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IN THIS ISSUE

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— ***STD Quarterly*:** Be on the lookout for lymphogranuloma venereum; continue the fight to stem gonorrhea spread

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Teens improve contraceptive use, but more women at risk for pregnancy

What do new contraceptive trends mean for your practice?

Just-released information from the National Survey of Family Growth offers family planning clinicians a mix of good and bad news: While sexually active teens are more likely to be using contraception, many teens are uninformed about birth control choices.[1] The research also indicates that the number of women ages 15-44 at risk of pregnancy but using no method of contraception rose from 7.5% in 1995 to 10.7% in 2002.[2]

While this 3.2% rise may appear small in numbers, it translates into potentially large problems with unintended pregnancy, says **James Trussell**, PhD, professor of economics and public affairs and director of the Office of Population Research at Princeton (NJ) University. In 1994, the last year for which data are available, the small minority (7.5%) of women using no contraception contributed almost half (47%) of the 3 million unintended pregnancies in the United States,[3] he reports.

"What we have witnessed is a 43% rise in that small minority, which

EXECUTIVE SUMMARY

Just released from the National Survey of Family Growth: While sexually active teens are more likely to use contraception, many teens are uninformed about birth control choices.

- The number of women ages 15-44 at risk of pregnancy but using no method of contraception rose from 7.5% in 1995 to 10.7% in 2002, putting more women at risk for unintended pregnancy.
- Sexual activity declined for younger teenage girls and for teenage boys between 1995 and 2002, and teen contraceptive use improved. However, many teens say they are not learning about birth control in school, and many are not getting such information from their parents.

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would lead, everything else held constant, to an 18% rise in unintended pregnancies," he explains.

The National Survey of Family Growth (NSFG) is conducted periodically by the Centers for Disease Control and Prevention's National Center for Health Statistics in Hyattsville, MD, with researchers collecting information on several topics, including contraception, infertility, pregnancy outcomes, and births. **(See the accompanying snapshot on p. 31 for an overview of the latest findings.)** Since the survey is so large and is known for its accuracy, reproductive health experts see the newly reported increase as a worrisome trend.[4]

What factors may be impacting women's nonuse of contraception? Declining insurance coverage, increasing costs of contraceptives, and the inability of publicly funded family planning services to keep up with inflation all could be contributing to the decline, says **Sharon Camp**, president and chief executive officer of the New York City-based Alan Guttmacher Institute (AGI).

Camp also points to the increase in abstinence-only sex education and what she terms "government-sponsored misinformation" as possible contributors to a lack of knowledge or misconceptions about the effectiveness, safety, and side effects of the various contraceptive methods available, particularly among teens and young adults. (For an overview of challenges to information on reproductive health, check AGI's review, "Top 10 Ways Sexual And Reproductive Health Suffered in 2004" on the organization's web page, www.guttmacher.org.) Among older women, a mistaken belief that they are unable to become pregnant may be influencing their contraceptive decision making, she surmises.

Are teens better off?

What do the survey findings show when it comes to teens? Information from the NSFG indicates good news on the adolescent front:

- The proportion of never-married females ages 15-17 who had ever had sexual intercourse dropped from 38% in 1995 to 30% in 2002. At ages 18-19, 68% had had intercourse in 1995, compared with 69% in 2002.
- For male teens, the percentage of those who were sexually experienced dropped in both age groups: from 43% to 31% at ages 15-17, and from 75% to 64% at ages 18-19.
- Teens are more likely to use contraception when they begin having intercourse (79% in

1999-2002, up from 61% in the 1980s).

• Teens are more likely to have used contraception at their most recent intercourse (83% in 2002, up from 71% in 1995). At their first premarital intercourse, teens were most likely to choose condoms for birth control; 66% reported using a condom when they became sexually active.[1]

However, the survey results also highlight some troubling developments:

• Many teens are not learning about birth control in school; one-third of teens report having received no formal instruction about contraceptive methods before age 18.

• Half of young women ages 18-19 and about one-third of men of similar age, said they had talked with a parent about birth control before they turned 18.[1]

"Although more teens are delaying first sex, and those who are sexually active are more likely to use contraceptives than they were previously, the fact that so many teenagers lack the information and services they need to protect themselves from unintended pregnancy and sexually transmitted infections is particularly alarming," says Camp. "As more schools move towards abstinence-only-until-marriage education that talks about contraception only in the context of its failure rates, family planning providers may increasingly find themselves on the front lines as teens' primary source of medically accurate information about consistent and correct contraceptive use."

Snapshot: What Are the Contraceptive Trends?

- The leading methods of contraception in the United States in 2002 among women 15-44 years of age were the oral contraceptive pill (11.7 million women), female sterilization (10.3 million), the male condom (6.9 million), male sterilization (3.5 million), and depot medroxyprogesterone acetate (DMPA) injectable (2.0 million). These five methods accounted for 90% of contraceptive users.
- For young women, the oral contraceptive pill is the top birth control choice; for women 35 and older, the leading method is female sterilization.
- Nearly all women of reproductive age have used contraception: 98% of all women who had ever had intercourse had used at least one contraceptive method. About 82% of women have used the Pill at some time in their lives; about 90% have had a partner use the male condom.
- Method choice varies sharply by such characteristics as education: College-educated women are four times as likely to use the Pill, four times as likely to rely on male sterilization, and one-fourth as likely to use female sterilization as women who did not graduate from high school.

Source: Centers for Disease Control and Prevention National Center for Health Statistics, Hyattsville, MD.

Is mandatory notice OK?

When it comes to obtaining contraceptives, one in five teenagers would have unsafe sex if their parents had to be notified before they could receive prescription birth control at a family planning clinic, according to just published nationally representative data.[5]

Results from the new study show that many teens — three in five — had parents who already knew about their clinic visit, usually because teens told them or their parents suggested it. But among those adolescents whose parents were unaware of their visit, 70% said they would stop coming to the clinic, and one-quarter said they would continue to have sex but would rely on withdrawal or not use any contraception if parental notification were mandated. Just 1% of all teens surveyed said they would stop having sex.[5] Researchers surveyed more than 1,500 women younger than 18 who were seeking sexual health services, including contraceptives, at family planning clinics in 33 states.

Texas and Utah now require parental consent for state-funded family planning services, and a similar restriction is in place in one Illinois county (McHenry), where research has found an increase in teen birthrates while other counties experienced declines.[6] In 2004, bills to impose new requirements for parental consent for adolescents seeking contraception were introduced in Congress and several states, including Kentucky, Minnesota, and Virginia. **(Review confidentiality policies in the April 2003 *Contraceptive Technology Update* article, "Maintain confidential care for adolescents," p. 41.)**

While the rate of teen pregnancy has dropped over the last decade, about 850,000 teenagers still get pregnant each year, with most such pregnancies unintended, according to the AGI, which performed the new study. Forcing parental involvement could drive teen pregnancy rates up, reproductive health experts contend.

Research shows that family planning clinics can play an important role in fostering parental/

teen communication.[7] National research conducted in 1999 found that 43% of agencies had one or more educational program to improve parent-child communication.[8]

The practices and educational programs provided by many family planning clinics are intended to improve parent-child communication around sexual health issues, explains **Rachel Jones**, PhD, senior research associate at AGI and lead author of the study. Some clinics incorporate this issue in one-on-one counseling sessions with teen clients, such as offering to help teens come up with strategies for talking to parents about sex and birth control, she notes.

"Formal educational programs — which can be directed at teenagers, parents, or both — often provide skills and information to improve communication around sexuality issues," states Jones. "Notably, educational programs are often labor-intensive, require a physical space to hold classes, and cost money, so clinics are less likely to be able to provide this resource to clients and community members."

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Easy EC access doesn't increase risky behavior

If it were easier for women to obtain emergency contraception (EC), would it result in an increase in unprotected intercourse, cause women to forego their current method of contraception, or increase the risk of sexually transmitted diseases (STDs)? Apparently not, according to the findings of a just-published study.[1]

Women enrolled at four California women's health clinics were randomly assigned to one of three EC sources: the clinic, nearby pharmacies without a prescription, or an advance supply of pills. Researchers found about the same percentage of women in each group had unprotected sex over a six-month period, incidents of sexually transmitted disease were equal, and about the same percentage in each group became pregnant. About 37% of women in the group with advance EC used it at least once during the six months, compared with 21% in the clinic access group and 24% in the pharmacy access group.

The results counter concerns voiced by opponents to expanded EC access, who have claimed that easier access will lead to increases in sexual promiscuity and STDs. Such concerns may have lead the Food and Drug Administration to issue an initial rejection to Pomona, NY-based Barr Pharmaceuticals' application to move its levonorgestrel-only EC pill Plan B to over-the-counter (OTC) status**. (Review the history of the Plan B application; see the following *Contraceptive Technology Update* articles: "Bulletin: Emergency contraception moves closer to over-the-counter," February 2004, p. 13, and "What is next for over-the-counter access to emergency contraception?"**

EXECUTIVE SUMMARY

Results from a new study indicate that women who have ready access to emergency contraception (EC) are no more likely to engage in unprotected sex or stop their use of other contraceptive methods than those who do not have easy access to the method.

- Women were randomly assigned to one source of emergency contraception: the clinic, nearby pharmacies without a prescription, or an advance supply of pills. About the same percentage of women in each group had unprotected sex over six months, incidents of sexually transmitted disease were equal, and about the same percentage in each group became pregnant.
- About 37% of women in the group with advance EC used it at least once during the six months, compared with 21% in the clinic access group and 24% in the pharmacy access group.

July 2004, p. 73.)

One of the concerns voiced by policy-makers, some providers, and even some women, is that women will "misuse" EC, says the study's lead author, **Tina Raine**, MD, MPH, an associate professor in obstetrics, gynecology, and reproductive sciences at the University of California-San Francisco. Such concern would be warranted if women used EC instead of regular contraception, if they adopted unsafe sexual behaviors (abandoning condom use or having multiple sexual partners), or if women used EC repeatedly, she points out.

"I don't think that anyone would consider using EC once or even twice over a six-month period as excessive or in any way dangerous, and we demonstrated no differences in use of regular contraception, condoms, or sexual practices [promiscuity] among women with increased access," comments Raine. "So our study is important in that we demonstrate that women with increased access to EC do not 'misuse' EC in this way."

The Washington, DC-based American College of Obstetricians and Gynecologists (ACOG) has issued a statement on the new research and calls on the FDA to approve expanded access to EC.

"These new data clearly add to the existing body of evidence previously reviewed by two FDA expert advisory panels," the ACOG statement reads. "They overwhelmingly had recommended OTC approval of Plan B by a 23-4 vote, after reviewing more than 15,000 pages of clinical data from approximately 40 studies submitted with the OTC application."[2]

Review the research

To study expanded access, researchers designed a randomized controlled trial, enrolling 2,117 women ages 15-24 at four San Francisco area women's health care clinics (New Generation Health Center/University of California-San Francisco, Planned Parenthood — San Francisco, City College of San Francisco Student Health Center, and Planned Parenthood — Daly City). Women were assigned to one of three groups: pharmacy access to EC, advance provision of three packs of Plan B EC, or clinic access (control).

Researchers found that the percentage of women in the pharmacy group (24.2%) and in the clinic group (21%) using EC essentially were the same. Women in the advance provision group (37.4%) were almost twice as likely to use EC than controls (21%) even though their reported frequency of unprotected intercourse was similar (39.8% vs. 41%, respectively). Only half (46.7%) of study participants who had unprotected intercourse used EC over the study period. Eight percent of the women in the trial became pregnant, and 12% acquired an STD; compared with controls, women in the pharmacy access and advance provision groups did not experience a significant reduction in pregnancy rate or increase in STDs. There were no differences in patterns of contraceptive or condom use or sexual behaviors by women in the study group.

The FDA continues to review Plan B's OTC application. Barr Laboratories resubmitted its application in July 2004 with "bifurcated labeling," seeking OTC access for women ages 16 and older, with prescription-only status for those below the age limit, says company spokeswoman **Carol Cox**. The regulatory agency extended its review past the scheduled Jan. 21, 2005, deadline. **(See the *Contraceptive Technology Update* article, "Plan B seeks OTC status for women ages 16-plus," September 2004, p. 103.)**

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Update: FDA strengthens mifepristone labeling

The Food and Drug Administration (FDA) has strengthened the warning information on the labeling for the abortion drug mifepristone. The labeling change is in response to reports of infection, bleeding, and death among women who have taken the drug, according to the FDA.[1]

Changes to the existing "black box" warning on the product, marketed in the United States as Mifeprex (Danco Laboratories, New York City), reflect heightened information on the risk of serious bacterial infections, sepsis, bleeding, and death that may occur following any termination of pregnancy, including use of Mifeprex. The

EXECUTIVE SUMMARY

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- Changes to the existing "black box" warning on the product, marketed in the United States as Mifeprex, reflect heightened information on the risk of serious bacterial infections, sepsis, bleeding and death that may occur following any termination of pregnancy, including use of Mifeprex.
- The drug's labeling, medication guide, and patient agreement have been revised to reflect the heightened information, and the drug's marketer has alerted providers regarding the change.

changes follow reports of such incidents to Danco and to the FDA. **(See the article, "Medical abortion update: Death sparks questions on abortion pill," December 2003, p. 133.)**

Danco Laboratories has revised the drug's labeling, medication guide, and patient agreement, and it has alerted providers regarding the new information. **(See the resource box on p. 35 for instructions on accessing the revised material.)**

According to Danco, about 360,000 women have been treated with Mifeprex in the United States since the drug received FDA approval in 2000. Since its approval, women and doctors nationwide have reported high levels of success and satisfaction with the early abortion option, says **Vanessa Cullins**, MD, MPH, vice president for medical affairs for the New York City-based Planned Parenthood Federation of America.

"Planned Parenthood supports the updated mifepristone labeling released by the U.S. Food and Drug Administration because it is based on the best scientific information available," she says. "At Planned Parenthood, our No. 1 priority is the health and safety of our patients, and we support responsible safeguards for women's health."

According to Danco, the rate of reported adverse events (AEs) for Mifeprex is less than 0.2%, and the vast majority are not serious, not emergencies, and are expected, such as ongoing pregnancy and incomplete abortion. Updating the labeling information is a standard procedure for all drugs, states **Cynthia Summers**, Danco director of marketing and public affairs.

"Our goal is to provide a safe and effective early option for women," she explains. "We are committed to the safety of our patients, and want to ensure that health care providers are aware of the need to watch for any potential side effects, and that patients are informed about when they should call their providers."

Check warning signs

While infection following medical abortion is rare, the new labeling calls for providers to be alert to the possibility of post-procedure infection. Look for any of the following potential indications of infection, and advise patients of such warning signals:

- sustained fever of 100.4° F or higher;
- severe abdominal pain;
- pelvic tenderness in the days after taking Mifeprex and misoprostol (a companion drug used in the medical abortion procedure).

Atypical presentations of serious infection and sepsis, without fever, severe abdominal pain, or pelvic tenderness, but with significant leukocytosis, tachycardia, or hemoconcentration can occur, the new labeling states.

Be watchful for prolonged heavy vaginal bleeding, the new labeling advises. Vaginal bleeding occurs in almost all patients during the mifepristone/misoprostol regimen; women usually experience vaginal bleeding or spotting for an average of nine to 16 days. Up to 8% of women may experience some type of bleeding for 30 days or more.[2]

Prolonged heavy bleeding, which is characterized as soaking through two thick full-size sanitary pads per hour for two consecutive hours, may be a sign of incomplete abortion or other complications. Prompt medical or surgical intervention may be needed to prevent the development of hypovolemic shock, according to the labeling. Counsel patients to seek immediate medical attention if they experience such prolonged heavy vaginal bleeding following a medical abortion. Providers may treat the excessive bleeding with uterotonics, vasoconstrictor drugs, curettage, administration of saline infusions, and/or blood transfusions.

Providers also should be on the lookout for an undiagnosed ectopic pregnancy in women who are undergoing a medical abortion, since some of the expected symptoms of a medical abortion may be similar to those of a ruptured ectopic pregnancy. The presence of an ectopic pregnancy may be missed even if the patient undergoes ultrasonography prior to being prescribed

RESOURCE

- **For more information on Mifeprex**, go to its web site, www.earlyoptionpill.com. PDF versions of the label, medication guide, patient agreement, and provider letter are available on the opening page. Medical questions regarding Mifeprex may be directed to its toll-free number, (877) 432-7596.

Mifeprex, the company states. **(Review further clinical information on determining ectopic pregnancy in the *Contraceptive Technology Reports* monograph, "Gauging the effectiveness of mifepristone and misoprostol," inserted in the February 2001 issue.)**

A small number of ruptured ectopic pregnancies have been reported to Danco during its postmarketing surveillance on Mifeprex; no causal relationship between these events and Mifeprex and misoprostol has been established, the company states.

Use medication guide

Mifeprex providers should give patients copies of the new medication guide to help patients understand the medical abortion process. Women also should be advised to take the medication guides to the emergency department or any other health care provider they may visit for problems. The guide will help those health care providers to understand that the patient is undergoing a termination of pregnancy and help them assess risks associated with that condition.

Help women to understand that mifepristone medical abortion is "extremely safe and extremely effective," says Cullins.

"It, like any other pregnancy-related situation, is not without risks," she adds. "It is much safer than carrying a pregnancy to term, whether or not that pregnancy ends in either vaginal delivery or cesarean section."

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Migraine and OCs: What options are open?

How many women do you see in your practice who say they have chronic or recurrent headaches? If the numbers are high, don't be surprised: Headaches are a frequent occurrence in women of reproductive age.[1] But what is your approach in determining whether these women may use combined oral contraceptives (OCs)?

A just-published meta-analysis of several studies highlights the risk of stroke in women who use oral contraceptives and who have migraine headaches.[2] What role does migraine headache play in determining OC use?

Clinicians must use their diagnostic skills in determining what type of headache women are describing when offering guidance on birth control, says **John Guillebaud**, MD, emeritus professor of family planning and reproductive health at University College in London. While guidelines from the Geneva-based World Health Organization (WHO) state that nonmigrainous headache, whether mild or severe, is not a contraindication to OC use,[3] the agency's Medical Eligibility Criteria lists migraine headaches with aura at any age as a clear contraindication to combined oral contraceptive use.[4]

Why is a differential diagnosis so important? Migraine headaches, particularly those where before the headache itself there is aura, are an independent risk factor for stroke among

EXECUTIVE SUMMARY

A just-published meta-analysis of several studies highlights the risk of stroke in women who use oral contraceptives (OCs) and have migraine headaches. Since the presence of true migraine headaches affects the decision to use OCs, clinicians need to use diagnostic skills to determine OC eligibility.

- Guidelines from the World Health Organization list migraine headaches with aura at any age as a clear contraindication to combined OC use.
- Age is a determining factor for women with migraines without aura; those younger than 35 with no other risk factors for stroke may safely initiate use the Pill, while the disadvantages outweigh the benefits for those ages 35 and older. Women who cannot use the Pill may consider nonestrogen methods.

Aura diagnosis: Watch the hands

When determining whether a woman has migraines with aura, it is important to not only listen to her description, but to watch how she illustrates the symptoms, says **John Guillebaud**, MD, emeritus professor of family planning and reproductive health at University College in London. He shares the following tip from fellow colleague Anne MacGregor, MD, of the City of London Migraine Clinic:

• When the patient is recounting symptoms prior to the beginning of a headache, and by the end of her discussion, has kept her hands down beside herself; however, she describes her symptoms, they probably do not denote aura.

• However, if the woman brings her hand up during her description and moves it in a wavy, circular area, and she describes her field of lost vision and occurrence of bright lights, consider it a diagnostic sign of aura.

"So as well as listening to what the patient says, you watch what her hands do," advises Guillebaud. "If one or other hand is waved, drawing in the air beside her head while she describes something that happened in the eyes BEFORE the headache, that's highly suggestive of aura." ■

reproductive-age women, says Guillebaud. In 99% of cases, aura involved some loss of part of the visual field, often described as surrounded by flashing lights or bright zigzag lines.

Migraine headaches represent more than half of all chronic, recurring headaches in the United States, and most of those with migraines are women.[5] Migraine symptoms may include:

• intense throbbing, pulsing, or dull aching pain on one or both sides of the head (six out of 10 migraine sufferers have pain on only one side of the head, while four out of 10 have pain on both sides);
• nausea with or without vomiting;
• changes in vision, including blind spots or blurry vision;
• pain that worsens with physical activity;
• pain that gets in the way of daily activities;
• sensitivity to light, sound, or odors;
• feeling cold or sweaty;
• tender or stiff neck;
• lightheadedness;
• scalp tenderness.[6]

If it is determined that headaches are migrainous in nature, clinicians then need to assess whether focal neurological symptoms within an aura are associated with the attacks.

Aura typically starts before the headache as a flickering, uncolored zigzag line in the center of the visual field and gradually progresses laterally to the periphery of one hemifield, usually leaving a scotoma, which is bright, not an area of blackness.[7] If sensory or motor symptoms occur, they usually are unilateral and rarely without associated visual symptoms.[7] These symptoms typically last less than one hour, resolving before the onset of headache.[8] Clinicians can identify aura by asking, "Have you ever had visual disturbances lasting five to 60 minutes followed by headache?"[9] **(Use visual cues to determine aura; see the diagnostic tip, left.)**

Why is it so important that a determination of aura be reached? A large case-control study performed in Europe found that women with migraines with aura had a fourfold increased risk of ischemic stroke.[10] Other studies have estimated relative risks as high as 6.2[11] or even 14.8.[12]

There remains some controversy in the literature regarding the potential link (positive association) between migraine and stroke; several studies have had conflicting results, says **Mahyar Etminan**, a postdoctoral fellow in clinical epidemiology at Royal Victoria Hospital in Montreal, who served as lead author of the just-published meta-analysis. The risk of migraine among users of oral contraceptives must be further investigated, authors of the meta-analysis conclude.[2]

"Those who have migraines, take [the] Pill, smoke, or may have other stroke risk factors may want to be more cautious and learn the signs and symptoms of migraine," states Etminan.

For women with no other risk factors for stroke (diabetes mellitus, hyperlipidemia, hypertension, obesity, family history of arterial disease below 45 years, and smoking cigarettes) who have nonmigrainous headaches, mild or severe, the WHO criteria place the least restrictions on combined OC use. WHO ranks initiation of combined OCs at 1 — a condition for which there is no restriction for the use of the contraceptive method.[4] The contraceptive transdermal patch and the contraceptive vaginal ring fall in this same category.

However, for women with migraine headaches without aura, age plays a determining factor, according to the WHO guidelines. For those younger than age 35 and without other risk factors, the benefits of initiating OC use outweigh the potential risks (WHO Category 2); however, for those 35 and older, the risks outweigh the

benefits. Initiation of OCs in these older women is ranked at 3 (a condition where the theoretical or proven risks usually outweigh the advantages of using the method), while continuation is ranked at 4 (a condition which represents an unacceptable health risk if the contraceptive method is used).[4]

What methods may these women use? Look at any nonestrogen-containing methods such as depot medroxyprogesterone acetate (DMPA) and progestin-only pills as well as intrauterine contraception, says Guillebaud.

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New research eyes OC in acne treatment

The next patient in your exam room is an adolescent female, who says she's interested in birth control pills. Her chief focus? While she's interested in contraception, she asks several questions about an "acne pill."

According to *A Pocket Guide to Managing Contraception*, all combined oral contraceptives (OCs) lower free testosterone due to their antiandrogenic compounds.[1] However, only two pills — Ortho Tri-Cyclen (Ortho-McNeil Pharmaceutical, Raritan, NJ) and Estrostep (Warner Chilcott, Rockaway, NJ) — carry an approved indication from the Food and Drug Administration (FDA) for treatment of mild-to-moderate acne. Ortho Tri-Cyclen uses a combination of ethinyl estradiol and norgestimate, while Estrostep uses a mix of ethinyl estradiol and norethindrone acetate. Ortho Tri-Cyclen received its indication based on research published in 1997[2]; Estrostep gained its approval on research published in 2001.[3]

Look for other OCs to seek similar acne indications; recently published research indicates that Yasmin (Berlex Laboratories, Montville, NJ), a combination of ethinyl estradiol and drospirenone, also is effective in treating the condition.[4] Other OCs are now being evaluated for possible treatment of acne[5]; two trials involving Alesse (Wyeth-Ayerst Laboratories, Philadelphia) showed total acne improvement of 23%-40% compared with 9%-23% with placebo.[6,7] Alesse relies on a combination of ethinyl estradiol and levonorgestrel.

Berlex Laboratories is conducting further research on potential use of Yasmin in acne treatment and awaits completion of those studies before filing with the FDA, says company spokes-woman **Kimberly Schillace**.

The Yasmin trial was designed as a double-blind study to compare the efficacy and tolerability of the drug. Ortho Tri-Cyclen was used as the comparison drug. Researchers at 56 international centers randomly assigned 1,154 women to use the study or the comparison drug. Of those who completed the

COMING IN FUTURE MONTHS

- Will clinicians see more extended-regimen options?
- Review testosterone use in women
- Update your cervical cancer screening strategies
- New STD diagnostic tools on the way
- How to enhance parent/teen communication

EXECUTIVE SUMMARY

New research indicates that the oral contraceptive (OC) Yasmin may be effective in treating acne.

- In a double-blind study comparing the OC with another pill, Ortho Tri-Cyclen, the formulation exhibited equal effectiveness in treating mild-to-moderate acne.
- While all combined oral contraceptives lower free testosterone due to their antiandrogenic compounds, only two pills — Ortho Tri-Cyclen and Estrostep — carry an approved indication from the Food and Drug Administration for acne treatment.

study, 505 received Yasmin and 486 received Ortho Tri-Cyclen.

Investigators reported that Yasmin use resulted in a greater reduction of acne lesions than the comparison drug; in addition, researchers observed an improvement of overall facial acne in women receiving Yasmin compared to those using the comparison drug.[2]

The unique pharmacologic activities of drospirenone may have resulted in Yasmin's performance, comments lead author **Ian Thorneycroft**, MD, professor of obstetrics and gynecology at the University of South Alabama and an obstetrician/gynecologist with the Bay Area Physicians for Women at Spring Hill Hospital, both in Mobile, AL.

Drospirenone first became available with the initial launch of Yasmin in Europe in 2000, followed by its U.S. launch in 2001. Scientists also are studying Yasmin's antimineralocorticoid and antiandrogenic properties for potential use in treatment of premenstrual dysphoric disorder. **(See a review of the research in the *Contraceptive Technology Update* article, "The Pill for PMS relief? New research says yes," June 2003, p. 52.)**

Canadian clinicians now may use Yasmin in their practices; the drug just received Canadian clearance for use as a contraceptive in January 2005.

U.S. clinicians may see a lower dose of the drug in 2005; Berlex submitted a New Drug Application in December 2003 for the new product. If approved by the FDA, the new version of Yasmin will contain 20 mcg ethinyl estradiol with 3 mg drospirenone.

If an adolescent chooses an OC strictly for use as an acne treatment, she may feel embarrassed about using a "birth control" pill. How should a clinician counsel for method success? Take a look at the following suggestions[8]:

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

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ASK THE EXPERTS

OCs, coexisting medical conditions: What to do?

Check options for scleroderma, antacid use

What are some of your questions when it comes to hormonal contraceptive use? Two readers' questions are tackled below by **Leon**

Speroff, MD, associate director of the Women's Health Research Unit at Oregon Health & Science University in Portland, and **David Archer**, MD, professor of obstetrics and gynecology and director of the Clinical Research Center at the Eastern Virginia Medical Center in Norfolk.

Question: Should scleroderma patients should use combined birth control (pills, patch, or ring)?

Speroff: I know of no study that has addressed this question. In my opinion, if there is no clinical or laboratory evidence of vascular disease, low-dose estrogen-progestin contraception can be used.

Question: I hear some practitioners telling patients that they can't take antacids within a couple of hours of taking oral contraceptive pills. Is this true, and what is the rationale? Are there any other medications that may interact with oral contraceptives?

Archer: There is no convincing evidence in the medical literature of an adverse interaction between antacids and oral contraceptives.[1] I would answer that oral contraceptives can be taken with antacids and antibiotics, two of the more commonly prescribed agents used by women. Anti-epileptics and rifampin, the anti-tuberculosis drug, do have an effect on oral contraceptives, reducing the absorption and/or increasing the metabolism of ethinyl estradiol and the progestin.

(*Editor's note: For more information on concomitant medications and oral contraceptives, consult the latest guidance from the Geneva-based World Health Information in the* Contraceptive Technology Update *article, "Update your practice: Check new WHO Medical Eligibility Criteria," June 2004, p. 61. Also check the answers to a similar question on drug interactions in the "Ask the Experts" column published in the April 2003 issue, p. 45.*)

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CTU PDATES
News ■ Resources ■ Events

Midwives conference scheduled for June

Make plans now to attend the annual meeting of the Washington, DC-based American College of Nurse-Midwives. Scheduled for June 10-16 in Washington, DC, the event, "With Women Through Time," will commemorate the organization's 50th anniversary.

The conference will feature seminars on such health issues as abnormal uterine bleeding and endometrial sampling, complementary and alternative medicine in women's health care, and psychopharmacology for midwives.

Participants can earn as many as 30 hours of continuing education credit. Other activities will include meetings with U.S. senators and representatives to promote legislation affecting the delivery of midwifery services.

On-line registration may be made by visiting the organization's web site, www.midwife.org; click on the conference links. Member cost is $375 if registration is received by March 11; $460 if received by May 27; and $510 when entered at the conference site. Nonmember cost is $465 by March 11, $535 by May 27, and $585 at the conference. ■

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 **"Migraine and OCs: What options are open?")**
- **Describe** how those issues affect service delivery and note the benefits or problems created in patient care in the participant's practice area. (See **"Snapshot: What Are the Contraceptive Trends?")**
- **Cite** practical solutions to problems and integrate information into daily practices, according to advice from nationally recognized family planning experts. (See **"CDC: Family planners should be on the lookout for lymphogranuloma venereum"** and **"Gonorrhea rates drop; stay focused on spread."**)

9. What is the top contraceptive method among young women, according to the latest statistics from the National Survey of Family Growth?

A. Contraceptive injectable
B. Transdermal contraceptive
C. Oral contraceptive pill
D. Condom

10. Which of the following is NOT a risk factor for stroke?

A. Diabetes mellitus
B. Hyperlipidemia
C. Smoking cigarettes
D. Fibroadenoma

11. In 2004, an outbreak of LGV was confirmed in the Netherlands. United States clinicians were asked to watch for symptoms of this sexually transmitted disease among their patients and focus particularly on which risk group?

A. Men who have sex with men
B. Women who report more than three sexual partners within the past six months
C. Heterosexual men who report more than six sexual partners within the past six months
D. African American women who are infected with HIV/AIDS

12. Which one of these drugs is NOT a fluoroquinolone?

A. Ciprofloxacin
B. Ceftriaxone
C. Ofloxacin
D. Levofloxacin

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

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™

CDC warning: Family planners should be on the lookout for lymphogranuloma venereum

Usually rare LGV cases spiked in European countries in 2003-2004

An outbreak of a type of *Chlamydia trachomatis*, lymphogranuloma venereum (LGV) has occurred in the Netherlands and other European countries, which has led infectious disease officials with the Centers for Disease Control and Prevention (CDC) to ask U.S. clinicians to look out for LGV cases.

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, notes **Catherine McLean**, MD, medical epidemiologist with the CDC Division of STD Prevention. "So it's important to alert health care providers to watch for these symptoms in their patients, especially among MSM [men who have sex with men], and evaluate and treat patients as appropriate," she says.

The systemic STD LGV is extremely rare in the United States and Europe, although its prevalence is greater in Africa, Southeast Asia, Central and South America, and Caribbean countries.[1] However, from April 2003 to September 2004, there were 92 confirmed cases of LGV reported among MSM in the Netherlands.[1]

"Typically, five cases a year are reported," McLean notes. "It's a fairly impressive increase, and this particular increase involved gay and bisexual men, and 77% of those in whom HIV status is known were HIV-positive."

There also were reported increases in LGV cases in Belgium, France, and Sweden, she says.

Dutch medical investigators have reported that men diagnosed with LGV during the 2004 outbreak all were Caucasian MSM younger than 50 who had further sexual contacts with MSM in Germany, Belgium, the United Kingdom, and France.[2,3]

"The increases have been linked to HIV, and nearly all of those affected reported risk behaviors

EXECUTIVE SUMMARY

The Netherlands has experienced an unusual outbreak of the rare sexually transmitted disease (STD) lymphogranuloma venereum (LGV), with 92 confirmed cases among men who have sex with men compared with the typical LGV caseload of five each year.

- In response to the European outbreak, the Centers for Disease Control and Prevention asked U.S. clinicians to watch for LGV cases, and the CDC notes that the STD has symptoms that may be difficult to identify because of their similarity to other health problems.
- Symptoms for LGV, which are similar to those caused by other conditions, include a small genital papule, which can ulcerate within a month of infection; tender and swollen lymph nodes; and gastrointestinal problems, including inflammation and bleeding from the rectum and colon.
- Standard treatment is 100 mg doxycycline, twice a day for 21 days.

such as unprotected anal sex," McLean notes. "The majority also attended casual sex parties."

LGV can increase HIV risk

LGV, like other ulcerative STDs, can increase the risk of HIV transmission, she says.

Although the recent outbreak has been associated with MSM populations, LGV also can be transmitted to women, so health care providers in HIV, STD, and other clinics need to watch for symptoms of the disease, McLean says.

A South African study of HIV-1 infection and genital ulcer disease found that LGV infection was higher among females.[4]

Here are the chief symptoms:

- LGV infection may begin with a small genital papule, which can ulcerate within a month of infection. It may be difficult to detect the lesion if it's within the urethra, vaginal vault, or rectum.[1]
- LGV also may cause tender and swollen lymph nodes and gastrointestinal problems, including inflammation and bleeding from the rectum and colon. This symptom may be similar to inflammatory bowel disease.[1]

Symptoms hard to pinpoint

Another obstacle to diagnosis is that HIV patients may report some of these same symptoms caused by other conditions and infections, McLean says.

The real challenge will be for clinicians to evaluate patients for the more common causes of gastrointestinal problems, while keeping in mind that LGV could be the cause, she says. Diagnosis of LGV is based mainly on the clinical findings, although it may be helpful to conduct a serologic test for *C. trachomatis* to support the diagnosis. Clinicians also could use nonculture nucleic acid testing to identify *C. trachomatis* from a lesion or site of infection, such as the rectum.[1] However, this method is not specific for LGV, and the Food and Drug Administration (FDA) has not approved the use of rectal swabs for nonculture nucleic acid testing.[1]

When presented with symptoms that could be LGV, clinicians also might consider the patient's HIV status; recent history of high-risk sexual behavior, especially unprotected, receptive anal intercourse; and whether the patient recently has traveled or had sexual contact with a European MSM, McLean says.

"Although LGV is infrequently diagnosed, sexual contact with European MSM may be a factor, but certainly is not required," McLean says. "The most important thing is for health care providers to watch for these symptoms and think of LGV in their patients who have these symptoms."

Once LGV is diagnosed, it's treatable with antibiotics. The CDC recommends these treatments:

- The most recommended choice is 100 mg doxycycline, twice a day for 21 days.[1]
- An alternative is 500 mg erythromycin, administered orally four times a day for 21 days.[1]
- The patient's sex partners from 30 days prior to the onset of symptoms should be evaluated and treated if diagnosed with LGV. If these sex partners do not have any symptoms, the CDC recommends they be treated with 1 g azithromycin in a single dose or with 100 mg doxycycline, twice a day for seven days.[1]

Left untreated, LGV infection could cause chronic scarring, constipation, rectal pain, and abscesses, McLean reports.

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Gonorrhea rates drop; stay focused on spread

Efforts to lower the rates of gonorrhea in the United States are dipping figures to all-time lows, but work remains to erase racial disparities and combat growing drug resistance to the sexually

EXECUTIVE SUMMARY

New statistics from the Centers for Disease Control and Prevention (CDC) indicate that U.S. gonorrhea prevalence dropped nearly 5% between 2002 and 2003, continuing a downward trend. However, a higher percentage of gonorrhea strains were resistant to traditional antibiotic treatments in 2003 than in the previous year.

- While gonorrhea rates dipped to 116.2 cases per 100,000 population, African Americans remained most heavily impacted, with reported rates of disease 20 times higher than for whites.
- The CDC now advises that fluoroquinolones no longer be used as first-line treatment for gonorrhea in men who have sex with men, due to an increase in cases of fluoroquinolone-resistant gonorrhea in that population.

transmitted disease (STD).

While gonorrhea rates dropped to 116.2 cases per 100,000 population between 2002 and 2003, African Americans remained most heavily affected by gonorrhea, with reported rates of disease 20 times higher than for whites, states **John Douglas Jr.**, MD, director of the Centers for Disease Control and Prevention (CDC) Division of STD Prevention in the agency's National Center for HIV, STD, and TB Prevention. Improved screening and treatment of at-risk individuals are critical to reducing the impact of gonorrhea, especially among African Americans, he states.

According to the CDC, gonorrhea is the second most commonly reported infectious disease in the United States, with 335,104 cases reported in 2003. An estimated 718,000 new infections occur each year.[1] New figures published in the agency's *Sexually Transmitted Disease Surveillance, 2003* indicate that the national gonorrhea rate dropped to an all-time low, decreasing by 4.8% between 2002 and 2003.[2] **(See the resource listing on p. 4 for instructions on how to access the publication. Also check the snapshot on p. 4 for an overview of other STDs.)**

State figures in the new report vary widely, ranging from 264.4 per 100,000 people in Louisiana to 5.1 per 100,000 people in Idaho. Forty-two states report rates above the goal of 19.0 cases per 100,000 population, the target listed in Healthy People 2010, a comprehensive set of national disease prevention and health promotion objectives developed through the Department of Health and Human Services.

Understand the disease

Caused by the bacterium *Neisseria gonorrhoeae*, gonorrhea can cause infection in the female reproductive tract as well as the urethra in men and women. It also can grow in the mouth, throat, eyes, and anus. Infection is spread through contact with the penis, vagina, mouth, or anus; ejaculation does not have to occur for the STD to be transmitted or acquired. It also can be spread from mother to baby during delivery.[3]

Gonorrhea is easily cured; untreated cases can lead to serious health consequences. In men, untreated gonorrhea can cause epididymitis, which can lead to infertility. For women, untreated gonorrhea can develop into pelvic inflammatory disease, which can translate into chronic pelvic pain, ectopic pregnancy, and infertility. Gonorrhea acquisition also increases the risk of HIV transmission in men and women.

The CDC lists the following first-line treatment options:

- Cefixime 400 mg orally in a single dose;
- Ceftriaxone 125 mg IM in a single dose;
- Ciprofloxacin 500 mg orally in a single dose;
- Ofloxacin 400 mg orally in a single dose; or
- Levofloxacin 250 mg orally in a single dose.[3]

The original manufacturer of cefixime, Wyeth Pharmaceuticals in Collegeville, PA, discontinued U.S. production in 2002. **(See the June 2003 *Contraceptive Technology Update* article, "Treatment options narrow for gonorrhea," p. 67.)** However, in 2004 the FDA granted Lupin Pharmaceuticals of Baltimore approval for manufacture of cefixime suspension 100 mg/5 ml, as well as cefixime in 400 mg tablet form. Lupin has relaunched its product under the same brand name, Suprax. **(See the resource box on p. 4 for company contact information.)**

If chlamydia is not ruled out, clinicians should use dual therapy in gonorrhea treatment, adding azithromycin, 1 g orally in a single dose, or doxycycline, 100 mg orally twice a day for seven days, to the gonorrhea treatment regimen. Such dual treatment has become more commonplace since patients infected with *N. gonorrhoeae* often are

RESOURCES

- To review the statistics in the ***Sexually Transmitted Disease Surveillance, 2003*** on-line, go to the CDC's National Center for HIV, STD, and TB Prevention web site, www.cdc.gov/std. Click on "2003 STD Surveillance Report."

For more information on Suprax (cefixime), contact:

- **Lupin Pharmaceuticals**, Harborplace Tower, 111 S. Calvert St., 21st Floor, Baltimore, MD 21202. Telephone: (800) 826-9556 or (410) 576-2000. Fax: (410) 576-2221. E-mail: suprax@lupinusa.com. Web: www.suprax.info.

coinfected with *C. trachomatis*.[3]

Be vigilant about use of the fluoroquinolones ciprofloxacin, ofloxacin, and levofloxacin; these drugs are not recommended for treatment of gonorrhea infections acquired in Hawaii, California, Asia, the Pacific, and in other areas with increased prevalence of fluoroquinolone resistance. Through the CDC's nationwide Gonococcal Isolate Surveillance Project (GISP), CDC found that the prevalence of fluoroquinolone-resistant gonorrhea (QRNG) more than doubled from 0.4% in 2002 to 0.9% in 2003, says **Stuart Berman**, MD, ScM, chief of the epidemiology and surveillance branch in the CDC's Division of STD Prevention.

"Most notably, QRNG increased among MSM [men who have sex with men] from 1.8% in 2002 to 4.9% in 2003," says Berman. "Based on these and other available data, in April 2004, CDC recommended that fluoroquinolones no longer be used as first-line treatment for gonorrhea in MSM." **(Review information on ciprofloxacin-resistant gonorrhea's rise in *CTU*'s article, "Ciprofloxacin-resistant gonorrhea on the rise," June 2002, p. 64.)**

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Snapshot: New trends in STDs in the U.S.

What are some emerging trends in other sexually transmitted diseases (STDs) in the United States? Check the following highlights from the Atlanta-based Centers for Disease Control and Prevention's (CDC) *2003 STD Surveillance Report*:

• Chlamydia.

Chlamydia retains its No. 1 status as the most commonly reported infectious disease in the United States. In 2003, 877,478 chlamydial infections were reported, an increase from 2002's 834,555 case level. The CDC estimates there are actually 2.8 million new cases of chlamydia each year, since many cases are not reported or diagnosed.[1]

• Syphilis.

The syphilis rate in the United States rose for the third consecutive year in 2003 and increased 19% from its all-time low in 2000. The national rate of primary and secondary (P&S) syphilis increased by 4.2% from 2002 to 2003, from 2.4 to 2.5 cases per 100,000 population.

What is fueling this rise? Outbreaks of syphilis among men who have sex with men (MSM) have been reported in several U.S. cities in recent years, and they may be a major factor in increasing the national syphilis rate. Recent research indicates more than 60% of all P&S cases reported in 2003 occurred among the MSM population.[2]

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