CONTRACEPTIVE TECHNOLOGY UPDATE®

A Monthly Newsletter for Health Professionals

AHC Media LLC

IN THIS ISSUE

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JULY 2007
VOL. 28, NO. 7 • (pages 73-84)

Continuous use oral contraceptive receives FDA regulatory approval

Wyeth Pharmaceuticals' Lybrel set to reach U.S. pharmacies this month

Clinicians now have a dedicated continuous use oral contraceptive. The Food and Drug Administration (FDA) has given final approval to Lybrel from Wyeth Pharmaceuticals of Collegeville, PA. The drug represents the first combination contraceptive pill designed to be taken 365 days a year, without a placebo phase or pill-free interval.

"I am excited about the fact that this approval is going to give a nod to something that we as clinicians have been doing for decades," says **Robert Hatcher**, MD, MPH, professor of gynecology and obstetrics at Emory University School of Medicine in Atlanta. "For many women, it makes a lot more sense than taking pills 21/7, 21/7, 21/7."

The drug, which received FDA approvable status in June 2006, is scheduled to reach U.S. pharmacy shelves this month, says **Natalie de Vane**, Wyeth spokeswoman. ***(Contraceptive Technology Update* reported on the approvable status in the article "New pill options give women choices while changing menstrual bleeding," August 2006, p. 85.)** Since the drug represents a departure from the standard dosing schedule of

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Lybrel from Wyeth Pharmaceuticals represents the first combination contraceptive pill designed to be taken 365 days a year, without a placebo phase or pill-free interval. Approved by the Food and Drug Administration in May 2007, it is scheduled to arrive on pharmacy shelves this month.

- The pill comes in a 28-day pill pack with combination tablets that contain 90 mcg levonorgestrel and 20 mcg ethinyl estradiol.
- While researchers in the clinical trial report that the incidence of uterine bleeding decreased with longer use, 21% of women had uterine bleeding by Pill Pack 13, with a median of four days of bleeding and three days of spotting per 28-day pill pack.

regular oral contraceptives, look to Wyeth to provide information to clinicians and women about the new OC, she reports.

The new birth control pill comes in a 28-day pill pack with combination tablets that contain 90 mcg levonorgestrel and 20 mcg ethinyl estradiol. While the new drug may represent a step forward in birth control, its 28-day packaging may prove problematic, Hatcher observes. While a price has not yet been set for Lybrel, new drugs traditionally are the most expensive, he says. With the 28-day packaging, women will be forced to return for monthly refills, which can be difficult for patients served by family planning clinics. It is much harder for a person with an income of $15,000-$20,000, living below the poverty line, to return to the clinic, pick up her pills, and pay her copay 12 or 13 times a year, than for someone with a higher family income, says Hatcher.

"The high cost and the necessity of returning to the clinic every month are very unattractive features of this new pill," Hatcher states. "I predict that it will have minimal impact in programs serving less advantaged women."

Review research data

Results from recently published research regarding Lybrel's safety and efficacy indicate the drug has a safety profile and efficacy similar to cyclic OCs. A total of 2,402 women were enrolled in the drug's clinical trial; 2,134 took at least one dose of the study drug, and 921 completed the study.[1] The study drug was supplied in 28-day pill packs; women took one pill daily for a period of 12 months with no pill-free intervals.

During the course of the study, which lasted more than 18 months, 19 women became pregnant while using the drug, yielding an on-treatment Pearl Index of 1.60 (95% CI = 0.96-2.49). Fifteen of these pregnancies were attributed to method failure (Pearl Index = 1.26; 95% CI = 0.71-2.08), and four were attributed to user failure (Pearl Index = 0.34; 95% CI = 0.09-0.86). **(See the article, "Research supports safety of continuous regimen pill," *CTU*, March 2007, p. 27.)**

Women may be concerned that return to fertility may be affected by use of a continuous regimen pill. To evaluate the return to fertility among women planning to become pregnant after the use of Lybrel, researchers followed 21 women for up to 12 months following their last dose of treatment.[2] Average duration of treatment with the drug was 197 days within the study group. The pregnancy rate was 57% (12/21) at three months and 81% (17/21) at 12 months after discontinuation, the scientists report. After the 12-month post-study follow-up, information was sought for the remaining four women who had not become pregnant. One woman conceived within 14 months of the last treatment for a total pregnancy rate of 86% (18/21).

Contraceptive Technology Update® (ISSN 0274-726X), including **STD Quarterly**™, is published monthly by AHC Media LLC, 3525 Piedmont Road, Building Six, Suite 400, Atlanta, GA 30305. Telephone: (404) 262-7436. Periodicals postage paid at Atlanta, GA 30304. POSTMASTER: Send address changes to **Contraceptive Technology Update**®, P.O. Box 740059, Atlanta, GA 30374.

Subscriber Information

Customer Service: (800) 688-2421 or fax (800) 284-3291. E-mail: (customerservice@ahcmedia.com). Hours of operation: 8:30 a.m.-6 p.m. Monday-Thursday; 8:30 a.m.-4:30 p.m. Friday, EST.

Subscription rates: U.S.A., one year (12 issues), $499. Add $9.95 for shipping & handling. Outside U.S., add $30 per year, total prepaid in U.S. funds. Discounts are available for group subscriptions. For pricing information, call Tria Kreutzer at (404) 262-5482. **Back issues**, when available, are $75 each.(GST registration number R128870672.) **Photocopying:** No part of this newsletter may be reproduced in any form or incorporated into any information retrieval system without the written permission of the copyright owner. For reprint permission, please contact AHC Media LLC. Address: P.O. Box 740056, Atlanta, GA 30374. Telephone: (800) 688-2421. World Wide Web: http://www.ahc media.com.

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In the remaining three women who did not conceive, one woman ceased trying to become pregnant by 12 months, and the other two were lost to follow-up after 12 months, note the researchers.[2] Eighteen pregnancies resulted in 17 live births and one spontaneous abortion. Data were obtained from 10 of the 17 newborns; all were uncomplicated term deliveries. **(See the article, "Research emerges on continuous regimen OC," *CTU*, January 2007, p. 6.)**

Counseling is key

Lybrel will add to what clinicians can offer women in terms of menstrual suppression, says **Susan Wysocki**, RNC, NP, president and CEO of the National Association of Nurse Practitioners in Women's Health. It will be welcomed by women who are willing to tolerate unscheduled bleeding in the first months of use, she says. Clinicians should counsel women that they will very likely have such unscheduled bleeding, she notes.

Most women will not achieve menstrual suppression until they have taken Lybrel for several months, says Wysocki. "Because there are no scheduled bleeding times, all the bleeding a woman will experience will be unscheduled," observes Wysocki. "Consider that the woman asking for Lybrel does not want to bleed, so she must know that it will take at least three to six months to achieve that goal."

While researchers in the clinical trial report that the incidence of uterine bleeding decreased with longer use, 21% of women had uterine bleeding by Pill Pack 13, with a median of four days of bleeding and three days of spotting per 28-day pill pack.[1] More than three-quarters (77%) of women who experienced bleeding on Pill Pack 13 reported they were satisfied with the method, with 7% as neutral and 16% as dissatisfied.

"This suggests that there is a subset of women who may not achieve amenorrhea with prolonged use of continuous OC," researchers state in the published study. "The lack of amenorrheic outcome may lead to the discontinuation of OCs in these women."

One approach that may be effective in dealing with unscheduled bleeding with a continuous regimen pill is to stop use of pills for two to three days to intensify the withdrawal bleed, says Hatcher. In a prospective analysis comparing a 21/7-day regimen vs. a 168-day extended regimen of an OC drospirenone/ethinyl estradiol formulation, users who had breakthrough bleeding/spotting for at least seven consecutive days were randomized to undergo a three-day hormone-free interval vs. continuing active pills. Instituting a three-day hormone-free interval was significantly more effective in resolving unscheduled bleeding/spotting than continuing active pills, researchers report.[3] Such an approach is not included in the Lybrel package insert, Hatcher notes.

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New data cast doubt on abstinence-only programs

Health advocates push for comprehensive sex ed

In 1997, federal block grant funding for abstinence-only sexuality education went into effect. Despite limited research on the efficacy of such programs, many states applied for a portion of the $50 million in federal dollars. **(See "Money is coming for abstinence-only programs . . . but do**

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Findings from an analysis of four abstinence-only education programs indicate that such programs do not keep teens from having sex. Such programs don't affect the likelihood that if teens do have sex, they will use a condom, the analysis concludes.

- The Title V federal education program dedicates $50 million per year to be distributed among participating states. States that take the funds are required by law to match every four federal dollars with three state-raised dollars.
- Reproductive health advocates intend to keep the focus on the need for support of comprehensive sex education programs that teach not only the benefits of abstinence, but prepare young people to be safe if and when they do become sexually active.

they work?" ***Contraceptive Technology Update*****, July 1997, p. 81.)**

Findings from a just-released analysis of four abstinence-only education programs indicate that such programs do not keep teens from having sex. Such programs neither increase nor decrease the likelihood that if teens do have sex, they will use a condom, the analysis concludes.[1]

Abstinence-only programs as they are known today were initiated in 1996 when the federal government attached a provision to the welfare reform law. Known as the Personal Responsibility and Work Opportunity Reconciliation Act, the legislation established federal dollars for abstinence-only-until-marriage programs. Programs that receive such funding are prohibited from discussing methods of contraception, including condoms, except in the context of failure rates.

The program, detailed under Section 510(b) of Title V of the Social Security Act, dedicates $50 million per year to be distributed among states that choose to participate. States that take the funds are required by law to match every four federal dollars with three state-raised dollars for a total of $87.5 million annually, and $787.5 million for the eight years from fiscal year 1998 through 2006.[2] More than 700 Title V, Section 510 programs now receive funding for programs that teach abstinence from sexual activity outside of marriage.[3] There also are hundreds of additional programs outside the Title V, Section 510 program that receive support from the federal government or the private sector, according to the Department of Health and Human Services.[3]

Federal abstinence funds under the Title V grant come up for congressional renewal this summer. Reproductive health advocates are calling for changes in the funding. "Sex education is the beginning of a lifelong spectrum of reproductive health care; like any other component of health care, it must be truthful, comprehensive, and widely available," says **Mary Jane Gallagher**, president and CEO of the National Family Planning and Reproductive Health Care Association. "We hope Congress will eliminate funding for ineffective abstinence-only programs and work instead to equip young people with the knowledge to make responsible, informed decisions about their sexual health."

Advocates for Youth, an adolescent health advocacy group, has mounted a major campaign to mobilize young people across America to urge congressional members to "start funding programs that work," says **James Wagoner**, president. The group has run three full-page ads in *Roll Call*, the congressional newspaper, and has sent out alerts to its activists to contact congressional members to urge them to cut funding for the abstinence-only programs, he reports.

Review the research

The new analysis, authorized by Congress in 1997 and performed by Mathematica Policy Research of Princeton, NJ, is a multiyear evaluation of four Title V, Section 510 abstinence education programs. The study evaluates behavioral outcomes as well as knowledge of risks associated with teen sexual activity by participants in the four programs. **(The full report online is available at www.mathematica-mpr.com; click on the link under "Abstinence Education Programs: New Report Examines Behavioral and Other Impacts.")** For its report, Mathematica looked at 2,057 students in four abstinence programs:

- *My Choice My Future* in Powhatan County, VA;
- *ReCapturing the Vision* in Miami;
- *Teens in Control* in Clarksdale, MS;
- *Families United to Prevent Teen Pregnancy* in Milwaukee.

The first two programs serve middle school students; the latter two primarily serve elementary students. The study looked at students enrolled in the programs, as well as students from the same communities who did not participate in the programs.

The study followed up with youths four to six years after they received the intervention in an elementary or middle school program, comparing those who participated in an abstinence program with peers in a control group that received "services as usual" provided by their school. Students were an average age of 11 to 12 when entering the programs in 1999. Most participated in the programs for one to three years.

Mathematica performed a follow-up survey in late 2005 and early 2006, with the average age of participants at 16.5. Results indicated about half of the students in the abstinence programs and an equal number from the control group reported that they remained abstinent.

According to Mathematica, the programs improved identification of sexually transmitted diseases (STDs) though had no overall impact on knowledge of unprotected sex risks and the consequences of STDs. Both program and control group youth had a good understanding of the risks of pregnancy but a less clear understanding

of STDs and their health consequences.

"Although a high proportion of youth reported that having unprotected sex just once could result in an STD, 47% of sexually active youth had unprotected sex in the previous 12 months," report authors state. "Moreover, on a scale measuring their understanding of the health consequences of STDs, youth on average got only about half of the answers correct; on a scale measuring STD identification, youth were correct only about two-thirds of the time."[1]

Taking the next step

What is the next step for abstinence-only programs? One finding from the study indicates that while peer support for abstinence may be protective in middle school, it erodes sharply during the teen years. Programs may want to consider including a peer support component in their activities due to this finding, observes **Christopher Trenholm**, senior researcher at Mathematica and program director for the project.

Also, aiming abstinence-only messages solely at people at young ages may not be sufficient. The programs included in the current analysis were targeted solely at middle school youth and did not continue to serve students as they entered high school. Delivering abstinence education programs in middle school may not be enough to sustain changes in attitudes and behaviors, the report suggests.

Not every state has participated in the Title V program. Eight states, including California (which never accepted the funding), Connecticut, Maine, Montana, New Jersey, Ohio, Rhode Island, and Wisconsin, have rejected the funding. **(Check what your state is spending on abstinence-only programs. Go to www.siecus.org/policy/states/index.html for *SIECUS State Profiles*, which provides an overview of abstinence-only-until-marriage programs and their intersection with U.S. sexuality education programs. The online publication, now in its third edition, includes individual profiles of every state and the District of Columbia. Click on individual states for detailed information.)**

As of *CTU* press time, the Title V program was set to expire on June 30, 2007. Reproductive health advocates intend to keep the focus on the need for support of comprehensive sex education programs that teach not only the benefits of abstinence, but prepare young people to be safe if and when they do become sexually active.

"We will continue to put pressure on Congress to de-fund these [abstinence] programs and to finally fund comprehensive sex education," says Wagoner. Research has shown that when teens have comprehensive sex education that includes science-based information about abstinence and contraception, they have better sexual health outcomes, he says. "They delay sexual initiation and, when they become sexually active, they use contraception better and have fewer partners," Wagoner says.

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Early condom use: Good for future teen health

The next patient in your exam room is a young female adolescent. How can you help motivate her when it comes to condom use?

Results from a new study suggest that teens

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Results from a new study suggest that teens who use condoms the first time they have sexual intercourse are more likely to continue using condoms into young adulthood. These adolescents also are less likely than their peers to have contracted a sexually transmitted disease (STD), the findings suggest.

- The study found that those who used condoms at sexual debut were 36% more likely to report condom use for their most recent sexual encounter and half as likely to test positive for chlamydia or gonorrhea when compared with those who did not use condoms at sexual debut.
- The lifetime number of sexual partners did not differ between those who had used condoms during their first sexual experience and those who had not.

who use condoms the first time they have sexual intercourse are more likely to continue using condoms into young adulthood.[1] These adolescents also are less likely than their peers to have contracted a sexually transmitted disease (STD), researchers note.[2]

The scientists looked at adolescents who participated in the National Longitudinal Study of Adolescent Health, a federally funded, nationally representative study that followed 4,018 sexually active adolescents between 1994 and 2002. All of the teens had had sexual intercourse by the second year of the study. Participants were tested for chlamydia and gonorrhea in 2001 or 2002.

The study found that those who used condoms at sexual debut were 36% more likely to report condom use for their most recent sexual encounter and half as likely to test positive for chlamydia or gonorrhea when compared with those who did not use condoms at sexual debut. The lifetime number of sexual partners did not differ between those who had used condoms during their first sexual experience and those who had not.[1]

A take-home message is that while the adolescents in the study who used condoms at sexual debut were similar in their number of sexual partners as those who did not, and had the same frequency of sex, they were less likely to test positive for an STD, says **Taraneh Shafii**, MD, MPH, lead author of the analysis and an assistant professor of pediatrics at the University of Washington in Seattle.

Shafii's research has centered on condom use at sexual debut.[2] She uses the analogy of use of seatbelts in cars or helmets in bicycle use; if condoms are used at the first time of intercourse, they become part of the expected experience. "We find through the research that (teens) continue to use (condoms) throughout their sexual activity; and with this most recent paper, even six to eight years later, they're still using condoms and are less likely to test positive for gonorrhea and chlamydia," she notes.

Talk with teens

What is your approach when talking with a young teen about condoms? It is important to gain an adolescent's trust prior to discussing sensitive subjects. A teenager must feel comfortable that the discussion will be confidential, says Shafii.

"As clinicians, we can establish rapport by spending time getting to know the adolescent and letting them have time to feel us out — to see if we are a safe person in which to confide," she states. "Before we start asking our patients about sensitive topics — like sex — we first ask them less intrusive questions about other areas like their home life, how they are doing in school, what they like to do for fun. Once they are comfortable talking with us, we can then proceed to the more difficult questions of alcohol/drug use and sexuality."

Once a trusting rapport has been established, it is time to assess whether the teen is contemplating or is sexually active. To talk about condom use, consider the following dialogues offered by **Melanie Gold**, DO, FAAP, FACOP, associate professor of pediatrics at the University of Pittsburgh and director of family planning services at Children's Hospital of Pittsburgh. Gold is the co-author of *Teen-to-Teen: Teens Talk about Sex, Self-Esteem and Everything In-Between* (Bridging the Gap Communications; 2005).

• ***Tell me what your thoughts are about what you plan to do in the future in terms of protecting yourself against pregnancy and protecting yourself against STDs.***

This open-ended question allows teens to share their thoughts about protection. All teens are familiar with condoms, and they have ideas and beliefs about them, Gold says.

• ***Have you ever used a condom before? What have your experiences been with using them?***

This portion of the dialogue allows the teen to list all the good and not-so-good things they perceive about condoms. If a teen starts out listing the "bad" things about condoms, Gold follows up with a statement such as, "You've told me the not-so-good things about condoms. What are some good things about them?"

• ***On a scale of 0-10, how important is it to you right now in your current situation to use a condom every time you have sex?***

Follow this question with:

• ***On the same scale, how confident are you that you could use condoms, or use them with your partner?***

Depending on which number is lower, focus on that question, Gold says. If a teen says, "My confidence is like an 8. I'm sure I could do it if I wanted to, but it's not important to me because I've been with my boyfriend for two years and we trust each other," Gold takes the lower number, and says, "You told me importance was like a 3. How come it's a 3 instead of a zero? What makes it that high?" She keeps asking, "What else makes it a 3 instead of a zero?" until the teen says, "There's nothing else." Then, she comes back with, "What would it take to make it a little more important,

say a 4 or 5 instead of a 3?"

If the teen cannot offer any reasons, Gold asks permission to say, "Some kids have told me it would be more important if they thought their partner was cheating on them, or if they got an STD, or if they learned something about their birth control that made them realize it doesn't work as well as they might like it to, or they have a pregnancy scare. For you, what would make it a little more important?"

Gold says this approach, an adaptation of "motivational interviewing," gets teens thinking about the reasons for using condoms, in terms of why they are important, or why they are confident they can use them, while providing the clinician with signals for possibly increasing the teen's use of protection.[3,4]

What if a teen rejects condom use? Gold suggests a series of sentences as follows: "You know best what is going to be the most helpful for you and your situation. I'm not here to tell you what to do. I'm here to provide you with some information, but ultimately it is your decision and your choice. I'm not going to go home with you and sit on your shoulder and whisper in your ear and tell you what to do."

Gold then reminds the teen that it is his/her choice, and that while she, as their clinician, might be worried or concerned, she hears/understands that to them the decision to not use condoms is completely risk-free. The "completely risk-free" statement may catch teens' attention, because they will recognize that nothing is risk-free, says Gold.

Help teens identify the things they don't like about condoms, and ask them first what ideas they have about ways to get around those things they don't like. If they cannot come up with any solutions, ask them if they would be interested in hearing some things that other teens have found that work for them, offers Gold. If they aren't satisfied with the fit or feel of condoms, offer the idea of lubricants and different condom styles, she notes. "As health care providers, we love to give the solutions, but a teen is more likely to follow the solution they come up by themselves," observes Gold. "They are very solution-oriented and very creative. Teens can come up with really great solutions to their own barriers."

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Add no-needle to no-scalpel vasectomy

How can providers ease fears when it comes to vasectomy? Take a look at no-needle, no-scalpel vasectomy (NSV), which utilizes a jet injector to spray an anesthetic solution through the skin and around the vas prior to no-scalpel vasectomy. After anesthesia is administered, the surgeon then performs the no-scalpel vasectomy procedure, using a ring clamp to hold the vas deferens in place and dissecting forceps to dissect the tubes.

Initially described in 2001 by **Charles Wilson**, MD, a Seattle urologist, the technique calls for delivery of local anesthetic through use of a MadaJet, a jet injection device developed by MADA Medical Products, Carlstadt, NJ.[1] Similar injection devices are used in dermatology, cosmetic and plastic surgery, gynecology, dentistry, and podiatry.

The hypospray injection using the MadaJet is more efficient, more effective, and quicker than

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No-needle, no-scalpel vasectomy uses a jet injector to spray an anesthetic solution through the skin and around the vas prior to no-scalpel vasectomy. The jet injector replaces needle injection, which eliminates a potential source of concern for prospective vasectomy clients.

- No-needle vasectomy helps reduce men's fear of the procedure and represents the next step in the evolution of minimally invasive vasectomy techniques. Research indicates the procedure is safe and effective.
- About 38% of physicians use the no-scalpel vasectomy method, according to a recent provider survey.

the needle injection, says Wilson. It is probably less traumatic to the tissues than inserting a needle, and may have less reported pain, depending on the patient, he notes.

Researchers in 2005 modified and refined the jet injection technique for vasectomy, and they attained a close to 100% efficacy rate with no need for supplemental anesthetic.[2] In the study, about 465 patients were anesthetized by the jet injection technique with great satisfaction. Researchers used an average volume of anesthetic solution per jet injection of 0.1 cc with 0.2 cc to 0.3 cc for each vas. They recorded almost immediate anesthetic onset — within 10-20 seconds after injection. Patients described the experience as the mild discomfort of a pinch, not unlike a rubber band, with the first injection.

"Probably the greatest advantage is enjoyed by the population of patients who simply hate needles," says Wilson. "For them, the relief of apprehension about the needle, especially in the area of a vasectomy, can significantly affect their perception of their experience, and, by extension, the degree of apprehension their friends might have when they contemplate the procedure."

Multiple benefits eyed

The no-needle approach to NSV has benefits for the physician as well as the patient, reports **Marc Goldstein**, MD, professor of reproductive medicine and professor of urology at Weill Medical College of Cornell University in New York City. The injector anesthetizes the vas more effectively than the needle; therefore, the volume of anesthesia is lessened. With less anesthesia, swelling is reduced, making the vas easier to "trap" with the NSV ring clamp, says Goldstein, who serves as director of the university's Center for Male Reproductive Medicine and Microsurgery.

The injector must be properly positioned over the vas; otherwise, the injection will go into the anterior scrotum, out the posterior scrotum, and right into the surgeon's finger, says Goldstein. A special finger protector can serve as a shield, he notes.

"The disadvantages of no-needle vasectomy are that it requires special equipment and careful maintenance and sterilization procedures," notes Wilson. "It requires learning an exacting technique to be successful; it depends on having advanced NSV skills to reliably keep within a 1-cm site during vasectomy."

According to *Contraceptive Technology,* no-scalpel vasectomy offers several advantages over the scalpel method: fewer complications, including infection and hematoma; less pain during the procedure and early follow-up period; and earlier resumption of sexual activity after surgery.[3]

Acceptance of method 'slowly edging up'

According to a 2002 provider survey, 37.8% of physicians reported current use of no-scalpel vasectomy.[4] Goldstein was the first American surgeon to be trained in, and perform the Chinese method of no-scalpel vasectomy in 1985; he says acceptance of the method is "slowly edging up."

It is more difficult to do, Goldstein says. "It is much easier to take a knife and make a nice generous cut and then you can easily find the vas, so the NSV requires much more training to get it out of this little puncture hole," he says. "I tell all my residents when I teach, is it that it is all feel." They are shocked at how difficult it is to learn how to do the procedure. Goldstein says.

While NSV may require more training, it is worth the time investment, because patients definitely prefer it, he says.

The procedure employs two unique instruments: a ring forceps to encircle and secure the vas without penetrating the skin, and sharp-tipped dissecting forceps that puncture and stretch a small opening in the skin and vas sheath. The vas is lifted out and occluded as with other vasectomy techniques. No sutures are needed to close the small wound.[3]

"I have my patients sit up after [the procedure] and I say, 'Where do you think I did it?" says Goldstein. "They can't find the puncture hole." **(Check Internet resources on no-needle, no-scalpel vasectomies at the Cornell University web site, www.cornellurology.com/infertility. Click on "No-Needle, No-Scalpel Vasectomy." Also review information on Wilson's web site, www.TheVasectomyClinic.com.)**

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WASHINGTON WATCH

Advocates seek new prevention programs

By **Adam Sonfield**
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Washington, DC

As the first year of the two-year 110th Congress gets under way — the first time in a dozen years that Democrats have been in charge of both chambers — reproductive health advocates are working with a sense of cautious optimism. The new House leadership, headed by Speaker Nancy Pelosi (D-CA), is firmly supportive of reproductive rights, and Senate Majority Leader Harry Reid (D-NV), although anti-abortion, is a strong advocate of family planning. Yet, the Democratic majorities are slim, and President Bush's veto threats have grown increasingly frequent.

In this fragile environment, pro-reproductive rights policy-makers and advocates are focusing on policies that would help women avoid unintended pregnancies, and the abortions and unintended births that follow. One such proposal — the Unintended Pregnancy Reduction Act, introduced on March 29 by Reid and Sen. Hillary Rodham Clinton (D-NY) — would dramatically expand access to family planning services under Medicaid by requiring states to provide such coverage to individuals up to the same income eligibility ceiling used by the state for pregnancy-related care under Medicaid. That level is at least 133% of the federal poverty level and, in many states, 185% or above; it is far above most states' regular Medicaid eligibility ceiling for adults.

The legislation builds on the demonstrated successes of 25 states that have obtained federal approval, through a typically long and difficult process, to expand Medicaid eligibility for family planning services; 17 of these states have established parity between the eligibility levels for family planning and pregnancy-related care.

The evidence of these programs' effectiveness continues to grow. Most recently, a 2007 article by researchers from the Medical University of South Carolina found that these expansions have significantly reduced states' overall birthrates.[1] A 2003 federally funded evaluation of programs in six states found that all yielded significant government savings by averting Medicaid-eligible unintended births.[2] And a 2006 report by Guttmacher Institute researchers found that the parity approach to an expansion, instituted nationwide, would save $1.5 billion annually and reduce unintended pregnancy and abortion rates by 15%.[3]

Reproductive health supporters also will be working during this Congress to challenge the preeminent role of abstinence-only-until-marriage education in the federal government's efforts to prevent teen and nonmarital pregnancy and sexually transmitted infections (STIs). Congress has allocated more than $1 billion over the past decade to promote premarital abstinence through programs that ignore or denigrate the effectiveness of contraceptives and safer-sex behaviors.

Between 1995 and 2002, a period in which abstinence-only funding grew exponentially, the proportion of U.S. teens who received any formal education about birth control methods declined sharply, while the proportion receiving only information about abstinence more than doubled.[4] Yet, improved contraceptive use and use of more effective methods — not teens abstaining from sex — were responsible for the vast majority (86%) of the steep declines in teen pregnancy during these same years.[5] Indeed, there is strong evidence that comprehensive sex education can both effectively delay sex among young people and increase condom and overall contraceptive use among those who are sexually active.[6] In contrast, a nine-year, $8 million, congressionally mandated evaluation of federally funded abstinence-only programs found that these programs have no beneficial impact.[7] **(See this**

COMING IN FUTURE MONTHS

- Boost chlamydia screening rates in your practice
- Breakthrough bleeding and spotting — look at pill formulations
- Obesity — Talk with patients on weight control
- Contraceptive coverage: Advocate for insurance coverage
- Mammogram rates drop — Are your patients at risk?

month's cover article on the new evaluation.)

Members of Congress are discussing various approaches to address the disconnect between the need for realistic sex education and the Bush administration's abstinence-only obsession. Some approaches would curb the worst aspects of the current policy, for example, by requiring medical accuracy in abstinence-only educational materials, by eliminating unscientific and ideologically driven program requirements, or by giving states the flexibility to use their abstinence education funds within a more comprehensive sex education program.

Yet, most advocates are now promoting the Responsible Education About Life Act, sponsored by Reps. Barbara Lee (D-CA), Christopher Shays (R-CT), and Sen. Frank R. Lautenberg (D-NJ). That act would provide funding for state programs that operate under a new, nine-point definition of family life education designed to reverse the flaws of the abstinence-only approach.

Congress has only a limited window for real legislative action before the 2008 elections overwhelm Washington, and the war in Iraq has so far dominated its attention. While the prospects for any of these proposals are uncertain, proponents and opponents will be on the lookout for opportunities.

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Letter to the Editor

To The Editor:

I am writing to provide important details from the Today contraceptive sponge worldwide Phase III clinical trial that were not presented in your recent article in ***Contraceptive Technology Update*, "Wider access eyed for contraceptive sponge," April 2007, p. 42**. I would also like to clarify some important effectiveness data from this trial, specifically these data surrounding effectiveness of the Today contraceptive sponge on parity.

First, missing from this article on the Today contraceptive sponge was a review of the results from the worldwide Phase III clinical trial, which was the basis for FDA approval.[1] This year-long clinical trial was conducted in 20 centers (13 U.S., seven international) and included more than 1,800 women. In this trial, the method effectiveness rate of the Today contraceptive sponge per 100 women for an entire year of intercourse was determined to be 89% to 91%.[1] Since these effectiveness rates were derived from clinical trial participants' entire year of intercourse, these effectiveness rates equate to approximately one pregnancy for every 1,250-1,500 acts of intercourse. Additionally, 103 women in a subset of U.S. centers in this same clinical trial continued to use the Today contraceptive sponge for a second year, and the method effectiveness rate was found to increase to greater than 96%.[1,2]

The levels of efficacy quoted in the April issue were taken from a substantially smaller trial

CE/CME Instructions

Physicians and nurses participate in this continuing medical education/continuing education program by reading the articles, using the provided references for further research, and studying the questions at the end of the issue. Participants should select what they believe to be the correct answers and refer to the list of correct answers to test their knowledge. To clarify confusion surrounding any questions answered incorrectly, please consult the source material. After completing this activity with the **December** issue, you must complete the evaluation form provided and return it in the reply envelope provided in that issue to receive a certificate of completion. When your evaluation is received, a certificate will be mailed to you. ■

(N=249)[3] and from a trial in which the Today contraceptive sponge was allowed to be used for longer than the labeled indication (i.e., left in place for up to two days vs. labeled restriction of 30 hours).[4,5] The method effectiveness rates for one year of use (89% to 91%), taken from the Phase III global clinical trial, were reviewed by the FDA and approved by the Non-Prescription Drug Advisory Committee and are currently found within the Today contraceptive sponge label.

First-Year Probability of Pregnancy* for Women Using Vaginal Barrier and Spermicide Methods

	% of Women Experiencing an Unintended Pregnancy Within the First Year of Use		% of Women Continuing Use At One Year
Method	**Typical Use**	**Perfect Use**	
Sponge:			
Parous Women	32	20	46
Nulliparous Women	16	9	57
Female Condom	21	5	49
Diaphragm	16	6	57
Spermicides	29	18	42
Withdrawal	27	4	43
Latex male condom	15	2	53

** See Table 27-1 in* Contraceptive Technology *for first-year probability of pregnancy for all methods.*

Source: Trussell J. "Choosing a Contraceptive: Efficacy, Safety, and Personal Considerations." In: Hatcher RA, Trussell J, Nelson AL, et al. *Contraceptive Technology:* 19th revised edition. New York City: Ardent Media; 2007.

Lastly, a statistical comparison as it relates to the effectiveness of the Today contraceptive sponge in nulliparous and parous women was also missing from the same April 2007 article. When reviewing these data contained within the worldwide Phase III clinical trial, the 12-month method pregnancy rates per 100 women were nine for nulliparous and 10.2 for parous sponge users.[1] Most importantly, the method pregnancy rates were found to be similar between these groups, with no statistically significant differences noted.

We believe the readers of *Contraceptive Technology Update* should be provided with a comprehensive review of the effectiveness of the Today contraceptive sponge that includes the efficacy results from the Phase III worldwide clinical trial that supported the approval of this product by the FDA.

Ron Spangler, PhD
Chief Scientific Officer
SYNOVA Healthcare Inc.
Media, PA

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5. Today contraceptive sponge package insert.

Editor's Reply:

The statistics included in the April 2007 article came from a 2003 systematic review of randomized controlled trials by Cochrane Collaboration reviewers that compared the vaginal contraceptive sponge with the diaphragm used with a spermicide. The McClure DA (1985) and North BB (1985) studies referenced above were not included in the Cochrane review.

The Today contraceptive sponge package insert carries an adaptation of the contraceptive effectiveness table published in *Contraceptive Technology*.

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.

1. Which states have not participated in the federal Title V abstinence education funding?

A. California, Connecticut, Maine, Montana, New Jersey, Ohio, Rhode Island, and Wisconsin
B. California, Connecticut, Maine, Montana, New Jersey, Ohio, Rhode Island, and West Virginia
C. California, Connecticut, Maine, Montana, North Carolina, Ohio, Rhode Island, and Wisconsin
D. California, Connecticut, Maine, Missouri, New Jersey, Ohio, Rhode Island, and Wisconsin

2. What is the name of the jet injection device used in no-needle, no-scalpel vasectomy?

A. Ped-O-Jet
B. MadaJet
C. CrossJect
D. EuroJect

3. Syphilis facilitates the spread of HIV, increasing transmission of the virus at least:

A. two- to fivefold.
B. three- to sixfold.
C. four- to sevenfold.
D. five- to eightfold.

4. The cumulative number of AIDS cases in U.S. adults ages 50 years or older increased how much from 1990 to 2001?

A. From about 12,000 to 50,000
B. From about 14,000 to 70,000
C. From just more than 15,000 to about 80,000
D. From just more than 16,000 to about 90,000

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

(See the table from the upcoming 19th edition, p. 83. The figures quoted for the sponge are the same as those included in the Today sponge package insert.) Sixteen percent of nulliparous women and 32% of parous women are estimated to experience an unintended pregnancy during the first year of typical use of the sponge. ■

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™

Syphilis rate on the increase in gay, bisexual men in the U.S.

Stats show upswing in disease among men who have sex with men

Get ready to tackle a resurgence of syphilis among males who have sex with males (MSM). Results from a new study indicate that increasing syphilis cases among this population group account for most of the recent overall increase in national syphilis rates and may be a harbinger of increasing rates of HIV infection among MSM.[1]

In the new report, researchers assessed the epidemiology of primary and secondary syphilis in the United States and estimated the percentages of cases occurring among men who have sex with men. The researchers analyzed national syphilis surveillance data from 1990 through 2003, and they estimated numbers of cases occurring among MSM by modeling changes in the ratio of syphilis cases among men to cases among women.

What were the results? During 1990 through 2000, analysts found that the rate of primary and secondary syphilis decreased 90% overall, declining 90% among men and 89% among women. However, the overall rate increased 19% between 2000 and 2003, reflecting a 62% increase among men and a 53% decrease among women. In 2003, an estimated 62% of reported cases occurred among MSM, according to the researchers.

EXECUTIVE SUMMARY

Increasing syphilis cases among males who have sex with males (MSM) account for most of the recent overall increase in national syphilis rates and may be a harbinger of increasing rates of HIV infection among MSM, suggest data from a just-released report.

- During 1990 through 2000, analysts found that the rate of primary and secondary syphilis decreased 90% overall, declining 90% among men and 89% among women. However, the overall rate increased 19% between 2000 and 2003, which reflects a 62% increase among men and a 53% decrease among women.
- In 2003, an estimated 62% of reported cases occurred among MSM, the new data reflect.

Why the uptick?

Many factors may contribute to the increases in syphilis among MSM, such as prevention fatigue, substance abuse, and the use of the Internet to find sex partners, says **James Heffelfinger**, MD, MPH, a medical epidemiologist at the Centers for Disease Control and Prevention (CDC) and lead author of the new analysis. ***(Contraceptive Technology Update* reported on the use of the Internet for sex activity. See the article, "Internet is new frontier for risky sex activity," March 2001, p. 27.)** Treatment optimism related to the availability of highly active antiretroviral therapy (HAART) also may increase risky behavior, Heffelfinger notes.

Also look to such factors as increased use of

crystal methamphetamine resulting in unsafe sexual practices, says **Khalil Ghanem**, MD, assistant professor of medicine and associate fellowship program director in the Division of Infectious Diseases at Johns Hopkins University School of Medicine in Baltimore. **(Read more about the drug; see "Crystal methamphetamine use poses sexual health risks in women and men," *CTU*, June 2006, p. 61.)**

Sexual networks with high syphilis prevalence among MSM also may fuel the increase, says Ghanem. Those who have sex within those networks are likely to be exposed to the disease, he notes.

Get an overview

In 2005, syphilis cases increased for the fifth consecutive year. The disease's all-time low was registered in 2000, notes **Jennifer Ruth**, a CDC spokeswoman. While MSM accounted for most increases, increased vigilance also is needed when it comes to African-Americans and women, Ruth states.

In 2005, syphilis rates among blacks increased for the second consecutive year, following more than a decade of declines, states Ruth. Between 2004 and 2005, the rate among blacks per 100,000 population increased 1.4% (from 8.8 to 9.8), with the largest growth found among black men. Between 2004 and 2005, the syphilis rate among black males moved up 12.9% (from 13.9 to 15.7), while the rate among black women increased 4.8% (from 4.2 to 4.4).[2]

While disparities still exist, racial gaps in syphilis rates are narrowing, according to the CDC statistics. The rate of primary and secondary syphilis per 100,000 population in 2005 was 5.4 times higher among blacks than among whites; in contrast, in 1999, the comparable rate was 29 times greater between the two groups.[2]

While syphilis rates remain lower among women than men, keep an eye on increased infection rates among females, public health officials caution. 2005 saw the first increase among women in over a decade, Ruth states. Rates moved up 12.5% from 2004 to 2005 (from 0.8 per 100,000 population to 0.9). The growth was driven by increased rates among black women and Hispanic women (up from 0.7 in 2004 to 0.9 in 2005); rates among women in all other ethnic groups declined or remained stable, the CDC reports.[2]

All the news about syphilis is not so grim. Rates for congenital syphilis continue to decline, the CDC reports.[2] Rates fell 12% between 2004 and 2005, as they dropped from 9.1 per 100,000 live births to eight. What is affecting the decline? CDC analysts point to reduction in syphilis rates among women in earlier years and the ongoing contribution of prenatal screening programs.[2]

Stop the spread

Syphilis is caused by the bacterium *Treponema pallium*. Infection is transmitted from person to person through direct contact with a syphilis sore. While sores occur mainly on the external genitals, vagina, anus, or in the rectum, they also can occur on the lips and in the mouth. Syphilis often has been called "the great imitator" because so many of its signs and symptoms are indistinguishable from those of other diseases. Like many other STDs, syphilis facilitates the spread of HIV; it increases transmission of the virus at least two- to fivefold.[3]

In May 2006, the CDC released its updated *National Plan to Eliminate Syphilis* to take direct aim at syphilis elimination. The plan is designed to sustain efforts in populations traditionally at risk, including women and African-Americans, and to support innovative solutions to fight the resurgence of syphilis among MSM. The CDC also has updated its Syphilis Elimination Effort (SEE) tool kit, which is designed to help public health practitioners plan, manage, and develop syphilis elimination/prevention efforts. New information has been added for reaching MSM; providers may download *Screening and Testing Men who Have Sex with Men (MSM) for Syphilis — A Guide for Health Care Professionals*, by going to the CDC web site, www.cdc.gov/stopsyphilis, then clicking "SEE tool kit" and "Special Focus: MSM."

The reversal in syphilis trends in recent years is a significant public health concern, and effectively reaching men who have sex with men will be critical to success, says Heffelfinger. National efforts are under way to improve monitoring of syphilis trends, better understand factors associated with the observed increases, and improve efforts to prevent syphilis transmission, according to the new analysis. "We must continue to adapt to meet the new challenges brought on by syphilis," Heffelfinger states. **(Read about**

innovative programs; see the articles "'Healthy Penis' campaign targets syphilis risk," April 2007, p. 44, and "Use the Internet to stem the spread of STD," *STD Quarterly*, May 2005, supplement 1.)

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Focus on care of HIV-positive seniors

EXECUTIVE SUMMARY

New public health strategies must be developed to reach those who are living longer with HIV. According to a survey of 260 HIV-positive older adults conducted by Ohio University researchers, one out of three sexually active older adults infected with HIV reported unprotected sex.

- More people are living longer with HIV. The cumulative number of AIDS cases in adults ages 50 years or older jumped from 16,288 in 1990 to 90,513 by the end of December 2001, according to the Centers for Disease Control and Prevention.
- Researchers at Ohio University have received federal funding to nationally test the effectiveness of a telephone support group for older adults with HIV.

HIV isn't contained to one age bracket. Many patients diagnosed with HIV in the 1980s and 1990s have survived and now are entering their golden years. The cumulative number of AIDS cases in adults ages 50 years or older jumped from 16,288 in 1990 to 90,513 by the end of December 2001, according to the Centers for Disease Control and Prevention.[1]

With the increase in lifespan comes a need for new public health strategies. According to a survey of 260 HIV-positive older adults conducted by Ohio University researchers, one out of three sexually active older adults infected with HIV reported unprotected sex.[2] The Ohio University researchers are planning to develop risk reduction interventions for HIV-infected older adults, reports **Travis Lovejoy**, a graduate student who is jointly enrolled in the university's clinical health psychology doctoral program and its public health master's program.

Traditionally, HIV prevention efforts have targeted younger risk populations such as men who have sex with men and intravenous drug users, says Lovejoy, who led the survey research. "Few interventions have been adapted or created that are appropriate for older adults," he says. "Our intention is to design and test the efficacy of age-appropriate sexual risk reduction interventions for this population."

Researchers also plan to corroborate their findings with more detailed lines of sexual behavior questioning, states Lovejoy. "For example, though we know that illicit drug users are more likely to engage in unprotected sex, we are unable to determine from our data whether persons are 'under the influence' during or prior to their sexual encounters, thus impairing their decision-making processes," Lovejoy notes. "We hope to clarify these points in future research."

Why take risks?

Why do HIV-positive seniors choose to have unprotected sex?

Some HIV-positive seniors may practice safe sex most of the time; however, as with many people, there are rare occasions when condoms are not used, says **Timothy Heckman**, PhD, professor of psychology and presidential research scholar at Ohio University. Heckman recently received a $1.5 million, four-year grant from the National Institute of Mental Health and the National Institute of Nursing Research to nationally test the effectiveness of a telephone support group for older adults with HIV.

Some seniors may not use condoms during intercourse due to mutual agreement with their sexual partner; the HIV-seronegative sex partner may see having unprotected sex as the ultimate

sign of love and commitment, he states. Others may not use condoms because their sexual partners also are HIV-seropositive; this scenario is troublesome because risks are increased for the acquisition of other sexually transmitted diseases, such as syphilis or gonorrhea, states Heckman. For some older women, particularly those who are post-menopausal, concerns are no longer present when it comes to pregnancy, so they perceive little need to use condoms, he observes.

"Finally, many older adults living with HIV/AIDS have undetectable viral loads and, as a result, may believe that they are incapable of transmitting their HIV to others," says Heckman.

Reach out via phone

Younger people with HIV may have several available resources when it comes to support and education. Seniors, however, often may feel embarrassment when attending traditional AIDS support groups. Heckman, who has spent the past eight years conducting AIDS research among the elderly and in rural populations, sees the telephone as a viable tool for delivering support to this group. The telephone support group is meant to bring patients together for a 12-week coping intervention to improve quality of life, Heckman said. A small group of six to eight participants call in toll-free at a certain time each week. Two facilitators help generate discussion relevant to reducing depression and improving quality of life.

"A separate study we conducted of older adults found that support groups that are designed to teach them skills to handle stress, obtain social support, and cope more adaptively are more effective than brief therapy sessions initiated by the person or support groups where participants only discuss problems but do not receive what is called coping intervention treatment," Heckman says.[3]

Heckman now plans to expand the geographical scope of the original study and increase the number of participants. Nearly 400 participants of the project will be divided among three therapy models, ranging from a 12-week telephone-delivered support group with sessions designed to improve the participants' coping skills to less active therapy sessions in which participants receive individual guidance only upon request. The project began in August 2006 and will end in July 2010.

"If successful, the research will identify a telephone-delivered intervention that can improve life quality in HIV-infected older adults who might otherwise lack access to mental health support services due to geographic isolation, physical limitations, and confidentiality concerns," Heckman states. **(Read more about seniors and HIV; see the *STD Quarterly* article, "Senior citizens and HIV: Age is no defense when it comes to infection with AIDS," April 2006, supplement 1.)**

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Circle date for HIV prevention conference

Plan now to attend the 2007 National HIV Prevention Conference, scheduled for Dec. 2-5 in Atlanta.

The Centers for Disease Control and Prevention joins with other governmental and nongovernmental prevention partners in orchestrating the conference. The meeting provides opportunities to share effective prevention approaches and research findings among governmental, community, and academic partners in HIV prevention, as well as strengthens collaborations between program practitioners and researchers in areas including behavioral interventions, biomedical interventions, monitoring the epidemic, implementing rapid and reliable tests for early HIV diagnosis, and improving access to early treatment and prevention services for people with HIV.

Registration fee is $350 before Sept. 16, $400 before Nov. 8, 2007, and $450 for on-site registration only after Nov. 8. Participants may register online at the conference web site, www.2007nhpc.org. ■