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A Monthly Newsletter for Health Professionals

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IN THIS ISSUE

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Research halted on cellulose sulfate microbicide — What's next in research?

Scientists push onward, candidates proceed in Phase III testing

While two advanced trials have been closed for one microbicide candidate for HIV prevention in women, researchers are pressing forward in examining other contenders that may prove safe and effective in the fight against the AIDS epidemic.

CONRAD, a reproductive health research organization in Arlington, VA, halted its Phase III clinical trial of a cellulose sulfate gel after preliminary results indicated it could lead to an increased risk of HIV infection in women who use the compound. A separate advanced study of the microbicide, conducted by Family Health International (FHI), a Research Triangle Park, NC-based research group, also was closed after scientists determined there was no evidence that the product was effective in preventing HIV. Announcement of both trials' closing was made in January 2007.

Known as Ushercell, the cellulose sulfate gel is a cotton-based compound developed by Polydex Pharmaceuticals Ltd. in Toronto. Prior to the

EXECUTIVE SUMMARY

Researchers are pressing forward in microbicide research following the cessation of two advanced trials of cellulose sulfate. The compound was eyed as a potential candidate for HIV prevention in women.

- A Phase III clinical trial of a cellulose sulfate gel, conducted by CONRAD, was halted after preliminary results indicated it could lead to an increased risk of HIV infection in women who use the compound.
- A separate advanced study, conducted by Family Health International, was closed after scientists determined there was no evidence that the product was effective in preventing HIV.
- Advanced trials continue on three other candidates: Carraguard, PRO 2000, and BufferGel.

advanced trials, the compound had been evaluated in 11 clinical safety and contraceptive trials involving more than 500 participants. Results from these studies indicated that the compound was safe; in laboratory studies, cellulose sulfate exhibited antimicrobial activity against several sexually transmitted infections, including HIV. ***(Contraceptive Technology Update* reported on the microbicide candidate in the article, "Progress under way on the microbicide front," December 2004, p. 136.)**

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A 'profound disappointment'

While the closing of the trials is a "profound disappointment" for the microbicide field, science must continue to advance in the search for female-controlled HIV prevention, says **Zeda Rosenberg**, ScD, chief executive officer of the International Partnership for Microbicides, a nonprofit research group. In 2006, about 17.7 million women around the world were living with HIV, an increase of more than 1 million compared with 2004 figures.[1]) "Prevention is the only way out of this epidemic, and a safe and effective microbicide can be a vital tool," said Rosenberg in a statement on the trials' closing. "This is why we and others have been working so hard to expand the microbicide pipeline."

Developing new tools to prevent HIV — particularly for women — is an urgent priority, says **Henry Gabelnick**, PhD, CONRAD executive director. "We are committed to learning as much as possible from the trials of cellulose sulfate and will use that knowledge to continue searching for compounds and collecting evidence to find a successful microbicide," said Gabelnick in a statement following the trial's cessation. "Continued support for microbicide research is critical to our eventual success."

What led to closing?

Recruitment for the CONRAD Phase III study began in July 2005. The research was held at sites in South Africa, Benin, Uganda, and India. To perform the double-blinded randomized trial, half of the participating women were given cellulose sulfate, and half were given a placebo gel. All women in the study received intensive HIV prevention counseling at each monthly visit and were provided condoms free of charge. Participants received regular testing and treatment for sexually transmitted infections (STIs).

It is not clear why use of cellulose sulfate was associated with an increased risk of HIV infection in the CONRAD trial. An independent advisory group of experts will conduct a detailed review of the data to better understand the findings and help determine any implications for other microbicide studies.

The FHI study was conducted among about

1,700 women in Lagos and Port Harcourt, Nigeria. As with the CONRAD trial, participants received HIV prevention counseling, condoms and, when needed, treatment for STIs. While an independent review board did not find any evidence of greater risk of HIV infection in the interim results from the trial, it also found no evidence that the study gel was effective in preventing HIV.

In a press statement on the Ushercell trial closings, Polydex said it will continue to evaluate Ushercell's attributes, including its potential use as a contraceptive product.[2] Research presented in 2006 indicates that Ushercell may be as effective as N-9 as a contraceptive.[3] ***(CTU* reported on the research in the article, "Science investigates contraceptive gels," August 2006, p. 92.)**

What will work?

The road to a safe, effective microbicide has not been a smooth one. Investigations of nonoxynol-9 (N-9) as a potential microbicide candidate ended after research indicated that multiple uses of a low N-9 gel formulation, known as COL-1492 or Advantage-S, could cause toxic effects, enhancing HIV-1 infection.[4] ***(CTU* reported on the research; see "Nonoxynol-9 fails test as female microbicide," October 2000, p. 119.)**

In August 2006, FHI halted a Phase 3 trial in Nigeria of a vaginal gel, Savvy (C-31G), after an interim data review concluded the trial was unlikely to provide convincing evidence that the gel conferred HIV protection. A Savvy trial in Ghana also was closed on similar grounds by FHI in November 2005.

Three Phase III studies are ongoing on the following microbicide candidates:

- **Carraguard.**

Carraguard (PC-915) is a noncontraceptive product made from carrageenan, which is derived from seaweed. The study, sponsored by the Population Council, a New York City-based research group, is being conducted in three sites in South Africa. Enrollment ended in June 2006. Results are expected at the end of 2007.

- **PRO 2000.**

PRO 2000 (polynaphthalene sulphonate) is a synthetic polymer that binds to the HIV virus. Under development by Indevus Pharmaceuticals of Lexington, MA, the candidate is being tested in one study in five sites in South Africa, Tanzania and Uganda, as well as in a second study in seven sites in Malawi, South Africa, Zambia, and Zimbabwe. Results from the five-site trial are expected in 2009, while results from the seven-site study are scheduled for 2008.

- **BufferGel.**

BufferGel (carbomer 974p), is a gel that reinforces the protective vaginal acidity to kill sperm and inactivate several STI organisms, including HIV. Under development by ReProtect in Baltimore, it is being evaluated in the same trial in Malawi, South Africa, Zambia, and Zimbabwe as PRO 2000.

BufferGel is considered a vaginal defense enhancer, while Carraguard and PRO 2000 are known as HIV entry inhibitors. **(To review further information on these candidates, see the article "What will it take for microbicides to go from research to reality?" July 2005, p. 77.)**

Research moves forward

While scientists continue to review the data from the closed cellulose sulfate trials, researchers are moving forward on other microbicide candidates. According to the Alliance for Microbicide Development, a Silver Spring, MD-based advocacy group, studies of vaginal defense enhancers, HIV entry/fusion inhibitors, and replication inhibitors are now in various stages of research.

While the halting of the cellulose sulfate trials is a "disappointing and unexpected setback," the need to continue research to find a user-controlled means of preventing HIV infection in women is urgent, say officials with UNAIDS and the World Health Organization. "Despite the effectiveness and availability of condoms, the HIV epidemic continues to spread, and the search for a safe and effective microbicide is a vital part of the effort to stem the spread of the HIV epidemic," organization officials said in a joint statement.

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Student health centers scramble due to prices

Students who seek contraceptive services at college and university health centers are facing sticker shock when it comes to picking up their supplies. As a result of changes to the federal Deficit Reduction Act (DRA) that were implemented in January 2007, institutions of higher education no longer qualify for special reduced pricing for contraceptive supplies. Pharmaceutical companies are charging colleges and universities significantly higher rates as a result.

Language in the legislation specifically states that "only 340B entities; intermediate care facilities for the mentally retarded; state-owned or operated nursing facilities; or any other facility or entity deemed a safety net provider by the Secretary of the Department of Health and Human Services will be eligible" for nominal pricing.[1] Title X-funded programs fall under the 340B Drug Pricing Program, which is named after a section of the Public Health Service Act and run by the Office of Pharmacy Affairs. Under 340B pricing, pharmaceutical companies are required to abide by a price ceiling that is discounted from their private-sector prices.[2]

For many years, some pharmaceutical companies have been willing — but certainly not required — to extend nominal prices to facilities, explains **Marilyn Keefe**, interim president and chief executive officer of the National Family Planning and Reproductive Health Association (NFPRHA). "Under the new language, pharmaceutical companies have little incentive to continue to extend nominal pricing to facilities that don't qualify for 340B pricing," she reports. "If a manufacturer continues to sell nominally-priced drugs to nonqualified clinics, their commercial 'best price' would be lowered, and the amount of Medicaid rebates that they have to pay would be increased."

In the case of student health centers, the impact has been two-pronged, says **Mary Hoban**, PhD, CHES, staff liaison for the American College Health Association (ACHA), which is monitoring the situation. Students are returning for prescription refills to find that the cost of a pack of branded pills has doubled, and student health center administrators are grappling with substituting generic products, which are not available for all contraceptive methods. While generic products may be less in price than branded drugs, their costs still are higher than what was available with nominal pricing, Hoban states.

When student health centers were able to purchase contraceptives at nominal pricing, some facilities charged a dispensing fee, which was used to fund or supplement such programs as condom distribution, screenings, and other education projects, says Hoban. To help keep contraceptive prices affordable for students, such fees may not be recouped, meaning lost revenue for the centers, she explains. Some services may have to be cut, or student health fees will need to be increased, says Hoban.

Pills are now costing from $35-$55 for a 28-day cycle; 13 cycles of pills in the course of a year costs a lot of money ($455-$715), says **Robert Hatcher**, MD, MPH, professor of gynecology and obstetrics at Emory University School of Medicine in Atlanta. Even if a college student has insurance, she is likely to pay $10-$25 a cycle for her pills, he notes.

"The efforts to retain nominal prices for clinics are to be applauded because one response to the very high price of pills is for women to stop pills for several months when they cease to be in a sexual relationship," says Hatcher. "Taking a break from pills for financial or any other reason is a recipe for unintended pregnancy."

Clinics feel pain, too

The DRA definitely affects entities beyond university health centers. NFPRHA is working on the issue, reports Keefe.

"The Deficit Reduction Act provision that went into effect on Jan. 1 of this year regarding 'nominal

EXECUTIVE SUMMARY

Changes to the federal Deficit Reduction Act (DRA) that were implemented in January 2007 have resulted in institutions of higher education no longer qualifying for special reduced pricing for contraceptive supplies.

- Language in the legislation specifically states only certain entities are eligible for nominal pricing. Title X-funded programs fall under such pricing; facilities that do not fall within the legislation's description are facing increases in prices.
- Advocacy groups are seeking changes to ensure that companies can continue to have the option to sell birth control products to clinics at nominal prices.

pricing' [defined as less than 10% of Average Manufacturer's Price] is having a major financial impact on hundreds of family planning providers across the country, an impact that was wholly unintended by Congress," says Keefe. "While some clinics were able to purchase a few months' supply to stave off financial hardship, these supplies will soon run out for many."

For those clinics, the prices paid in 2006 could increase by more than 600%, costs such providers can't even come close to absorbing, states Keefe. Some clinics may be forced to "script out," meaning they will give a prescription to low-income clients who may or may not have the resources to fill it, says Keefe.

Advocacy now in action

What is the next step? The ACHA board of directors met with members of the Senate Finance Committee and other federal legislators during its annual Capitol Hill visit to discuss the matter, says Hoban. At press time, the association also planned to submit comments to the Centers for Medicare & Medicaid Services (CMS), which will oversee the final implementation of the DRA Medicaid pricing ruling. Deadline for public comment on the CMS ruling was Feb. 20, 2007.

Changing the ruling is seen as the most expeditious form of action, says Hoban. It would grant college and university health centers an exception to participate in the nominal pricing plan, she explains. If the ruling isn't changed, legislative action will need to be pursued, representing a more lengthy process, says Hoban.

NFPRHA is working with health care providers and members of Congress to ensure that companies can continue to have the option to sell birth control products to family planning clinics at nominal prices, says Keefe. While there have been few legislative vehicles to attach such a change since Congress went into session, advocates are hopeful that the language will be fixed in the coming months, she notes.

"After all, it is the kind of fix that members can feel good about; it costs nothing, lowers costs to the health care system overall, and was an unintended consequence of a complex and poorly understood law," says Keefe. "There also are ongoing efforts to find an administrative fix by clarifying that non-340B family planning clinics are 'safety net' providers whose prices should continued to be excluded from the calculation of Medicaid 'best price.'"

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Add another 'acne pill' to list of current OCs

The next patient in your examination room is an adolescent female who says she wants the "acne pill." What are your options?

While all combined oral contraceptives (OCs) prevent acne through several mechanisms, three pills now carry approved acne indications from the Food and Drug Administration (FDA). Yaz, a 20 mcg ethinyl estradiol/3 mg drospirenone pill from Berlex of Wayne, NJ, just received FDA approval for the acne indication. It joins Ortho Tri-Cyclen (Ortho-McNeil Pharmaceutical, Raritan, NJ) and Estrostep Fe (Warner Chilcott; Rockaway, NJ). Ortho Tri-Cyclen uses a combination of ethinyl estradiol and norgestimate, while Estrostep uses a formulation of ethinyl estradiol and norethindrone acetate, with seven days of ferrous fumarate.

Yaz, an oral contraceptive with 24 days of active hormones and four days of placebo pills, was approved for contraceptive use in March 2006. **(*CTU* reported on the approval in its article, "Shortening the pill-free interval: New contraceptives take next step," May 2006, p. 49.)** It also carries an indication for the treatment of

EXECUTIVE SUMMARY

Three oral contraceptives now carry approved acne indications from the Food and Drug Administration: Ortho Tri-Cyclen, Estrostep Fe, and now Yaz.

- Yaz, an ethinyl estradiol/drospirenone oral contraceptive with 24 days of active hormones and four days of placebo pills, was approved for contraceptive use in 2006. It also carries an indication for the treatment of emotional and physical symptoms of premenstrual dysphoric disorder.
- Acne affects 85% of people ages 15 to 24. Use of oral contraceptives represents one strategy in treating mild to moderate cases of the dermatologic condition.

emotional and physical symptoms of premenstrual dysphoric disorder. **(See the article, "Review the options for premenstrual syndrome," *CTU*, January 2007, p. 8.)**

Drospirenone is unique among contraceptive steroids in that it is an anti-androgen and therefore inhibits the action of androgens on target tissues, says **Ian Thorneycroft**, PhD, MD, professor of obstetrics and gynecology at the University of South Alabama in Mobile. Additionally, it inhibits ovulation, thereby reducing ovarian androgen production. Combined with estrogen in an oral contraceptive, it increases sex hormone-binding globulin, thus reducing free testosterone.

According to Berlex, two six-month multicenter, double-blind, placebo-controlled, randomized clinical trials of more than 1,000 patients were conducted to assess the safety, efficacy, and tolerability of Yaz in treating moderate acne. Treatment with the study drug resulted in significant reductions in total, inflammatory, and noninflammatory acne lesion counts, states the company. The study drug was well tolerated by most women in these clinical studies, with the most common side effects including upper respiratory infection, irregular bleeding, headache, nausea, sinusitis, and yeast infection.

Posters of the data will be presented by J. Michael Maloney, MD, of Cherry Creek Research in Denver at the American College of Obstetricians and Gynecologists (ACOG) annual clinical meeting in May 2007, says **Rose Talarico**, Berlex spokeswoman. Results of the trials have not been published, she states.

Review Pill's effects

It is no surprise that patients may seek treatment when it comes to acne; it affects 85% of people ages 15 to 24.[1] Use of oral contraceptives represents one strategy in treating mild to moderate cases of the dermatologic condition.

Combined OCs prevent acne by reducing the production of the androgen testosterone by suppressing luteinizing hormone.[2] Androgen bioavailability also is reduced due to an increase in the level of sex hormone-binding globulin, which binds free androgens. Oral contraceptives act on multiple sites to decrease the total and free androgen levels, ultimately leading to a reduction in sebum production.[1] The Pill has been the focus of several studies in acne treatment[3] and has been shown to be effective alone or in combination with other oral or topical treatments.

Adolescent patients who seek acne treatment may feel embarrassed about using a "birth control" pill. How can you counsel for method success? Take a look at the following suggestions[4]:

- Discuss the fact that the Pill is a medical treatment, similar to drugs that are prescribed for other medical conditions. Consider the drug as a "hormone pill."
- Remind the adolescent that the Pill has additional noncontraceptive benefits, including period regulation, correction of hormonal imbalances, reduction of hirsutism, and prevention of iron deficiency anemia, pelvic inflammatory disease, and ectopic pregnancy. Oral contraceptives also help to decrease the risk of ovarian and endometrial cancers.

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Wider access eyed for contraceptive sponge

Women who are interested in nonhormonal contraception will see wider access to the Today contraceptive sponge now that a new company is in charge of its marketing and distribution.

Synova Healthcare Group of Media, PA, has acquired the exclusive worldwide rights to the Today brand contraceptive sponge from Allendale (NJ) Pharmaceuticals. Allendale Pharmaceuticals will continue to operate as a wholly owned subsidiary of Synova.

Look for a new consumer advertising campaign, as well as physician outreach, to begin soon, says **David Harrison**, Synova's chief operating officer. There has been a whole generation of women who really have not been exposed to the Today sponge, Harrison says. "What we want to do is to introduce it to that segment and introduce it as a contraceptive option," he says. "We also want to broaden access via the physician community

EXECUTIVE SUMMARY

The Today contraceptive sponge has a new owner. Synova Healthcare Group has acquired rights to the barrier method from Allendale Pharmaceuticals.

- Allendale Pharmaceuticals took over manufacturing and marketing rights to the sponge in 1999. Manufacture of the device was halted in 1994 when its original owner determined it cost too much to correct problems caused by water quality issues at the factory where the sponge was made.
- While vaginal barriers such as the contraceptive sponge are relatively simple to use and can be used with little advance planning, consistent and correct use is essential. The sponge offers no protection against sexually transmitted diseases.

because similarly, there has been a whole generation of physicians who have not been presenting the sponge as an option to their patients."

Allendale Pharmaceuticals originally acquired manufacturing and marketing rights to the sponge in 1999 after the product had been shelved by its first owner, Whitehall-Robins Healthcare of New York City. Whitehall-Robins ceased manufacture of the device in 1994 when it determined it cost too much to correct problems caused by water quality issues at the factory where the sponge was made. Allendale worked with the Food and Drug Administration (FDA) to update labeling and manufacturing for the over-the-counter contraceptive, with final approval won in April 2005. **(To review the history of the sponge, see the *Contraceptive Technology Update* articles "Revival of the Today sponge: Vaginal contraceptive returns," May 1999, p. 49, and "Update: Today contraceptive sponge returns to U.S. drugstore shelves," June 2005, p. 65.)**

Pricing for the product will remain competitive with similar contraceptives, says Harrison. It currently sells for about $7.99 per three-pack at such retail outlets as CVS, Drug Mart, Drug Fair, Pathmark, Publix, Rite Aid, Target, Walgreens, and Wal-Mart, as well as Internet resources such as Amazon.com and Drugstore.com.

Weigh the options

The Today Sponge is circular in shape, 2 inches in diameter and three-quarters of an inch thick, with an attached loop. Made of polyurethane, it contains 1,000 mg of the spermicide nonoxynol-9 (N-9). It is moistened with tap water prior to use and inserted deep into the vagina. Removal is achieved by pulling the attached loop.

A single Today Sponge allows for as many acts of intercourse as desired within a 24-hour timeframe without the need to change protection. According to the company's product information, the Today sponge should not be left in place for more than 30 hours after insertion (which includes the six-hour waiting period after the last act of intercourse). It should not be used during menstruation, immediately after childbirth, miscarriage, or other termination of pregnancy, or by a women who has ever been diagnosed with toxic shock syndrome; a physician should be consulted in such cases, the company advises. Women using the sponge who experience two or more of the warning signs or symptoms of toxic shock syndrome — including fever, vomiting, diarrhea, muscular pain, dizziness, or rash similar to sunburn — are advised to contact a provider immediately. **(Review further medical information in the *Contraceptive Technology Reports* supplement, "An analysis of the Today Sponge — Prepare for its return to the U.S.," inserted in the April 2004 *CTU.)***

While vaginal barriers such as the contraceptive sponge are relatively simple to use and can be used with little advance planning, consistent and correct use is essential, state the authors of *Contraceptive Technology.* Most pregnancies occur because the method is not used, they state.[1] One-fifth of parous women will experience an unintended pregnancy in the first year of perfect use; that number rises to 40% in typical use. Nine percent of nulliparous women will experience an unintended pregnancy in the first year of perfect use; 20% with typical use.[1]

In a 2003 review of available data,[2] the sponge was found to be statistically significantly less effective in preventing overall pregnancy than was the diaphragm in the two trials that met analysts' inclusion criteria, one performed in the United States[3] and one in the United Kingdom (UK).[4]

The 12-month cumulative life table termination rates per 100 women for overall pregnancy were 17.4 for the sponge vs. 12.8 for the diaphragm in the U.S. trial, and 24.5 for the sponge and 10.9 for the diaphragm in the UK trial. Discontinuation rates at 12 months were higher with the sponge than with the diaphragm.[2]

Allergic-type reactions were more common with the sponge in both trials, although the frequency of discontinuation for discomfort differed in the two studies. In the U.S. trial, the 12-month cumulative life-table discontinuation rate for

allergic-type reactions per 100 women were 4.0 for the sponge, vs. 0.7 for the diaphragm. The corresponding figures from the British trial were 0.9 and 0.0. Allergic-type complaints included dermatitis, erythema, and irritation, with vaginal itching as the chief discomfort-related complaint.[2]

Help women to assess their risk of sexually transmitted disease (STD) exposure when choosing the sponge as a contraceptive method, advise authors of *Contraceptive Technology*. The sponge does not protect against STDs; encourage condom use for protection, they state.[1]

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'Healthy Penis' campaign targets syphilis risk

EXECUTIVE SUMMARY

A social marketing campaign, "Healthy Penis," has been associated with an increase in syphilis testing among gay and bisexual men in San Francisco.

- San Francisco experienced a sharp increase in early syphilis, with the number of cases rising from 44 to 494 between 1999 and 2002. To evaluate the effectiveness of the Healthy Penis campaign, researchers conducted two surveys at six months and 2.5 years after campaign initiation.
- Findings indicate that gay and bisexual men who were aware of the campaign were more likely than those unaware to have tested recently for syphilis and to have greater knowledge about syphilis.

What is your clinic doing to boost syphilis testing? An innovative social marketing campaign, "Healthy Penis," has been associated with an increase in syphilis tests in gay and bisexual men in San Francisco.[1]

While progress has been made in reducing the nationwide burden of syphilis, overall syphilis rates have been on the rise since 2001, largely due to increasing rates of syphilis among men who have sex with men (MSM), according to the Centers for Disease Control and Prevention. Between 2004 and 2005, the rate of primary and secondary syphilis increased 8.5% among men: from 4.7 cases to 5.1 cases per 100,000 men. During this same time, the rate increased among women from 0.8 to 0.9 cases per 100,000 women.[2] **(*Contraceptive Technology Update* reported on the trend; see the article "Focus continues on syphilis elimination," *STD Quarterly* insert, August 2005, p. 3.)**

San Francisco experienced a sharp increase in early syphilis, with the number of cases rising from 44 to 494 between 1999 and 2002, says **Katherine Ahrens**, MPH, an epidemiologist with the San Francisco Department of Public Health's (SFDPH) STD Prevention and Control division. More than 85% of these cases were among men who identified themselves as gay or bisexual, she notes.

In response to the rapidly expanding epidemic, SFDPH officials decided in late 2001 to initiate its Healthy Penis campaign, aimed at promoting syphilis testing in gay/bisexual men. The department hired a local advertising agency, Better World Advertising, to create the campaign, and launched it in June 2002.

Cartoons carry message

Syphilis is known as "the great imitator" because its symptoms — enlarged lymph glands, headaches, skin rashes, fever, sore throat, and swelling in joints — mimic those of many other diseases.[3] The Healthy Penis campaign incorporated the use of humorous cartoon strips featuring Healthy Penis and Phil the Sore characters to promote syphilis testing; publicize the rise of syphilis among gay and bisexual men; provide information on syphilis transmission, symptoms, and prevention; and delineate the connection between syphilis and HIV.

The campaign was promoted in neighborhoods where the greatest concentration of gay or bisexual men lived and where there were businesses that catered to gay and bisexual men, says Ahrens. Cartoons were placed in a gay newspaper, and poster-sized reproductions were posted on the

streets, on bus shelters, on gay web sites, and in gay bars. Media advertising also was developed in the form of a 30-second television commercial and banner advertising on Internet sites popular for meeting gay and bisexual sexual partners, she notes.

To tie in with the campaign, T-shirts and Healthy Penis and Phil the Sore stress grips were handed out at several gay pride events, which also included outreach activities conducted by health care workers wearing 7-foot Healthy Penis and Phil the Sore costumes. To facilitate syphilis testing, campaign materials also provided a web site, www.healthypenis.org, and a telephone hotline for people to get additional information, including hours and locations for testing and treatment sites in San Francisco, says Ahrens.

> "Feedback from members of the gay/bisexual community in San Francisco emphasized that our syphilis prevention campaign be positive about sex, educational about syphilis, and not focus on changing sexual behavior to prevent syphilis transmission. . ."
>
> **— Katherine Ahrens, MPH**

Message received

To evaluate the effectiveness of the program, Ahrens and fellow researchers conducted two surveys at six months and 2.5 years after campaign initiation. Researchers asked gay and bisexual men whether they were aware of the campaign and about their sexual health.

Survey findings indicate that gay and bisexual men who were aware of the campaign were more likely than those unaware to have tested recently for syphilis and to have greater knowledge about syphilis.[1] This effect was sustained for almost three years.[1]

In 2005, incidence of early syphilis in San Francisco was lower than in the previous three years, with decreases in cases in gay/bisexual men accounting for the drop.[1] The campaign was effective in augmenting syphilis testing and increasing syphilis awareness and knowledge in the San Francisco gay and bisexual community, and it may have contributed to the decrease, say authors.[1]

While the Healthy Penis campaign ended in San Francisco in 2005, its material has been adapted by other agencies for similar audiences. Elements from the campaign have been used by public health organizations in Seattle and Santa Clara, CA, Ahrens reports. Both campaigns were intentionally shorter than in San Francisco and involved cartoon strips and posters tailored to gay/bisexual men living in those locales, says Ahrens. Seattle employed the campaign in 2004, with Santa Clara using the campaign in 2006. **(See resource listing, below, for contact information for the campaign.)**

Santa Clara chose the campaign to combat rising syphilis rates, says **Kevin Hutchcroft**, local HIV/AIDS program director. It used one-time HIV education and prevention funds to fund its campaign.

To raise awareness about testing, Santa Clara placed posters in targeted areas, ran a several-month advertisement in a gay magazine, used penis costumes for Gay Pride Parade, and distributed stress grip novelties with testing site information, says Hutchcroft. The material was very well received by the target audience, he reports.

Start-up cost for the San Francisco program was $75,000 in 2002. The campaign continued through the end of 2005 at an additional cost of $295,000. Three-quarters of the campaign's first-year funds were spent on campaign development, with the remaining quarter spent on displaying campaign materials.[1]

Get tested, treated, stop syphilis

Why is it so important that gay and bisexual men be reached with a "Get Tested" message when it comes to syphilis? Getting tested and treated for syphilis is the main way to control its spread, as it is largely asymptomatic after the initial infection, Ahrens explains. Convenient, accurate, and inexpensive tests for the infection are widely available, she notes.

RESOURCE

For more information on adapting the Healthy Penis campaign for your STD program, contact:

- **Jacqueline McCright**, MPH, Community-based STD Services Manager, San Francisco Department of Public Health, STD Prevention & Control Services, 1360 Mission St., No. 401, San Francisco, CA 94103. Telephone: (415) 355-2015. E-mail: jacque.mccright@sfdph.org.

"Feedback from members of the gay/bisexual community in San Francisco emphasized that our syphilis prevention campaign be positive about sex, educational about syphilis, and not focus on changing sexual behavior to prevent syphilis transmission," says Ahrens. "They agreed that stressing 'Get Tested' would get the best response from gay/bisexual men in San Francisco."

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Toolkit offers tips on syphilis elimination

CDC offers information, publicity materials

Working to eliminate syphilis in your patient population? Use the practical materials available in the Syphilis Elimination Effort (SEE) toolkit developed by the Centers for Disease Control and Prevention (CDC).

The CDC launched its national plan in 1999 to eliminate syphilis from the United States to capitalize on a decade of declining rates of syphilis. The plan was designed to end the sustained transmission of the disease in the United States by focusing efforts on the populations most affected by syphilis: heterosexual minority populations, particularly African Americans. While progress has been made in reducing the burden of syphilis in these populations, overall syphilis rates have been on the rise since 2001, largely due to increasing rates of syphilis among men who have sex with men (MSM).

An updated syphilis plan

To overcome these emerging challenges, while continuing progress among African Americans and women, CDC has issued an updated syphilis elimination plan and expanded its SEE Toolkit.

The SEE Toolkit is designed for public health practitioners to help plan, manage, and develop community coalitions to increase awareness of and garner support for syphilis elimination/prevention efforts. Elements in the toolkit, available free of charge at the CDC web site, www.cdc.gov/stopsyphilis, include:

- instruction guide for community mobilization;
- camera-ready print ads;
- brochures, posters, banners, educational materials specifically developed for health care providers, leaders of the community-based and faith-based organizations, and for elected officials;
- sexual history taking guide;
- physicians' pocket guide on syphilis;
- form letters for use to partners, policymakers, etc.;
- radio public service announcements;
- tip sheets for, for example, working with the press, giving key messages' talking points, and communicating in a crisis.

The CDC has added information targeted for reaching MSM populations on the SEE web site. Providers may download *Screening and Testing Men who Have Sex with Men (MSM) for Syphilis — A Guide for Health Care Professionals*, available free, to help with outreach efforts. The site also offers guidance on mobilizing community-based organizations in syphilis elimination efforts in MSM populations. (Click on "SEE Toolkit," then "Special Focus: MSM," to access these resources.) ■

CTUPDATES
News ■ Resources ■ Events

NPWH issues guidance on cervical screening

The National Association of Nurse Practitioners in Women's Health (NPWH) has announced its endorsement of cervical cancer screening guidelines that support the use of HPV (human papillomavirus) testing along with the Pap test for routine screening of women 30 and older.

"As more data emerge documenting that cervical cancer can be prevented and how, it is increasingly important for women of all ages to know

the facts — including which prevention and detection strategies are appropriate for them," says **Susan Wysocki**, RNC, NP, NPWH president and chief executive officer. "While the Pap test is still a good tool, we recognize it is not perfect; this is why we support expanding routine screening to include the HPV test for women 30 and older, who are at highest risk of developing cervical cancer."

Use Pap, regardless of vaccine status

NPWH also recognizes guidelines associated with the new HPV vaccine for females ages 9-26. However, health care professionals should continue to screen all women with the Pap and (in age-appropriate women) HPV tests, regardless of whether they have received the vaccine, NPWH advises.

The NPWH guidelines for HPV testing are as follows:

• **Women 30 and older — routine screening with Pap and HPV DNA testing.**

Given the increased sensitivity, women 30 and older may benefit from expanded screening using a Pap and the HPV DNA test. In this case, the HPV test is performed regardless of the Pap result, and both tests are used to determine the timing of the next screen or the need for colposcopy.

Women whose HPV test is negative and whose Pap smear is normal do not need to be retested for three years. (Women who get just the Pap need to be tested more frequently.)

• **Women of all ages — HPV testing following an inconclusive (ASC-US) Pap test result.**

It is appropriate to test for HPV in women of all ages for triage of an inconclusive or borderline Pap result. Women with an inconclusive Pap who test positive for HPV should be evaluated further with a colposcopy. Those who test negative for HPV should have their Pap repeated in one year.

• **Women who have received the HPV vaccine.**

NPWH strongly recommends that health care professionals continue to screen all women with a Pap and (if 30 or older) the HPV test, regardless of whether they have received the vaccine. ■

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. ■

COMING IN FUTURE MONTHS

■ Research progresses on chlamydia vaccine

■ What do women think about emergency contraception?

■ ACOG calls for increased support for breast-feeding

■ Pilot program broadens access to vasectomies

■ Mammogram use declines; what's behind the drop?

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.
- **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.

13. The microbicides Carraguard and PRO 2000 are known as:
A. combination inhibitors.
B. IV entry inhibitors.
C. vaginal defense enhancers.
D. replication inhibitors.

14. The three oral contraceptives with an approved indication for acne treatment are:
A. Ortho Tri-Cyclen, Estrostep Fe, and Seasonale.
B. Ortho Tri-Cyclen, Yaz, and Seasonale.
C. Ortho Tri-Cyclen, Estrostep Fe, and Yaz.
D. Ortho Tri-Cyclen, Yaz, and Seasonique.

15. The Today contraceptive sponge should *not* be left in place for:
A. more than 12 hours after insertion, which includes the six-hour waiting period after the last act of intercourse.
B. more than 15 hours after insertion, which includes the six-hour waiting period after the last act of intercourse.
C. more than 24 hours after insertion, which includes the six-hour waiting period after the last act of intercourse.
D. more than 30 hours after insertion, which includes the six-hour waiting period after the last act of intercourse.

16. What types of human papillomavirus does the vaccine candidate Cervarix target?
A. HPV 16 and 18
B. HPV 6, 11, 16, and 18
C. HPV 6 and 11
D. HPV 16, 18, and 20

Answers: 13. B; 14. C; 15. D; 16. A.

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™

Head-to-head study of cervical cancer vaccines now under way at about 50 different sites

Phase III study has been launched for Cervarix and Gardasil

As clinicians begin to integrate use of the first cervical cancer vaccine (Gardasil, Merck & Co., Whitehouse Station, NJ) into their practice, developers of an investigational vaccine have launched a head-to-head study of the two vaccines.

The study is designed to compare the immunogenicity of Gardasil vs. Cervarix, a cervical cancer candidate vaccine under development by GlaxoSmithKline's Rixensart, Belgium-based GSK Biologicals. The trial will compare the immune responses to human papillomavirus (HPV) types 16 and 18 in U.S. women ages 18-26, as well as evaluate the immune responses to HPV 16 and 18 in women ages 27 to 35 and 36 to 45. In addition, the study will compare immune responses to other cancer-causing HPV types.

The trial is a Phase III, randomized, observer-blind study of 1,042 U.S. women. The study is designed with two arms, with each arm stratified by three age groups, 18-26 (n = 374), 27-35 (n = 334), and 36-45 (n = 334). Some 50 sites in the United States will participate in the research, reports **Jennifer Armstrong**, a spokeswoman for GlaxoSmithKline. Scientists plan to issue initial study results 12 months after study enrollment is completed, with extended follow-up scheduled for another 17 months.

The company is moving forward with its search for U.S. regulatory approval. It plans to file its biologics license application with the Food and Drug Administration review by April 2007.

EXECUTIVE SUMMARY

Developers of an investigational cervical cancer vaccine, Cervarix, have launched a head-to-head study of the vaccine against Gardasil, a currently marketed vaccine.

- The trial will compare the immune responses to human papillomavirus (HPV) types 16 and 18 in U.S. women ages 18-26, as well as evaluate the immune responses to HPV 16 and 18 in women ages 27 to 35 and 36 to 45. In addition, the study will compare immune responses to other cancer-causing HPV types.
- The American Cancer Society has issued guidelines calling for routine vaccination of females ages 11 to 12.

Is it effective?

GSK's cervical cancer candidate vaccine is targeted to prevent infection and lesions from the two most prevalent cancer-causing types of HPV: types HPV 16 and 18. It is formulated with AS04, a proprietary adjuvant system designed to sustain antibody levels over time.

GlaxoSmithKline says about 16,000 women worldwide have been vaccinated with the candidate vaccine as part of completed and ongoing clinical trials. Advanced trials of the vaccine are under way in more than 25 countries, with more than 35,000 subjects enrolled in ongoing trials, the company states. It is seeking regulatory

approval in Europe, Australia, parts of Asia and parts of Latin America.

Published research indicates that the vaccine demonstrated protection up to 4.5 years against persistent infection with HPV 16 and HPV 18 and protection from pre-cancerous lesions.[1] Protection also was demonstrated against infection with the third and fourth most prevalent cancer-causing types of HPV: types 45 and 31.[1] **(Read more about the research; see the article, "Men next target in HPV research drive," *Contraceptive Technology Update*, April 2005, p. 46.)** More recent findings show that the cervical candidate vaccine, formulated with its proprietary adjuvant system, induced higher antibody levels and immune memory response compared to a similar HPV vaccine composition formulated with an aluminum hydroxide adjuvant.[2]

How will the two vaccines compare in the study? The FDA approved Gardasil, which targets HPV types 6, 11, 16 and 18, in June 2006. **(Review news of the approval; see the article, "HPV vaccine, with nod from FDA, is first one approved to prevent cervical cancer," *CTU*, September 2006, p. 97.)** Gardasil also protects against vaginal and vulvar cancers, two other gynecological cancers that are linked to HPV, according to research presented in June 2006 at a meeting of the American Society of Clinical Oncology in Atlanta.[3]

ACS issues guidelines

The American Cancer Society (ACS) has issued guidelines calling for routine vaccination of females ages 11 to 12.[4] The new guidelines join those of other major health groups, including the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices, the American Academy of Pediatrics, and the American Academy of Family Physicians, calling for immunization in this age group. ***(CTU* reported on similar guidelines in the article, "Support is growing for HPV vaccine for girls," March 2007, p. 32.)**

The ACS guidelines were developed by an expert panel, which reviewed existing data to create the recommendations. The panel concluded:

- Routine HPV vaccination is recommended for females ages 11 to 12.
- Females as young as age 9 may receive HPV vaccination.
- HPV vaccination also is recommended for females ages 13 to 18 years to catch up missed vaccine or complete the vaccination series.

The panel determined there is insufficient data at the present time to recommend for or against universal vaccination of females ages 19 to 26; women in this age group should discuss risk of previous HPV exposure and potential benefit from vaccination with their health care providers.[4]

"Ideally, the vaccine should be administered prior to potential exposure to genital HPV through sexual intercourse because the potential benefit is likely to diminish with increasing number of lifetime sexual partners," the committee members state.

Continue cancer screens

Screening for cervical cancer and precancers should continue in vaccinated and unvaccinated women, according to current ACS early detection guidelines. Why is it so important for clinicians to continue to emphasize the need for screening?

Virtually all cervical cancer is caused by HPV, says **Debbie Saslow**, PhD, director of the ACS's breast and gynecologic cancer division and lead author of the new guidelines. While there are more than 100 types of HPV, between 13 and 15 types are associated with cervical cancer, she explains.

Gardasil protects against two types of HPV, which together are responsible for about 70% of cervical cancer, says Saslow. Girls and women who receive this vaccine will therefore be vulnerable to the 30% of cervical cancers that are caused by other types of HPV. Also, if these females have already been sexually active when they get vaccinated, they may have already been exposed to one or both of the HPV types in the vaccine, she states. While the vaccine prevents HPV infection, it does not have any benefit if exposure already has occurred, notes Saslow. Another point of vulnerability is that some women will receive only one or two vaccine doses instead of the recommended three; these women will not receive full protection, she states.

Screening with the Pap test can detect dangerous changes in the cervix before they ever turn into cancer, or at least find cervical cancer at an early stage, when it is easier to treat. "Until we have a vaccine that prevents all or almost all types of HPV that can cause cervical cancer, women still need to get regular Pap tests and,

if they are age 30 or older, they can also get the HPV test," states Saslow.

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Informing partners can help lower STD rates

What is your approach when it comes to treatment of partners of patients with sexually transmitted diseases (STDs)? A new research analysis indicates that patient-delivered partner therapy (PDPT) and home sampling for partners can be effective management strategies to reduce STD occurrence in partners of patients with an existing infection.[1]

EXECUTIVE SUMMARY

New research indicates that patient-delivered partner therapy and home sampling for partners can be effective management strategies to reduce sexually transmitted disease (STD) occurrence in partners of patients with an existing infection.

- Providers often may rely on simple patient referral in which patients are encouraged to tell their partners to seek treatment. Such an approach may not be effective; research indicates that only 40%-60% of named sexual partners are reached by such methods.
- Providers may face legal roadblocks within their scope of practice when it comes to expedited partner therapy (EPT). To assist state and local STD programs to implement EPT as a partner management tool, a collaborative project has developed information to help understand EPT's legal framework.

Providers often may rely on simple patient referral in which patients are encouraged to tell their partners to seek treatment. Such an approach may not be effective; research indicates that only 40%-60% of named sexual partners are reached by such methods.[2]

Secrecy, stigma, and blame

The cultures of secrecy, stigma, and blame that surround sexually transmitted infections make it difficult to deal with them effectively, says **Nicola Low**, MD, FFPH, reader in epidemiology and public health in the Department of Social and Preventive Medicine at the University of Bern, Switzerland, and a co-author of the current analysis. Having hard evidence that shows the benefits of open and informed discussion should help to destigmatize sexually transmitted infections and improve sexual health, Low states.

Researchers participating in the analysis wanted to look at new innovations in partner notification, says Low. The basic model of patient referral, in which a clinician tells the patient with a sexually transmitted infection that it is important that their sexual partners get treated is really not very successful in practice, she states.

To perform the analysis, researchers identified 14 studies involving 12,389 women and men diagnosed with a common sexually transmitted infection, including chlamydia, gonorrhea, and nonspecific urethritis. "We found three interventions that improve the success of patient referral: PDPT, giving the patient urine sampling kits to give to their partners, and giving the patient written information that they can give to their partners," states Low. "The interesting thing about these three interventions is that all of them make it easier for the patient to contact their partners and talk about the infection."

EPT gaining ground

Expedited partner therapy (EPT), the practice of treating sex partners of STD patients without an intervening medical evaluation or professional prevention counseling, is gaining ground as

an effective option in STD treatment. Patient-delivered partner therapy, the most recognized form of EPT, has been spotlighted by the Centers for Disease Control and Prevention (CDC) as an option in partner treatment, particularly for male partners of women with chlamydia or gonorrhea.

Research shows that expedited partner care can decrease the patient's risk of reinfection and increase the number of treated partners.[3-5] **(Read more about the research; see the article, "Evidence supports use of patient-delivered partner therapy for sexually transmitted diseases," May 2005 *STD Quarterly* supplement, p. 1.)** In August 2006, CDC recommended the practice of EPT for certain populations and specific conditions in its updated *STD Treatment Guidelines*.[6] **(*Contraceptive Technology Update* reported on the CDC's endorsement in the article, "Repeat chlamydia infection: Improve partner notification and treatment," October 2006 *STD Quarterly* supplement, p. 1.)**

Overcoming legal obstacles

Providers may face legal roadblocks within their scope of practice when it comes to EPT. To assist state and local STD programs to implement EPT as a partner management tool, the CDC, the Center for Law and the Public's Health at Georgetown University, and Johns Hopkins University have worked together to assess the legal framework concerning EPT, says **John M. Douglas Jr.**, MD, director of the CDC's Division of STD Prevention. The group had two goals in mind in undertaking the project, says Douglas. The first objective was to provide state and local public health partners with a tool to help them work with such local legal counsel as in-house counsel, attorneys general, and city attorneys, to understand and address potential legal barriers to EPT implementation. The second objective was to provide state and local public health partners with information about the EPT legal landscape in other jurisdictions to facilitate collaboration and encourage sharing of lessons learned, he notes.

The CDC has developed state-specific information on its web site, www.cdc.gov/std/ept. At the current time, EPT is permissible in 11 states: California, Colorado, Minnesota, Mississippi, Nevada, New Mexico, Pennsylvania, Tennessee, Utah, Washington, and Wyoming. States with laws that currently prohibit EPT include Arizona, Arkansas, Florida, Illinois, Kentucky, Louisiana, Michigan, North Dakota, Ohio, Oklahoma, South Carolina, West Virginia, and Vermont. EPT is possible in the remaining 28 states, according to the web site.

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