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IN THIS ISSUE

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New research indicates recovery of bone density after teen DMPA use

More research to emerge — continue to advise teens on bone health

New research indicates that lower bone density appears to recover in adolescent females once they stop using the contraceptive injection depot medroxyprogesterone acetate (DMPA, Depo Provera, Pfizer, New York City).[1] Ten percent of adolescent females in the United States rely on the birth control method.[2]

The Food and Drug Administration moved in late 2004 to add a "black box" warning to the labeling for DMPA to highlight that prolonged use may result in the loss of bone mineral density, which raised concerns about its potential impact in teen users. **(*Contraceptive Technology Update* reported on the new labeling; see the article, "Be prepared to counsel on use of DMPA and bone health issues," February 2005, p. 17.)** Providers still will have to weight the benefits of DMPA, such as its contraceptive efficacy with low motivation, compared to the potential risk of long-term minimal loss of bone density, says **David Archer**, MD, professor of obstetrics and gynecology and director of the Clinical Research Center at the Eastern Virginia Medical Center in Norfolk.

"Obviously at this stage, we need further data to definitively answer

EXECUTIVE SUMMARY

Lower bone density appears to recover in adolescent females once they stop using depot medroxyprogesterone acetate (DMPA), new research indicates.

- Previous studies have shown that women who use DMPA experience bone mineral density loss during the time they use the contraceptive. Earlier research had suggested that older women who stopped using the method gained back bone density; investigators wanted to see if the finding held true for adolescent females.
- Adolescence is an important time in terms of bone health: Half of a woman's bone mass is gained during puberty and the first several years after menarche.

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all of the questions," he states. "It should be stressed that despite black box warnings, DMPA is effective as a contraceptive, and this should be the primary consideration in prescribing at this time."

Review earlier research

Concerns about DMPA's potential impact on bone health have been raised since the 1990s, when initial research determined that women using DMPA had bone density values intermediate between those of normal premenopausal and postmenopausal women.[3] A subsequent study of some of the original DMPA users who discontinued the method found that bone density tended to increase after the method was stopped.[4]

Research published in 2004 indicated that women using DMPA for two years recorded a decline in bone mineral density (BMD) of roughly 6%, compared with a loss of 2.6% among women on oral contraceptives.[5] **(*CTU* reviewed the study in its article, "Latest research sheds new light on DMPA's impact on bone health," October 2004, p. 109.)**

DMPA's revised labeling now states that bone loss in women who use Depo-Provera is greater with increased duration of use and may not be completely reversible. The contraceptive injection should be used as a long-term birth control method (longer than two years) only if other birth control methods are inadequate, the label advises. Women who continue to use Depo-Provera past the two-year mark should have their BMD evaluated, according to the new labeling.

Adolescence is an important time when it comes to bone health: Half of a woman's bone mass is gained during puberty and the first several years after menarche; peak bone mass is achieved in the early to mid-20s.[6]

To conduct the newly-reported study, researchers measured hip, spine, and whole body bone mineral densities in 170 healthy female adolescents ages 14-18.[1] In this group, 80 had used DMPA, and 90 had not. Some of the 90 teens who had not used the contraceptive injection had used other forms of birth control, including oral contraceptives (OCs). Participants' bone mineral densities were checked at the beginning of the study and every six months thereafter for the next two to three years. During that time, 61 of the DMPA

users stopped using the drug, which allowed the researchers to see how their bone density changed once they discontinued the method.

What did the researchers find?

• DMPA users experienced an average loss of bone density at the hip of 1.81% per year compared with a loss of 0.19% per year among nonusers.

• Looking at spine BMD, DMPA users had a bone loss of 0.97%, while nonusers had an increase in bone density of 1.32%. Researchers note these bone loss rates are similar to that of women who are breast-feeding or going through menopause.

• Women who were new DMPA users lost bone density more rapidly than did longer-term users.

However, when DMPA users stopped using the method, they gained a significant amount of bone density compared to nonusers for the same period. For example:

— The average amount of bone gained in a year for those who stopped using DMPA was 1.34% at the hip, compared to a slight loss of 0.19 for women who were not taking the drug.

— Density at the spine increased 2.86% for women who stopped using DMPA compared to an increase of 1.32% for women who were not using the method.

The current study was conducted to follow up on an earlier study of women ages 18-39.[7] In that research, findings indicated that women lost bone density while using DMPA and increased bone mass after discontinuing the contraceptive. **(For a review of the research, see the *Contraceptive Technology Update* article, "Bone loss in DMPA users mostly reversible," December 2002, p. 136.)** However, the younger women in the current study lost bone density and increased bone density more rapidly than did the older women in the previous study.

"I think our results showing bone recovery following discontinuation of Depo-Provera are quite reassuring," says **Delia Scholes**, PhD, senior investigator at Group Health Cooperative's Center for Health Studies in Seattle and the study's lead investigator. "In my mind, this is an important additional part of the 'story' for women and providers as they weigh the risks and benefits of this method and try to make an informed decision about its use."

What are you advising?

While it is prudent to offer women an alternative method of contraception after they have used DMPA for two years or more, clinicians, together with their patients, should determine whether DMPA continues to be the best contraceptive option or whether women could switch to another method, says **Susan Wysocki**, RNC, NP, president and chief executive officer of the Washington, DC-based National Association of Nurse Practitioners in Women's Health.

Women who choose DMPA at the family planning and teen clinics at Grady Memorial Hospital in Atlanta are counseled that DMPA product labeling does not recommend long-term use (defined as two consecutive years) unless no other method is right for them. Women still may choose to continue to use DMPA for longer terms if they find other methods unacceptable, according to **Miriam Zieman**, MD, family planning program director and associate professor of obstetrics and gynecology at Emory University in Atlanta.

The 2004 World Health Organization (WHO) committee gave Depo-Provera use in teens a "2" meaning ". . . advantages of using the method generally outweigh the theoretical or proven risks."[8] The heightened FDA "black box" warning may be viewed in the same vein as the WHO "3" category, where "use of the method not usually recommended unless other, more appropriate methods are not available or acceptable," observes **Robert Hatcher**, MD, MPH, professor of obstetrics and gynecology at Emory.

"A Category 3 rating does not mean you cannot provide the method, but that the classification may be overridden if the person cannot find another appropriate method of contraception," he states.

Clinicians should continue to advise all young women to maintain bone health, including information on eating a healthy diet, smoking cessation, limitation of alcohol, and getting regular weight-bearing exercise such as walking, running, and weight lifting, Hatcher advises.

"Just a small percentage of U.S. teens are getting the recommended amount of daily calcium to build bone health," he notes. "The current questions about DMPA use and bone health serve to reinforce the importance of adequate calcium intake for all adolescents."

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New research in: Patch is cost-effective

Since the transdermal contraceptive (Ortho Evra, Ortho-McNeil Pharmaceutical, Raritan, NJ) was approved by the Food and Drug Administration in 2001, it has gained an increasing share of the contraceptive option mix offered by family planning providers. New research indicates that use of the contraceptive patch results in greater cost savings and reductions in pregnancy, compared with combination oral contraceptives (OCs), due to improved compliance by patients.[1]

Such news may aid family planning administrators when making decisions in stocking the formulary mix offered in their clinics. The patch has proven popular with patients — more than 90% of 2004 respondents to the *Contraceptive Technology Update* Contraception Survey indicated their facilities already were offering or implementing the method — and administrators have had to make adjustments in their supplies to keep up with the demand**. (For more information on the results of the *CTU* Contraception Survey, see *CTU*, November 2004 issue.)**

At Planned Parenthood Springfield (IL) Area, clinicians offer all methods to suit individual preferences and lifestyles, then allow patients to decide what works best, reports **Stephani Cox**, APN, CNP, DPS, director of patient services.

"Our formulary reflects all methods now; however, I do see that we are offering fewer different oral contraceptive choices as the demand for other methods increases," she notes.

EXECUTIVE SUMMARY

New research indicates that use of the contraceptive patch results in greater cost savings and reductions in pregnancy, compared with combination oral contraceptives, due to improved compliance by patients.

- Based on a theoretical model that analyzes existing data from clinical trials, the new paper weighs the cost-effectiveness of using the transdermal patch compared with the Pill.
- Since the patch's 2001 U.S. regulatory approval, it has become a popular birth control option.

Review the research

Two previous randomized comparative trials of the patch and OCs showed that the patch's efficacy was equivalent to that of the Pill and that compliance was greater with the patch.[2,3] In particular, there was a bigger difference in compliance in younger women, observes **Frank Sonnenberg**, MD, lead author of the new research and professor of medicine at the University of Medicine and Dentistry, New Jersey's Robert Wood Johnson Medical School in New Brunswick.

Younger women are known to be more noncompliant with oral contraceptives than older women; in the trials, use of the patch seemed to be relatively constant across age groups, says Sonnenberg. In all age groups, researchers found use was at least equivalent, but overall was better for the patch and especially better in the youngest age groups, he notes.

Research published in 2004 indicated that the weekly change schedule of the contraceptive patch is associated with a significantly greater proportion of cycles in which there is perfect dosing compared to an OC.[4] In performing the new analysis, researchers set out to examine such implications of increased perfect use on the cost-effectiveness of the contraceptive patch compared with the Pill.

In designing the study, researchers compared the patch with low-estrogen OCs and worked from the assumption that the risks of developing a medical condition during use would be the same for the two hormonal methods. Using a pharmacoeconomic model, both methods were compared with a hypothetical reference case of contraception nonuse. The base-case model considered women, ages 15 to 50,

in average health in a long-term, mutually monogamous, heterosexual relationship.

The base-case analysis showed that use of the patch resulted in a savings of $249 and 0.03 pregnancies per woman over two years compared with the Pill. Researchers concluded that patch use would offer cost savings compared with Pill use, due to reduced costs of pregnancy.

"It is pretty clear that if both methods cost the same, then the patch would save money because it would result in fewer pregnancies, and that is especially true in the youngest age groups," says Sonnenberg. "In our analysis, we looked at the implications of various alternative scenarios; for example, if you were comparing the patch with generic oral contraceptives vs. brand-name ones, the savings would be a little bit less because the patch would cost more than the oral contraceptive, but even there, using an average for generic for oral contraceptives, the difference in our estimated effectiveness still resulted in an estimated cost savings."

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Does increased weight impact OC efficacy?

EXECUTIVE SUMMARY

Results from new research indicate that overweight and obese women who take oral contraceptives may be 60%-70% more likely to get pregnant while on the Pill than women of lower weight.

- The new study findings suggest that among 100 women taking OCs for a year, an additional two to four women will get pregnant due to being overweight or obese.
- Possible factors in decreased efficacy could lie in increased metabolism, which could shorten the duration of the Pill's effectiveness; increased liver enzymes, which may lead to a drop in circulating blood levels of the Pill; and possible storage of active ingredients in body fat, diminishing the Pill's impact.

Results of new research suggest that being overweight may increase women's risk of becoming pregnant while using oral contraceptives (OCs).[1] How do these findings play into contraceptive counseling for clinicians?

The new findings are quite similar to those found in a 2002 pilot study, says **Victoria Holt**, PhD, MPH, a professor in the department of epidemiology at the University of Washington in Seattle who served as lead author for both studies. In the pilot study, investigators found that women in the highest weight quartile or highest body mass index (BMI) quartile had a significantly increased risk of OC failure.[2] **(*Contraceptive Technology Update* reviewed the initial research in its article, "Does weight play a role in effectiveness?" July 2002, p. 81.)**

Results from the new study indicate that overweight and obese women who take oral contraceptives are 60%-70% more likely to get pregnant while on the birth control pill than women of lower weight.[2] Among 100 women taking OCs for a year, the new study results suggest that an additional two to four women will get pregnant due to being overweight or obese.

However, more research is needed on the subject before clinicians change their prescribing habits, says **Paul Norris**, MD, assistant professor of obstetrics and gynecology at the University of Miami who performed similar research. His investigation suggested a positive correlation between contraceptive failure in combination OC users and increased BMI; of 514 combination OC users, pregnancies occurred in seven women. Five of those women had a BMI greater than 25; three of those five had a BMI greater than 30.[3]

"So far, the data is light; I don't think it is enough to change prescribing habits," he states. "When I lecture at medical school or if I'm doing lectures for a group, I will mention it, but I will say more data needs to come out."

What is the difference between being overweight and obese? The Geneva-based World Health Organization breaks weight down into four categories, defined by BMI (the measure of

body fat based on height and weight): underweight (18.5 or lower), normal (18.5 to 24.9), overweight (25 to 29.9), and obese (30 or greater).

In conducting the new study, researchers compared weight and body mass index of 248 women who became pregnant while on OCs to an age-matched comparison group of 533 nonpregnant Pill users. Study participants were enrolled in the Group Health Cooperative, a Seattle health maintenance organization.

Researchers found the association between extra pounds and pill failure first surfaced among overweight women whose body mass index was 27.3 or higher, which is equivalent to a 5-foot, 4-inch woman who weighs 160 pounds or more. These women faced a 60% greater risk of getting pregnant while on OCs, while those considered obese, with a BMI of 32.2 or greater, faced a 70% greater risk.

What factors could be at play in decreased efficacy? Researchers say possible factors could include increased metabolism, which can shorten the duration of a medication's effectiveness; an increase in liver enzymes, which may lead to a drop in circulating blood levels of a drug; and possible storage of active ingredients in body fat, diminishing the impact of the drug.

What's your move?

Other research does not indicate that clinicians need change their prescribing habits when it comes to advising OC use in overweight women.[4,5]

According to information provided by the Washington, DC-based National Association of Nurse Practitioners in Women's Health (NPWH), a woman's ultimate contraceptive decision should be based on:

- effectiveness;
- incidence of side effects;
- convenience;
- desired duration of contraception;
- reversibility;
- noncontraceptive benefits;
- cost. **(See the resource box, below left, for more NPWH information on the subject.)**

"Will it change my prescribing habits? No, not at all," says Norris of the new research. "Oral contraceptive pills are still very effective in the obese patient; even though there is an increased failure rate, pills are still very effective."

RESOURCE

The Washington, DC-based National Association of Nurse Practitioners in Women's Health offers a continuing education module, "Contraceptive Failure and Body Weight: Fact or Fiction." Go to the organization's web site, www.npwh.org. Click on "Other Current CE Opportunities," then "Contraceptive Failure and Body Weight: Fact or Fiction."

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Men next target in HPV research drive

Researchers are taking a hard look at the forgotten half of the transmission equation of human papillomavirus (HPV). Investigators are recruiting 3,000 healthy men, ages 18 to 44, in the United States, Mexico, and Brazil to determine men's roles in spreading the sexually transmitted organism, which is linked to cervical cancer in women.

Anna Giuliano, PhD, a professor of interdisciplinary oncology at the University of South Florida College of Medicine and a program leader at the H. Lee Moffitt Cancer Center & Research Institute, both in Tampa, is heading the multinational investigation, which is funded through a $10 million grant from the National Institutes of Health. Study subjects will be followed every six months for four years at study sites in Tampa; Cuernavaca, Mexico; and São Paulo, Brazil.

According to the Centers for Disease Control and Prevention, at least half of all sexually active men and women acquire genital HPV infection at some point in their lives.[1] However, most who have such an infection are unaware of it because the virus lives in the skin or mucous membranes

EXECUTIVE SUMMARY

Investigators are recruiting 3,000 healthy men, ages 18 to 44, in the United States, Mexico, and Brazil to determine men's roles in spreading human papillomavirus (HPV), the sexually transmitted organism linked to cervical cancer in women.

- At least half of all sexually active men and women acquire genital HPV infection at some point in their lives, according to public health estimates; however, many who are infected are unaware of it, because the virus lives in the skin or mucous membranes and usually causes no symptoms.
- HPV causes more than 90% of cervical cancer in the United States. About 10,370 cases of invasive cervical cancer will be diagnosed in the United States in 2005.

and usually causes no symptoms.

If symptoms do appear, they usually are in the form of genital warts, soft pink or flesh-colored swellings. Warts can be raised or flat, single or multiple, small or large, and can appear on the vulva, in or around the vagina or anus, on the cervix, and on the penis, scrotum, groin, or thigh. (Get more information on counseling patients with HPV; see the latest edition of the Washington, DC-based Association of Reproductive Health Professionals' publication, *Health & Sexuality*. Go to the organization's web site, www.arhp.org, and click on "*Health & Sexuality*: Cervical Cancer Prevention and HPV DNA Testing.")

Exposure to HPV has significant health implications, particularly for women. Some strains of the virus, including HPV-16 and HPV-18, can trigger cancers of the cervix. Researchers believe HPV causes more than 90% of cervical cancer in the United States.[2] Such disease continues to be a threat to women: About 10,370 cases of invasive cervical cancer will be diagnosed in the United States in 2005, according to the American Cancer Society (ACS).[3] About 3,710 women will die from the disease in 2005, the society estimates.[3]

"The biggest obstacle is whether men will be interested in this study," says Giuliano. "If men are committed to making a difference in this issue, the study can succeed."

Is vaccine on the way?

A vaccine against HPV may hold the key to stemming its spread. Through development of recombinant DNA techniques, researchers have been able to produce viruslike particles that mirror the chemical structure of proteins found on the outer coat of HPV. These particles are tested for their ability to trigger an immune response, which signals viability as a potential vaccine candidate.

Merck & Co. in Whitehouse Station, NJ, is expected to file in the second half of 2005 for Food and Drug Administration approval of its multivalent vaccine, Gardasil. The vaccine is aimed at types 6, 11, 16, and 18 of HPV. Research of a component monovalent vaccine has shown effectiveness in reducing HPV incidence.[4,5] In a study of 2,391 women ages 16-23, the monovalent vaccine was 100% effective in preventing the development of HPV 16-related high-grade cervical pre-cancer, the immediate precursor to invasive cervical cancer.[5] **(*Contraceptive Technology Update* reported on initial research in its article, "HPV vaccine research yields promising results," February 2003, p. 17.)**

Another vaccine, under development by GlaxoSmithKline (GSK) Biologicals in Rixensart, Belgium, is the focus of a large-scale Phase III study. Investigators at more than 90 sites in 14 countries are enrolling approximately 13,000 young women ages 15-25 in the four-year study of the vaccine. The investigational vaccine contains viruslike particles for HPV types 16 and 18, plus a substance called AS04, a novel proprietary adjuvant under development by GSK Biologicals in collaboration with Corixa Corporation of Seattle that increases the immune system's response to a vaccine.

Researchers conducted a double-blind, controlled trial of the vaccine in which 1,113 young women in the United States, Canada, and Brazil were randomized to receive three doses formulated with AS04 adjuvant or placebo. Results indicate the vaccine prevented most HPV-16 and HPV-18 infections, as well as most abnormal Pap smears and cervical lesions associated with HPV-16 and HPV-18.[6]

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Up the radar for LGV: New cases reported

Put your diagnostic skills into high gear to spot lymphogranuloma venereum (LGV), a sexually transmitted disease (STD) caused by a type of *Chlamydia trachomatis*. The Centers for Disease Control and Prevention (CDC) has identified a number of cases from specimens submitted from health departments in New York City, San Francisco, and Atlanta.

Up to now, LGV infections rarely occurred in the United States and other industrialized nations; however, U.S. public health officials called for providers to monitor for the STD following a late 2004 outbreak of the infection, primarily in men who have sex with men, in the Netherlands and other European countries.[1,2,3] **(See the *STD Quarterly* article, "CDC: Be on the lookout for lymphogranuloma venereum," inserted in the March 2005 issue of *Contraceptive Technology Update*, p. 1.)**

Since LGV is not a nationally notifiable disease, public health officials do not have information about how much LGV has been present previously compared to what is being seen now, says **Catherine McLean**, MD, medical epidemiologist with the CDC Division of STD Prevention.

"At this point, in response to increases that have been reported in Europe, we at CDC have been applying more specific laboratory typing techniques to determine whether in fact LGV is present here, and we have confirmed that it is," she states.

Two cases of the STD have been confirmed in New York City, prompting local public health officials to send an alert to physicians warning them to be on the lookout for the disease.[4] Three other cases have been spotted: two in San Francisco, and one in Atlanta.[4]

"We are deferring to the state and local health jurisdictions to report on individual cases in their areas," states McLean.

EXECUTIVE SUMMARY

The Centers for Disease Control and Prevention has identified cases of lymphogranuloma venereum (LGV), a sexually transmitted disease (STD) caused by a type of *Chlamydia trachomatis*, from specimens submitted by New York City, San Francisco, and Atlanta health departments.

- Public health officials called for providers to monitor for LGV following a late 2004 outbreak of the infection, primarily in men who have sex with men, in the Netherlands and other European countries.
- Its symptoms are not recognized as typical STD symptoms and are similar to those that are caused by other conditions and infections.

Spot the symptoms

To help clinicians detect and treat LGV, the CDC has posted an information sheet on its Division of STD Prevention web site, www.cdc.gov/std. **(See the resource box on p. 49 to learn how to access this information.)**

How can you spot LGV? Symptoms include:

- mucous or purulent anal discharge;
- rectal bleeding;
- constipation;
- inguinal/femoral lymphadenopathy (buboes);
- genital or rectal ulcer or papule;
- anal spasms;
- tenesmus.

Clinicians may find it difficult to diagnose LGV since its symptoms are not recognized as typical symptoms of an STD and are similar to those that are caused by other conditions and infections. The CDC is asking clinicians to complete a questionnaire for any patient suspected of having LGV. Completion of the questionnaire will aid public health officials in understanding characteristics of persons with LGV in the United States and will contribute to controlling the disease.

The CDC's chlamydia laboratory is providing laboratory support for states that lack laboratory capacity to perform LGV diagnostic testing. Specimens are tested for *C. trachomatis*, if such testing is not available locally, then typed for LGV if tests are positive for the STD. Clinicians and laboratories may submit specimens to the CDC lab using procedures outlined in a CDC specimen collection form. **(See the resource box**

RESOURCES

The Centers for Disease Control and Prevention's Division of STD Prevention provides information on LGV surveillance activities, and LGV diagnosis and treatment on its web site, www.cdc.gov/std. Click on "LGV Surveillance" to access information that includes versions of a provider information sheet, patient questionnaire, and specimen collection form for clinicians who have a patient suspected of having LGV.

above, to learn how to access the form.)

Once LGV is diagnosed, it is treatable with antibiotics. If left untreated, the disease can lead to chronic scarring, constipation, rectal pain, and abscesses. Like other ulcerative STDs, LGV also can increase the risk for HIV transmission.

"LGV is a serious condition, and its emergence in New York City reflects continuing high levels of unsafe sexual activity among men who have sex with men," states **Thomas Frieden**, MD, MPH, New York City's health commissioner. "Medical providers who care for gay and bisexual men should be alert for symptoms of LGV."

References

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ASK THE EXPERTS

Answers to questions on intrauterine devices, EC

What is your approach when checking for copper allergy in women considering use of the Copper T380A (ParaGard, FEI, Addison, TX)? What are your directions on use of the levonorgestrel-only EC, Plan B (Barr Pharmaceuticals, Pomona, NY)?

Comments are offered by **David Archer**, MD, professor of obstetrics and gynecology and director of the Clinical Research Center at the Eastern Virginia Medical Center in Norfolk; **Philip Darney**, MD, professor of obstetrics and gynecology at the University of California-San Francisco; and **Robert Hatcher**, MD, MPH, professor of gynecology and obstetrics at Emory University School of Medicine in Atlanta.

Question: How do you recommend screening for copper allergies in women who want a ParaGard intrauterine device (IUD)? We usually ask if the woman is able to wear cheap jewelry. If no, then we have assumed that that woman is not a candidate. Recently, we have had women who can't wear cheap jewelry but have successfully used a copper IUD previously. We would like to know what we should be asking a woman to best screen for a copper allergy. Should we have her go out and buy a copper bracelet and wear it for a period of time?

Archer: Metal allergies are unusual. See this report (Hostynek JJ, Maibach HI. Copper hypersensitivity: Dermatologic aspects. *Dermatol Ther* 2004; 17:328-333). In the report, it states, ". . . considering the widespread use of copper IUDs and the importance of copper in coinage, items of personal adornment and industry, unambiguous reports of sensitization to the metal are extremely rare, and even fewer are the cases which appear clinically relevant."

Darney: I think your latter suggestion is the best one because most cheap jewelry won't give direct copper exposure. I have been inserting copper IUDs since they were first made and have never seen an allergy.

Question: What are the dosing instructions for Plan B?

Hatcher: Women using Plan B should be told: "If you are taking progestin-only emergency contraceptive pills, swallow the two pills as one dose as soon as possible within 120 hours after unprotected sex. Do not take any extra pills. More pills will not decrease the risk of pregnancy any further." These instructions were written by Felicia Stewart, MD, James Trussell, PhD, and Paul Van Look, MD, PhD, and may be found on p. 298 of the 18th edition of *Contraceptive Technology*

(Ardent Media, New York City). For progestin-only emergency contraception, anti-nausea medicine is not recommended in the *Contraceptive Technology* instructions for using Plan B. ■

Adoption program undergoes changes

By **Cynthia Dailard**
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In late September 2004, the Department of Health and Human Services (HHS) announced a new round of national and regional grantees for the infant adoption awareness-training program. Given the dubious track record of this program during its first three years of operation, many family planning providers are hopeful that this will bring much-needed changes to the national training curriculum — one that has the potential to result in a positive and meaningful collaboration between family planning counselors and adoption experts.

The Infant Adoption Awareness Act (IAAA) of 2000 supports the training of certain federally funded health care providers, including Title X family planning providers, on how to provide adoption information and referral on par with other options in nondirective pregnancy options counseling. Federal regulations for the Title X family planning program require pregnancy counselors to "offer pregnant women the opportunity to be provided information and counseling regarding each of the following options: prenatal care and delivery; infant care, foster care, or adoption; and pregnancy termination." If such information and counseling is requested, counselors must "provide neutral, factual information and nondirective counseling on each of the options, and referral upon request, except with respect to any option(s) about which the pregnant woman indicates she does not wish to receive such information and counseling."

Former Rep. Tom Bliley (R-VA), a staunch family planning opponent who for many years sought to prevent Title X providers from discussing abortion with women facing an unintended pregnancy and to require Title X providers to actively promote adoption instead, authored the IAAA.

Funding for this program was first released in October 2001 to four adoption organizations to the tune of $8.6 million. The lion's share of the funding ($6.1 million) went to the National Council for Adoption (NCFA), an organization that takes credit for having played a key role in developing the IAAA and whose leaders share many of Bliley's views. Under its grant, NCFA was charged with developing a national curriculum and implementing a training program based on that curriculum.

Review the history

Interviews conducted by the Alan Guttmacher Institute between September 2003 and July 2004 with more than 20 family planning providers in 15 states about their IAAA training experience reflect decidedly mixed experiences. Many reported an overall positive experience or praised their trainers for their "evenhanded approach" in discussing all the options available to pregnant women. Others found valuable specific components of the training (most notably a session with an adoption attorney who discussed the legal aspects of adoption) or the opportunity it presented to build relationships with other service providers in their community, particularly local adoption program directors.

However, most family planning providers interviewed reported a far more negative training experience. Collectively, these dissatisfactions

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raised significant concerns about the implementation of the infant adoption awareness-training program by NCFA.

A fundamental complaint raised by a number of participants was the directive nature of the training. In January 2004, Charles Marquardt, the program coordinator and lead trainer for the Title X training program at the California Family Health Council (the largest Title X grantee in the nation), highlighted his concerns about his training experience in a seven-page letter to his federal regional health administrators. He wrote: "The trainer promoted tactics and techniques for attempting to persuade the client to choose adoption by 1) discouraging abortion as a viable option; 2) overly promoting adoption; 3) highlighting the difficulties [the] child will encounter if [a woman] should choose to raise it herself; and 4) encouraging counselor opinions in scenarios by having the counselor choose for the client the best option." Others echoed these complaints and said they were given tips and techniques for promoting adoption that bordered on coercion, in clear violation of Title X guidelines and principles of medical ethics.

Other key criticisms included that the trainers promoted a negative view of clients (portraying them as deluded, ignorant, and unable to make good choices for themselves); a hostile training environment due to the presence of trainers and trainees from crisis pregnancy centers and other antiabortion organizations; and the religious overtones of the training (which some participants noted included prayer and emphasized the importance of placing children in "good Christian homes").

The new national grantee, as announced by HHS in October, is Spaulding for Children, based in Southfield, MI. More regional training projects will be run by Harmony Adoptions of Maryville, TN; Arizona Children's Association in Tucson; Lutheran Social Services of South Dakota in Sioux Falls; Independent Adoption Center in Pleasant Hill, CA (serving Northern California); and Latina Family Institute of West Covina, CA (serving six counties in the Los Angeles area).

Whether this new round of grants will result in the development of training programs that are responsive to the criticisms of those family planning providers who attended past training remains to be seen. Many family planning providers, however, are hopeful that for the first time under this program; it presents a real opportunity for a productive and mutually satisfying collaboration between adoption educators and pregnancy counselors. ■

Warn patients about bogus at-home tests

Alert your patients about the dangers of certain at-home diagnostic tests. The Food and Drug Administration (FDA) has issued an alert concerning use of unapproved home-use diagnostic test kits marketed over the Internet.

The kits, marketed by Globus Media of Montreal, are labeled as Rapid HIV Test Kit, Rapid Syphilis Test Kit, One Step Cassette Style Cocaine Test, One Step Cassette Style Marijuana (THC) Test, One Step Cassette Style Amphetamine Test, Rapid Dengue Fever Test, and One Step Midstream Style HCG Urine (Home) Pregnancy Test.

The tests were sold through web sites such as www.htkit.com and www.hstkits.com, and were distributed throughout the United States, usually by overnight delivery services, according to the FDA. The kits usually are packaged in a paper envelope, with instructions inside the packaging. The envelope, instructions, and packaging may not accurately identify the manufacturer, packer, or distributor; however, the name of the kit appears on the instructions, states the FDA.

No home-use test kits intended for diagnosing HIV, syphilis, and dengue fever are approved for sale in the United States, according to the FDA. It advises that use of such products could result in false results that could lead to significant adverse health consequences. ■

CE/CME Instructions

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

CE/CME Questions

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

- **Identify** clinical, legal, or scientific issues related to development and provisions of contraceptive technology or other reproductive services. (See "**New research indicates recovery of bone density after teen DMPA use"** and **"Men next target in HPV research drive.")**
- **Describe** how those issues affect service delivery and note the benefits or problems created in patient care in the participant's practice area. (See **"Up the radar for LGV: New cases reported.")**
- **Cite** practical solutions to problems and integrate information into daily practices, according to advice from nationally recognized family planning experts. (See **"Does increased weight impact OC efficacy?")**

13. According to updated labeling for DMPA, what should women do if they continue to use the method for more than two years?

A. Have their bone mineral density evaluated
B. Have a colposcopy
C. Have a colonoscopy
D. Have a loop electrosurgical excision procedure

14. What is the body mass index range classification for overweight women, according to the World Health Organization?

A. Lower than 18.5
B. 18.5 to 24.9
C. 25 to 29.9
D. 30 or greater

15. Gardasil, the investigational multivalent vaccine, is aimed at what types of HPV?

A. 6 and 11
B. 6 and 16
C. 6, 11, 16, and 18
D. 16 and 18

16. Which of the following is NOT a symptom of lymphogranuloma venereum?

A. Mucous or purulent anal discharge
B. Rectal bleeding
C. Constipation
D. Dizziness

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

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.*

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