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IN THIS ISSUE

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Teen birth rate rises for first time in 14 years — What lies behind the change?

It's time to redouble efforts to stem adolescent pregnancy. Preliminary birth statistics released by the Centers for Disease Control and Prevention indicate the U.S. birth rate rose by 3% between 2005 and 2006 among females 15-19 after dropping 34% between 1991 and 2005.[1]

According to the report, prepared by the National Center for Health Statistics, the birth rate for ages 15-19 rose from 40.5 live births per 1,000 females to 41.9 births per 1,000 in 2006. This increase follows a 14-year downward trend in which the teen birth rate fell by 34% from its all-time peak of 61.8 births per 1,000 in 1991.

The increase raises several important questions, says **Bill Albert**, deputy director of The National Campaign to Prevent Teen and Unplanned Pregnancy in Washington, DC. Why did the rate increase?" he asks. "Is the increase the beginning of a trend or a statistical anomaly, and, of course, what can be done to reverse the increase and continue to drive down rates of teen births?"

Throughout the 1990s, teen sexual activity in the United States decreased and contraceptive use improved, says **John Santelli**, MD,

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- Release of the new data has reignited debate about abstinence-only sex education programs, which receive about $176 million a year in federal funding.

MPH, professor and chair of the *Heilbrunn Department of Clinical Population and Family Health* and professor of clinical pediatrics at Columbia University in New York City. In an estimate of trends in use and nonuse of effective protection among adolescents from 1991-2003, analysts found that condom use increased significantly, from 46.2% in 1991 to 63% in 2003.[2] The percentage of teens reporting use of withdrawal or no method steadily declined, from 32.6% to 18.8%.[2]

However, an analysis of data from the 2005 Youth Risk Behavior Survey indicates a deterioration in contraceptive use, says Santelli.[3] For the very first time in almost 20 years, analysts saw a small decrease in condom use for young women, and they noted an increase in nonuse of birth control.

Complacency sets in?

Does the increase signal just an increase or the start of a trend? It does represent a reversal in the downturn of births among adolescents, observes **Anita Nelson**, MD, professor in the Obstetrics and Gynecology Department at the University of California in Los Angeles (UCLA) and medical director of the women's health care programs at Harbor-UCLA Medical Center in Torrance.

Complacency may have become the enemy of progress when it comes to lowering teen pregnancy rates, says Albert. Fourteen consecutive years of declines in the teen birth rate may have led to complacency and may have diverted attention, resources, and funding to other pressing issues, he observes. "The birth rate is up among women of *all* ages — women in their teens, 20s, 30s, and 40s — and among all racial and ethnic groups, which suggests that a broader set of forces may be at play," Albert notes.

Improvement in teen birth rates in the 1990s may have come as a result of an emphasis on condom use, heightened by concerns about HIV, observes Santelli. Today's teens may not see HIV in the same light and may not be as consistent in using protection, he notes.

Less contraceptive use?

In the United States, there were 441,832 teen births in 2006. Compare this number to 50,752 teen births in the United Kingdom for 2004 and 2,549 in the Netherlands for 2006.[3] For Santelli, who wrote an editorial for the online version of the British newspaper, *The Guardian*, the major behavioral difference between European and U.S. teenagers is better use of contraceptives among European adolescents. Rates of sexual activity are similar among the two groups, but European teens report a higher use of oral

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Editorial Questions

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

Editor: **Rebecca Bowers**.
Senior Vice President/Group Publisher: **Brenda Mooney** (404) 262-5403 (brenda.mooney@ahcmedia.com).
Associate Publisher: **Coles McKagen** (404) 262-5420 (coles.mckagen@ahcmedia.com).
Senior Managing Editor: **Joy Daughtery Dickinson** (229) 551-9195 (joy.dickinson@ahcmedia.com).
Senior Production Editor: **Nancy McCreary**.

contraceptives and use of the "Double-Dutch" method — simultaneous use of condoms and hormonal methods, states Santelli.[3]

"I think the problem is that we're a pretty anti-contraceptive society," Santelli comments. "To the Europeans, if you want to talk about responsibility as an adolescent, you talk about not getting pregnant and you talk about contraception," he says. "People are very open about that, and that is the social norm."

America as a society is much different, Santelli points out. The social norm promoted to teenagers may be more along the lines of "don't get a disease, and you shouldn't have sex anyway," he observes.

"I think in a society where sexuality is expected and understood and seen as normal, it's much easier for people to use contraception," Santelli comments. "I think we haven't gotten there yet."

Abstinence-only debated

Release of the new data has reignited debate about abstinence-only sex education programs, which receive about $176 million a year in federal funding.[4] Findings from a 2007 analysis of four abstinence-only education programs indicated that such programs do not keep teenagers 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.[5] **(*Contraceptive Technology Update* reported on the analysis in the article, "New data cast doubts on abstinence-only programs," July 2007, p. 75.)** A 2006 paper concludes there is no evidence base for providing "abstinence-only" or "abstinence-until-marriage" messages as a sole option for teenagers. The report finds abstinence-only programs demonstrate little evidence of efficacy in delaying initiation of sexual intercourse.[6]

In contrast, a new report released by the National Campaign to Prevent Teen and Unplanned Pregnancy showed that a growing number of sex education programs that support abstinence and the use of contraception for sexually active teens have demonstrated positive effects in delaying first intercourse, improving contraceptive use, and preventing pregnancy or sexually transmitted among teens.[7] Two-thirds of sex education programs examined in the National Campaign report that focused on abstinence and contraception had a positive effect on teen sexual behavior. None of the programs that discussed abstinence and contraception hastened the initiation of sex or increased the frequency of sex among adolescents.[7]

What is the next step?

What needs to happen in light of the new report? In the upcoming weeks, the National Campaign to Prevent Teen and Unplanned Pregnancy and others will try to determine what might account for the rise in the teen birth rate, says Albert.

"At the same time, we will redouble our own efforts to shine a spotlight on the importance of continuing to focus on teen pregnancy," states Albert. "We will also encourage colleagues nationwide to use this sobering news to intensify their own programs and outreach to policy-makers, practitioners, the press, parents, and, of course, teens themselves."

If you are a family planning clinician who is working with an adolescent population, don't let frustration cloud your efforts in helping teens make wise decisions about their reproductive health, says Santelli.

"People who work in family planning are primarily responsible for those big declines up until 2005," Santelli observes. "We saw birth rates drop by a third among teenagers and even higher among the younger teens, so people who have been doing this work, even though they're not getting rewarded, clearly were the people responsible for that decline."

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FDA issues warning for nonoxynol-9 products

Over-the-counter contraceptive products that contain the spermicide nonoxynol-9 (N-9) now will carry a warning label to alert consumers that such products do not protect against sexually transmitted diseases (STDs) and HIV/AIDS, following a final ruling by the Food and Drug Administration (FDA).

The move comes after the agency's January 2003 proposal to issue new warning statements and other labeling information for such products. The agency says the rule is being finalized following a public comment period and a thorough analysis of information and views from consumers, health care providers, academicians, and industry representatives.

The ruling comes as no surprise to *Contraceptive Technology Update* readers. Clinicians have been counseling patients on the ineffectiveness of N-9 against HIV since 2000, based on the results of microbicide research.[1] This message was reinforced again in 2002, when further research indicated that N-9 failed to protect against such STDs as urogenital gonorrhea and chlamydia.[2] **(Review the data in the article, "Nonoxynol-9 fails test as female microbicide," October 2000, p. 119, and "Nonoxynol-9 not protective against STDs," June 2002, p. 63. *CTU* reported on the FDA proposed labeling in the article "Labeling change: New warning proposed for nonoxynol-9 contraceptive drugs," March 2003, p. 25.)**

"FDA is issuing this final rule to correct misconceptions that the chemical N-9 in these widely available stand-alone contraceptive products protects against sexually transmitted diseases, including HIV infection," said **Janet Woodcock**, MD, FDA's deputy commissioner for scientific and medical programs, chief medical officer, and acting director of the Center for Drug Evaluation and Research in an announcement on the final ruling. "Clinical research has shown that N-9 provides no protection against sexually transmitted diseases to the woman if her sexual partner is infected with an STD pathogen or HIV."

The guidance is specifically aimed at over-the-counter (OTC) stand-alone vaginal contraceptive and spermicidal products such as gels, foams, films, or inserts. The new warning information includes the following language:

- For vaginal use only.
- Not for rectal (anal) use.
- Sexually transmitted diseases (STDs) alert: This product does not protect against HIV/AIDS or other STDs and may increase the risk of getting HIV from an infected partner.
- Do not use if you or your sex partner has HIV/AIDS. If you do not know if you or your sex partner is infected, choose another form of birth control.
- When using this product you may get vaginal irritation (burning, itching, or a rash). Stop use and ask a doctor if you or your partner get burning, itching, a rash, or other irritation of the vagina or penis.

Other information in the new labeling includes:

- Studies have raised safety concerns that products containing the spermicide nonoxynol 9 can irritate the vagina and rectum. Sometimes this irritation has no symptoms. This irritation may increase the risk of getting HIV/AIDS from an infected partner.
- You can use nonoxynol 9 for birth control with or without a diaphragm or condom if you have sex with only one partner who is not infected with HIV and who has no other sexual partners or HIV risk factors.
- When used correctly every time you have sex, latex condoms greatly reduce, but do not eliminate the risk of catching or spreading HIV, the virus that causes AIDS.
- Use a latex condom without nonoxynol 9 if you or your sex partner has HIV/AIDS, multiple sex partners, or other HIV risk factors.
- Ask a health professional if you have questions about your best birth control and STD prevention methods.[3]

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- The guidance is specifically aimed at over-the-counter stand-alone vaginal contraceptive and spermicidal products such as gels, foams, films, or inserts.
- It does not apply to condoms lubricated with N-9, which are primarily regulated as medical devices.

While the news on N-9 may not be new, reports about the new label warning may be of concern to couples who rely on spermicides for contraception, advises **Anita Nelson**, MD, professor in the Obstetrics and Gynecology Department at the University of California in Los Angeles (UCLA) and medical director of the women's health care programs at Harbor-UCLA Medical Center in Torrance. Clinicians may wish to recap the following message from *Contraceptive Technology* on spermicides: "Do not use spermicides to reduce risks of sexually transmitted diseases. Use male or female condoms for this purpose."[4]

How about condoms?

The final rule requiring warnings for all OTC vaginal contraceptives/spermicides containing N-9 applies to drug products, notes the FDA. It does not apply to condoms lubricated with N-9, which are primarily regulated as medical devices.

The agency issued draft guidance on condom labeling in 2005. Final ruling on the draft guidance has not been handed down yet. ***(CTU* reported on the proposed labeling in the article, "Condoms protect against herpes, study shows, February 2006, p. 18.)**

The draft guidance calls for retail packaging of latex condoms with N-9 to include a statement indicating "that the lubricant on the condom contains N-9, which kills sperm, but that the extent of pregnancy protection contributed by the N-9 has not been measured."[4] It also calls for packaging to include a statement that the N-9 in the product does not provide protection from HIV/AIDS or other sexually transmitted diseases.[5]

While some manufacturers have ceased manufacture of condoms of N-9, some brands continue to carry the spermicidal coating. A check of the retail web site www.condomania.com, yields eight choices: Beyond Seven, Life Styles Ultra Sensitive, Trojan Her Pleasure, Trojan Supra, Trojan Ultra Pleasure, Trojan Ultra Ribbed, Trojan Ultra Thin, and Trojan Very Sensitive.

Several organizations, including the Global Campaign for Microbicides and the San Francisco AIDS Foundation, have called for the removal of N-9 from condoms. If manufacturers will not remove N-9 from condoms, such groups are asking that the FDA require warning labels for condoms containing N-9.

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Analysis eyes abortion counseling requirements

Results from a new Guttmacher Institute analysis indicate that current state-mandated abortion counseling requirements often violate core principles of informed consent.[1] In 23 states where providers are required to give information in verbal or written form, such information often falls short of fundamental ethical principles due to inaccuracies or irrelevancy, the analysis reveals.

In the review, analysts found that written materials in 18 states include descriptions of abortion procedures performed after the first trimester of pregnancy, even though this information is irrelevant to the nine in 10 women who have an abortion during the first 12 weeks of pregnancy. In addition, four states (Idaho, Oklahoma, South Dakota, and

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- In 23 states where providers are required to give information in verbal or written form, such information often falls short of fundamental ethical principles due to inaccuracies or irrelevancy, the analysis reveals.
- Written materials in 18 states include descriptions of abortion procedures performed after the first trimester of pregnancy, even though such information is irrelevant to the nine in 10 women who have an abortion during the first 12 weeks of pregnancy. Four states use graphic descriptions of late-term procedures that attempt to steer women away from having an abortion, the analysis notes.

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Written counseling materials in six states (Alaska, Kansas, Mississippi, Oklahoma, Texas, and West Virginia) inaccurately assert that a link may exist between abortion and breast cancer, a claim that has been rejected by the National Cancer Institute (NCI) and thoroughly studied[2,3] ***(Contraceptive Technology Update* reported on the NCI's stand in the article, "No link found between abortion, breast cancer," May 2003, p. 55, as well as covered the results of a supporting meta-analysis, "Abortion, breast cancer not linked, data say," June 2004, p. 70.)**

In addition, when analysts looked at materials from South Dakota, Texas, Utah, and West Virginia, they found statements that assert that a woman undergoing an abortion may experience suicidal thoughts or suffer from "post-abortion traumatic stress syndrome," a disorder that is not recognized by major mental health organizations. "If you're going to mandate materials, and your point is that you want women to have true, informed consent, then this material needs to be accurate," says **Vicki Saporta**, president and CEO of the National Abortion Federation (NAF). "We believe that women should have access to all the accurate medical information that they need to make informed decisions about their pregnancies, and they can't do that if they are being given misleading information."

Check NAF materials

NAF's clinical policy guidelines are evidence-based and are based on known patient outcomes, says Saporta. The guidelines are reissued every year to reflect the most information, she states. *(Editor's note: Review the guidelines at the organization's web site, www.prochoice.org; click on "Professional Education," "Educational Resources," and "Clinical Policy Guidelines.")*

Obtaining informed consent and assessing that the decision to have an abortion is made freely by the patient are essential parts of the abortion process, explains Saporta. NAF guidelines uphold five standards:

- Accurate information must be provided regarding the risks and benefits of abortion.
- There must be documentation that the patient affirms that she understands the procedure and its alternatives, the potential risks, benefits and complications, that her decision is uncoerced, and that she is prepared to have an abortion.
- Women must undergo the abortion as expeditiously as possible in accordance with good medical practice.
- Birth control information must be available to patients at the facility.
- All reasonable precautions must be taken to ensure the patient's confidentiality.

NAF periodically reviews state mandates and regulations for accuracy when it comes to abortion policy, says Saporta. It will supply published documentation and other support material so that such mandates and regulations reflect accurate information. "Sometimes we have more success than other times in having them actually change the language of these materials so that they do in fact reflect accurate, evidence-based information," Saporta states.

Watch the language

Inaccurate or irrelevant information in state-mandated materials is problematic in light of the Supreme Court's recent decision in *Gonzalez v. Carhart* which gives deference to legislatures, rather than the weight of the evidence, in cases where there is medical disagreement on the potential consequences of abortion, according to the new analysis.[1,4] Some state legislatures may view the ruling as a green light to add information that may run counter to the principles of informed consent.

In the *Gonzales v. Carhart* opinion, Justice Anthony Kennedy states in his decision that women who have abortions come to regret their choices and consequently suffer from "severe depression and loss of esteem" — even though he cites no evidence in support of this claim, and, in fact, concedes there is "no reliable data to measure the phenomenon," notes **Eve Gartner**, JD, senior staff attorney with the Planned Parenthood Federation of America. In sharp contrast to Justice Kennedy's stance about the emotional effects of abortion, Justice Ginsburg's dissent makes it clear that the most credible medical and scientific evidence demonstrates that abortion does not cause mental health problems, notes Gartner.

"While nothing in Justice Kennedy's opinion alters the standard set out in the Supreme Court's 1992 *Planned Parenthood of Southeastern Pennsylvania v. Casey* decision that information required to be given to a woman seeking abortion is 'truthful and not misleading,' we fully anticipate that legislatures, relying on Justice Kennedy's words, will nonetheless push the envelope by attempting to pass laws

requiring that women seeking abortion be given unnecessary, ideologically motivated, and in some cases, inaccurate and deceptive information — all under the pretext of ensuring that women are informed about their decision," states Gartner. "Planned Parenthood Federation of America pledges to continue to fight for laws that ensure that our patients receive honest and accurate information about abortion and other reproductive health care services."

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Student health centers look for price relief

Tick off the contraceptive options now available at your clinic. If you are a provider at a university health center, chances are your list may be shorter than it was in 2007.

Why? When institutions of higher education no longer qualified for special reduced pricing for contraceptive supplies in 2007 as a result of changes in the federal Deficit Reduction Act (DRA), pharmaceutical companies began charging college and university health centers significantly higher rates. While some health centers were able to stockpile or stretch their supplies, many centers had to immediately revise their formularies to carry lower-priced options, says **Mary Hoban**, PhD, CHES, staff liaison for the American College Health Association (ACHA), which is monitoring the situation. **(*Contraceptive Technology Update* reported on the DRA changes in the article, "Student health centers scramble due to prices," April 2007, p. 40.)**

The pricing impact has hit centers in waves, notes Hoban. For institutions that had enough cash on hand in 2007 to stockpile existing contraceptive choices, providers initially were able to continue to offer contraceptive options at pre-legislation change prices. With stockpiled resources dwindling, centers have had to reformulate their formularies to offer lower-priced drugs, says Hoban. In the cases in which no generic equivalent is available, such as NuvaRing (Organon USA; Roseland, NJ) and Ortho Tri-Cyclen Lo (Ortho-McNeil Pharmaceutical; Raritan, NJ), use of such options has been dropped or severely curtailed. "I'm hearing from our providers that they are frustrated," states Hoban. "They feel like they are having to prescribe based on the cost, rather than what they think is the best product or medication for their patient."

Some centers are reporting upticks in requests for emergency contraception and pregnancy tests, while other facilities are reporting that women's health visits are down, Hoban states. Because some students may be foregoing hormonal contraception due to price increases, they may not be coming in for clinic visits, she surmises. A decline in patient visits results in less revenue, further impacting centers, says Hoban.

Student health centers aren't the only reproductive health clinics impacted by the legislative change. About one-quarter of Planned Parenthood Federation of America centers were extended the same type of nominal pricing. Under the old legislation, these clinics, as well as university health centers, were considered "safety net providers" and were extended the same type of nominal prices as those in the 340B Drug Pricing Program, run by the federal Office of Pharmacy Affairs. With the legislation change, however, 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" are qualified for such pricing.[1]

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College and university student health centers are being affected by higher contraceptive costs, due to changes enacted in 2007 following a revision in the federal Deficit Reduction Act (DRA).

- Because the health centers no longer qualify for special reduced pricing for contraceptive supplies as a result of changes in the DRA, pharmaceutical companies have begun charging significantly higher rates. Many centers have had to adjust their formularies in a variety of methods, including fewer options with and more generic oral contraceptives.
- Relief may be in sight in the form of companion bills, HR 4054 and S 2347, both termed the Prevention through Affordable Access Act.

Is relief in sight? Legislation in the form of companion bills, HR 4054 and S2347, both termed the Prevention through Affordable Access Act, have been introduced, says Hoban. The bills will make a technical correction to the DRA and restore safety net and university clinics' ability to access low-cost contraceptives. The bipartisan legislation will not cost the federal government or state Medicaid agencies any monies; it will merely allow drug manufacturers to offer deeply discounted prices to safety net health care providers, Hoban explains. ACHA is working behind the scenes with key legislators to help propel the legislation forward, she states.

While the legislation is in motion, one school has stepped in to help keep contraceptives affordable for its students. In response to student concerns, the president and provost of Princeton University have agreed to provide funds to subsidize the cost of oral contraceptives available at Princeton University Health Services (UHS), pending continued federal discussions about funding, says **Cass Cliatt**, university spokeswoman. "The university's subsidy is designed to restore the price of oral contraceptives currently offered at University Health Services for students to levels preceding the federal changes, and this began Dec. 1, 2007," she states. "On that date, birth control pills sold at UHS returned to being sold for $6 per pack, reduced from the $15 resulting from the federal changes."

The UHS ran out of brand-name oral contraceptives in March 2007 and began selling the generic brand Cryselle for $15 per pack that month and the generic brand Aviane for the same price in May 2007, says Cliatt. Cryselle (0.3 mg norgestrel and 0.03 mg ethinyl estradiol tablets) and Aviane (0.10 mg levonorgestrel and 0.02 mg ethinyl estradiol tablets) are manufactured by Barr Pharmaceuticals, Pomona, NY, and are the generic equivalents of Lo/Ovral and Alesse, both manufactured by Wyeth Pharmaceuticals, Madison, NJ.

To get out the news about the subsidy, UHS officials notified current student clients directly, as well as peer health educators on campus, the Women's Center, the Student Health Advisory Board, the Graduate School Government, and other student networks, says Cliatt. An announcement also was posted on the University Health Services web site, she states.

How much money is included in the subsidy? According to Cliatt, early estimates for the cost to the university come in at about $69,000. While university officials expect the cost to be significantly below this figure, they do not as of yet have a forecast to provide a final figure, she states. The subsidy is being supported through discretionary funding.

How has the university subsidy allowed the center to better serve students when it comes to contraception? "There were a number of students who voiced concern about losing access to affordable oral contraception as a result of the federal changes, and the university provided the subsidy to address these concerns," states Cliatt. "To be clear, the goal is not to introduce new products and subsidize oral contraceptives globally; rather, we are returning to the former status quo for the oral contraceptives the university already provides."

Clinicians at the health services continue to provide prescriptions for students who prefer to use brand-name contraceptives, says Cliatt. Students may use their prescription plans to help pay for them, she states.

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Sterilization update: More options to come?

What percentage of women choose sterilization as their contraceptive option in your practice? Chances are it is a significant proportion. According to the National Center for Health Statistics, 17% of all women ages 15-44 rely on female sterilization for birth control.[1] Along with the birth control pill, female sterilization has been one of the two leading methods in the United States since 1982.[1]

More providers are eyeing use of transcervical sterilization, which can be performed without an incision under local anesthesia, using a hysteroscope to locate the tubes. The Food and Drug Administration (FDA) approved Essure (Conceptus; Mountain View, CA) in 2002 as the first transcervical sterilization option. In July 2007, the U.S. regulatory agency approved the third-generation Essure system. Health Canada followed suit in November 2007. The new generation includes changes to the delivery system that reduce the number of steps a physician is required to perform during a placement procedure.

In a multicenter Phase II trial of the original Essure system, successful bilateral microinsert placement was achieved in 88% of women. Correct device placement was confirmed in 97%

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More providers are eyeing transcervical sterilization, which can be performed without an incision under local anesthesia, using a hysteroscope to locate the tubes.

- Essure has recently received approval for the third generation of its system. The new generation includes changes that reduce the steps during placement.
- Another transcervical option, Adiana, is under review by the Food and Drug Administration. As with Essure, it can be performed in an office setting using a hysteroscope.
- Both methods calls for hysterosalpingography after 12 weeks to determine tubal occlusion.

of cases at three months. After 6,015 woman-months of exposure to intercourse, no pregnancies had been recorded.[2]

Providers may soon see another transcervical sterilization option. In December 2007, the FDA's Obstetrics and Gynecology Devices Advisory Panel recommended approvable status for the pre-market application for the Adiana Permanent Contraception, developed by Hologic of Bedford, MA. While the agency is not required to accept the panel's ruling, it traditionally follows the recommendations of such advisory panels. The approval was given contingent upon several conditions, including long-term follow up of current trial patients, a new post-approval study of new patients and physicians, and more specific labeling recommendations.

According to **Ellen Sheets**, MD, chief medical officer for Hologic, the FDA will conduct an audit of the clinical trial and manufacturing system at Adiana. It then will consider the results of the audit along with the panel's recommendation. At press time, news regarding FDA action was expected in February 2008.

The Essure procedure involves the use of a soft microinsert that is placed into the fallopian tubes through the cervix using a hysteroscope. Once in place, the device is designed to elicit tissue growth in and around the microinsert to form an occlusion or blockage in the tubes over a three-month time period. A hysterosalpingography must be performed after 12 weeks to determine tubal occlusion. **(For a more detailed description of the system, see the article, "Women who want permanent birth control now have a second option," *Contraceptive Technology Update*, January 2003, p. 1.)**

A major advantage of Essure's third generation system of is its ease of use, says **Mark Levie**, MD, director of the Department of Obstetrics & Gynecology and Women's Health at Montefiore Medical Center in New York City. With the new system, physicians now have easier visual markers to cue them about proper device placement, says Levie, who presented data on the Essure system at the November 2007 American Association of Gynecological Laparoscopists conference.[3]

"There is no longer a need for the cumbersome movement of 10 counterclockwise turns to detach the device from the delivery catheter; this now occurs with the simple spin of a wheel on the handpiece," observes Levie. "Furthermore, the new system has a DryFlow introducer which prevents fluid from escaping through the operative channel, keeping the physician dry and the office clean."

Conceptus has developed resources available to new and experienced practitioners, says **Kristen Sargent**, a Conceptus spokeswoman. The company offers several resources for Essure practitioners, such hands-on training and demonstrations, and a web site, www.EssureMD.com, where providers can download training materials, procedure documents, and other information, she states.

The Adiana procedure can be performed utilizing local anesthesia in a physician's office. To perform the sterilization method, a catheter is positioned immediately inside the opening of the patient's fallopian tube using a hysteroscope. The catheter applies a low level of bipolar radiofrequency energy to remove a thin layer of cells inside the fallopian tube, then delivers an implantable, soft polymer matrix that remains within the prepared section of the tube. The procedure then is repeated on the other fallopian tube. A hysterosalpingogram is conducted at three months post-procedure to ensure the fallopian tubes are completely blocked and that the woman can begin relying on the method for permanent contraception.

Ted Anderson, MD, PhD, associate professor of obstetrics and gynecology at Vanderbilt University Medical Center and an investigator in Adiana's clinical trial, says the procedure is easy to learn, easy to perform, and well tolerated by patients.

In a multicenter prospective trial of the method, 604 women were enrolled, and 509 were brought to hysteroscopy after screening. A total of 499 women had attempted catheter placement, with bilateral success in 473 patients (94.8%). The observed one-year pregnancy prevention rate was 99.7%.[4] Because the nonmetallic implant remains fully outside the uterine cavity, advantages over other

systems may include easier insertion and future access to intracavitary diagnostic or therapeutic interventions, should they become necessary.[4]

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Microbicide news: Eyeing data on Invisible Condom

With results just published for a Phase I clinical trial and data for a Phase I/II trial in analysis, developers of what is being dubbed the Invisible Condom are looking toward initiation of a Phase III randomized controlled trial to test the safety and efficacy of the potential microbicide.[1]

Developed by researchers at the Infectious Diseases Research Centre at the Université Laval in Québec, the Invisible Condom offers a physical barrier in the form of a gel that blocks the entry of pathogens into the mucosa, and a chemical barrier, sodium lauryl sulfate, within the gel that kills sexually transmitted pathogens including HIV.[2,3] The Canadian research team also has designed a special applicator that delivers the product uniformly throughout the vagina and cervix. **(Review previous *Contraceptive Technology Update* news on the Invisible Condom. See "Get ready: Women to have more options for preventing disease," April 1999, p. 37, and "Progress under way on the microbicide front," January 2002, p. 5.)**

EXECUTIVE SUMMARY

With results just published for a Phase I clinical trial and data for a Phase I/II trial now in analysis, developers of what is being dubbed the Invisible Condom are looking toward initiation of a Phase III randomized controlled trial to test the safety and efficacy of the potential microbicide.

- The Invisible Condom offers a physical barrier in the form of a gel that blocks the entry of pathogens into the mucosa, and also a chemical barrier, sodium lauryl sulfate, within the gel that kills sexually transmitted pathogens including HIV.
- A special applicator delivers the product uniformly throughout the vagina and cervix.

The current published paper reports the results of a Phase I trial conducted among 41 women and 23 men in the Quebec City region. The trial was designed with three cohorts: sexually abstinent women applying gel twice daily for 14 days; sexually active women with tubal ligation applying gel once daily for 14 days and their sexual partners who did not use gel; and women on oral contraceptives applying gel once daily and their sexual partners. Women had to be healthy and be between ages 18-49. A follow-up was conducted following the 14 days of gel application.

No serious adverse events were reported during the trial, report the research team. Colposcopy examination showed no genital ulceration or epithelial lesions, and no major changes in vaginal flora or vaginal pH were detected. None of the women had to stop product application due to adverse events. Common side effects were itching, dryness, burning sensation, erythema, and discharge. Results of a satisfaction questionnaire showed that the gel and applicator were acceptable.[1]

A separate Phase I/II placebo-controlled trial has been conducted in Cameroon, says study coauthor **Rabeea Omar**, PhD, CCRP, an associate professor at the Université and project chief of its Infectious Diseases Research Centre. Results of the trial, conducted among 452 healthy women,

COMING IN FUTURE MONTHS

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■ Counseling tips for teens and the vaginal ring

■ FDA cracks down on custom-mixed hormones

■ Up the radar for antibiotic-resistant MRSA strain

■ Study finds link between bisphosphonates, bone necrosis

are in analysis, he reports. The research teams plans to publish the results upon analysis completion, says Omar. Funding is being sought for a Phase III trial; scientists hope to enroll 5,000 women in the Phase III study, says Omar.

Look for new developments on the microbicides front to stem from Microbicides 2008, scheduled for Feb. 24-27 in New Delhi, India. At press time, the Université Laval research team was scheduled to present a poster at the international conference.

Of special interest this year is the anticipated results of the large-scale efficacy trial of Carraguard, says **Anna Forbes**, MSS, deputy director of the Global Campaign for Microbicides, an international coalition of organizations working to accelerate access to new HIV prevention options. Carraguard, developed by the Population Council, is an odorless, tasteless, clear gel made from carrageenan, a derivative of seaweed.

More than 6,000 women were enrolled and randomly assigned to use Carraguard or a placebo gel an hour or less before each act of vaginal intercourse. The trial was conducted at three sites in South Africa: the Setshaba Research Centre, through the University of Limpopo/Medunsa campus; the Empilisweni Centre for Wellness Studies, through the University of Cape Town; and the Isipingo Clinic, through the Medical Research Council of South Africa. Data collection for the Phase III trial was completed in March 2007. **(For more information on the trial, see the article "Check advances made in microbicide development," *CTU*, May 2006, p. 58.)**

The year 2007 saw the cessation of two advanced trials of cellulose sulfate, which was eyed as a potential microbicidal candidate. One trial, 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. **(For a full report on the closing of the two trials, see "Research halted on cellulose sulfate microbicide — What's**

CNE/CME Instructions

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

CNE/CME Questions

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

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

9. According a report prepared by the National Center for Health Statistics, the birth rate for U.S. teenagers ages 15-19 rose by how many percentage points from 2005 to 2006?

A. 10%
B. 7%
C. 5%
D. 3%

10. Which over-the-counter contraceptive products containing the spermicide nonoxynol-9 will now carry a warning label to alert consumers that such products do not protect against sexually transmitted diseases and HIV/AIDS?

A. Gels, foams, films, and inserts
B. Condoms
C. Gels, foams, films, and condoms
D. Gels, foams, condoms, and inserts

11. The Adiana method of transcervical sterilization now under Food and Drug Administration review places what material in the fallopian tubes?

A. A microinsert
B. A soft polymer matrix
C. A clip
D. A Falope-Ring

12. What is the primary chemical barrier used in the Invisible Condom now in research?

A. Nonoxynol-9
B. Carrageenan
C. Sodium lauryl sulfate
D. Cellulose sulfate

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

next in research?" ***CTU,*** **April 2007, p. 37.)** How did this news affect microbicide development?

"I think that microbicide research is very much on track," observes Forbes. "I think what is really important for people to understand is that trials being stopped and products not working is absolutely par for the course in research into any new drug development."

With scientists continually learning more about how to test potential drugs, as well as identifying potential markers for safety and efficacy, the state of microbicides may well be at the same point as was seen with antiretroviral drugs in 1994, prior to proof of concept, says Forbes. "Once we know what works, it becomes much easier to look back and say, 'What reasonably can be considered to be the surrogate markers of this efficacy?'" states Forbes. "But right now, we are in the process of still having to look forward and not knowing what constitutes a marker, because we don't yet have proof of concept."

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