses are delayed.

In the first study specifically designed to evaluate bleeding patterns after use of the emergency contraceptive pill (ECP) Plan B (Barr Pharmaceuticals, Pomona, NY), data indicate that intermenstrual bleeding following treatment is uncommon.[1]

Researchers found that the single-dose regimen alters the timing and duration of the menstrual period that immediately follows emergency contraception.[1] If taken early in the cycle, EC use causes the menstrual period to begin earlier than usual, and if taken late in the cycle, it prolongs the next menstrual period. Menstrual timing resumes in a normal pattern by the second cycle.

The findings support the recommendation that a pregnancy test should be considered if menses are delayed, says **Elizabeth Raymond**, MD, MPH, associate medical director at Family Health International in Research Triangle Park, NC. In addition, women should be informed that after using this ECP regimen, their next ovulation may come earlier than expected and, therefore prompt initiation of regular contraception is advisable, she adds.

Previous studies have suggested that ECPs provoke intermenstrual bleeding.[2,3] Data from the new study suggest that ECPs hasten the end of the current menstrual cycle, but thereafter the hormonal cycle is "reset" and proceeds normally.[1]

Take a closer look

While the Plan B dosing regimen approved by the Food and Drug Administration (FDA) calls for 0.75 mg levonorgestrel, followed by an identical second dose 12 hours later, more recent research supports the safety and efficacy of a single-dose (1.5 mg) regimen.[2,4] ***(Contraceptive Technology Update* reported on the single-dose regimen in the January 2004 article, "Clinicians change practice when it comes to EC," p. 9.)**

To perform the bleeding pattern study, researchers asked 120 women who had been treated with the regimen to keep daily bleeding diaries for nine weeks. Investigators compared bleeding patterns observed after treatment with usual patterns reported by the participants and with patterns observed in a prior study on women who had not taken ECPs.

Treatment in the first three weeks of the menstrual cycle significantly shortened that cycle as compared both with the usual cycle length and with the cycle duration in a comparison group. The magnitude of this effect was greater the earlier the pills were taken.

In contrast, the duration of the first menstrual period after treatment increased significantly with cycle week of treatment and was longer in women who used the treatment than in those who did not, researchers report. Intermenstrual bleeding occurred in only 5% of women in the first cycle after treatment.[1]

How do you discuss the implications of the new study with patients? **Anita Nelson**, MD, professor in the obstetrics and gynecology department at the University of California in Los Angeles (UCLA) and medical director of the women's health care programs at Harbor-UCLA Medical Center in Torrance, offers this approach:

"Rather than emphasizing the single-dose regimen, I just say, 'Plan B,' then mention that it's given as a single dose; because [if not], it raises the issue that if I gave it traditionally, would it have the same effects?" she explains. "I think it is the EC itself, rather than the way it is given, that is making the difference."

If your family planning facility hasn't yet implemented advance prescriptions for EC, take advantage of a new public awareness

campaign implemented by the American College of Obstetricians and Gynecologists (ACOG). Called "Ask Me," the campaign is aimed at educating women about EC and encouraging them to get an advance prescription from their provider. The campaign was unveiled in May at the organization's annual meeting, held in Washington, DC.

ACOG developed the campaign to help eliminate the logistical and political barriers that make EC largely inaccessible to women. The campaign's theme centers on "Accidents happen. Morning afters can be tough." Campaign materials include posters for physician examination and waiting rooms and an "Ask me" button, which is designed to promote dialogue between the patient and provider about emergency contraception. *(Editor's note: As of* CTU *deadline, ACOG planned a late May mailing of posters and buttons to its members. The association is reviewing plans for material sales;* CTU *will publish ordering information when it is released.)*

"By getting women to ask about emergency contraception and by OB/GYNs giving them an advance prescription for it, we hope to make EC a forethought, not an afterthought," says ACOG president **Michael Mennuti**, MD.

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Transcervical methods eyed for sterilization

EXECUTIVE SUMMARY

Scientists continue to examine female sterilization options using transcervical methods.

- Hysteroscopic sterilization using the Essure method is safe for women who may be high-risk surgical candidates, according to new research.
- A small number of women have achieved pregnancy with in vitro fertilization following use of the Essure method. However, more research is needed.
- The Adiana method of transcervical sterilization is under review. A catheter-based system delivers radiofrequency energy to each fallopian tube followed by placement of a soft, porous biomaterial. The biomaterial remains implanted within the fallopian tube, where surrounding tissue grows into it over a few weeks. This results in permanent and total occlusion of the tube.

Your next patient is a 35-year-old mother of three and has a body mass index of 36. She says she is interested in permanent birth control. What are her options?

Tubal sterilization is one of the leading contraceptive options for American women; 27% of all contracepting U.S. women in 2002 relied on the method.[1] Of the 700,000 annual bilateral procedures, about half are performed postpartum and half as ambulatory interval procedures.[2] When it comes to obese patients, though, anesthesia and surgery can be problematic, and special care must be taken to prevent complications.[3]

Hysteroscopic sterilization using the Essure nonincisional permanent birth control procedure (Conceptus; San Carlos, CA) represents a safe choice for such high-risk women, according to new information presented at the May 2006 annual meeting of the American College of Obstetricians and Gynecologists (ACOG).[4] The method has a high margin of safety and bypasses the risk of potential intra-abdominal laparoscopic complications, says **Mark Levie**, MD, who presented the paper. Levie is director of obstetrics and gynecology at Montefiore Medical Center and an associate professor at the Albert Einstein College of Medicine, both in New York City.

To assess the procedural and post procedural outcome of women undergoing hysteroscopic sterilization who have high-risk medical and surgical conditions, a cohort of 75 women were identified within a group of 972 women who underwent the Essure method of hysteroscopic sterilization. The women were identified as having a significant surgical or medical condition that normally would place them in a high-risk group for a conventional laparoscopic sterilization procedure carried out under general anesthesia. All women in the cohort underwent the procedure without suffering an

intra or post-procedural adverse event.[4]

"Essure is a good alternative for women who don't want a bilateral tubal ligation," says Levie. "The Essure procedure is minimally invasive, doesn't require a general anesthesia, allows for rapid patient recovery, and by avoiding general anesthesia and abdominal incisions, the risk to the patient is almost eliminated." **(To review information on the Essure procedure, see the *Contraceptive Technology Update* articles: "Changes in store for sterilization method," August 2005, p. 91; "Women who want permanent birth control now have second option," January 2003, p. 1; and "Sterilization in the office: The concept is now a reality," inserted in the February 2003 issue.)**

Is it permanent?

Women must consider any sterilization technique as permanent because reversal is not always successful and reversal procedures may not be available to all who want them, according to *Contraceptive Technology*.[5] Informed consent documents that are presented to the patient prior to any sterilization procedure include language on the intended permanence of sterilization.[5]

However, regret following sterilization does occur; women who are ages 30 and younger at the time of sterilization are most likely to experience regret.[6] Pregnancy with in vitro fertilization is possible in women who have previously undergone Essure hysteroscopic sterilization, suggests information presented at the ACOG session and the November 2005 annual meeting of the American Association of Gynecologic Laparoscopists.[7,8]

A small number of pregnancies have been achieved in Australian women who underwent in vitro fertilization following Essure procedures, says **Barbara Levy**, MD, assistant clinical professor of obstetrics and gynecology at the University of Washington School of Medicine in Seattle, who presented information at the ACOG session. Since tissue gradually encapsulates the coils of the Essure micro-insert that trail into the uterine cavity following hysteroscopic sterilization, the device is compartmentalized away from the uterine cavity, according to second-look hysteroscopies.[9] Further research is needed to further prove that such reversals can be achieved successfully.

The Adiana method of transcervical sterilization (Adiana; Redwood City, CA) is under review by the Food and Drug Administration (FDA). Its procedure is performed in two steps; first, a catheter is delivered through a hysteroscope into the intramural portion of the fallopian tube. Using low-level bipolar radiofrequency energy, a superficial lesion is created to remove surface epithelium. The second step calls for placing a matrix (a porous, nonbiodegradable implant material) into the lesion. The matrix remains implanted within the fallopian tube, where surrounding tissue grows into it over a few weeks. The ingrowth results in permanent and total occlusion of the fallopian tube.[10] ***(CTU* reported on Adiana in its article, "Research eyes new sterilization option," September 2005, p. 107.)**

Further away in the research pipeline is Ovion, a self-expanding, stent-like device that causes the fallopian tube tissue to grow shut. Developed by Ovion of Redwood City, CA, the device is being researched by American Medical Systems of Minneapolis, which acquired the California company in 2005.[11]

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Research eyes new ways to spot ovarian cancer

You're reviewing the medical history for a new patient. The 26-year-old woman complained of back pain for months before a neurologist ordered a magnetic resonance imaging test to check for a herniated disc. The test detected something else: ovarian cancer that has spread to the spine.

While this patient became a cancer survivor, thanks to extensive surgery and chemotherapy, many women are not so lucky. According to the American Cancer Society, ovarian cancer ranks fifth in leading causes of cancer death in women. About 20,180 new cases of ovarian cancer will occur in the United States in 2006, the society estimates. About 15,310 women will die of the disease. Early detection is key: When ovarian cancer presents at a late clinical stage, it is associated with a five-year survival rate of 35%; by contrast, the five-year survival for patients with Stage I ovarian cancer exceeds 90%, and most patients are cured of their disease by surgery alone.[1]

Ovarian cancer often has few early symptoms and is often diagnosed late, when chances of survival are poor.[2] Researchers are looking at several possible diagnostic tools — mainly blood tests and sonograms — to screen for the disease. However, no one test can pick up most early cases without false-positive reports.[3]

Scientists at the University of Pittsburgh School of Medicine are using a new technology to analyze a large number of proteins, or potential biomarkers, from a very small sample of serum from women with ovarian cancer. They have identified a combination of several biomarkers that could help detect the disease much earlier than it is being diagnosed.

"By the time women are diagnosed, their cancers have already spread and are extremely difficult to treat successfully," says **Anna Lokshin**, PhD, lead investigator and assistant professor of medicine and pathology at the University of Pittsburgh School of Medicine. "To improve the long-term outcome for women diagnosed with ovarian cancer, we sought to identify a panel of proteins that could signify the presence of early disease," she adds.

The researchers are looking at known proteins at defined concentrations, says Lokshin. By using a new technology called LapMAP, the scientists are able to analyze multiple proteins in a single drop of blood or serum.

By testing 450 serum samples for 46 biomarkers that had previously been correlated with ovarian cancer, Lokshin's research team says it has been able to identify a multi-marker panel, comprised of 20 proteins that correctly recognized more than 98% of serum samples from women with ovarian cancer. The team is performing a case control study to further test its theories, she says.

Repository may help

The National Cancer Institute (NCI) is spearheading a clinical trial that is aimed at building a repository of blood samples in order to develop an accurate means of detecting ovarian cancer soon after the disease returns. By collecting this information, scientists may have a strong lead on how to detect ovarian cancer at an early stage when it can be most effectively treated.

The NCI trial is recruiting patients and, when completed, researchers hope it will give them the needed repository to conduct a detailed proteomic study, says **Michael Miller**, NCI spokesman. Clinical sites include Fred Hutchinson Cancer Research Center and the University of Washington, both in Seattle; Cedars Sinai Medical Center, Los Angeles; University of Alabama at Birmingham; Duke University Medical Center in Durham; Fox Chase Cancer Center in Philadelphia; University of Texas MD Anderson Cancer Center in Houston; Massachusetts General Hospital in Boston; Northwestern Memorial Hospital in Chicago; Evanston (IL) Northwestern University Hospital; and New York University School of Medicine.

Researchers are looking at several potential screening tests for ovarian cancer; however, none

EXECUTIVE SUMMARY

Scientists at the University of Pittsburgh School of Medicine are using new technology to analyze a large number of proteins, or potential biomarkers, from a very small sample of serum from women with ovarian cancer.

- They have identified a combination of several biomarkers that could help detect the disease much earlier than it is now being diagnosed.
- Early detection of the disease is key. According to the American Cancer Society, ovarian cancer ranks fifth in leading causes of cancer death in women. About 20,180 new cases of ovarian cancer will occur in the United States in 2006, the Society estimates, About 15,310 women will die of the disease.

are ready for widespread use. A blood test that measures levels of a protein (CA-125) shed by ovarian cancer cells as well as benign inflamed cells, is used by providers to monitor ovarian cancer patients. Scientists also are eyeing use of transvaginal ultrasound, a sonogram performed with an instrument inserted into the vagina, as a potential screening tool.

More work is needed on use of such techniques in screening for the disease. A 2005 NCI study shows that while transvaginal ultrasound and CA-125 tests, alone or in combination, can detect ovarian cancer, such screening approaches also can produce many false-positive test results.[4]

While early research on a testing approach known as OvaCheck proved promising, the test has yet to be approved by the Food and Drug Administration (FDA).[5] The test uses mass spectroscopy to look for a protein pattern in blood samples that its research group reported as indicative of ovarian cancer.[6] However, some scientists have questioned the design and results of the original studies.[3] Correlogic Systems in Bethesda, which is developing the test, says it is performing expanded validity tests.[7]

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Check your approach to the well-woman exam

When it comes to the periodic well-woman visit, how do you and your staff balance time management and patient care?

Many clinical experts now agree that:

- Pelvic exams may not be required annually.
- Pelvic exams are not required for initiating hormonal contraception.
- Not all women 30 years of age and older require annual cervical cytology screening.
- Women should be encouraged to pay attention to symptoms or changes in their breasts rather than being taught breast self-exam.[1] **(For changes in cervical cytology screening recommendations, see *Contraceptive Technology Update*'s article, "Get ready to take cervical cancer screening to the next level," June 2003, p. 61. *CTU* examined evidence regarding pelvic exams prior to contraception initiation; see the article "Should access to birth control be streamlined?" October 2001, p. 117.)**

One thing that should be included is counseling on contraceptive options and emergency contraception. Current guidelines from the American College of Obstetricians and Gynecologists (ACOG) recommend that adolescents and older reproductive-age women receive counseling on both topics at each periodic assessment.[2]

With today's ever-growing array of birth control methods, how can clinicians maximize their counseling time and still perform necessary screenings? Efficient use of ancillary staff can conserve the clinician's time, increasing the time available for counseling, according to a new review of the well-woman exam.[3]

For example, ask staff members to provide self-administered history forms to patients to fill out in the waiting room. Use the results to comment on positive findings and inquire on any

EXECUTIVE SUMMARY

The periodic well-woman visit contains several elements of care; counseling on contraceptive options and emergency contraception should be included at each session.

- Many clinical experts agree that pelvic exams may not be required annually and are not required for initiating hormonal contraception.
- Have self-administered history forms distributed to patients to fill out in the waiting room. Use the results to comment on positive findings and inquire on any incomplete responses. Also, allow staff members to record height, weight, and blood pressure readings; review allergies and medications; and confirm the reason for the patient's visit.

RESOURCES

The Association of Reproductive Health Professionals (ARHP) has produced a set of computerized graphic slides, "New Dynamics in Health Care: Contraception and the Periodic Well Woman Visit" that can be used as a free teaching tool. Visit the organization's web site, www.arhp.org. Click on "resources," "slide show library," and the slide show title.

Also check out a companion issue of ARHP's *Clinical Proceedings.* At www.arhp.org, highlight "healthcare providers" and "online publications," then click on "*Clinical Proceedings*" and "Periodic Well Woman Visit: Individualized Contraceptive Care."

incomplete responses. Also, allow staff members to record height, weight, and blood pressure readings; review allergies and medications; and confirm the reason for the patient's visit.

Also, use handouts to explain current guidelines for Pap smear screening. Take-home reading materials can reinforce topics of discussion, and refer to Internet resources to provide more information following the exam. If issues are not resolved during the counseling session, schedule another visit or a telephone appointment.[3] **(The Association of Reproductive Health Professionals has developed a slide set and a clinical publication on the well-woman exam; see the resource listing, above, for access information.)**

Making adequate time for the contraceptive counseling segment of a well-woman exam is important. Research shows that women report greater satisfaction with reproductive counseling, have better understanding and recall of the information provided, and are more likely to use their chosen method successfully if there is a two-way dialogue with their provider.[4,5]

Take a look at what birth control method is currently in place. Even if a woman has found success with using an older oral contraceptive formulation, she may find that one of the newer hormonal options may be better suited to her current reproductive needs and lifestyle and may be better tolerated.[3]

"For a woman who has never used an effective method, I find it useful to use a contraceptive wall chart to 'walk' the patient down the different methods," says **Andrew Kaunitz**, MD, professor and assistant chair in the obstetrics and gynecology department at the University of Florida Health Science Center/Jacksonville. "This helps to present the cafeteria of options and allows her to narrow in about which options she was hoping to find out more about or what direction she'd like to go."

He keeps a box in the exam room with samples of the contraceptive patch, vaginal ring, and intrauterine devices so that patients can directly examine the devices. If the patient selects an intrauterine device, Kaunitz schedules a second visit for the actual insertion. By keeping the counseling and insertion functions in separate visits, the patient is able to fully absorb the information given in the counseling session and confirm in her own mind about use of a long-acting contraceptive, explains Kaunitz. The separate visits also allow office staff to check insurance coverage and work with the patient on payment options, he notes.

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Restrictions tighten on abstinence programs

By **Cynthia Dailard**
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While running for president in 2000, then-Republican candidate George W. Bush promised that his answer to the problem of teenage pregnancy would be to dramatically

increase federal funding for abstinence-only education. Sure enough, President Bush has made good on that pledge. Since taking office, federal funding for abstinence-only education has risen from $60 million to $177 million. The president has requested an additional $28 million for next year and has proposed raising the total funding to $270 million by the administration's end.

Not unexpectedly, the administration has also instituted several policy changes — some draconian in nature. Such change was heralded when the administration, in the summer of 2004, announced that it was transferring administration of the two largest abstinence programs from the Health Resources and Services Administration [the division of the U.S. Department of Health and Human Services (HHS) responsible for administering the public health bureaucracy] to the more political and ideologically driven Administration for Children, Youth, and Families (ACF), which houses the administration's marriage promotion effort, among other things.

Since 1996, federal law has required abstinence-only education programs funded by the U.S. government to comply with an eight-point definition. As a result, programs must teach that "sexual activity outside the context of marriage may have harmful physical and psychological effects," and that "a mutually faithful monogamous relationship in the context of marriage is the expected standard of human behavior." The Clinton administration clarified that states receiving federal grants did not have to emphasize all eight points of this definition, but in fact could pick and choose among the eight, as long as they did not promote a message contrary to any of the remaining eight points. Nonetheless, programs are statutorily precluded from discussing contraceptives in any positive way due to the requirement that they exclusively teach the benefits of abstinence.

Objecting to this modicum of flexibility, the Bush administration in 2005 stipulated that states receiving funding from the $50 million grant program place "equal emphasis" on each of the eight elements. This changed prompted Maine to drop out of the program, joining California and Pennsylvania as the only states to reject the funding.

The administration's hard-line approach to abstinence education, however, did not become fully clear until it issued a notice of grant availability in early 2006 for the Community-Based Abstinence Education (CBAE) program, which currently provides $113 million in competitive grants to community-based organizations, including crisis pregnancy centers and faith-based organizations. For the first time, the meaning of abstinence and sexual activity is defined as a matter of federal policy: "Abstinence means voluntarily choosing not to engage in sexual activity until marriage. Sexual activity refers to any type of genital contact or sexual stimulation between two persons including, but not limited to, sexual intercourse." While this expansive definition may be designed to quell long-standing criticism that abstinence-only education, and virginity pledges in particular, may be causing some youth to engage in anal or oral sex in order to preserve their virginity, it is so broad as to preclude even kissing.

The announcement also elaborates on the administration's attitude toward contraception. A funded program "must not promote contraception and/or condom use (as opposed to risk elimination)" or "promote or encourage the use of any type of contraceptives outside of marriage." At the same time, the announcement encourages programs to teach that:

- "contraception may fail to prevent teen pregnancy and that sexually active teens using contraception may become pregnant;"
- "the published failure rates associated with contraceptives relative to pregnancy prevention, including 'real use' vs. trial or 'laboratory use,' human error, product defect, teen use and possible side effects of contraceptives";
- "the limitations of contraception to consistently prevent [sexually transmitted diseases]."

Curiously, the announcement flatly prohibits programs from even referring to abstinence "as a form of contraception," presumably to shield it from the program requirement that failure rates be discussed for all contraceptive methods.

COMING IN FUTURE MONTHS

- New 365-day oral contraceptive under review
- Look at intrauterine device for menorrhagia treatment
- Panel examines mifepristone's role in bacterial infections
- Update report on single-rod contraceptive implant
- Research eyes monthly male contraceptive injection

Finally, the announcement makes clear that an important goal of the CBAE program is to prepare young people for marriage.

Programs must emphasize "that the best life outcomes are more likely obtained if an individual abstains until marriage"; that "nonmarital sex can undermine the capacity for healthy marriage, love, and commitment"; and "that abstinence is beneficial in preparation for successful marriage and significantly increases the probability of a happy, healthy marriage." The announcement also encourages funded curricula to promote the moral value of abstinence, including that "abstinence reflects qualities of personal integrity and is honorable."

In a Feb. 16 letter to HHS Secretary Michael Leavitt, Rep. **Henry Waxman** (D-CA), ranking minority member of the House Committee on Government Reform, called for the grant announcement's retraction. "The new guidelines eliminate the requirement that federally funded abstinence-only education programs have health-based goals," he said, and if that omission is allowed to stand, "funding for abstinence education will be awarded based on ideology, not the effectiveness of programs in reducing teen sexual activity." This, he deemed, would be a "dangerous development." ■

CTUPDATES

News ■ Resources ■ Events

Explore on-line resource on chronic vulvar pain

Learn more about chronic vulvar pain: Use the Internet to check out "Vulvodynia: Integrating Current Knowledge into Clinical Practice," the National Vulvodynia Association's updated teaching program on chronic vulvar pain for health care professionals.

Available on-line and free to all viewers, the program includes a self-guided presentation on the differential diagnosis, treatment, and etiology of vulvodynia. In addition to information on the disorder's prevalence, a historical overview of the evolving terminology and classification is included. Once the program has been viewed, the presentation and other resources, such as selected medical journal articles and patient handouts, can be downloaded for future use.

To access the program, go to the organization's web site, www.nva.org. Click on "Teaching Program," and follow the prompts. **(For further information about vulvodynia, also refer to the *Contraceptive Technology Update* article, "New guideline details care of vulvodynia," May 2005, p. 56.)** ▼

Get updated women's health statistics from web

Get the latest federal statistics on women's health findings for your area: Check out the updated National Women's Health Indicators Database developed by the Office on Women's Health. The database includes comprehensive U.S. data for men and women on a variety of issues, including reproductive health, maternal health, and access to care.

National, regional, state, and county data are available, and the data can be stratified by gender, race/ethnicity, and age concurrently. Access is free, and users can make their own tables, graphs, and maps out of any data in the database. Age-adjusted data and three-year averages are included for many of the health indicators.

Go to the agency's web site, www.4woman.gov, and click on "Women's Health Indicators Database (Soon to be known as Quick Health Data Online — New Data Available." Follow the prompts to use the database. ■

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

[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: ahc.customerservice@thomson.com. Web: www.ahcpub.com.]

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

- **Identify** clinical, legal, or scientific issues related to development and provisions of contraceptive technology or other reproductive services.
- **Describe** how those issues affect services and patient care.
- **Integrate** practical solutions to problems and information into daily practices, according to advice from nationally recognized family planning experts.

1. What is the name of the tubes that carry sperm from the testicles?

A. Vasa deferentia
B. Epididymis
C. Semeniferous tubules
D. Efferent ducts

2. What is the dosage of the "single-dose" of the levonorgestrel-only emergency contraceptive pill Plan B?

A. 0.75 mcg
B. 1.5 mg
C. 3 mg
D. 5 mg

3. What is the name of the transcervical sterilization method that uses bipolar radiofrequency energy?

A. Essure
B. Ovion
C. Adiana
D. Intratubal ligation

4. What is the name of the protein that is measured in a blood test used to monitor ovarian cancer patients?

A. Apolipoprotein A1
B. Mesothelin
C. Transthyretin
D. CA-125

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

Contraceptive Technology Update *is endorsed by the National Association of Nurse Practitioners in Women's Health and the Association of Reproductive Health Professionals as a vital information source for health care professionals.*

S·T·D QUARTERLY™

Immunization schedule may soon grow, HPV vaccine under regulatory review

Quadrivalent vaccine up for evaluation, bivalent vaccine to follow

(Editor's note: This article discusses pharmaceuticals not approved by the Food and Drug Administration.)

As you perform physical exams for your college-bound patients, you tick off the number of vaccinations needed to bring their immunizations up to schedule. You may soon be adding another shot. At press time, the Food and Drug Administration (FDA) was scheduled to take action on a vaccination that protects against cervical cancer.

The regulatory agency was scheduled to take action on Gardasil, developed by Merck & Co. in Whitehouse Station, NJ, by June 8, following an advisory panel's May 18 recommendation of the vaccination. If approved, it will be the first such vaccine on the market.

Clinical trials on Gardasil are ongoing, but primary data have been submitted to the FDA, reports **Kelley Dougherty**, Merck spokeswoman. The company submitted data in December 2005, and it was accepted in February for priority review, she states.

Another vaccine, Cervarix, is under development by GSK Biologicals in Rixensart, Belgium. The company has said it plans to submit Cervarix to the FDA for approval in late 2006. **(Read more on the vaccines in the article, "HPV vaccine on the horizon — Will it be added to immunization schedules?" January 2006 *STD Quarterly*, p. 1.)**

Both vaccines in development target human papillomaviruses (HPVs). There are more than 100 strains of HPV; about 30 of these viruses are sexually transmitted. Some strains of HPV may cause abnormal Pap tests and may lead to cancer of the cervix, vulva, vagina, anus, or penis. Other strains may cause mild Pap test abnormalities or genital warts.[1]

The Centers for Disease Control and Prevention (CDC) estimates about 20 million people currently are infected with HPV.[1] About half of sexually active men and women acquire genital HPV infection at some point in their lives; the CDC estimates that by age 50, at least 80% of women will have acquired genital HPV infection.

HPV types 16 and 18 and others, known as

EXECUTIVE SUMMARY

At press time, the Food and Drug Administration (FDA) was scheduled to take action by June 8 on a vaccination that protects against cervical cancer. The regulatory agency is set to review Gardasil, developed by Merck & Co. If approved, the vaccine will be the first such vaccine on the market.

- Another vaccine, Cervarix, is under development by GSK Biologicals in Rixensart, Belgium. The company has said it plans to submit Cervarix to the FDA for approval in late 2006.
- Both vaccines in development target human papillomaviruses (HPVs). The Merck vaccine targets HPV types 6, 11, 16, and 18; the GSK vaccine targets types 16 and 18.

"high-risk" HPV types, may cause abnormal Pap tests and cervical cancer in women, as well as several other cancers in the vulva, vagina, anus, or penis. While other risk factors may come into play, being infected with a high-risk type HPV appears to be a necessary factor for cervical cancer development.[2]

Merck's Gardasil is a quadrivalent vaccine, targeting HPV types 6, 11, 16 and 18. In a Phase II randomized, double-blind, placebo-controlled study, the vaccine significantly reduced the combined incidence of persistent HPV 6, 11, 16, or 18 infection and related diseases, including new cervical precancers and genital warts compared to placebo.[3] **(Review the research in the article, "Research moves HPV vaccines within view," *Contraceptive Technology Update*, July 2005, p. 81.)**

GSK's Cervarix is a bivalent vaccine, targeting types 16 and 18. In a just-published study, the development vaccine exhibited 100% efficacy over 4.5 years against precancerous lesions associated with the two HPV types.[4]

Long-term, sustained protection is important when it comes to HPV infection, says the paper's lead author, **Diane Harper**, MD, MPH, MS, associate professor of community and family medicine & obstetrics and gynecology at Dartmouth Medical School in Hanover, NH.

HPV takes a very long time to turn into cancer, so a vaccine has to offer long-term protection; otherwise, boosters are needed continually, and they are costly and a bother to remember, she says. If women are vaccinated too early, there is a chance that an alum-based vaccine would wane in efficacy and require a booster, Harper notes. The Cervarix vaccine is formulated with a proprietary innovative adjuvant system, AS04, which is designed to sustain antibody levels.

In addition to demonstrating high antibody levels of response, the current study also shows that the bivalent vaccine is protective for HPV 45 and 31, the third and fourth most prevalent cancer-causing types of HPV, says Harper. The Gardasil vaccine under development by Merck covers external genital warts and two cancer-causing types, she adds.

Who will get vaccine?

If an HPV vaccine is approved, who will get it? At press time, the FDA's Vaccines & Related Biological Products Advisory Committee was set to look at the question for Gardasil. Merck is seeking approval for use of the vaccine in women ages 9 to 26.

In February 2006, CDC's Advisory Committee on Immunization Practices HPV Vaccine Workgroup recommended routine vaccination of females ages 11 to 12 with the quadrivalent HPV vaccine. The vaccination series could be started as young as age 9 at the discretion of the physician, according to the advisory committee.[5]

Most pediatricians would administer

If a vaccine is approved, education on both the provider and patient fronts will be key to immunization success, say public health officials. Most pediatricians say they would administer the vaccine.[6] More pediatricians support vaccination at older age groups (ages 15 and older) than at younger age groups (age 12).[7]

Will parents accept HPV vaccinations? Research indicates yes. Reservations generally are overcome when parents are educated about HPV, cervical cancer, and the vaccine.[8] Research undertaken by scientists at Indiana University in Indianapolis indicates that parents will be in favor of such a move.[9]

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Take it to the streets: Reach homeless teens

How can homeless youth be reached with services for sexually transmitted diseases (STDs)? New research indicates good results can be achieved through field-based STD testing, field-delivered therapy, and patient-delivered partner therapy.[1,2]

If you think homeless youth aren't a problem in your community, think again; homelessness among young people in the United States is becoming more common, with an estimated annual prevalence of at least 5% for those ages 12 to 17.[3]

These adolescents are at increased risk for STDs, says **Colette Auerswald**, MD, MS, assistant professor of pediatrics in the division of adolescent medicine at University of California, San Francisco (UCSF) and lead author of the current study. Runaway and homeless youth often engage in survival sex (the exchange of sex for financial or other resources such as shelter, food, or clothing); at the same time, these young people seek care less often than teens in stable situations.[4]

EXECUTIVE SUMMARY

New research indicates that homeless adolescents can be reached through field-based testing for sexually transmitted diseases (STDs), field-delivered therapy, and patient-delivered partner therapy.

- Homeless adolescents may not seek clinic-based care due to previous poor relationships with authority. By delivering services on the street, at-risk youth are served.
- Outreach workers from the San Francisco Department of Public Health, the University of California, San Francisco, and Larkin Street Youth Services, a San Francisco community-based agency, have joined in a collaborative project: Street START (Street Testing and Rapid Testing) Program. They test homeless youth for chlamydia and gonorrhea and dispense field-delivered therapy and patient-delivered partner therapy.

Much less likely to trust clinics

Many homeless adolescents may not seek clinic-based care due to previous poor relationships with authority, notes Auerswald. As children, they may have been entrusted to authority figures, such as parents, foster parents, or the juvenile justice system, and been failed by them, she notes.

"They are much less likely to trust a clinic, to trust a nurse, to go someplace and reach out for help, because in the past when they have done that, they have gotten slapped," observes Auerswald. "By meeting people in an environment that is their turf, it makes it more likely that they will accept service."

Through a collaborative partnership of the San Francisco Department of Public Health, UCSF, and Larkin Street Youth Services, a San Francisco community-based agency, outreach workers have been trained through the Street START (Street Testing and Rapid Testing) Program. They test homeless youth for chlamydia and gonorrhea, and they dispense field-delivered therapy and patient-delivered partner therapy.

"We think that it is important to reach out to the segment of homeless youth most at risk for infection and least likely to access clinics: street youth," says **Dina Wilderson**, PhD, director of research, evaluation, and technology at Larkin Street Youth Services, which provides services to San Francisco's homeless and runaway youth. "By providing both screening and treatment as part of a street outreach program, we are able to provide services to a high-risk group least likely to come into a clinic setting for care."

Review the results

In a longitudinal study, funded in part through a grant from the National Institute

of Child Health and Development, researchers enrolled 218 ethnically diverse homeless youth, ages 15-24, recruited from street sites in San Francisco.

Study participants completed a computer-administered self-interview survey and provided a first-void urine sample for testing for chlamydia and gonorrhea. Those youth who tested positive for infection were offered field-delivered therapy and patient-delivered partner therapy. A random subset of 157 youth was followed prospectively; 110 (70%) were interviewed, and 87 (55%) were retested at six months.

The Street START program has been successful because it has been able to use street outreach workers who have the skills to locate and evaluate youth on the street.

At baseline, 99% of youth in the study consented to STD testing; 6.9% and 0.9% tested positive for chlamydia and gonorrhea, respectively. Ninety-four percent of positive youth were treated, 50% within one week. The incidence rate for chlamydia was 6.3 per 100 person-years [95% confidence interval (CI): 1.3-18.4], and the rate for gonorrhea was 4.2 per 100 person-years (95% CI: 0.5-15.2). None of the youth treated by study staff and tested six months later had an STD infection.[1]

The experience in the longitudinal study is being translated to practice in the Street START Project led by Wilderson and Auerswald.[2] Larkin Street Youth Services and UCSF received an award to train outreach workers serving homeless youth in San Francisco to provide street-based testing and treatment. To date, 159 youth have been tested in the outreach setting. All positive youth have been treated, Auerswald reports.

With nucleic acid amplification tests, single-dose treatment regimens, and patient-delivered partner therapy, clinics can expand their services outside the walls of their facilities, say the researchers. The Street START program has been successful because it has been able to use street outreach workers who have the skills to locate and evaluate youth on the street. The workers have received training in STD testing, field-delivered therapies, and research principles to help them test and treat youth at risk.

"The transient nature of this group can make it hard to locate youth who test positive; however our outreach team has a great deal of experience tracking youth to conduct check-ins as part of their larger activities," says Wilderson. "In addition, the San Francisco Department of Public Health has been able to help us locate youth who might otherwise be lost."

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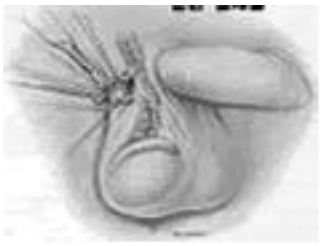
VASECTOMY
"It Makes A Vast Difference in Your Vas Deferens"

WHAT IS A VASECTOMY?



Vasectomy, or male sterilization, is the operation which blocks the tubes (called the vas deferens) that carry a man's sperm to the outside. It is performed in an office or clinic and involves cutting and tying off or cauterizing (burning) the vas deferens - the tubes that transport sperm out of the scrotum (sac) from the testicles. ***This operation should be considered permanent. You should be certain you want no more children and will not change your mind.*** *Complete information about this surgical procedure is available through your clinician or by going to the web site.*

WHAT ARE THE ADVANTAGES?

- A vasectomy is a minor operation. It is safe, extremely effective, and permanent.
- It is excellent for men who have had all the children they want.
- A vasectomy is less expensive and causes fewer complications than tubal sterilization.
- Any time, even years later, you can have your semen checked to see if your operation is "still working." If your semen has no sperm, your operation is working! Used in this manner, vasectomy can be close to 100% effective. Semen ayalysis can be done several times in the 1-3 years after a vasectomy just to be sure your Vas deferens has not recanalized.
- A vasectomy gives the man the opportunity to play a responsible role in the contraceptive process.
- It does not affect a man's ability to enjoy sexual intercourse.

WHAT ARE THE DISADVANTAGES?

- A vasectomy requires surgery. Some men are afraid.
- Some men fear the operation will affect their ability to have intercourse or will interfere with erection.
- There is some pain or discomfort and scrotal discoloring (usually not severe) for several days after the operation. Pain can usually be relieved with mild pain medications. Keep an ice pack on the scrotum for at least 4 hours to reduce the chances of swelling, bleeding and discomfort. Wear a scrotal support for 2 days (jockey shorts will be adequate).
- The operation is not effective immediately. You will need to use condoms until the sperm clears from the tubes. To find out if you are sterile, have your semen examined under a microscope after about 20-30 ejaculations. It is important to know that you have no mobile (moving) sperm. Then and only then can you be sure you are protected. Until one (or even two) semen test have shown not moble sperm, you should use another contraceptive.
- A very small percentage of men have chronic pain after a vasectomy.
- Regret after vasectomy is greater if the man's partner is under 25, if he divorces or remarries, if a child dies, or when the vasectomy is done immediately after a new baby.
- The operation to reverse a vasectomy does not always work. It is highly technical, expensive, and its results cannot be guaranteed.
- Vasectomy provides no protection against sexually transmitted infections including HIV (the AIDS virus).

WHERE DO I GO TO GET THIS OPERATION?

- Most urologists, many family practitioners and some nurse practitioners perform vasectomies.
- You can get a referral to a clinician who does vasectomies from your primary care clinician, health department, family planning clinic or local medical society. Or call the national organization involved in sterilization training and service **(ENGENDER HEALTH).** Their number is **212-561-8000.**

WHAT IF I HAVE SEX AND DON'T USE BIRTH CONTROL?

Did you know that for 120 hours after sex, you can take emergency contraceptive pills to avoid becoming pregnant? AND for 5 to 7 days after sex, you can have an IUD put in? Emergency postcoital insertions of the Copper T IUD (ParaGard) is the most effective currently available postcoital contraceptive. If you want more information or would like the phone numbers of clinicians near you that prescribe emergency birth control, call the toll-free hotline (1-888) NOT-2-LATE. PLAN B is the emergency contraceptive pill that causes the least nausea and the least vomiting.

Source: Bridging The Gap, January 2004. Brief descriptions of 28 contraceptive options are available from the Managing Contraception web site: http://www.managingcontraception.com/cmanager/publish/ch-vasectomy.shtml.