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IN THIS ISSUE

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Injectable update: Subcutaneous form of Depo-Provera is approved

Injectable will be packaged in single-use subcutaneous injection device

Get ready to add a new form of Depo-Provera [depot medroxyprogesterone acetate (DMPA), Pfizer, New York City] to your formulary: Depo-SubQ Provera 104 (DMPA-SC).

The drug, approved by the Food and Drug Administration (FDA) in December, should be available on retail pharmacy shelves in mid-May, says **An Phan**, Pfizer corporate spokeswoman. Pricing has not been set yet on the drug, she adds.

The new formulation is designed to be administered subcutaneously, not intramuscularly, as with the conventional quarterly injection of DMPA. The 104 refers to the 104 mg of its active ingredient, medroxyprogesterone acetate. It, too, is administered every three months to achieve contraceptive efficacy. **(*Contraceptive Technology Update* reported on the drug in its March 2004 article, "Lower-dose injectable contraceptive moves through research pipeline," p. 25.)**

DMPA-SC continues the benefits of highly effective injectable

EXECUTIVE SUMMARY

The Food and Drug Administration has approved Depo-SubQ Provera 104 (DMPA-SC), a low-dose formulation of medroxyprogesterone acetate injectable suspension provided in a pre-filled single-use syringe.

- DMPA-SC continues the benefits of highly effective injectable contraception with the additional advantage of a smaller injection volume and a smaller needle size. The drug will be packaged in a single-shot subcutaneous injection device with a passive needle safety unit.
- As with DMPA, DMPA-SC's labeling states that bone loss in women who use Depo-Provera is greater with increased duration of use and may not be completely reversible. The contraceptive injection should be used as a long-term birth control method (longer than two years) only if other birth control methods are inadequate.

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contraception with the additional advantage of a smaller injection volume and a smaller needle size, says **Andrew Kaunitz**, MD, professor and assistant chair in the obstetrics and gynecology department at the University of Florida Health Science Center/Jacksonville. The subcutaneous route of administration opens the door to self-administration at home, an approach that would increase access to this approach to birth control, says Kaunitz, who served as one of the clinical investigators in studies of the injectable.

While the drug will be packaged in a single-shot subcutaneous injection device with a passive needle safety unit, it can be administered only by a health care professional, Phan says.

The major advantage of the subcutaneous form of DMPA is the potential for eventual approval of the consumer to self-administer the medication, observes **David Archer**, MD, professor of obstetrics and gynecology and director of the Clinical Research Center at the Eastern Virginia Medical Center in Norfolk. "This is also possible with the IM [intramuscular] formulation but is potentially more painful," he adds.

Review research on drug

Two large, open-label, Phase III studies assessed the one-year contraceptive efficacy, safety, and patient satisfaction with DMPA-SC administered every three months.[1] Zero pregnancies were reported in both studies, which included a total of 16,023 woman-cycles of exposure to DMPA-SC and substantial numbers of overweight or obese women.[1]

In a prospective, randomized, single-dose trial designed to evaluate the pharmacokinetics of DMPA-SC in comparison to original formulation, researchers found the lower-dose formulation of Depo-Provera suppressed ovulation for more than 13 weeks in all subjects and was not affected by body mass index or race.[2] Median time for return to ovulation was 30 weeks, with a 97.4% cumulative rate of return to ovulation at 12 months.[2]

In the clinical trials, most women using DMPA-SC experienced changes in menstrual bleeding patterns, such as amenorrhea, irregular spotting or bleeding, prolonged spotting or bleeding, and heavy bleeding. As women continued using the drug, fewer experienced irregular bleeding and more experienced amenorrhea.

In the trials, 39% of women experienced amenorrhea during month six, and 56.5% experienced

amenorrhea during month 12.

In the clinical trials, 10% of women discontinued treatment for adverse reactions. Among these women, the most common reasons for discontinuation were uterine bleeding irregularities, increased weight, decreased libido, acne, and injection site reactions.

"The subcutaneous dosage is smaller — 104 mg — than the standard IM and has a similar duration of action and bleeding profile," Archer points out. "I would hope that this route would be more acceptable to physicians and health care providers."

What about bone issues?

As with Depo-Provera, clinicians will need to be prepared to counsel patients on the drug's impact on bone health. Research published in 2004 indicated that women using DMPA for two years recorded a decline in bone mineral density (BMD) of roughly 6%, compared with a loss of 2.6% among women on oral contraceptives.[3] **(*CTU* reviewed the study in its article, "Latest research sheds new light on DMPA's impact on bone health," October 2004, p. 109, and reported on the updated drug labeling in its article, "Be prepared to counsel on use of DMPA and bone health issues," February 2005, p. 17.)**

As with DMPA, DMPA-SC's labeling states that bone loss in women who use Depo-Provera is greater with increased duration of use and may not be completely reversible. The labeling states that it is "unknown if use of Depo-SubQ Provera 104 during adolescence or early adulthood, a critical period of bone accretion, will reduce peak bone mass and increase the risk for osteoporotic fracture in later life."

The contraceptive injection should be used as a long-term birth control method (longer than two years) only if other birth control methods are inadequate, the label advises. Women who continue to use DMPA-SC past the two-year mark should have their BMD evaluated, according to the labeling.

Although there are no studies addressing whether calcium and vitamin D lessen BMD loss in women using DMPA-SC, all patients should be advised to have adequate calcium and vitamin D intake, according to the package insert.

Who can use the drug?

What are the contraindications to DMPA-SC? According to the labeling, they include:

- known or suspected pregnancy;
- undiagnosed vaginal bleeding;
- known or suspected breast malignancy;
- active thrombophlebitis, or current or past history of thromboembolic disorders, or cerebral vascular disease;
- significant liver disease;
- known hypersensitivity to medroxyprogesterone acetate or any of its other ingredients.

Follow these precautions

Before initiating the method, ensure the patient is not pregnant at the time of the first injection. For women who are sexually active and having regular menses, the first shot should be given only during the first five days of a normal menstrual period. Women who are breast-feeding may have their first injection during or after their sixth postpartum week. Remind all patients that the method does not protect against sexually transmitted diseases, including HIV.

DMPA-SC must be given by subcutaneous injection into the anterior thigh or abdomen once every three months (12-14 weeks). If more than 14 weeks elapse between injections, pregnancy should be ruled out before the next injection. The pre-filled syringe must be vigorously shaken just before use to create a uniform suspension.

Patients who are switching from combined hormonal contraceptives should have their first injection of DMPA-SC within seven days after the last day of using that method, state the package instructions. If patients are switching from DMPA use, contraceptive coverage will be maintained if the next injection is given within the prescribed dosing period for DMPA.

Pfizer plans to provide patient education on the drug through its patient package insert, a web site, and consumer hotline, says Phan. Provider education will be available via a video, which will be available this fall, she adds. (Look for ordering information in *CTU* when the video is released.)

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New guideline details care of vulvodynia

As you flip through the next patient's chart, you review notes from several past visits, and all detail pain and burning on or around the vulva. According to the chart documentation, the patient states the vulvar area hurts most of the time, even when nothing is touching it.

If you already have ruled out infection, inflammation, neoplasia, and neurologic disorder, you may well be dealing with vulvodynia. Also known as vulvar vestibulitis syndrome or vulvar dysesthesia, vulvodynia now is defined by the Waxhaw, NC-based International Society for the Study of Vulvovaginal Disease as "vulvar discomfort, most often described as burning pain, occurring in the absence of relevant visible findings or a specific, clinically identifiable neurologic disorder."

A new vulvodynia diagnosis and treatment guideline has just been published by the Hagerstown, MD-based American Society for Colposcopy and Cervical Pathology.[1] It covers general vulvar care, topical medications, oral medications, injectables, biofeedback and physical therapy, as well as dietary changes with supplementations, acupuncture, hypnotherapy, and surgery.

There is no one specific approach to treatment of vulvodynia, which can be very frustrating for the patient and the provider, says the guideline's lead author, **Hope Haefner**, MD. Haefner, who is an associate professor of obstetrics and gynecology at the Ann Arbor-based University of Michigan and director of its Center for Vulvar Diseases, worked in concert with a broad cross-section of medical disciplines in developing the new guideline.

"The key is to start treatment early," she suggests. "The longer these patients have pain, the harder the condition is to treat."

EXECUTIVE SUMMARY

The American Society for Colposcopy and Cervical Pathology has just issued a new vulvodynia diagnosis and treatment guideline. According to a 2004 study, the condition is more prevalent than previously thought: 3% of women surveyed in the study reported chronic vulvar pain, and 1.7% said they currently have pain.

- The condition is now defined as vulvar discomfort, most often described as burning pain, occurring in the absence of relevant visible findings or a specific, clinically identifiable neurologic disorder.
- There is no one specific approach to treatment. Early treatment is key.

Offer suggestions for relief of vulvar pain

- **Avoid exercises that put direct pressure on the vulva** such as bicycle riding and horseback riding.
- **Limit intense exercises** that create a lot of friction in the vulvar area. Try lower-intensity exercises such as walking.
- **Use a frozen gel pack** wrapped in a towel to relieve symptoms after exercise.
- **Enroll in an exercise class** such as yoga to learn stretching and relaxation exercise.
- **Don't swim in highly chlorinated pools.** Avoid the use of hot tubs.

Source: National Vulvodynia Association, Silver Spring, MD.

How prevalent is it?

Chronic unexplained vulvar pain is a highly prevalent disorder that often is misdiagnosed, according to a 2003 study.[2] In that analysis, researchers found that approximately 16% of respondents to a Boston-based population survey reported histories of chronic vulvar pain for at least three months or longer, with nearly 7% of respondents experiencing the pain at the time of the survey. The analysis showed that Caucasian and African American women reported similar incidence rates; Hispanic women were 80% more likely to experience symptoms compared to Caucasian and African American women; researchers do not yet understand the variations in prevalence.[2] Based on survey data, the researchers conservatively estimate that approximately 5% of all women will experience chronic vulvar pain before age 25.[2]

In a 2004 study based on the results of an Internet survey of 994 women, researchers found 27.9% of women had experienced pain at the vulvar vestibule (the opening to the vulva) and 3% reported chronic pain.[3] Researchers found that African American women had symptoms in the same numbers as did Caucasian women.[3]

"At the time, the prevalence of vulvodynia still was thought to be quite low and was estimated

RESOURCES

- **The American Society for Colposcopy and Cervical Pathology** is a professional organization aimed at the study, prevention, diagnosis, and management of lower genital tract disorders. Its official publication, *Journal of Lower Genital Tract Disease*, contains "The Vulvodynia Guideline" in its January 2005 issue. The article may be accessed free of charge through the Society's web site, www.asccp.org. Click on "Journal." For additional information, contact: American Society for Colposcopy and Cervical Pathology, 20 W. Washington St., Suite 1, Hagerstown, MD 21740. Telephone: (301) 733-3640. Fax: (301) 733-5775. Web: www.asccp.org.
- **The International Society for the Study of Vulvovaginal Disease** is a professional organization focused on care of vulvar diseases. The organization offers a patient education material section on its web site, with freely reproducible handouts on such topics as vulvar pain. Contact: International Society for the Study of Vulvovaginal Disease, 8814 Peppergrass Lane, Waxhaw, NC 28173. Telephone: (704) 814-9493. Fax: (704) 814-9571. E-mail: issvd@carolina.rr.com. Web: www.issvd.org.
- **The National Vulvodynia Association** is a nonprofit organization created in 1994 to improve the lives of individuals affected by vulvodynia. It has produced a 24-page patient guide titled "*I Have Vulvodynia . . . What Do I Need to Know?*" that provides an overview of vulvodynia from gynecological and chronic pain perspectives. The brochure includes treatment information, self-help tips and coping strategies for vulvodynia patients, as well as information on general gynecological health. Health care providers may request a complimentary copy of the guide prior to purchase by contacting Gigi Brecheen at (301) 649-2236 or e-mailing gigi@nva.org. Bulk order costs (which include shipping fees) are as follows: 25 guides, $40 members, $50 nonmembers; 50 guides, $75 members, $95 nonmembers; and 100 guides, $125 members, $160 nonmembers. Health care providers may join the association for an annual dues fee of $60, which includes the cost of subscriptions to its print newsletter and quarterly electronic research newsletter. Contact: National Vulvodynia Association, P.O. Box 4491, Silver Spring, MD 20914-4491. Telephone: (301) 299-0775. Fax: (301) 299-3999. Web: www.nva.org.
- **The University of Michigan Center for Vulvar Diseases** web site has a number of links on vulvar diseases. Read on-line its patient education booklet, "Vulvar Conditions & Management," which contains information on medications, diets, and treatment strategies for vulvar pain. Web: www.med.umich.edu/obgyn/vulva/links.htm.

to be very rare in black women," says **Barbara Reed**, MD, MSPH, professor of family medicine at the University of Michigan's School of Family Medicine, lead author of the article."The web survey allowed us to survey a larger number of women who were not necessarily being seen in a doctor's office to get a better idea of the prevalence of symptoms suggesting the presence of vulvodynia."

Where does it hurt?

When making a diagnosis of vulvodynia, the guideline suggests using a diagram of the pain location. Using a cotton swab to test for pain locations on the vulva, start at the thighs and move medially to the vestibule. The vestibule is tested at the two o'clock, four o'clock, six o'clock, eight o'clock, and 10 o'clock positions; each time the vestibule is touched, if pain is present, ask the patient to quantify the pain as mild, moderate, or severe.[1] Be sure to perform vaginal cultures to rule out conditions such as yeast infection.

Offer the following self-care tips:

• Wear cotton underwear during the day and none at bedtime.

• Avoid vulvar irritants such as perfumes, dyed toilet articles, shampoos, detergents, and douches.

• Use mild, nonirritating soap for the body, but none on the vulva. The vulva can be cleaned gently with water and patted dry. After cleansing, an emollient without preservatives (vegetable oil or plain petrolatum) helps to hold moisture in the skin.[2] **(See additional tips from the National Vulvodynia Association, p. 56.)**

Topical therapies and oral medications may provide relief; be sure to check the patient's medical history for any possible interaction. (Read the listing of drug therapies in the guideline, published in the January 2005 issue of the *Journal of Lower Genital Tract Disease.* **See the resource listing, left, on how to access it, as well as review a number of provider resources.)**

Vulvodynia has many possible treatments, but very few controlled trials have been performed to verify their efficacy, says Haefner. The National Institutes of Health has sponsored two national conferences on the subject, but more work is needed, she states.

Vulvodynia can take time to treat; improvement may take weeks to months, according to Haefner.

"No one single treatment is successful in all

women," she notes. "It can be a difficult process to treat."

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Bacterial vaginosis is focus of new research

A check of the next patient's file indicates a repeat visit for treatment of bacterial vaginosis (BV). What is your next step?

If you are puzzled, you are not alone. Recurrent bacterial vaginosis is a difficult clinical condition that is not uncommon, says **Jack Sobel**, MD, professor of medicine and infectious diseases at Wayne State University in Detroit. According to the Centers for Disease Control and Prevention (CDC), bacterial vaginosis is the most common vaginal infection in women of childbearing age.[1]

Sobel now is heading a multicenter Phase III clinical study to demonstrate the safety and effectiveness of tinidazole (Tindamax, Presutti Laboratories, Rolling Meadows, IL) for the potential treatment of BV. Other sites participating in the company-sponsored study include Medical University of South Carolina in Charleston; Magee-Womens Hospital in Pittsburgh; Duke University in Durham, NC; Medical College of Georgia in Augusta; Drexel University in Philadelphia; Louisiana State University in New Orleans; and University of Washington in Seattle.

"BV has been difficult to treat because although we know the organisms associated with it, we do not understand the cause of the infection," says **Jane Schwebke**, MD, professor of medicine in the division of infectious diseases at the University of Alabama at Birmingham who is heading a single-site investigation of the drug funded by the National Institute of Allergy and Infectious Diseases (NIAID). "If we could blame it on a particular bacteria, it would be much easier to treat."

Common symptoms of BV include a fishlike odor or a thin white or gray vaginal discharge. Some women may note burning during urination or itching around the outside of the vagina. About half of women with BV may be asymptomatic.[2]

Clinicians can diagnose BV by using clinical or Gram stain criteria. Clinical criteria include the presence of clue cells on microscopic examination; a homogeneous, white, noninflammatory discharge that coats the vaginal walls; a pH reading of greater than 4.5 on vaginal fluid; and a fishy odor of vaginal discharge before or after addition of 10% potassium hydroxide (also known as the "whiff test"). **(Review diagnostic steps in *Contraceptive Technology Update*'s article, "New guidelines are up for bacterial vaginosis, March 2002, p. 31.)**

In most cases, BV causes no complications. However, the infection can give rise to some serious risks, including increasing a woman's susceptibility to HIV infection if she is exposed to the virus.[3]

Pregnant women with BV more often have babies who are born early or with low birth weight.[4]

Look at options

The CDC's 2002 treatment guidelines list the following drugs for treatment of BV:

- metronidazole (Flagyl, G.D. Searle, Chicago; also generic versions), 500 mg orally twice a day for seven days;
- clindamycin cream 2% (Cleocin, Pharmacia Corp., Peapack, NJ), one full applicator (5 g) intravaginally at bedtime for seven days;
- metronidazole gel 0.75% (MetroGel vaginal gel, 3M, St. Paul, MN), one full applicator (5 g) intravaginally twice a day for five days.

EXECUTIVE SUMMARY

Researchers now are looking at use of tinidazole for treatment of bacterial vaginosis (BV), the most common vaginal infection in the United States.

- Common symptoms of BV include a fishlike odor or a thin white or gray vaginal discharge. Some women may note burning during urination or itching around the outside of the vagina. About half of women with BV may be asymptomatic.
- Clinical criteria include the presence of clue cells on microscopic examination; a homogeneous, white, noninflammatory discharge that coats the vaginal walls; a pH reading of greater than 4.5 on vaginal fluid; and a fishy odor of vaginal discharge before or after addition of 10% potassium hydroxide (also known as the "whiff test").

Alternate regimens include:

- metronidazole, 2 g orally, in a single dose;
- clindamycin, 300 mg orally twice a day for seven days;
- clindamycin ovules (Cleocin Vaginal Ovules, Pharmacia Corp.) 100 mg, intravaginally, once at bedtime, for three days.[5]

Another treatment option has been added since the publication of the CDC guidelines: clindamycin phosphate (Clindesse) vaginal cream, 2%, a single-dose cream. The new drug, manufactured by KV Pharmaceutical Co. in St. Louis and marketed through its Ther-Rx subsidiary, received Food and Drug Administration approval in December.

The multisite trial of tinidazole will evaluate a dosing regimen of 2 g of the drug once daily for two days and 1 g of the drug once a day for five days. The NIAID-funded investigation will compare a seven-day regimen of 500 mg metronidazole, taken twice daily, with two different seven-day dosing regimens of tinidazole — 500 mg and 1 g — taken twice daily. Tinidazole is approved for treatment of trichomoniasis, giardiasis, intestinal amebiasis, and amebic liver abscess. **(*CTU* reported on the drug's FDA approval in the article, "Trichomoniasis drug given FDA approval," August 2004, *STD Quarterly* supplement, p. 3.)**

With metronidazole, the standard treatment for the disease, the cure rate is only about 70%, and recurring infection is a problem, notes Schwebke.

"We're interested to see if tinidazole, shown to be better tolerated with fewer sides effects, can be given in higher doses to achieve a greater cure rate," she states. "Even a small increase in the cure rate for such a prevalent disease, with so many public health implications, could be of great benefit."

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EC in the ED: What is your state's policy?

When it comes to emergency contraception (EC), it is an accepted standard of care in your clinic. But when it comes to the emergency department (ED) at your local hospital, is it the same story?

Not likely — and that is a concern for women who have been sexually assaulted. Women's health advocates had looked to the publication of the first-ever national medical guidelines for sexual assault treatment to rectify the matter; however, no mention of EC is included.

The 130-page document, released by the Department of Justice (DOJ) in September 2004, represents an important step toward ensuring that all sexual assault victims receive high-quality medical and forensic services, notes **Jennifer McAllister-Nevins**, state strategy attorney with the New York City-based American Civil Liberties Union (ACLU) Reproductive Freedom Project. However, failure to include EC in the guidelines is a "lost opportunity," she says.

The guidelines devote five pages to evaluation and care of sexually transmitted diseases. Yet, just one page is given to pregnancy risk evaluation and care, where the guidelines direct providers to "discuss treatment options with patients, including reproductive health services."[1] No mention is made of EC, although previous drafts of the document had included discussion of the method.[2]

EXECUTIVE SUMMARY

The U.S. Department of Justice has issued its first medical guidelines for treating sexual-assault victims; however, the document contains no information about emergency contraception (EC).

- American College of Obstetricians and Gynecologists standards state that physicians should administer pregnancy tests and offer EC as part of their overall sexual assault exam. Similar guidelines established by the American Medical Association require that rape victims be counseled about their risk of pregnancy and offered EC.
- A handful of states have specific laws on EC in the emergency department. Women's health advocates are working in many states to have specific legislation approved.

The new federal regulations are out of compliance with Washington, DC-based American College of Obstetricians and Gynecologists (ACOG) standards, which specifically state that physicians should administer pregnancy tests and offer EC as part of their overall sexual assault exam,[3] states **Anita Nelson**, MD, professor in the obstetrics and gynecology department at the University of California in Los Angeles (UCLA) and medical director of the women's health care clinic and nurse practitioner training program at Harbor-UCLA Medical Center in Torrance. Similar guidelines established by the Chicago-based American Medical Association require that rape victims be counseled about their risk of pregnancy and offered EC.[4] **(*Contraceptive Technology Update* reported on ED practices in its November 2001 article, "Is EC available in your local emergency department?" p. 129.)**

The Dallas-based American College of Emergency Physicians includes information on emergency contraception in its recommendations on the evaluation and management of sexual assault patients.[5] Most ED providers surveyed at a national medical conference said they were willing to provide EC.[6]

EC not used in sexual assault treatment

A 2002 study found that EC is not part of routine ED procedures.[7] According to the analysis of national ED data by researchers at the Newark-based University of Medicine and Dentistry of New Jersey, just 21% of sexual assault victims were given EC.[7]

In a recently released ACLU briefing paper, analysts found that in eight out of eleven states studied, fewer than 40% of emergency care facilities routinely provide EC on-site to women who have been sexually assaulted. The results varied from a low of 6% of facilities in Louisiana and 8% in Idaho, rising to 28% in New Mexico, Pennsylvania, and Wisconsin, to 80% in New Hampshire and 85% in New York.[8]

Women's health advocates are working within their individual states to see that EC language is included in legislation for sexual assault treatment, says McAllister-Nevins. There is much room to cover, though; only a handful of states have legislation on EC in the ED, according to the New York City-based Alan Guttmacher Institute:

- Five states (California, Illinois, New Mexico, New York, and Washington) require EDs to provide information about EC to women who have been sexually assaulted.
- Five states (California, New Mexico, New York, South Carolina, and Washington) require EDs to dispense upon request EC to women who have been sexually assaulted.
- One state — Ohio — requires health care providers that object to dispensing EC to refer patients to another health care provider.[9]
- Oregon law authorizes state payment when EC is dispensed to women who have been assaulted, although it does not mandate treatment or information.[10]

A broad coalition of national, state, and local organizations have banded together to seek inclusion of EC information in the DOJ guidelines. In addition, a "Best Help for Rape Victims Act" bill (HR 1214) has been filed in the federal House of Representatives to require the Department of Justice to include EC in its new guidelines.

"It is really important to have a national protocol," says McAllister-Nevins. "The document in many ways is so thorough and addresses several important points; EC should be one of them."

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Funding cuts threaten family planning source

Is your clinic seeing more women without insurance coverage whose care is now funded by Medicaid? New statistics from the New York City-based Alan Guttmacher Institute (AGI) confirm your observations: Researchers estimate that in 2003, one in five women of reproductive age were uninsured, which signals a 10% increase since 2001. About 400,000 more women joined the ranks of those needing publicly subsidized care in that same two-year span.[1]

Increased needs are not translating into increased dollars, however; Medicaid cost-cutting proposals are under way in Congress and state legislatures. The fiscal year 2006 budget submitted in February by the Bush Administration includes changes to the Medicaid program that could effectively result in $45 billion-$60 billion in cuts to the program over the next 10 years.[2] These proposed cuts represent a major challenge to family planning services, says **Rachel Benson Gold**, AGI's director of policy analysis.

Half of all women who are at risk for unintended pregnancy if they do not use birth control need publicly funded family planning services, says Gold. With proposed funding cuts on the federal and state levels, the potential for a "perfect storm" is brewing that could make it harder for women to get the family planning services they need to help them plan their pregnancies and protect their health, Gold observes.

Senate supporters were able to turn back proposed Medicaid cuts in a March 17 vote. By a vote of 52-48, senators moved to stop the reductions and in their place establish a commission to explore policy changes to slow the program's growth.[3] However, expect further deliberations as Congress moves toward a final budget.

"I don't think the question of Medicaid is going to be solved quickly and easily," says Gold.

EXECUTIVE SUMMARY

The fiscal year 2006 budget under review by Congress is calling for substantial cuts to the Medicaid program, a move that could severely impact access to family planning services for low-income women.

- New research shows that in 2003, one in five women of reproductive age were uninsured, which signals a 10% increase since 2001. About 400,000 more women joined the ranks of those needing publicly subsidized care in that same two-year span.
- Senate supporters of Medicaid were able to turn back proposed cuts in a March 2005 vote. However, expect further deliberations as Congress moves toward a final budget.

Check your coverage

States cover a broad package of preventive care under Medicaid guidelines. Forty-seven states and the District of Columbia (DC) include their major prescription contraceptive methods under Medicaid; 32 states and DC cover over-the-counter methods such as condoms. Many states also cover testing and treatment of sexually transmitted diseases as part of their Medicaid-funded family planning programs.[4]

According to AGI research, 27 states and the District of Columbia have seen family planning funding decline or stagnate since 1994.[5]

The proposed cuts to Medicaid come even as evidence mounts that it can be used to improve access to contraception and reduce health care costs, says Gold. Nationally, each dollar spent to provide publicly funded family planning services saves $3 in expenditures for pregnancy-related and newborn care just to the Medicaid program alone.[6]

A national evaluation of Medicaid family planning waivers was performed by CNA Corp. in Alexandria, VA, with research assistance from Atlanta-based Emory University and the University of Alabama at Birmingham.[7] It showed that such programs result in significant savings to the federal and state governments. **(Review an analysis of the evaluation in the column, "Family planning waivers work, research shows," in *Contraceptive Technology Update*, May 2004, p. 58.)**

Such cost-saving documentation should garner support for the program; however, it does not, says **Judith DeSarno**, president and chief executive officer of the Washington, DC-based National Family Planning and Reproductive Health Association.

"Unfortunately, these well-established facts are ignored, and instead, family planning services and women facing unintended pregnancy are included in this administration's rhetoric of 'optional services' and 'optional populations,'" she states.

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ASK THE EXPERTS

Contraceptive implant, sponge await FDA action

What is the U.S. market status for two forms of birth control, the single-rod contraceptive implant and the contraceptive sponge? Answers to these questions are provided by **Marcia Diljak**, spokeswoman for West Orange, NJ-based Organon, and **Gene Detroyer**, president and chief executive officer of Allendale (NJ) Pharmaceuticals.

Question: I want to attend the Contraceptive Technology April 2005 preconference on progestin-only implants, but my agency won't allow me to attend unless there is a new method approved by the Food and Drug Administration (FDA). What is the status of Implanon?

Diljak: As of *Contraceptive Technology Update* deadline, Implanon still is in approvable status at the FDA.

The FDA issued an approvable letter for the single-rod implant in November 2004. **(*CTU* reported on the issuance in the January 2005 article, "Bulletin: FDA issues approvable status for single-rod contraceptive implant," p. 1.)** According to the FDA, an approvable letter signals that the agency is prepared to approve the product dependent on the company meeting specified conditions.

Implanon is inserted under the skin of the upper arm and provides contraception for up to three years. Consisting of a nonbiodegradable rod measuring 40 mm in length and 2 mm in diameter, the device releases the progestin etonogestrel at an average release rate of 40 mcg per day. Since the device does not contain estrogen, it may be safely used by women who do not tolerate or are contraindicated to estrogen use.

Progestin-only implant contraception options have been lacking since the 2000 removal of the six-rod Norplant implant from U.S. pharmacy shelves. Wyeth Pharmaceuticals, Madison, NJ, suspended shipment of implants in August 2000 when concerns arose about efficacy of suspect lots. While the lots were found effective in July 2002, the manufacturer chose not to reintroduce the product in the United States. **(See the following *CTU* articles: "Check Norplant stock, company says: Recent batches might be ineffective," October 2000, p. 117; "Are Norplant's days numbered in the U.S.? Test results could decide its fate," November 2000, p. 129; and "Don't count implants out: 2 options may take Norplant's place," October 2002, p. 109.)**

Although the Norplant contraceptive system was highly effective and convenient, the removal challenges associated with the six-rod system proved to be a major downside for many, says **Andrew Kaunitz**, MD, professor and assistant chair in the obstetrics and gynecology department at the University of Florida Health Science Center/Jacksonville. Implanon would address these challenges.

Question: What is the U.S. status of the Today Contraceptive Sponge?

COMING IN FUTURE MONTHS

- Mifepristone for emergency contraception?
- Review midlife contraceptive options
- Low-dose OCs: Check benefits and disadvantages
- Intrauterine device for menorrhagia treatment?
- Tips for talking to teens about contraception

Detroyer: Allendale Pharmaceutical recently received labeling approval from the FDA. As of *CTU* press time, the company awaits further action as to full marketing status.

The sponge was released in the Canadian market in 2003; in the last year and a half, the company has sold more than 500,000 sponges with no reports of an adverse event or unplanned pregnancy. **(*CTU* reported on the Canadian release in its article, "Time for Today sponge in Canada; will U.S. see vaginal contraceptive?" May 2003, p. 49.)**

Women have waited for news of the sponge's re-emergence on U.S. market shelves; some 250 million sponges were sold between Today's 1983 market debut and its 1995 removal.

The sponge was not removed from the market by the FDA; its former manufacturer, Whitehall-Robins Healthcare of New York City, ceased production when it determined it cost too much to correct problems caused by water quality issues at the old factory where the sponge was made. Allendale Pharmaceuticals acquired manufacturing and marketing rights to the sponge in 1999 and has been working with the FDA to have updated labeling and manufacturing approved for the over-the-counter contraceptive. The Today Sponge is circular in shape, 2 inches in diameter and three-fourths of an inch thick, with an attached loop. Made of polyurethane, it contains 1,000 mg of the spermicide nonoxynol-9. **(See the *CTU* article, "Revival of the Today sponge: Vaginal contraceptive returns," May 1999, p. 49, for a review of the sponge's manufacturing history.)** ■

CDC offers continuing education on STDs

Need to brush up on your knowledge of current treatment practices when it comes to sexually transmitted diseases (STDs)? The Centers for Disease Control and Prevention's (CDC's) Division of Sexually Transmitted Diseases is offering new on-line STD education modules.

The modules offer free continuing education credit for seven STD topics: chlamydia, gonorrhea, syphilis, pelvic inflammatory disease, vaginitis, herpes simplex virus, and human papillomavirus. Each module covers epidemiology, pathogenesis, clinical presentation, diagnosis, treatment, prevention, and partner services information, along with an interactive case study.

The modules are aimed at clinicians in primary care settings, such as nurses, nurse practitioners, nurse-midwives, physician assistants, and physicians, who desire a basic introduction to STD diagnosis and management.

To access the modules, visit the division's web page, www.cdc.gov/std. Under "Resources," click on "Training," "Continuing Education Online," and "STD Curriculum Self-Study Modules." ■

Plan now to attend HIV prevention conference

Circle June 12-15, 2005, on the calendar to attend the 2005 National HIV Prevention Conference in Atlanta.

The Centers for Disease Control and Prevention (CDC) plans the annual conference. Conference participants share effective prevention approaches and research findings on such topics as behavioral interventions, vaccine development, HIV testing, and improving access to early treatment and prevention services.

Registration fees prior to April 27 are $350; after that date, registration fees are $400 and may be made on site only. For questions about registration, contact the registration coordinator at (703) 548-0618 or via e-mail at info@2005HIVPrevConf.org. To learn more about the conference, visit the conference web site, www.2005HIVPrevConf.org. ■

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

CE/CME Questions

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

- **Identify** clinical, legal, or scientific issues related to development and provisions of contraceptive technology or other reproductive services. (See **"Injectable update: Subcutaneous form of Depo-Provera is approved"** and **"Bacterial vaginosis is focus of new research."**)
- **Describe** how those issues affect service delivery and note the benefits or problems created in patient care in the participant's practice area. (See **"Evidence supports use of patient-delivered partner therapy for sexually transmitted diseases."**)
- **Cite** practical solutions to problems and integrate information into daily practices, according to advice from nationally recognized family planning experts. (See **"New guideline details care of vulvodynia."**)

17. What is the active ingredient in Depo-SubQ Provera 104?
A. Levonorgestrel
B. Medroxyprogesterone acetate
C. Norethindrone enanthate
D. Lynestrenol

18. To test for pain locations on the vulva, a clinician should use a cotton-tipped swab to touch the vestibule at the following locations:
A. One o'clock, four o'clock, six o'clock, eight o'clock and 10 o'clock positions
B. Two o'clock, three o'clock, six o'clock, eight o'clock, and 10 o'clock positions
C. Two o'clock, four o'clock, six o'clock, eight o'clock, and 10 o'clock positions
D. Two o'clock, four o'clock, seven o'clock, eight o'clock, and 10 o'clock positions

19. What is the correct pH reading to make a diagnosis of bacterial vaginosis?
A. Greater than 3.5 on vaginal fluid
B. Greater than 4.0 on vaginal fluid
C. Greater than 4.3 on vaginal fluid
D. Greater than 4.5 on vaginal fluid

20. What is the standard dosage of azithromycin used for treatment of chlamydia?
A. 1 g
B. 0.50 g
C. 0.025 g
D. 1 mcg

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

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S·T·D QUARTERLY™

Evidence supports use of patient-delivered partner therapy for sexually transmitted diseases

Programs must overcome legal, financial barriers

As you tell the patient in front of you that she has a positive test for chlamydia, you explain the importance of having her boyfriend treated. You encourage her to have the boyfriend come in for care, but what are the odds that you will see him?

Not too good, according to research findings.[1-3] Many partners of patients fail to receive treatment for sexually transmitted diseases (STDs) such as as chlamydia and gonorrhea, and reinfection and further disease transmission are common occurrences.[4-7] Just-published research indicates that a new model of expedited partner care can change the equation by decreasing the patient's risk of reinfection and increasing the number of treated partners.[8]

Researchers at the Public Health — Seattle & King County and the University of Washington, both in Seattle, and the Centers for Disease Control and Prevention (CDC) developed a system whereby STD patients diagnosed with gonorrhea or chlamydial infection were given medications to give to their partners. This system allowed the partners to get treated without first seeing a medical provider. To conduct the study, researchers randomly assigned women and heterosexual men diagnosed with gonorrhea or chlamydial infections to receive partner medications or be given standard referrals to have partners seek medical care.

Patients provided with medications to give to their partners were more likely to report that all their partners were treated than those assigned to a standard referral procedure. In addition, they were less likely to report having sex with an untreated partner.[8]

No progress has been made in this decade toward achieving the goals of lower gonorrhea and chlamydia rates as set forth by the Department of Health and Human Services' Healthy People 2010 initiative, state authors of an editorial accompanying the new research.[9] Expedited partner therapy may provide a way to help reach those goals, says **Matthew Golden**, MD, MPH, acting director of the

EXECUTIVE SUMMARY

New research indicates that patient-delivered partner therapy is effective in reducing rates of recurrence of sexually transmitted diseases such as gonorrhea and chlamydia; however, few states have enacted specific laws allowing its use.

- To conduct the new study, researchers randomly assigned women and heterosexual men diagnosed with gonorrhea or chlamydial infections to receive partner medications or be given standard referrals to have partners seek medical care.
- Patients who received medications to give to their partners were more likely than those assigned to standard referral of partners to report that all of their partners were treated. They also were less likely to report having sex with an untreated partner.

STD Control Program at Public Health — Seattle & King County and an assistant professor of medicine at the University of Washington's Center for AIDS & STDs.

"We have a multimillion-dollar program to fight chlamydial infection in this country," says Golden, who served as lead author of the new research. "Are we willing to spend an increment more to increase partner treatment? I would say that is probably a good investment."

Review the research

More than 1,800 women and heterosexual men were involved in the new study. All of them were newly diagnosed with chlamydia, gonorrhea, or both, and claimed at least one untreated partner within the previous 14 days. The study was conducted at the University of Washington in Seattle from September 1998 to March 2003.

Patients assigned to the standard referral group were advised to have partners seek treatment at a free clinic. Those patients receiving expedited treatment were offered free packets of medication, a written prescription, or directly mailed medication for up to three partners. The treatment packets included medications for gonorrhea (cefixime, 400 mg) and chlamydia (azithromycin, 1 g), as well as condoms and health information on STD transmission and medication side effects. Participants in both groups were retested and interviewed three months later to determine who had received treatment and who may have been reinfected.

The expedited treatment group showed a 3% reinfection rate of gonorrhea compared to 11% among the standard referral group. With chlamydia, those receiving expedited care had an 11% reinfection rate, compared to 13% of those receiving standard referrals.

Is model in practice?

Whether you call it expedited partner therapy (EPT) or patient-delivered partner therapy (PDPT), know that this method is widely but inconsistently used in the United States. According to a survey of more than 3,000 physicians, about half reported ever using PDPT for gonorrhea and chlamydial infection, and less than 15% said it was a customary practice.[10]

While some health departments have adopted the practice, very few states have enacted specific laws allowing its use. Legislation specifically articulating the legality of EPT has been passed in California and Oregon.[11] California was first to draft such legislation; its 2001 action allows providers to prescribe or dispense antibiotic therapy for the partners of patients with genital chlamydia infection. **(*Contraceptive Technology Update* reported on the California legislation in its article, "Meet 'Joe Partner': New STD treatment plan," April 2001, p. 42.)**

Results of a 2004 survey of state pharmacy and medical examiner boards indicate that new laws may be needed if PDPT is to be widely instituted.[12] According to the survey results, the legal status of PDPT is poorly defined, and the practice is considered illegal in much of the United States.[12]

Some providers may hesitate providing treatment without direct examination, since PDPT may result in missed opportunities for the diagnosis and treatment of comorbid conditions, says Golden. Findings from a just-published study may help to allay some of those fears: They suggest that comorbidities in heterosexuals are relatively uncommon.[13]

Who will pay?

Instituting proper medico-legal procedures for expedited therapy is one portion of the treatment puzzle, but funding of such practice is another matter. Many third-party payers will not pay for prescriptions to partners who may not be covered by the patient's plan or who might not be insured at all.[9] In California, HMOs have been very reluctant to pay for nonmembers' medication, says **Anita Nelson**, MD, professor in the obstetrics and gynecology department at the University of California in Los Angeles (UCLA) and medical director of the women's health care clinic and nurse practitioner training program at Harbor — UCLA Medical Center in Torrance.

For now, Public Health — Seattle & King County is picking up the costs for partner therapy, says Golden. However, when weighed against the burden of untreated STD infection, the costs of expedited therapy represent a step forward in effective care, he says.

"This expedited care model may help redesign the current national partner notification system to treat more partners," states Golden. "Currently, approximately half of gonorrhea or chlamydia patients' sex partners do not get treated."

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Use the Internet to stem the spread of STD

On-line syphillis testing service offered

Facing an upward spike in its number of syphilis cases, the San Francisco Department of Public Health has spun its detection web in new directions, using a broad range of innovative Internet-based prevention interventions to stem the spread of the sexually transmitted disease (STD).

The agency is working with San Francisco-based Internet Sexuality Information Services (ISIS), a community-based organization that creates tools to deliver sexual health information, to develop a wide range of prevention interventions to reach those at risk. Its confidential on-line syphilis testing service, STDTest.org, allows people to print out a laboratory requisition slip, have their blood drawn, and receive their test results on-line. This service provides a convenient alternative to getting tested at the San Francisco municipal STD clinic and offers an additional means for detecting syphilis cases.[1]

Syphilis cases in San Francisco rose from 41 in 1998 to 553 in 2004, says **Jeffrey Klausner**, MD, MPH, director of the health department's STD Prevention Section. The San Francisco agency began to look at the Internet as a possible prevention venue after reports indicated that the STD's spike was associated with men meeting new sex partners through Internet chat rooms and at web sites that facilitate partner meeting.[2]

The STDTest.org site is just one example of

EXECUTIVE SUMMARY

The San Francisco Department of Public Health is using innovative Internet-based prevention interventions to stem the spread of syphilis following an upward spike in cases. The agency is working with Internet Sexuality Information Services to develop a wide range of prevention interventions to reach those at risk.

- Its confidential on-line syphilis testing service, STDTest.org, allows people to print a laboratory requisition slip, have blood drawn at the nearest participating laboratory in San Francisco, and receive test results on-line.
- Its InSPOT web site, www.inspot.org, is a partner notification web site aimed at men who have sex with men. It uses peer-to-peer e-mail postcards to alert partners of the need for testing.

3 simple steps to syphillis testing

Visitors to the STDTest.org site follow three simple steps to obtain syphilis testing and results:

- **Visitors complete and print out an on-line "syphilis test packet," which includes a lab slip with a unique identification number.** Information on laboratory testing sites with addresses and telephone numbers is included in the packet.
- **Visitors take their completed packets to a participating lab to have their blood drawn for the syphilis test.** They are instructed to keep the first page of the test packet so they can use the unique identification number to get their test results.
- **After the test is completed, visitors are asked to wait three to seven days and return to the web site to get their results.** If test results are positive, visitors are instructed to go to the San Francisco City Clinic or their regular medical provider for treatment. ■

Internet-based intervention, says **Deb Levine**, executive director of ISIS.[3] Its approach to testing offers convenience, accessibility, and an alternative for people at risk who might otherwise not get tested, she states.

During the site's first year of operation in 2003, a total of 218 tests were performed. Thirteen subjects had positive screening tests, and six new syphilis infections were diagnosed and treated.

Klausner estimates about $20,000 was used to implement the program, with costs covering content development and programming. Since the web site is hosted on a city server, there are no additional costs for hosting the site, he notes. Ongoing costs include the costs of blood draw, testing, follow-up, and treatment.

Get out the word

San Francisco public health officials are looking again to the Internet to boost partner notification with the InSPOT (www.inspot.org) web site. The partner notification web site is aimed at men who have sex with men (MSM), using peer-to-peer e-mail postcards or "e-cards" to alert partners of the need for testing.

At the InSPOT site, MSM who have been diagnosed with an STD can choose from several e-cards to let their partners know they may have been exposed and suggest they get tested. Links to both web sites are listed on the San Francisco City Clinic web site, www.sfcityclinic.org.

Cards can be sent anonymously

The InSPOT web site allows users the option of sending cards anonymously or to multiple people at the same time. It helps to reduce the stigma associated with treatable STDs by providing a quick, easy, and light-hearted way to talk about them, says Levine.

"Given the recent increases in STDs in gay men and the value of partner notification in breaking the cycle of continued transmission, we were looking for another way to help gay men approach the subject of STDs that protects an individual's privacy and empowers men to take the responsibility of informing partners themselves ," says Klausner. "We know that increasing the options for partner notification can effectively reduce the transmission of STDs including HIV infection by encouraging individuals to get tested, diagnosed, and treated."

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RESOURCE

For more information on Internet-based prevention messages, contact:

- **Deb Levine**, Executive Director, or **Tom Kennedy**, Director of Communications, Internet Sexuality Information Services, P.O. Box 14287, San Francisco, CA 94114-0287. E-mail: deb@isis-inc.org or tom@isis-inc.org. Web: www.ISIS-Inc.org.