2009 Reader Survey Inside

CONTRACEPTIVE TECHNOLOGY UPDATE®

A Monthly Update on Contraception and Sexually Transmitted Diseases

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Second generation of female condom receives FDA committee approval

Next for FDA review: Package label and package insert language

When the female condom first gained Food and Drug Administration (FDA) approval in 1993, women's health advocates hailed it as a form of female-controlled protection; however, use of the method has been underwhelming among American women since its introduction.

One roadblock to use has been the device's high manufacturing cost. The original female condom, known as the Reality or FC1 female condom, is made of polyurethane. Due to the manufacturing process involved in making the FC1, its price, approximately 72 cents per unit, could not be affected by bulk purchasing. The new generation, known as the FC2, is made of nitrile, carries a less expensive manufacturing cost, and can be made available for as little as 22 cents per unit in bulk-purchasing programs.[1]

The FC2 condom, available in 77 countries, has gained backing from a U.S. Food and Drug Administration (FDA) advisory panel. The agency is not bound by the committee's recommendation, but it does take its advice into strong consideration when reviewing potential products.

EXECUTIVE SUMMARY

The second generation of the female condom, called the FC2 condom, now is available in 77 countries and has gained backing from a Food and Drug Administration advisory panel. Its package labeling and insertion instructions must be confirmed prior to final U.S. regulatory review.

- The second female condom is made of nitrile and is less expensive to manufacture than the original FC1 polyurethane female condom.
- Marketed in the United States as the fc female condom, the FC1 female condom in 2008 underwent new packaging, a new advertising campaign, and establishment of a dedicated web site by its U.S. retail distributor.

IN THIS ISSUE

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What is the next step in the FDA regulatory process for the condom, manufactured by the Chicago-based Female Health Company? The company is working with the FDA to finalize an approvable package label and package insert language, says **Mary Ann Leeper**, PhD, the company's senior strategic adviser. It expects the process to take several months, she adds.

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In developing the FC2 condom, the company wanted to find a material that would allow it to switch from a more costly welding process to a dipping process, much like the dipping process used to make male condoms, explains Leeper. The replacement of polyurethane with nitrile, a synthetic rubber, allowed the company to make that switch, she notes. "As a result, the FC2 female condom does not have a welded seam, and its outer ring is rolled, not welded," states Leeper. "The new material and dipping process allow for increased output, and they reduce material and labor expenses."

Will women with a latex allergy be able to use the FC2 condom? Yes, says Leeper. "We are not aware of any allergies to the FC2 nitrile compound," Leeper states. "It is similar to the material used in synthetic latex surgical gloves, used by people allergic to latex."

Will the company continue to make the original FC1 condom available in the United States if the FC2 condom receives FDA approval? "We are transitioning all FC1 purchasers to FC2 as soon as regulatory agency requirements are met around the world, including the U.S.," says Leeper. "We will ultimately stop the manufacture of FC1."

Is it safe and effective?

At a December 2008 meeting of the FDA's Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Committee, committee members reviewed the Female Health Company's pre-market approval application for the FC2 female condom for prevention of HIV/AIDS and unintended pregnancy. The company filed the pre-market approval request in January 2008. **(See "Status report on the female condom: What will increase use in the U.S.?" *Contraceptive Technology Update*, February 2008, p. 13.)**

The pivotal study presented for the FDA review was a multicenter, crossover, randomized trial conducted in South Africa.[2] The trial was designed to compare clinical failure modes for the FC1 and FC2 condoms. More than 200 women completed the study, with a total of 1,910 FC1 and 1,881 FC2 condoms used. Total clinical failure was 5.24% in FC1 and 4.3% in FC2.[2] The 18th edition of *Contraceptive Technology* lists the perfect use failure rate for the female condom (FC1) as 5%, and typical use as 21%, with 49% of women continuing use at one year.[3]

A 2006 review of the second-generation synthetic latex female condom by the World Health

Organization's Department of Reproductive Health and Research concluded that the design and physical characteristics of FC2, supported by the clinical data, suggest that the two devices are functionally equivalent, when used correctly.[4] The committee's review ruled that the FC2 is acceptable for bulk procurement by United Nations agencies. Since then, more than 22 million FC2 female condoms have been distributed in 77 countries, according to the Female Health Company.

New look boosts use

Mayer Laboratories of Berkeley, CA, is the exclusive retail distributor of the FC1 condom in the United States. It markets the product as the fc female condom. The fc female condom retails from $13.99-$16.99, says **Jenice Urcuyo**, assistant general manager at Mayer Laboratories. The condom also is available for order through a link on the product's web site, www.fcfemalecondom.com. Click on "fc female condom," then click on "Purchase." A package of three is $10, with a package of five listed at $15.

In 2008, the company redesigned the product's packaging, launched new advertising, and established the product's dedicated web site. What led to the change? Historically, the fc female condom package was similar to many pharmaceutical products and exhibited a strong clinical feel, explains Urcuyo. Its shelf appearance lagged considerably behind male condoms and other consumer products. After considerable thought and market information, Mayer Laboratories elected to take the product package design into the 21st century, says Urcuyo.

The fc female condom advertising campaign reinforces the product message, focusing on three mediums: a new web site, print advertisements, and retailer shelf promotions, states Urcuyo. The web site focuses on "smart-and-sexy" information, which allowed those without prior knowledge of fc female condoms to learn about the product, while being clear that fc female condoms are a part of sex and intimacy, she explains. The print ad goes beyond the public health message to "use as protection against pregnancy and sexually transmitted diseases." It also promotes the sexual satisfaction that will come from using the product, similar to how male condoms are advertised today, says Urcuyo.

"We immediately saw an increase in retail sales coinciding with the launch of the new package and ads," states Urcuyo. "For example, at Rite Aid, sales increased over 10% in the first three months of the new package and the promotion program."

While Mayer Laboratories has been selling the fc female condom on its web site since 2001 for consumers who could not locate the product at their local drugstores, it decided to establish a separate web site for the fc condom as an information resource, says Urcuyo. It has received overwhelming support from customers and consumers, she reports.

"Our unique features, "fc stories" and "fc questions," have especially received positive feedback, and consumers are definitely taking advantage of these forums. We can't keep up with the number of submissions we receive," states Urcuyo.

Female method is needed

The female condom offers numerous benefits: Its use does not rely on the assistance of a health care provider, it is immediately reversible, and it has few to no side effects, says **Beth Jordan**, MD, medical director of the Association of Reproductive Health Professionals (ARHP).

As with any contraceptive method, with solid education from a health care provider or other trusted source, a female condom can be used very effectively, states Jordan, who testified on behalf of ARHP at the FDA December 2008 committee hearing.

Female condoms are the only existing female-initiated and controlled HIV prevention method, states Jordan. When used consistently and correctly, female condoms offer between 90%-97% risk reduction of HIV infection,[5] she notes. In addition to serving as a safe and effective method protecting against HIV, sexually transmitted infections, and pregnancy, studies show that effective promotion and use of the female condom results in a significant increase in the total number of protected sex acts between partners.[6] Because it remains the only female-controlled HIV prevention tool, women who can't negotiate condom use with their male partners will especially benefit from the availability of a female condom, says Jordan.

In the absence of an effective HIV vaccine or microbicide, public health officials need to think more seriously about female condoms, says **Robert Hatcher**, MD, MPH, professor of gynecology and obstetrics at Emory University School of Medicine in Atlanta. Female condoms are available now; they are not a promise on the horizon, he says.

"There needs to be an increase in funding and

programs to expand access to this female-initiated method which offers a protection option for women," says Hatcher. "The markedly lower price of the new female condom may facilitate its use more widely in the prevention of HIV and other infections."

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OCs eyed for relief of endometriosis pain

Endometriosis is a common gynecologic disorders; about 3%-10% of American reproductive-age women have endometriosis.[1] Dysmenorrhea is the most common symptom reported by patients with endometriosis. What is your approach when it comes to treatment of such pain?

Research published in November 2008 assesses the use of oral contraceptives (OCs) in treating pain associated with endometriosis.[2] In a double-blind, randomized, placebo-controlled trial, scientists assessed the outcomes of 100 women who used a combined oral contraceptive (0.035 mg ethinyl estradiol plus 1 mg norethisterone) or placebo. Women who used the Pill took active pills for 21 days plus seven days of placebo, while the control group used placebo pills for 28 days. Women were treated for four cycles, with a verbal rating scale and a visual analog scale used to assess dysmenorrhea-related disability and analgesic use.

EXECUTIVE SUMMARY

Just-published research assesses the use of oral contraceptives (OCs) in treating pain associated with endometriosis. Women were assigned to OCs or placebo; while both groups showed improvements in total dysmenorrhea scores relative to their baseline values, dysmenorrhea was significantly less in women treated with the Pill throughout the treatment period. The number of days analgesics were used were reduced in the women who used OCs.

- Pain associated with endometriosis requires careful evaluation to exclude other potential causes, advises a new practice committee report issued by the American Society for Reproductive Medicine.
- Research is ongoing into other hormonal options, such as the levonorgestrel intrauterine system and the contraceptive implant, to treat pain associated with endometriosis.

Total dysmenorrhea scores significantly decreased at the end of treatment in the OC and placebo groups; however, the reduction in pain score was significantly higher in the OCP group[2] compared with the placebo group (0.6) ($P < 0.0001$). Women who used OCs also reduced the number of days analgesics were used, researchers note.[2]

Use careful evaluation

Pain associated with endometriosis requires careful evaluation to exclude other potential causes, advises a new practice committee report issued by the American Society for Reproductive Medicine in Birmingham.[3] Medical and surgical treatments for pain related to endometriosis are effective, and choice of treatment must be individualized, the report states.

Other conditions of the reproductive tract can cause chronic pelvic pain, such as adenomysosis, pelvic adhesions, pelvic inflammatory disease, congenital anomalies of the reproductive tract, and ovarian or tubal masses. Conditions such as irritable bowel syndrome, interstitial cystitis, and fibromyalgia also can lead to pelvic pain. A thorough evaluation to exclude other causes of pelvic pain should be pursued prior to aggressive therapy for endometriosis, the report advises.[3]

Oral contraceptives can be a valuable adjunct to the treatment options used by clinicians for the

pelvic pain caused by endometriosis, says **David Adamson**, MD, director of Fertility Physicians of Northern California in San Jose. An adjunct clinical professor at Stanford University and associate clinical professor at the University of California San Francisco, Adamson is past president of the American Society for Reproductive Medicine and a founding board member of the World Endometriosis Research Foundation in London. Since OCs are relatively safe, well tolerated, and inexpensive in comparison with other treatment modalities, they are often a first-line defense against pain experienced by those with endometriosis, he states.

Check GnRH agonists

Gonadotrophin-releasing hormone (GnRH) agonists, such as leuprolide acetate and nafarelin acetate, are modified forms of GnRH that bind to receptors in the pituitary. They serve to induce amenorrhea and progressive endometrial atrophy. While often used in medical management of endometriosis, side effects can include hot flushes, vaginal dryness, emotional lability, and loss of libido.[2] Use of these drugs has been linked to loss in bone mineral density, which might not be reversed until a few years after completion of treatments.[4]

Some patients respond better to use of leuprolide acetate, says Adamson. Due to potential bone issues, use of the drug is generally recommended for six months. Research indicates that GnRH agonist and norethindrone acetate, alone or combined with low-dose conjugated equine estrogens, administered to symptomatic endometriosis patients for 12 months provided extended pain relief and bone mineral density preservation after completion of therapy.[5]

A 2007 *Cochrane Database of Systematic Reviews*, which looked at all studies regarding the use of OCs for pain associated with endometriosis from 1966-2006, noted one randomized clinical trial that met its inclusion criteria.[6] That trial, which looked at use of a low-dose OC vs. goserelin, a GnRH agonist, found no evidence of a significant difference between the groups with regard to reduction in recurrence of dysmenorrhea at the end of its six-month follow-up period.[7]

What are other options?

Research also is looking into other hormonal options when it comes to treating pain associated with endometriosis. One small trial looked at patients with dysmenorrhea, nonmenstrual pelvic pain, and dyspareunia associated with histologically proven endometriosis using the contraceptive implant Implanon or the contraceptive injection depot medroxyprogesterone acetate (DMPA). Researchers report that after six months, the average decrease in pain was 68% in the Implanon group and 53% in the DMPA group.[8] In the research examining OC use, the visual analog scale score for dysmenorrhea fell from 58.7 to 27.6 in the OC group, and from 55.8 to 46.2 in the placebo group.[2]

Scientists also have considered use of the levonorgestrel intrauterine system (LNG-IUS) for treatment of endometriosis-related pain. Results of a 2005 study, which looked at use of the LNG-IUS and a GnRH analogue, indicate both were effective in the treatment of chronic pelvic pain-associated endometriosis, although no differences were observed between the two treatments.[9]

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Check dosing regimens to treat genital herpes

Think about the last five women who have entered your examination room. How many of them have had genital herpes simplex virus Type 2 (HSV-2) infection? While the percentage of Americans with genital herpes infection has decreased over the past decade — from about 21% to 17% — genital HSV-2 infection is more common in women.[1,2] According to the Centers for Disease Control and Prevention (CDC), about one out of four women have been infected, compared to almost one out of eight men.[3]

While there is no treatment that can cure herpes, the antiviral medications acyclovir, famciclovir, and valacyclovir can shorten and prevent outbreaks during the period of time the medication is taken. A number of management approaches with antiviral medications are commonly used, including episodic and suppressive treatments.[4] Episodic treatment is taken only at the outbreak of a recurrent infection. Suppressive therapy relies on daily dosing to reduce the frequency of genital herpes recurrences in patients who have frequent outbreaks.

The traditional course of antiviral therapy for herpes recurrences has consisted of five-day regimens.[5] However, researchers in the past decade have looked at short-course episodic treatment for recurrent HSV-2. Short-course episodic treatment listed by the CDC include:

- acyclovir 800 mg orally three times a day for two days;
- famciclovir 1,000 mg orally twice daily for one day;
- valacyclovir 500 mg orally twice a day for three days.[6]

Famciclovir (Famvir, Novartis Pharmaceuticals Corp.; East Hanover, NJ) gained supplemental Food and Drug Administration approval in 2007 for use of the drug as a single-day treatment for immunocompetent patients with recurrent genital herpes. Data indicate that when patients were treated with the drug within six hours of prodromal symptoms, it shortened the duration of outbreaks and improved the time to resolution of symptoms.[7]

Single-day dosage of Famvir is 1,000 mg twice daily for one day. Therapy should be initiated within six hours of the first sign of such prodromal symptoms as tingling, itching, burning, or lesion appearance.[8]

Results of a 2008 multinational, randomized, double-blind, comparative trial indicate that single-day famciclovir was as effective as three-day valacyclovir for treating genital herpes.[9] To perform the study, 1,179 adults with recurrent genital herpes were randomly assigned to begin treatment with famciclovir or valacyclovir within six hours after a recurrence. About one-third of patients in each treatment group had aborted genital herpes episodes, which suggested that both treatments have similar efficacy in preventing outbreaks or progression of lesions. There was no significant difference in time to resolution of symptoms associated with recurrence, researchers note.[9] The overall incidence of adverse events was similar (23.2% for the famciclovir group vs. 22.3% for the valacyclovir group); headache, nausea, diarrhea, vomiting, and abdominal pain were the most often reported.[9]

Since the single-day regimen of famciclovir was similar in efficacy and safety to the three-day valacyclovir regimen, it represents a more convenient treatment, researchers conclude.[9]

Scientists have looked at a one-day regimen of valacyclovir for recurrent HSV-2 episodes.[10] In an open-label pilot study, patients with recurrent HSV-2 infection were given a one-day course of valacyclovir (2,000 mg given by mouth twice daily) to be taken at the first sign of recurrence or prodrome. Ninety patients (78%) had a recurrence or the signs of initial symptoms, and four patients (5%) developed a second recurrence during the 14 days after treatment. The average duration of genital sores was five days, and the average duration of pain was three days.

EXECUTIVE SUMMARY

While there is no treatment that can cure genital herpes simplex virus Type 2 (HSV-2) infection, the antiviral medications acyclovir, famciclovir, and valacyclovir can shorten and prevent outbreaks during the period of time the medication is taken.

- A number of management approaches with antiviral medications are commonly used, including episodic and suppressive treatments. Episodic treatment is taken only at the outbreak of a recurrent infection. Suppressive therapy relies on daily dosing to reduce the frequency of genital herpes recurrences in patients who have frequent outbreaks.
- Researchers in the past decade have looked at short-course episodic treatment for recurrent HSV-2. Recent research indicates single-day famciclovir was as effective as three-day valacyclovir for episodic treatment of genital herpes.

Viral shedding was detected in 60 patients and lasted an average of two to three days. Of those with viral shedding, 14 (23%) had an additional shedding episode after the initial sore healed, with the second recurrence lasting approximately two days.

"A one-day course of valacyclovir may be a convenient treatment for recurrent genital herpes and comparative trials are warranted," researchers note.

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Research eyes new oral contraceptives

Review the list of oral contraceptives (OCs) in your current formulary. While it might seem there are several options, research scientists are focusing on development of new pills to expand women's choices.

Three pill formulations under investigation in the United States include a four-phasic pill composed of estradiol valerate (E2) and a new progestin, dienogest; a monophasic oral contraceptive containing E2 and the progestin nomegestrol acetate; and an estrogen/progestin/androgen pill. The first pill is being developed by Bayer Schering Pharma AG in Berlin, Germany; the E2/nomegestrol acetate OC is under investigation by Schering-Plough Corp. of Kenilworth, NJ; and the third formulation is under research by BioSante Pharmaceuticals in Lincolnshire, IL.

The E2/dienogest pill is poised for release in Europe. Bayer Schering Pharma AG reported completion of the European drug approval procedure in October 2008. The pill will be marketed as Qlaira. Phase III studies are being conducted for U.S. regulatory authorities.

Two pivotal Phase IIIa trials for the E2/nomegestrol acetate formulation are scheduled to be completed in 2009. More than 180 centers in 24 countries, including the United States, are taking part in the trials.

Dienogest and nomegestrol acetate are considered new progestins, along with drospirenone, trimegestone, and Nestorone.[1] These new progestins have been designed to bind very specifically to the progesterone receptor and not to other steroid receptors in an effort to avoid androgenic, estrogenic, or glucocorticoid side effects.[1]

Developers of the estrogen/progestin/androgen pill, dubbed "Pill-Plus," see the addition of

EXECUTIVE SUMMARY

Three combined oral contraceptive formulations now under investigation in the United States include a four-phasic pill composed of estradiol valerate (E2) and a new progestin, dienogest; a monophasic oral contraceptive containing E2 and the progestin nomegestrol acetate; and an estrogen/progestin/androgen pill.

- Dienogest and nomegestrol acetate are considered new progestins, along with drospirenone, trimegestone, and Nestorone. These new progestins have been designed to bind very specifically to the progesterone receptor and not to other steroid receptors in an effort to avoid androgenic, estrogenic, or glucocorticoid side effects.
- Almost 80% of current hormonal contraceptive users have concerns about their current birth control method; however, 39% have stayed with their chosen method for five or more years, according to results from a new national survey.

androgen as a way to prevent androgen deficiency that might occur with combined pill use. The Pill-Plus for oral use is licensed to Pantarhei Bioscience, a Netherlands-based pharmaceutical company for development and marketing in the United States, while BioSante retains rights to the Pill-Plus for transdermal development and marketing.

Little is known about the effects of OCs on sexual functioning; a 2004 review of research found that overall, women experience positive effects, negative effects, as well as no effect on libido during OC use. Better-designed studies are needed to establish the independent, causal effects of OCs on libido, researchers concluded.[2]

Results from a small 2006 retrospective study indicate that use of birth control pills is associated with elevated sex hormone-binding globulin (SHBG) levels and reduced bioavailable testosterone. This effect may persist even after discontinuation of pill use, researchers note.[3]

The study examined SHBG levels in 124 premenopausal women who had reported sexual dysfunction for at least six months; 62 of the women were current Pill users who had been taking OCs for longer than six months (called continued users), 39 who had used OCs for longer than six months and then discontinued use, and 23 women who had never used the method. All patients were offered use of transdermal testosterone therapy to improve sexual function.

Sex hormone-binding globulin levels were measured at four points during the study: at baseline, while using oral contraceptives, at a mean of 80 days after discontinuing pills, and then again at more than 120 days after discontinuation.[3] According to the research, SHBG levels in the women who continued to use pills were four times higher than those in the never-users group. Despite a decrease of more than 50% in SHBG values after discontinuation of Pill use, SHBG levels in women discontinuing pills remained elevated for more than 120 days (mean of 234 days) in comparison with those who had never used the method.[3]

BioSante reports that results of a completed Phase II double-blind randomized clinical trial of the Pill-Plus indicated that the addition of an oral androgen resulted in restoration of testosterone levels to the normal and physiological range for healthy women. The Pill-Plus is in various Phase II/III trials measuring women's response to testosterone while taking OCs, says **Alan Zachary**, PhD, a spokesman for BioSante Pharmaceuticals. The company is doing preclinical research on a transdermal version of the Pill-Plus, he states.

Zachary declined to identify the hormonal components found in the Pill-Plus. Results of the Phase II trial have not yet been published, he reports.

Are more options needed when it comes to contraception? Evidently so, according to a 2008 survey conducted on behalf of Schering-Plough by Harris Interactive. Women's feelings and behaviors concerning contraception are conflicted, yet many don't seek out methods that could better satisfy their needs, research findings indicate.[4]

Almost 80% of current hormonal contraceptive users have concerns about their current birth control method, the survey reports; however, 39% have stayed with their chosen method for five or more years. About 25% of 18- to 34-year-old women said daily birth control would be most convenient for them, yet 46% of women in the same age group who currently use a hormonal contraceptive said they have more difficulty remembering to use their current method correctly when their daily routine is interrupted.[4]

Researchers are eyeing changes in pill regimens. Trials of the E2/dienogest pill are using a regimen with two days of placebo pills, while the E2/nomegestrol acetate formulation is being studied with a four-day placebo phase.

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Case study: SPOT hits mark with at-risk youth

How can clinicians reach at-risk teens? Take a look at the SPOT (Supporting Positive Opportunities with Teens), a one-stop, drop-in center in St. Louis aimed specifically at the 13- to 24-year age group.

The center, which opened in September 2008, provides testing for HIV and sexually transmitted diseases (STDs), contraceptive services, health care and counseling, social support, prevention, and case management services at no cost. The center was

EXECUTIVE SUMMARY

The SPOT (Supporting Positive Opportunities with Teens) is a one-stop, drop-in center in St. Louis aimed specifically at the 13-24 year age group. The center was launched by Washington University in St. Louis's School of Medicine's Project ARK (AIDS/HIV Resources and Knowledge) and the Adolescent Center in the Department of Pediatrics in collaboration with community partners.

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- The SPOT offers STD treatment, contraception, Pap smears, pregnancy tests, and some medical visits for common medical complaints.

launched by Washington University in St. Louis's School of Medicine's Project ARK (AIDS/ HIV Resources and Knowledge) and the Adolescent Center in the Department of Pediatrics in collaboration with community partners

The youth of St. Louis contend with serious health risks which can have lifelong consequences, says **Kim Donica**, LCSW, Project ARK program director. Those risks include sexually transmitted infections, HIV, and teen pregnancy, she notes.

In 2004, St. Louis had the highest rate of gonorrhea and the second-highest rate of chlamydia of all the cities in the United States, Donica says. These numbers have continued to increase. In the city of St. Louis, the number of chlamydia cases climbed from 3,206 in 2002 to 4,393 in 2007; of those, 73.8% were people ages 13-24, she states.

"Likewise, HIV infection rates among youth have continued to rise," says Donica. "In a strikingly similar pattern, youth ages 13-24 comprised 11.6% of the total new HIV infections in the region in 2001, and by 2007, the proportion had increased to 31.9%."

The center offers STD treatment, contraception, Pap smears, pregnancy tests, and some medical visits for common complaints such as rashes, sore throats, and colds, says **Katie Plax**, MD, the facility's medical director. The SPOT maintains partnerships with primary care providers and links people into those services if needed, says Plax, an assistant professor of pediatrics at Washington University School of Medicine and director of the Adolescent Center at St. Louis Children's Hospital.

The facility is staffed with two nurses (who share a position), three doctors, who each work a half-day, and a psychiatrist, who works a half-day, she says. Other staff members include a full-time counselor, a full-time case manager, a part-time case manager, a program manager, and a youth development specialist. The director of the center is **Regina Whittington**, MSW.

Get youth input

How did program officials devise the cafeteria of services at the SPOT? Donica says input from young people helped.

"A survey was conducted with youth in which they were asked which services were most important to them; in addition, the Youth Advisory Committee [a group of young people who serve as an advisory board for the St. Louis region and Missouri] also provided input regarding the range of needed services," Donica states. "In addition to input from youth, we looked at model programs in other cities to learn from them what services they felt had been most important to youth."

How has the facility been designed to put young people at ease? The drop-in center is colorful and modern, featuring a living room with cozy furniture. Everything is developed from a positive youth development perspective, says Whittington. "We believe in low threshold and high engagement with the youth. We only ask them to complete a short card, which includes their name, age, and what service they would like to access for the day," says Whittington. "Our staff are committed to engaging with the youth to identify potential needs, as well as encourage them to access services."

How is the facility getting the word out to teens about the availability of services at the SPOT? Media coverage, including television, radio, and newspaper articles, have helped get the word out, as well as cooperation from community partners, who have done a "tremendous" job of linking youth to services, says Whittington.

"The best source of information are the youth themselves," states Whittington. "We have many youth accessing services for the first time stating they came on the recommendation of a friend."

Funding for the facility has come from various foundations, including Missouri Foundation for Health, Barnes Jewish Hospital Foundation, Children's Hospital, Barnes Jewish Care, and the city of St. Louis, states Whittington. As of the end of December 2008, the center had served 491 unduplicated youth, with a total of more than 3,700 encounters for those youth, she states. ■

Teen TOPICS

New research emerges on teen sexuality issues

By **Melanie Gold**, DO
Clinical Associate Professor of Pediatrics
University of Pittsburgh School of Medicine
Staff Physician
University of Pittsburgh Student Health Service
and **Kaiyti Duffy**, MPH
Assistant Director of Medical Education
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New York City

Need to catch up on your reading when it comes to teen sexuality issues? Stay current on adolescent health topics with the following reviews of six recently published papers:

• LGB adolescents.

Sexual minority youth face disproportionate risk of negative health outcomes. Though it has been widely believed that this is due to external and internal homophobia, there has been little empiric evidence to support this hypothesis until now. New research establishes a clear linkage between families rejecting lesbian, gay, and bisexual (LGB) adolescents and negative health outcomes in early adulthood.[1] Published in the January 2009 issue of *Pediatrics*, this study demonstrates that parents' rejecting behaviors toward their LGB children dramatically compromises their children's health. This new study has important implications for the provision of services to LGB youth. Based on the article's findings, providers are encouraged to:

— ask all LGB adolescents about their families' reactions to their sexuality and gender expression, and refer them for counseling as needed;

— identify community LGB support programs and online resources for parents and teens;

— counsel parents that negative reactions to their children's LGB identities may negatively affect their children's' health;

— advise parents and caregivers to modify highly rejecting behaviors that have the greatest influence of health risks.

Though it is known that LGB youth are vulnerable, there is little data available about the prevalence of those youth in the United States. A new prospective study of 13,450 adolescents found that, overall, 8.5% of males and 16.1% of females reported a minority sexual orientation.[2]

• Virginity pledges.

A new study published in the January 2009 issue of *Pediatrics* describes the effect of taking a virginity pledge on the sexual behaviors of youth. In this study, pledgers were matched with nonpledgers in their religiosity and attitudes toward sex and birth control. Results indicated that five years after taking the pledge, 82% of pledgers denied having ever pledged. Pledgers and matched nonpledgers did not differ in their rates of sexually transmitted diseases, or their reports of anal and oral sex. Though pledgers had 0.1 fewer past-year partners, they did not differ in the number of lifetime sexual partners or their age at first intercourse. Importantly, fewer pledgers than matched nonpledgers used birth control and condoms in the past year, and fewer used birth control at last intercourse. Researchers concluded that clinicians should provide birth control information to all adolescents, especially those who take virginity pledges.[3]

• Contraception and BMD.

Researchers continue to examine the effect of hormonal contraception on bone mineral density (BMD) in young women. In a December 2008 study, 423 females using injectable depot medroxyprogesterone acetate (DMPA) or combination oral contraceptive pills (COCs) containing 20 mcg ethinyl estradiol and 100 mcg levonorgestrel were followed for 24 months.[4] BMD measurements were obtained by using dual X-ray absorptiometry (DEXA). Though the mean percentage change in spine BMD decreased by 1.4% in the first 12 months in the DMPA group, this decrease slowed to a 0.1% decrease over the second 12 months.

COMING IN FUTURE MONTHS

- STD alert: Chlamydia cases on rise
- Teen birth rates rise — What's behind the increase?
- Six things women need to know about the Pap test
- Add new hepatitis B resources to your practice
- Research eyes circumcision's role in decreased risk of HPV

Echoing earlier findings, adolescent girls receiving DMPA in this study had significant loss in BMD compared with BMD gain in the COC and untreated groups. However, no BMD loss reached the level of osteopenia.

• **HPV vaccine in males.**

The first study evaluating the immunogenicity and safety of the human papillomavirus (HPV)-16/18 AS04-adjuvanted vaccine (Cervarix) in males was published in the January 2009 issue of the *Journal of Adolescent Health*.[5] Healthy males, ages 10-18, were randomized to receive HPV-16/18 AS04-adjuvanted vaccine or hepatitis B virus (HBV) control vaccine at zero, one, and six months. Participants were followed for seven months. Results indicated that all initially seronegative participants in the HPV-16/18 group seroconverted for HPV-16 and -18 at the second month. At the seventh month, all participants were seropositive, and the HPV-16 and -18 antibody levels were, respectively, four- and twofold higher than at the second month. The reactogenicity profiles of the HPV-16/18 AS04 and HBV vaccines were similar, except that pain and swelling at the injection site were more common in the HPV-16/18 group. Vaccine-related symptoms did not affect compliance with the three-dose course, which was equally high (97%) in both groups.

The authors concluded that the HPV-16/18 AS04-adjuvanted vaccine is immunogenic and well tolerated in boys ages 10-18. However, further data on the potential public health benefits of vaccination of boys are required before any recommendations can be made.

• **Access to EC.**

A new study was published in the January 2009 issue of *Obstetrics and Gynecology* exploring the effects of providing unrestricted access to emergency contraception (EC) in advance of need on various psychosocial outcomes and pregnancy.[6]

A total of 1,490 sexually active women ages 14-24 were randomly assigned to increased access to EC (two free packs at enrollment with unlimited free resupply) or standard access. On average, women in the increased access group had significantly stronger perceptions of both the "relative benefit" and "accessibility" of EC. Women in the increased access group were significantly more likely to report that they had ever used EC because they did not want to use condoms or another contraceptive method. Interestingly,

CNE/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. ■

CNE/CME Questions

After reading *Contraceptive Technology Upd*ate, 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.

9. What material is used to manufacture the FC1 female condom?
A. Polyurethane
B. Nitrile
C. Linen
D. Sheep cecum

10. Which of the following have been shown to be effective in treatment of endometriosis?
A. Depot medroxyprogesterone acetate injection
B. Oral contraceptives
C. Implanon contraceptive implant
D. All of the above

11. Which drug is NOT used for episodic treatment of herpes simplex virus type 2?
A. Acyclovir
B. Famciclovir
C. Doxycycline
D. Valacyclovir

12. New progestins, such as dienogest and nomegestrol acetate, are designed to bind specifically to which receptor?
A. Glucocorticoid receptor
B. Androgen receptor
C. Estrogen receptor
D. Progesterone receptor

Answers: 9. A; 10. D; 11. C; 12. D.

advanced access to EC had a protective effect on those with the least aversion toward pregnancy. Among those with the most aversion toward pregnancy, increased access had a deleterious effect.[6]

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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™

Study eyes states' STD prevention spending — Can improvements be made in current climate?

Study: States invest less than 25¢ per capita for STD prevention

The burden of sexually transmitted infections (STIs) in the United States is high. Public health officials estimate there are 36 new STD infections every minute, with half of those among people ages 15-24.[1] The annual cost to treat those infections? The estimate is $14.7 billion.[1]

When left untreated, STIs can result in severe consequences including infertility, tubal pregnancy, chronic pain, cancer, prematurity, low birth-weight, congenital infections in newborns, and even death.[2] However, a new study by the American Social Health Association (ASHA) shows that states invest on average just $0.23 per capita for prevention of sexually transmitted diseases (STDs).[3] The federal government invests $0.60 per capita for such services.[4] **(See resource listing on p. 2 for online version of the report.)**

"We believe investments in STI prevention programs are cost-effective and are hopeful policy-makers will utilize the findings from this research as they consider the specific resources needed for STI control in their own states," says **Lynn Barclay**, ASHA president and CEO.

EXECUTIVE SUMMARY

A new study by the American Social Health Association shows that states invest on average just $0.23 per capita for prevention of sexually transmitted diseases (STDs). The federal government invests $0.60 per capita for such services, the report notes.

- Public health officials estimate there are 36 new STD infections every minute, with half of those among people ages 15-24. The annual cost to treat those infections is estimated at $14.7 billion.
- When looking at a list of 11 STD prevention program goals, just seven states — California, Hawaii, Illinois, Louisiana, Minnesota, Alabama, and Missouri — reported the existence of at least five policies in their state operations.

Get an overview

To perform the study, researchers gathered state financial data from state laboratory directors and directors of state STD, hepatitis, and immunization programs. ASHA hosted a survey web site, with the response rate enhanced by follow-up telephone and e-mail contacts.

The report used the following indicators of state STD funding:

- percentage of state funding in STD prevention budget, calculated as the percent of state funding in the total state STD prevention budget;
- per capita state STD prevention funding,

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Consulting Editor **Robert A. Hatcher**, MD, MPH, Author **Rebecca Bowers**, Associate Publisher **Coles McKagen**, and Senior Managing Editor **Joy Dickinson** report no consultant, stockholder, speaker's bureau, research, or other financial relationships with companies having ties to this field of study. **Sharon Schnare** (Nurse Reviewer) discloses that she is a retained consultant and a speaker for Barr Laboratories, Berlex, and Organon; she is a consultant for 3M Pharmaceuticals; and she is a speaker for FEI Women's Health, Ortho-McNeil Pharmaceuticals, and Wyeth-Ayerst Pharmaceuticals.

RESOURCE

To access a free version of *Show Me the Money: State Investment in STD Prevention, FY2007*, go to the American Social Health Association, www.ashastd.org, and click on "Study examines state level investment in STD prevention." A link to the report is on the following page.

calculated by dividing the amount of reported state funding for STD prevention by the state population;

- per capita state public health funding, calculated by dividing the reported state public health funding by the state population;
- percentage of state public health funding directed toward STD prevention, calculated by dividing reported STD prevention funding by the state public health funding, and multiplied by 100.

Who pays for prevention?

When it comes to funding for STD prevention, the federal government carries the load, contributing $181,319,992 in 2007. The report analysis shows that just nine states — Louisiana, Hawaii, Rhode Island, Connecticut, Alabama, Arkansas, New Hampshire, Florida, and Michigan — reported sharing at least 50% of the financial responsibility for STD prevention in their jurisdictions. When looking at the percentage of state public health spending directed toward STD prevention, the leading states were Louisiana (3.68%), Connecticut (2.04%), Arkansas (1.96%), Mississippi (1.93%), and Rhode Island (1.53%).

How are STD-related vaccines funded in your state? The report shows that while several states purchased such vaccines with state funding, just 12 states distributed funding specifically earmarked for this purpose. They are California, Connecticut, Illinois, Louisiana, Missouri, New York, North Dakota, Ohio, Oklahoma, Pennsylvania, Texas, and Virginia. Five states noted such funding for the first time in the last two years, perhaps reflecting an emerging policy priority for such financing.[3]

Most of the funding went toward hepatitis B vaccination for adults and those children not eligible for the federal Vaccines for Children program. Two states, Texas and Virginia, directed almost all their earmarked funding for purchase of the human papillomavirus (HPV) vaccine.

What's the overall climate when it comes to state policies for STD prevention? Report researchers devised a list of 11 policies that enhance STD prevention, such as prenatal STD screening, electronic laboratory reporting for STDs and related conditions, opt out for written consent for HIV testing in STD clinics, expedited partner therapy, and insurance coverage (public and private) for HIV/STD screening. Looking at the report analysis, states have work to do when it comes to improving the climate for STD prevention.

Twenty-five states indicate they have policies that call for prenatal screening, and 22 states say they have electronic laboratory reporting capabilities. Only 14 states have expedited partner therapy policies.

When looking at all 11 policies, just seven states — California, Hawaii, Illinois, Louisiana, Minnesota, Alabama, and Missouri — reported the existence of at least five policies in their state operations. Policies most often cited include insurance coverage for HIV/STD screening, prenatal STD screening, electronic lab reporting, mandates for specific vaccines, and mandates or policies requiring the storage of vaccine data in a state immunization registry.[3]

Some states are moving forward with prevention policies not found in the report. For instance, California, Louisiana, Maryland, Missouri, and New Hampshire mandate that minors have access to STD diagnosis and treatment without parental consent, with Maryland requiring that such services be free.[3]

Funding on way?

What's the forecast on funding? State health department budgets are shrinking, according to a recent survey of state and territorial health agencies, conducted by the Association of State and Territorial Health Officials (ASTHO) in Arlington, VA.

According to the ASTHO survey, nearly 30% of states' FY '08 health department budgets were cut below their FY '07 level. About two-thirds of state health departments said they expected FY '09 budgets to be cut below their previous year's level. All health departments that experienced reductions in 2008 said they looked to further cuts

in the coming year; 22% of health departments said they look to at least a 10% reduction for 2009.[5]

In light of current federal/state financial belt-tightening, why is it so important that spending be stepped up for STD prevention?

Times are really tough for states, and even more so for public health generally, says **Beth Meyerson**, PhD, MDiv, co-author of the report, and president of Policy Resource Group, a health policy research organization in McCordsville, IN. Preventative services often get short shrift, even in good financial times, she notes.

What states have yet to realize is that with STD prevention, the situation is a "pay-now-or-pay-much-more-later" scenario, notes Meyerson. "Nationally reported costs of treatment for STIs and their sequelae are indicators that we are missing many opportunities to prevent them in the first place and spending much more than necessary because we don't invest in prevention," she says. "We want states to connect the dots so that they can invest in the prevention side and save money — and lives and health issues — in the long run."

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Take to the fields with HIV message for Latinos

EXECUTIVE SUMMARY

While Hispanics/Latinos comprise 15% of the U.S. population, they accounted for 17% of all new HIV infections occurring in the United States in 2006.

- Researchers at Wake Forest University School of Medicine have partnered with Chatham Social Health Council and AIDS Care Service to develop the *"HoMBReS: Hombres Manteniendo Bienestar y Relaciones Saludables"* (MEN: Men Maintaining Wellness and Healthy Relationships) program.
- By training soccer team leaders to teach their own teammates about HIV and how to prevent it, researchers are helping to distribute information about HIV and sexually transmitted diseases.

How can Hispanic men be reached with an HIV prevention message? It's time to spread the word. While Hispanics/Latinos comprise 15% of the U.S. population, they accounted for 17% of all new HIV infections occurring in the United States in 2006.[1]

Researchers at Wake Forest University School of Medicine in Winston-Salem, NC, have partnered with Chatham Social Health Council in Siler City, NC, and AIDS Care Service in Winston-Salem to meet Hispanic/Latino men on their own turf: the soccer field. By training soccer team leaders to teach their own teammates about HIV and how to prevent it, researchers are helping to distribute information about HIV and sexually transmitted diseases (STDs).

How the project started

The project began in 2004 with initial funding from the Centers for Disease Control and Prevention (CDC), says **Scott Rhodes**, PhD, MPH, lead investigator for the project and an associate professor in the University's Department of Social Sciences and Health Policy. Researchers learned that Latino men lacked the knowledge and skills to protect themselves from HIV and STDs, so they worked with community members to develop a culturally relevant and gender-specific intervention, explains Rhodes, who also is affiliated with the Maya Angelou Center for Health Equity at Wake Forest.

The "*HoMBReS: Hombres Manteniendo Bienestar y Relaciones Saludables"* (MEN: Men Maintaining Wellness and Healthy Relationships) program has been designed to assist

Latino men in learning the best way to protect themselves, developing the skills to protect themselves, and changing some of the factors that are associated with at-risk behavior, says Rhodes. For example, adhering to traditional masculine norms of what it means to be a man can contribute to not using condoms, Rhodes explains. Research findings indicate men who identify with machismo-like values strongly dislike condoms.[2]

Funded by a $2.4 million grant from the National Institutes of Health, the program is designed to provide health and disease prevention education to increase condom use and HIV testing in a peer-to-peer program. The five-year intervention study is based on social cognitive theory and the theory of empowerment education.

Identify the challenges

When it comes to reaching Hispanic/Latino men, several cultural, socioeconomic, and health-related factors factor into the equation.

One of the challenges faced by HoMBReS is that many Latinos in the area are undocumented, says **Jaime Montano**, project coordinator for HOMBRES at Chatham Social Health Council. Program workers have had to gain the trust of those in the community to help establish the program, he explains.

Establishing a rapport is important, because talking about sexual health matters does not come easily, says Montano. "I'm a Latino, myself — I come from Mexico City — and we are not that open to talk about it," he explains. "Sometimes, some of the questions we use are very intimate, so it's very hard for people to talk about it."

For the soccer program, 10 teams from Forsyth County and 10 teams from Chatham County are recruiting a peer leader, or trained lay health advisor, known as a *"navegante." Navegantes* are elected by teammates and are paid $50 per month for data collection. They keep simple logs of their work, says Rhodes. *Navegantes* are trained on how to avoid and prevent HIV and other STDs, as well as receive education on condom use skills. *Navegantes* learn how to reframe the negative aspects and bolster the positive points of what it means to be a man, as well as how to communicate effectively with teammates. The *navegante* then applies that training in interactions with his own teammates.

How will the program measure its effectiveness? Rhodes says various data collection steps have been devised. Researchers are collecting quantitative data from members of the soccer teams to measure and examine changes in the use of condoms and services for HIV testing, he notes; *navegantes* distribute condoms at no charge.

Scientists also are looking at potential factors that may be associated with risk such as knowledge about HIV transmission and prevention and local resources and eligibility, trust in condoms and condom use skills, adherence to traditional masculine norms, and sense of mastery over life's circumstances.

"We are training soccer team leaders as peer leaders to teach their own teammates about HIV and how to prevent it," Rhodes says. "We also are addressing norms and expectations about what it means to be a man. Men in general don't think about their own health, and we are training the peer leaders to talk to their teammates about how men can ask for help and seek care when needed, rather than waiting until it gets more serious." **(To help educate Hispanic/Latino men on the importance of HIV testing, see the resource listing, above.)**

RESOURCE

The Health and Human Services National HIV Testing Mobilization Campaign has developed a free patient fact sheet in English and Spanish, "Hispanics and HIV/AIDS." To download the sheets, go to the web site, www.hhs.gov/aidsawarenessdays. Click on "National Latino HIV Awareness Day," then under "Resources," click on "Fact Sheets."

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