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New data on abstinence — What do they mean for teen pregnancy prevention?

U.S. teen pregnancy rate rose 3% in 2006 after decade of decline

Results from new research of a theory-based, abstinence-only intervention appear to be associated with a lower rate of sexual involvement among African American sixth- and seventh-graders.[1] How does the inclusion of these new data affect the landscape when it comes to teenage pregnancy prevention?

"State and communities now have a slightly larger and more diverse list of successful interventions to choose from in their attempts to help teens make more responsible decisions about sex and contraception," says **Sarah Brown**, CEO of The National Campaign to Prevent Teen and Unplanned Pregnancy in Washington, DC. "At a time when the teen pregnancy and birth rates are on the rise for the first time since the early 1990s, at a time when one of the nation's great success stories of the past two decades is in danger of unraveling, we need more proven options rather than fewer."

Publication of the abstinence education study follows the release of an analysis by the Guttmacher Institute that indicates that the nation's teen pregnancy rate rose 3% in 2006, reflecting increases in teen birth

EXECUTIVE SUMMARY

Results from new research of a theory-based, abstinence-only intervention appear to be associated with a lower rate of sexual involvement among African American sixth- and seventh-graders.

- The abstinence-only program in the current study does not meet the restrictive federal criteria for programs that, until 2010, have been eligible for federal abstinence-only-until-marriage funding.
- The new research appears just as the federal administration is eliminating federal financing for abstinence-only programs and starting a pregnancy-prevention initiative that will finance programs that have been shown in scientific studies to be effective.

and abortion rates of 4% and 1%, respectively.[2] The uptick reflects an increase following a decade of decline in such numbers.

"It is too soon to tell whether the increase in the teen pregnancy rate between 2005 and 2006 is a short-term fluctuation, a more lasting stabilization, or the beginning of a significant new trend, any of which would be of great concern," says **Lawrence Finer**, PhD, Guttmacher's director of domestic research. "Either way, it is clearly time to redouble our efforts to make sure our young people have the information, interpersonal skills, and health services they need to prevent unwanted pregnancies and to become sexually healthy adults."

Look at the data

To conduct the study, researchers enrolled 662 African American students in grades six and seven. The average age was 12.2 years; 53.5% were female. Participants were randomized to the following groups: an eight-hour abstinence-only intervention targeting reduced sexual intercourse; an eight-hour safer sex-only intervention targeting increased condom use; an eight-hour comprehensive intervention focusing on sexual intercourse and condom use; a 12-hour comprehensive intervention aimed at sexual intercourse and condom use; and an eight-hour health promotion control intervention targeted health issues unrelated to sexual behavior. Participants also were randomized to receive or not receive an intervention maintenance program to extend intervention efficacy. Researchers designed the primary outcome as self-report of ever having sexual intercourse by the 24-month follow-up.

At 24 months, 84.4% of the students still were enrolled in the study. Researchers report that the abstinence-only intervention reduced sexual initiation [risk ratio (RR), 0.67; 95% confidence interval (CI), 0.48-0.96]. The model-estimated probability of ever having sexual intercourse by the 24-month follow-up was 33.5% in the abstinence-only intervention and 48.5% in the control group. Fewer abstinence-only intervention participants (20.6%) than control participants (29%) reported having sexual intercourse in the previous three months during the follow-up period (RR, 0.94; 95% CI, 0.90-0.99). Abstinence-only intervention did not affect condom use. The eight-hour (RR, 0.96; 95% CI, 0.92-1.00) and 12-hour comprehensive (RR, 0.95; 95% CI, 0.91-0.99) interventions reduced reports of having multiple partners compared with the control group. No other differences between interventions and controls were significant.

The abstinence-only program in the current study does not meet the restrictive federal criteria for programs that until 2010, have been eligible for federal abstinence-only-until-marriage funding.[3] Its target behavior was "abstaining from vaginal, anal, and oral intercourse until a time later in life when the adolescent is more prepared to handle the consequences of sex," not abstinence until marriage.[1]

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According to a Guttmacher Institute review of the data, the program was not infused with morality, was medically accurate, and did not disparage contraception.[3] The intervention did not contain inaccurate information, portray sex in a negative light, or use a moralistic tone.[1] Its training and curriculum manual explicitly instructed the facilitators not to disparage the efficacy of condoms or allow the view that condoms are ineffective to go uncorrected.[1]

While the new abstinence-only research shows promise for one particular program, it does not contradict the body of evidence that abstinence-until-marriage programs are ineffective, the Guttmacher Institute review notes. Findings from a 2007 analysis of four abstinence-only education programs indicate that abstinence-until-marriage programs do not keep teens from having sex.[4] **(Review the analysis of the four programs; see the *Contraceptive Technology Update* article "New data casts doubts on abstinence-only programs," July 2007, p. 75.)** In that same year, the National Campaign to Prevent Teen and Unplanned Pregnancy released a comprehensive review of sex education evaluation research that concluded that "there does not exist any strong evidence that any abstinence program delays the initiation of sex, hastens the return to abstinence, or reduces the number of sexual partners."[5] Two reviews by the U.S. Government Accountability Office found that many of the curricula used by grant recipients for abstinence-only programs included false claims about condoms, other contraceptive methods, abortion, and sexually transmitted infections.[6,7]

The new research on abstinence-only education appears just as the current federal administration is eliminating federal financing for abstinence-only programs and starting a pregnancy-prevention initiative that will finance programs that have been shown in scientific studies to be effective.[8] **(See the *Washington Watch* column, "Advocates seek support for 'real' sex education," *CTU,* June 2009, p. 69.)**

The Obama administration has eliminated more than $170 million in annual federal funding targeted at abstinence programs. It has announced plans to launch a $114 million pregnancy prevention initiative that will fund only programs that have been shown scientifically to work, and it has proposed to expand that funding to $183 million.[9]

"The Obama administration is on the right track in funding only science-based programs with evidence of effectiveness," states a blog from Advocates for Youth, a Washington, DC, youth advocacy group.[10] "The administration should also consider how scarce resources are best invested and recognize the rights of all young people to complete, accurate, and honest information about their sexual health."

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Use research to minimize bone loss in DMPA users

Findings from a new study identify women at higher risk of significant bone loss on injectable birth control.[1] The study, conducted by researchers at the University of Texas Medical Branch at Galveston over two years, followed 95 users of DMPA (depot medroxyprogesterone

EXECUTIVE SUMMARY

Findings from a new study identify women at higher risk of bone loss on injectable birth control. Using logistic regression analysis, researchers determined that women who have not delivered a child, smoke, and do not consume much calcium in their diet are at risk for higher bone loss while using DMPA (depot medroxyprogesterone acetate). These women require additional counseling on how to decrease their risk of bone loss.

- The study followed 95 users of DMPA for two years.
- In that time, 45 women had at least 5% bone loss in the lower back or hip. Fifty women had less than 5% bone loss at both sites during the same period.

acetate; Depo-Provera, Pfizer, New York City; Medroxyprogesterone Acetate Injectable Suspension; USP, Teva Pharmaceuticals USA, North Wales, PA). In that time, 45 women had at least 5% bone mineral density (BMD) loss in the lower back or hip. Fifty women had less than 5% bone loss at both sites during the same period.

Using logistic regression analysis to examine predictive factors, researchers determined that women who have not delivered a child, smoke, and do not consume much calcium in their diet are at risk for higher bone loss while using DMPA. These women require additional counseling on how to decrease their risk of BMD loss to avoid putting their bone health at risk. The risk of higher BMD loss associated with DMPA use might be reduced by quitting smoking and increasing calcium intake; having had a child is also protective, researchers conclude.[1]

This study reports that BMD loss is not a significant concern for all women who choose DMPA for contraception because it is associated with certain risk factors. Those who had delivered a child, did not smoke, and consumed at least 600 mg a day of calcium did not lose more than 2% of their BMD at the spine or hip over 24 months. Thus, concerns about their bone health are minimal, the paper states.[1]

"Bone mineral density loss is not a significant concern for all women who choose DMPA," says senior author **Abbey Berenson**, MD, MMS, professor in the Department of Obstetrics and Gynecology and director of the Center for Interdisciplinary Research in Women's Health at the university. "Based on these findings, clinicians have the information they need to recommend basic behavior changes for high-risk women to minimize BMD loss."

DMPA continues as a top choice for birth control, particularly for adolescents, say respondents to the 2009 *Contraceptive Technology Update* Contraception Survey. **(To review a provider snapshot, see the article "Contraceptive injection: snapshot of providers," March 2010, p. 32.)**

In the current study, findings indicate BMD loss was higher in women who were current smokers, had never given birth, and had a daily calcium intake of 600 mg or less. The National Institutes of Health recommends that women ages 14-18 have a daily intake of 1,300 mg of calcium per day to maintain bone health, with 1,000 mg recommended for women ages 19-50.[2]

Researchers report BMD loss substantially increased among the women with all three risk factors. Age, race, ethnicity, previous contraceptive use, and body mass index were not associated with higher BMD loss, they found.

Twenty-seven women were followed for an additional year. Researchers found that those who experienced significant BMD loss in the first two years continued to lose bone mass. Co-author **Mahbubur Rahman**, MD, PhD, MPH, assistant professor in the Department of Obstetrics and Gynecology and Center for Interdisciplinary Research in Women's Health, says, "These losses, especially among women using DMPA for many years, are likely to take an extended period of time to reverse."

What can you do?

What can you do to help women preserve their bone health? Researchers in the current study reported that about 8.9% of the women using DMPA took calcium supplements at least four days a week, demonstrating that few young women of reproductive age understand the importance of adequate calcium consumption. (The National Institute of Arthritis and Musculoskeletal and Skin Diseases offers an easy-to-read, freely downloadable handout at its site, www.niams.nih.gov. Under "Health Information Index," select "B," then "Bone Health and Diseases," and "Bone Health." Under "Related Information," select "Bone Health for Life." **Also see the box item on p. 41 for sources of dietary calcium.)**

Also, take the opportunity to discuss smoking cessation programs in your area when counseling patients, researchers suggest. Review available medications that can assist with patients' efforts to

What Are Good Sources of Calcium?

- Tofu (calcium-fortified)
- Soy milk (calcium-fortified)
- Green leafy vegetables (e.g., broccoli, brussels sprouts, mustard greens, kale)
- Chinese cabbage or bok choy
- Beans/legumes
- Tortillas
- Sardines/salmon with edible bones
- Shrimp
- Orange juice (calcium-fortified)
- Pizza
- Bread
- Nuts/almonds
- Dairy products (e.g., milk, cheese, yogurt)

Source: National Institute of Arthritis and Musculoskeletal and Skin Diseases. Bone Health for Life. Fact sheet. Accessed at www.niams.nih.gov/Health_Info/Bone/Bone_Health/bone_health_for_life.asp#s.

quit. (The National Cancer Institute offers freely downloadable information sheets at its web site, www.cancer.gov. Under "Cancer Topics," select "Prevention, Genetics, Causes," then "Smoking Home Page," then "Quitting Tobacco: Challenges, Strategies, and Benefits." Select from such topics as "Why to Quit and How to Get Help" and "Enjoying Meals . . . Without Smoking.")

Prevention of bone loss while using DMPA is not well understood and remains an important topic for future research, say the authors of the current study. Research has examined using estrogen supplementation. For example, in a double-blind, placebo-controlled trial in women with a mean age of 37 years, findings suggest such supplementation can result in a 1% increase in spinal BMD per year among users of DMPA as compared with a 2.6% loss annually among those who did not take estrogen.[3] While such research suggests that low-dose estrogen supplementation can slow bone DMPA bone loss, the American College of Obstetricians and Gynecologists does not recommend such practice.[4] **(To review the organization's guidance on DMPA, see "New guidance underscores DMPA's safety, efficacy in long-term use," November 2008, p. 121.)**

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Research sheds light on HPV transmission

If your clinical practice includes care of college-age youth, you will want to review the results of a new study of university students. Why? Its findings indicate that more than half of young adults in a new sexual relationship were infected with human papillomavirus (HPV).[1] Among those infected, nearly half (44%) of infections were from an HPV type that causes cancer, the scientists report.[1]

Researchers at the McGill University, its Cancer Epidemiology Unit, and the Université de Montréal/Centre Hospitalier de l'Université de Montréal, all in Montréal, Canada, conducted the HITCH (HPV Infection and Transmission in Couples through Heterosexual Activity) Cohort Study to determine the prevalence of HPV infections among 263 recently formed couples. The scientists believe this is the first large-scale study of HPV infection among couples early in their sexual relationships when transmission is most likely.

EXECUTIVE SUMMARY

A new study of Montreal university students indicates that more than half of those in a new sexual relationship were infected with human papillomavirus (HPV). Among those infected, nearly half (44%) of infections were from an HPV type that causes cancer.

- Study results indicate there is a high probability of HPV transmission between partners. Researchers found 583 type-specific HPV infections among 169 couples for whom at least one partner was infected. Of these, 42% were of the same type for both partners.
- The scientists believe this is the first large-scale study of HPV infection among couples early in their sexual relationships, when transmission is most likely.

Participants in the study are young women attending university or junior college in Montreal, Quebec, and their male partners, with new couples defined as those who have been together for six months or less. Study participants fill out questionnaires regarding their sexual history and provide genital specimens for laboratory testing for the presence of 36 HPV genotypes. Recruitment for the study is continuing.

Current study results indicate there is a high probability of HPV transmission between partners. Researchers found 583 type-specific HPV infections among 169 couples for whom at least one partner was infected. Of these, 42% were of the same type for both partners. Results suggest that the presence of HPV in one partner was the strongest predictor of finding the same HPV type in the other partner.[1]

How might clinicians in reproductive health settings include the findings of this recent paper in their clinical practice when it comes to care of young adults? "In our HITCH study, more than half — 56% — of all participants were infected with at least one HPV type, almost half — 44% — were infected with an HPV type that causes cancer, and our results suggest that HPV is an easy virus to get and transmit," says **Ann Burchell**, PhD, the project coordinator and a postdoctoral fellow at the Cancer Epidemiology Unit. "For me, the take-home message is that all young people should expect that they will be exposed to HPV."

Getting the HPV vaccine and employing safer sex practices, such as using condoms, will help to reduce young adults' chances of getting infected, says Burchell. "Most importantly, we should educate all women about the importance of cervical cancer screening throughout adulthood and emphasize that you don't need to have had many partners to be at risk," Burchell says.

Screening programs key

How do the findings of the current study underscore the importance of prevention programs for HPV-associated diseases such as cervical cancer screening and HPV vaccination?

The HITCH study examines early events related to the natural history of HPV infection, observes study leader **Eduardo Franco**, DrPH, professor of epidemiology and oncology director in the Division of Cancer Epidemiology at McGill University. The fact that researchers found such high rates of HPV infection in young couples underscores how common the virus is and how inconsequential these infections are at this young age, he states. The vast majority of HPV infections will be effectively cleared by the immune system by the time young adults reach age 25 or 30. However, the concern exists for a few women whose infections with the high-risk types of HPV become persistent, Franco notes. These women might develop cervical precancerous abnormalities, which if left undetected and untreated, might progress to cervical cancer, he states.

Screening with the Pap test permits detecting these abnormalities, which prompts treatment and eventually eradicates the lesions, says Franco. Testing for HPV, using clinically validated assays, might in the future replace or serve as an adjunct to Pap test screening, notes Franco. This testing might improve the efficiency and accuracy of cervical cancer screening in the future. In developing countries, HPV testing also might help improve coverage, while requiring less stringent quality assurance than Pap cytology in screening programs, states Franco.

Put prevention first

The effectiveness of screening notwithstanding, preventing HPV infection from happening in the first place is a more attractive goal, says Franco. HPV vaccination prior to first sexual exposure, as has been recommended, has been proven effective in reducing risk of infections with the two main genotypes that can cause cervical cancer, HPV 16 and 18, and in the case of the quadrivalent vaccine, two types that cause genital warts, HPV 6 and 11.[2] These four types of HPV are relatively common and represent a substantial proportion of the infections in the HITCH study, observes Franco.

Screening will have to continue, says Franco. Although the available vaccines can prevent up to 75% of cervical cancers, women who have been vaccinated still can develop infections with high-risk HPV types other than those present in the vaccines, he states. "There is much ongoing research that is attempting to find the most cost-effective strategies for screening in the post-HPV vaccination era," says Franco. "Our group is also conducting research in this area, exploring the most promising technologies and their combinations."

Consistent condom use also is important in disease prevention. Previous research indicates that consistent condom use offers protection against high-risk and low-risk types of HPV.[3] **(See the article "Condoms protect women against HPV infection," *CTU*, September 2006, p. 101.)**

Researchers in the current report that frequent condom use was protective in men, particularly if his partner was HPV-infected [odds ratio (OR) = 0.64, 95% confidence interval (CI): 0.50-0.82]. This effect was less so among women with an infected partner (OR = 0.88, 95% CI: 0.69-1.11).[1]

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Science explores new contraceptive pathways

Family planning clinicians are familiar with the hormones that regulate human reproduction. Research has identified a new hormone that suppresses reproduction, which opens the door to possible development of a new class of contraceptive.[1]

The hormone, gonadotrophin inhibitory hormone (GnIH), has the opposite effect from gonadotrophin-releasing hormone (GnRH), a key reproductive hormone. While GnRH triggers a cascade of hormones that prime the body for sex and procreation, GnIH halts the process.

GnIH was discovered in 2000 in quail and has been studied in other birds, as well as in mice and in sheep.[2] Scientists have been challenged to identify its role in humans. While the human genome contains the gene for GnIH, scientists have not been sure when and where the protein hormone is produced and whether it affects reproduction.

In the current research paper, neuroscientists at the University of California, Berkeley extracted two versions of the hormone from human brains. Findings indicate the hormones are present in the hypothalamus region of the brain, the area that controls reproduction, and affect nerve cells that secrete GnRH. Based on their findings, the scientists believe the hypothalamus and pituitary — two key parts of the reproductive axis in the brain — have receptors for the hormones.[1]

GnIH pushes the pause button on reproduction, but in a variety of ways, says **George Bentley**, PhD, assistant professor of integrative biology at the university and a co-author of the study. It can act on GnRH neurons in the hypothalamus and inhibit GnRH release; it can act directly on pituitary; or it can influence the gonads directly. The overall effect is to inhibit reproduction, but at different levels of the reproductive axis, he notes.

The identification of a hormone in humans that inhibits reproduction opens the door to possible contraceptive development; however, researchers have a long way to go, notes Bentley. Berkeley scientists continue to investigate how GnIH acts in humans, as well as in starlings and zebra finches.

EXECUTIVE SUMMARY

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- The hormone, gonadotrophin inhibitory hormone (GnIH), has the opposite effect from gonadotrophin-releasing hormone (GnRH), a key reproductive hormone. While GnRH triggers a cascade of hormones that prime the body for sex and procreation, GnIH halts the process.
- In other contraceptive news, scientists have concluded a dose-finding Phase II trial for a contraceptive gel containing the progestin Nestorone and estradiol.

Gel study moves forward

In other news, progress has been reported in research of a novel contraceptive gel containing the progestin Nestorone and estradiol that uses an advanced transdermal delivery system. Scientists have concluded a dose-finding Phase II trial for the gel, which is being developed by Antares Pharma of Ewing, NJ, and the Population Council, based in New York City. The patented transdermal delivery system is used in another Antares Pharma product, Elestrin, which is used as hormone replacement therapy (HRT) in postmenopausal women. **(See "Research to examine new contraceptive gel," *Contraceptive Technology Update,* February 2009, p. 15.)**

Scientists designed the current research as a dose-finding, open-label, crossover study to evaluate the effect of the transdermal gel on ovulation suppression in normal women of fertile age. Eighteen women participated in the trial, which took place in three sites: Los Angeles; Santo

Domingo, Dominican Republic; and Santiago, Chile. Each woman completing the study received each of the three doses of the gel for 21 days, separated by a washout month in which no products were administered, which allowed the women to return to normal ovulation.

Research was focused on determining the lowest acceptable dose of the gel to achieve ovulation suppression, as measured by progesterone levels and ultrasound evaluation of follicular development. Scientists also looked at determining the plasma profile of estradiol and the evaluation of bleeding patterns, as well as examined the gel's general safety and tolerability. "We have demonstrated that the transdermal gel combining Nestorone and estradiol is able to suppress ovulation at all doses tested, and we determined the dose that gave the most stable levels of hormones to the subjects," says **Régine Sitruk-Ware**, MD, executive director for research and development in the Population Council's reproductive health program. "Most women who participated in the study found the gel very easy to use and convenient."

Antares Pharma and the Population Council look to partner with a worldwide or regional pharmaceutical company to take the contraceptive gel to full commercial development. **Dario Carrara**, PhD, Antares senior vice president and managing director and the inventor of the ATD system, says, "The advantage of using transdermal delivery has been seen with HRT products where recent studies have shown a reduced side-effects profile when compared to orally administered products. The system offers a patient-friendly, fast-drying, and cosmetically appealing gel product that can be easily applied daily."

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More data emerge on emergency contraception

For women who request emergency contraception, ulipristal acetate might be an effective alternative to levonorgestrel, according to results of a new study.[1] Manufacturers are seeking U.S. approval of the drug.

Watson Pharmaceuticals of Corona, CA, and HRA Pharma of Paris have announced an exclusive licensing agreement for Watson to become the commercial partner for ulipristal acetate, now marketed by HRA Pharma in Europe as ellaOne. **(*Contraceptive Technology Update* reported on the drug in the article "Options now eyed in emergency contraception," March 2010, p. 29.)**

The drug is now at the New Drug Application stage with the Food and Drug Administration. Manufacturing officials are hopeful that the agency will act on the application in 2010, says **Patty Eisenhaur**, Watson's vice president of investor relations and corporate communications.

Review the findings

For the current study, researchers at 35 family planning clinics in the United Kingdom, Ireland, and the United States enrolled women with regular menstrual cycles who presented requesting emergency contraception within five days of unprotected sexual intercourse. To conduct the randomized, multicenter, noninferiority trial, a total of 2,221 women were randomly assigned to receive a single, supervised dose of 30 mg ulipristal acetate (n = 1,104) or 1.5 mg levonorgestrel (n = 1,117). Follow-up was done five to seven days after expected onset of next menses.

Scientists designated the primary endpoint as

EXECUTIVE SUMMARY

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- Watson Pharmaceuticals of Corona, CA, and HRA Pharma of Paris have announced an exclusive licensing agreement for Watson to become the commercial partner for ulipristal acetate, now marketed by HRA Pharma in Europe as ellaOne.
- In a noninferiority trial of ulipristal and levonorgestrel, researchers report the most frequent adverse event as headache [ulipristal acetate, 213 events (19.3%) in 1,104 women; levonorgestrel, 211 events (18.9%) in 1,117 women].

pregnancy rate in women who received emergency contraception within 72 hours of unprotected sexual intercourse, with a noninferiority margin of 1% point difference between groups (limit of 1.6 for odds ratio). Analysis was done on the efficacy-evaluable population, which excluded women lost to follow-up, those over age 35, women with unknown follow-up pregnancy status, and those who had re-enrolled in the study. Researchers also used a meta-analysis of the trial and an earlier study to assess the efficacy of ulipristal acetate compared with levonorgestrel.[2]

In the efficacy-evaluable population, 1,696 women received emergency contraception within 72 hours of sexual intercourse; 844 women received ulipristal acetate, while 852 received levonorgestrel. Researchers recorded 15 pregnancies in the ulipristal acetate group [1.8%, 95% confidence interval (CI) 1.0-3.0] and 22 in the levonorgestrel group [2.6%, 1.7-3.9; odds ratio (OR) 0.68, 95% CI 0.35-1.31]. In the 203 women who received emergency contraception 72-120 hours after sexual intercourse, there were three pregnancies, all which occurred in the levonorgestrel group.

Researchers report the most frequent adverse event was headache [ulipristal acetate, 213 events (19.3%) in 1,104 women; levonorgestrel, 211 events (18.9%) in 1,117 women]. Two serious adverse events were judged as possibly related to use of emergency contraception: a case of dizziness in the ulipristal acetate group and a molar pregnancy in the levonorgestrel group.

In the meta-analysis, scientists recorded 22 (1.4%) pregnancies in 1,617 women in the ulipristal acetate group, and 35 (2.2%) pregnancies in 1,625 women in the levonorgestrel group (OR 0.58, 0.33-0.99; p = 0.046).[1]

How do they compare?

For women who presented on the fourth or fifth day after sexual intercourse in the trial, ulipristal acetate provided significant prevention of pregnancy, whereas levonorgestrel did not, the scientists state. Unlike levonorgestrel, ulipristal acetate is licensed for use beyond 72 hours and up to 120 hours, they state.

In looking at the two drugs, researchers note that the safety of levonorgestrel has been proven by its use by millions of women in a variety of formulations and doses, and so it can be made available without prescription. Although ulipristal acetate possibly could be made available from pharmacies and nurses, it cannot be made as easily accessible as levonorgestrel until there are more safety data, they note.

Progesterone-receptor modulators, including ulipristal acetate, given at high or repeated doses have an effect on endometrial histology and histochemistry that could theoretically impair implantation of a fertilized oocyte, note researchers.[3,4] "Although an endometrial effect, and therefore an additional postovulatory mechanism of action, cannot be excluded, the dose of ulipristal acetate used in this trial was specifically titrated for emergency contraception on the basis of inhibition of ovulation and might be too low to inhibit implantation," they state.

Research demonstrates no decrease in pregnancies over time in women who have used a levonorgestrel emergency contraceptive pill,[5,6] notes **Robert Hatcher**, MD, MPH, professor of gynecology and obstetrics at Emory University School of Medicine in Atlanta. The more effective ulipristal acetate pill would be a positive improvement in the options clinicians can offer women after unprotected sex; however, the real problem is that women who need emergency contraception once are likely to need it multiple times in the course of a year, Hatcher notes.

"In my opinion, our entire approach to emergency contraception should shift from emergency contraceptive pills to emergency insertion of a copper or levonorgestrel intrauterine device," Hatcher states.

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See how to increase care for HIV-positive women

HIV-positive women have a much higher risk of developing cervical and uterine cancers than do women without the disease, due to their impaired immune function.[1] However, many women with HIV do not receive necessary cancer screening due to a reluctance to seek care or other barriers such as psychosocial factors.

One program has stepped up its care by integrating gynecologic care into overall HIV management. The Christiana Care Health Services HIV Program, based in Wilmington, DE, has implemented a weekly women's clinic, where HIV-infected patients can receive necessary screening, such as Pap tests, as well as pregnancy management and contraceptive/reproductive counseling in a comfortable setting.

Numbers for the women's clinic have risen from 178 in 2008 to 380 in 2009, according to **Arlene Bincsik**, RN, MS, CCRC, ACRN, program director. To meet the increased demand, the clinic has been expanded to include two days per month at one of the program's southern satellite clinics in Smyrna and has added an additional half day per week at the program's main site in Wilmington.

The program has increased cervical cancer screening rates, which in turn has led to the identification and treatment of many cervical cancer cases. More than half of HIV program patients receiving a Pap test in the first 10 months of the women's clinic had abnormal results; of these patients, 60% have received colposcopy and follow-up care at the Christiana Care Women's Health Clinic.

Before the implementation of the women's clinic, 90% of the women seen in the Christiana Care HIV Clinic were referred annually for routine Pap tests, yet less than 10% actually followed through with the screening. Many women, especially working, single mothers, found it difficult to make the time for appointments, as well as arrange transportation, clinic officials say. Others might have been reluctant to reveal their HIV-positive status to outside gynecologic providers, they note.

To operate the women's clinic, officials have allocated funding for an obstetrician/gynecologist who works one-half day per week, as well as a full-time nurse practitioner and nurse, who devote 50% of their time to direct gynecologic patient care and the other 50% to the HIV primary care clinic. Program expenses include labor; equipment such as a colposcope, ultrasound machine, and associated tools; and disposable gynecologic care supplies. The equipment cost about $45,000.

"We have all seen women who have developed cervical cancer, so we are all very committed to prevention," says Bincsik. "This is particularly true of my nurse practitioners, who are very willing to do pelvic exams and Pap [tests] during routine clinical visits."

Two of the program's nurse practitioners have become certified to do on-site colposcopies to follow up on abnormal results, says Bincsik. She also notes the leadership provided by clinic medical director Lisa Phillips, MD, who has demonstrated commitment to quality patient care and is involved in the program's implementation and evaluation.

How does it work?

To schedule clinic visits, HIV program nurses review patients' medical records before each physi-

EXECUTIVE SUMMARY

The Christiana Care Health Services HIV Program, based in Wilmington, DE, has implemented a weekly women's clinic, where HIV-infected patients can receive necessary screening, such as Pap tests, as well as pregnancy management and contraceptive/reproductive counseling in a comfortable setting.

- HIV-positive women have a much higher risk of developing cervical and uterine cancers than do women without the disease, due to their impaired immune function.
- Many women with HIV do not receive necessary cancer screening due to a reluctance to seek care or other barriers such as psychosocial factors.

COMING IN FUTURE MONTHS

- How to reach Hispanic patients with HIV prevention message
- Microbicides: What is on the horizon?
- Review the noncontraceptive benefits of hormonal contraceptives
- HPV vaccination: What have we learned?
- Check new STD point-of-care tests

cian visit to determine whether certain components of preventive gynecologic care are needed, including annual cervical cancer screening. If a screening has not been done in the past year, the nurse asks the patient if she has obtained screening elsewhere or if she would like an appointment at the weekly clinic. If the patient desires an appointment, the front office staff schedules the next HIV appointment for a Friday morning so that HIV care can be provided in conjunction with a gynecological exam. Patients receive a reminder call from a peer educator one or two days in advance of the appointment.

Women who attend the clinic are provided with a routine gynecology exam, including a pelvic exam and Pap test; an evaluation for sexually transmitted diseases; education on breast health, mammography, and breast self-exam; and family planning services, including birth control and education on reproductive health and safe sexual practices including condom use, based on a standardized treatment protocol. Women who attend gynecology appointments also receive a goodie bag with small soaps, shower gels, and other products.

Other health professionals are involved in the weekly clinic. A clinical social worker is available to address patients' psychosocial needs, while a female peer educator is available in the waiting room to provide comfort and support. Transportation to the clinic is provided, if needed.

To provide follow-up care for those with abnormal findings, the gynecology nurse telephones patients with abnormal Pap smear results to schedule an on-site colposcopy. If results suggest the need for more comprehensive follow-up care, patients are referred to Christiana Care's Women's Health Center, where the women's clinic physician is on staff and can provide or coordinate necessary care.

The Christiana Care HIV Program, as a Ryan White Part D grantee, supports the provision of family-centered care to HIV-infected women who are pregnant, abusing drugs, have advanced HIV disease, or have mental illness. The women's clinic program was developed in response to research indicating that many women referred for cervical cancer screening did not obtain that screening. The on-site clinic now allows women to easily and sensitively access needed services.

"We are very pleased with the clinical outcomes associated with this program and feel that it truly meets the needs of our patient community," says Bincsik.

(Continued on page 48)

CNE/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;
- **provide** practical information that is evidence-based to help clinicians deliver contraceptives sensitively and effectively.

13. In the research study by Rahman M, et al. *(Obstet Gynecol* 2010; 115:35-40), bone loss was higher in women who were:

A. current smokers, had never given birth, and had a daily calcium intake of 600 mg or less.
B. current smokers, new mothers, and had a daily calcium intake of 600 mg or less.
C. prior hormonal contraceptive users and current smokers.
D. current smokers, had never given birth, and had a high body mass index.

14. What is the hormone described in the following research paper by Ubuka T, et al. *(PLoS One* 2009; 4:e8400)?

A. Gonadotrophin-releasing hormone
B. Gonadotrophin inhibitory hormone
C. Follicle-stimulating hormone
D. Luteinizing hormone

15. Ulipristal acetate is:

A. a cyclooxygenase-2 (COX-2) inhibitor.
B. a nonsteroidal anti-inflammatory drug.
C. a selective progesterone receptor modulator.
D. an antifibrinolytic agent.

16. Which three sexually transmitted infections are many teenage girls likely to acquire within two years of becoming sexually active, according to the following study by Tu W, et al. *(Arch Pediatr Adolesc Med* 2009; 163:1,106-1,111)?

A. Syphilis, gonorrhea, or trichomoniasis
B. Chlamydia, syphilis, or trichomoniasis
C. Chlamydia, gonorrhea, or bacterial vaginosis
D. Chlamydia, gonorrhea, or trichomoniasis

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

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CNE/CME Instructions

Physicians and nurses participate in this continuing nursing 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. ■

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™

STD alert: 50% of urban teen girls acquire STDs within 2 years of first sexual activity

Repeat infection common, 25% reinfected within 6 months of treatment

Half of urban teenage girls may acquire at least one of three common sexually transmitted diseases (STDs) — chlamydia, gonorrhea, or trichomoniasis — within two years of becoming sexually active, according to results of a recent study.[1]

Researchers at the Indiana University School of Medicine and Regenstrief Institute, both in Indianapolis, followed 381 females enrolled at ages 14-17 in three inner-city adolescent medicine clinics. At enrollment, teens completed a questionnaire and an interview to establish lifetime and recent sexual behaviors, as well as lifetime STD history, and were tested via cervical and vaginal specimens. Study participants returned for follow-up every three months for interviews and testing. In alternating quarters, they were instructed to complete daily behavioral diaries and submit weekly self-administered vaginal swabs for STD testing.

By age 15, 25% of the women acquired their first STD, with chlamydia the most common first infection, researchers found. Depending on the organism, within four to six months after treatment of the previous infection, a quarter of the women were reinfected with the same organism, says **Wanzhu Tu**, PhD, associate professor of medicine at the Indiana University School of Medicine and a Regenstrief Institute investigator.

Within two years, about 75% of participants with an initial STD were diagnosed with a second infection, although not necessarily of the same type. Within four years of an initial infection, 92% of the participants had a subsequent STD, researchers found. "To our knowledge, this study provides the first data on the timing of the initial sexually transmitted infection [STI] and subsequent STI following the onset of sexual activity in urban adolescent women," says Tu.

As a result of their findings, the Indiana researchers call for STI screening in sexually active teenage girls within a year after first intercourse

EXECUTIVE SUMMARY

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- Depending on the organism, within four to six months after treatment of the previous infection, a quarter of the women were reinfected with the same organism.

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and for retesting of infected females every three to four months. Continuing surveillance might be necessary due to the continuing high risk of infection, even if the first rescreening test result is negative, they conclude.[1]

When to start screening?

In your practice, when do you begin screening teens for STDs? Researchers in the Indiana study found that STD screening might not be initiated until several years after sexual activity begins, especially for girls with earlier onset of sexual activity.[1]

The U.S. Preventive Services Task Force recommends screening all women younger than age 25 years for chlamydia and gonorrhea.[2,3] The Centers for Disease Control and Prevention suggests annual chlamydia screening for sexually active women within one year of first sexual intercourse and gonorrhea screening for women at increased risk until age 26.[4] **(See "Spotlight on chlamydia: Boost your screening rate in young women, "*Contraceptive Technology Update*, August 2007, p. 85, and "Task force issues new gonorrhea guidelines," *CTU*, January 2006, p. 7.)** However, neither group has made evidence-based recommendations on the most appropriate starting age and the most appropriate frequency of screening, the Indiana researchers note.[1]

Some clinicians might be reluctant to address sexual activity with younger teens when it comes to STD prevention. This reluctance must be overcome, says **Dennis Fortenberry**, MD, MS, professor of pediatrics at the Indiana University School of Medicine and senior author of the current study. Discussions about sexuality and sexual activity between adolescents and clinicians gives clinicians information needed to accomplish all of the activities of a clinic visit: education, reassurance, diagnosis and treatment, prevention and, when necessary, referral, he notes. Discussions of sexuality and sexual behavior not only will identify adolescents with needs for STD screening or contraception, but also might identify those with questions about sexual orientation, normal development, or sexual violence, Fortenberry observes.

"Establishing an empathetic relationship where confidential matters may be discussed with an objective, knowledgeable person is the cornerstone of all clinician-patient relations," says Fortenberry. "This applies to adolescent patients as well as adults."

Why might clinicians be reluctant to address issues of sexuality and sexual activity? Fortenberry points to several sources: clinicians' personal discomfort with sexual issues, perceived lack of training and expertise, perception that parents will be offended if such issues are addressed, and perception that adolescents will not be honest in response to a clinician's inquiry about sex.

"None of these serve as a sufficient reason to omit this aspect of a clinical encounter with adolescents," Fortenberry states.

Let's talk about sex

When taking an adolescent sexual history, educate and empower to facilitate behavior change, says **Yolanda Wimberly**, MD, MSc, assistant professor of clinical pediatrics at the Morehouse School of Medicine in Atlanta. Wimberly spoke on providing reproductive health care to teens at the 2008 *Contraceptive Technology* Quest for Excellence conference in Atlanta.[5]

Use motivational interviewing. Ask teens if they think their behavior is risky and what they can do to change it, she says. Meet teens where they are, and empower them to make the changes they want. Avoid lecturing, and be clear in your counseling, Wimberly advises. Ask teens if they understand or quiz them on what you just counseled. Help teens set goals for change, she states.

In questioning teens about sexual behavior, she lists the following "do's": assure confidentiality; explain why you are asking sensitive questions; and ask the teen to describe specific sexual behaviors and contraceptive practices.

What are some approaches to avoid? Wimberly notes the following "don'ts":[5]

- Don't ask, "Are you sexually active?"
- Don't use gender-biased pronouns when referring to sexual partners.
- Don't use judgmental language.
- Don't use slang unless the teen uses it first.

To assess sexual behavior, the following questions may be asked:

- How old were you when you first had voluntary sex?
- What was the date of your last intercourse?
- Do you have a current partner? How long have you been with your partner?
- How many sexual partners have you had?

• How many sexual partners have you had in the past three months?[5]

Help teens to understand the scope of STDs in their age group. Results of a 2008 study indicate that 26% of women ages 14-19 are infected with at least one of the most common STDs: human papillomavirus (HPV), chlamydia, herpes simplex virus, and trichomoniasis.[6] **(To read more about the report, see "1 in 4 teen females has an STD, study says," *CTU*, May 2008, p. 56.)**

Why are youth and young adults more at risk for STDs? Several factors come into play, says Wimberly. Many teens might have poor knowledge or misperceptions of STD risks for themselves, which leads to deficits in decision-making skills. Teens also might be using condoms incorrectly or infrequently, she notes.

To assess and facilitate condom use, ask the question, "Did you use condoms the last time you had sexual intercourse?" Follow up with the question, "How often do you use condoms: all of the time, most of the time, or some of the time?" To check condom skills, Wimberly suggests asking the teen, "Can you tell me how to put on a condom?" **(Get more tips on encouraging adolescent condom use. See the article "Condoms: Fear of partner disapproval, less pleasure linked to teens' nonuse," *CTU*, December 2008, p. 133.)**

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Public health officials focus on HIV efforts in DC

When it comes to HIV/AIDS, the nation's capitol is experiencing some of the highest rates in the United States. At least 3% of District of Columbia (DC) residents have HIV or AIDS, according to a 2009 epidemiology report by the DC HIV/AIDS office.[1] HIV and AIDS cases increased 22% from 2006 statistics and touched every race and sex across the city's population and neighborhoods.[2]

To combat the problem, the National Institutes of Health (NIH) and the city of Washington, DC, have rolled out the DC Partnership for HIV/AIDS Progress, a collaborative research initiative between the federal agency's National Institute of Allergy and Infectious Diseases (NIAID) and the DC Department of Health. NIH has allocated $26.4 million for the first two years of the partnership through funding from the NIAID and the NIH Office of AIDS Research.

The collaboration is designed to decrease the rate of new HIV infections in the city, improve the health of district residents living with HIV infection, and strengthen the city's response to the HIV/AIDS epidemic.

"Tragically, our nation's capital has one of the highest rates of HIV/AIDS, where about 3% of adults and adolescents are infected with the virus," said **Anthony Fauci**, MD, NIAID director, in announcing the partnership. "By collaborating with Mayor [Adrian] Fenty's administration to

EXECUTIVE SUMMARY

The DC Partnership for HIV/AIDS Progress is being rolled out to combat the spread of HIV/AIDS in the District of Columbia.

- At least 3% of District of Columbia residents have HIV or AIDS, according to a 2009 epidemiology report by the district's HIV/AIDS office. African Americans comprise 76% of the district's HIV/AIDS cases.
- The collaboration is designed to decrease the rate of new HIV infections in the district, improve the health of residents living with HIV infection, and strengthen the district's response to the HIV/AIDS epidemic.

establish the new DC Partnership for HIV/AIDS Progress, NIH will seek to answer critical HIV research questions that could positively affect the district's HIV/AIDS problem and serve as a model for programs in other U.S. cities as well."

Focus on four areas

The new partnership will focus on four strategies of attack:

- identifying populations at high risk for HIV acquisition and developing effective risk reduction interventions;
- establishing a citywide data analysis mechanism to identify and address health issues and outcomes for those receiving HIV care and treatment;
- enhancing the city's HIV-related subspecialty medical care and supplementing access to research studies;
- conducting a pilot program to study the voluntary test-and-treat concept to curtail new HIV infection cases.

According to DC Department of Health statistics, African Americans make up 76% of the district's HIV/AIDS cases.[1] Two NIAID observational studies are including DC residents to better understand the risk factors for HIV infection in developing effective interventions for reducing risk. Both studies are being conducted by the agency's HIV Prevention Trials Network (HPTN). Local efforts are being coordinated through a HPTN clinical site at the George Washington University School of Public Health and Health Services.

The first study, HPTN 061, focuses on black men who have sex with men. Participants receive HIV risk-reduction counseling and condoms; testing for HIV and other sexually transmitted infections; screenings for substance use, mental health issues, and partner and/or homophobic violence; and a peer system to help them navigate the health care system and use HIV services. Already under way, the two-year study will enroll 2,460 men in six U.S. cities, including about 400 DC participants.

The second study, HPTN 064, is designed to estimate HIV incidence among African-American women from areas with high rates of HIV and poverty. The six-city study will enroll 1,200 women, including 200 DC women.

An important element of the new partnership will be the development of a districtwide data system, achieved by linking information from 13 of the city's largest health care providers. By establishing such a system, public health officials hope to better assess the clinical and treatment status of individual HIV-infected patients, evaluate outcomes of specific clinics and health programs, and measure the impact of HIV testing and treatment initiatives within the city.

Partnership officials also are focusing on enhancing care for HIV-related medical issues, because non-AIDS defining illnesses and HIV coinfections, such as cardiovascular disease, diabetes, and hepatitis, are significant causes of illness and death for many HIV-infected patients.

The NIH and the DC Department of Health are working with Washington medical providers to establish clinics designed to provide HIV-related subspecialty care to underinsured patients in district communities most in need. At the present time, three clinics — Family & Medical Counseling Service, Walker Jones Health Center of Unity Health Services, and Whitman-Walker Clinic — have been included in the collaborative effort.

Henry Masur, MD, chief of the NIH Clinical Center's Critical Care Medicine Department, says, "The goals of the clinics are to enhance subspecialty medical care for underinsured HIV-infected patients, assess the need for specific clinical trials on given issues, and if clinical trials are deemed necessary, provide those patients with access to the latest treatments available. This program also will focus on mentoring promising young leaders in HIV medicine who could enhance the district's reputation as a leader in developing new strategies for the prevention, diagnosis, and treatment of HIV/AIDS."

Partnership officials also plan a test-and-treat pilot study to compare current community standards for HIV testing and treatment with accelerated expansion of routine testing services. The study will be designed to identify HIV-infected people and evaluate enhanced methods to rapidly link them to care and successful treatment.

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