

# CONTRACEPTIVE TECHNOLOGY

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A Monthly Newsletter for Health Professionals

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FEBRUARY 2006

VOL. 27, NO. 2 • (pages 13-24)

## Aim toward success in OC compliance, better communication improves use

*More than 33% have sex when OC reliability may be compromised*

The next woman in your examination room has been using oral contraceptives (OCs) as her chosen method of birth control for the past three months. During her checkup, she tells you that she often misses a pill in her pack, but doesn't take further precautions for protection.

This woman is not alone in her dilemma. According to a new international study, more than one-third of women continue to have unprotected sexual intercourse when they know the Pill's reliability may be compromised.<sup>1</sup> What can providers do to help women achieve success with daily pill-taking?

About 60% of the 62 million women ages 15-44 in the United States are using a contraceptive method; about 30% of those women are using the Pill for birth control.<sup>2</sup> The Pill represents a very effective form of contraception. When used correctly, for every 1,000 women who take pills for one year, just three will become pregnant in the first year of use.<sup>3</sup> But in a typical use setting, the Pill's failure rate rises to 8% in the first year.<sup>3</sup>

## EXECUTIVE SUMMARY

Helping women to achieve success with oral contraceptives is challenging. More than one-third of women continue to have unprotected sexual intercourse when they know the Pill's reliability may be compromised, according to a new international study.

- About 60% of the 62 million women ages 15-44 in the United States are using a contraceptive method. About 30% of those women are using the Pill for birth control.
- The Pill represents a very effective form of contraception. When used correctly, for every 1,000 women who take pills for one year, just three will become pregnant in the first year of use. But in a typical use setting, the Pill's failure rate rises to 8% in the first year.

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What can you do to help women achieve success with oral contraceptives? Know that the office/clinic visit is just the start of the patient's/client's process of effective contraceptive use, says **Deborah Oakley**, PhD, professor emeritus in the University of Michigan School of Nursing in Ann Arbor. "The provider can help with this future behavioral process by asking about

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

### Subscriber Information

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

**Subscription rates:** U.S.A., one year (12 issues), \$499. Outside U.S., add \$30 per year, total prepaid in U.S. funds. Discounts are available for multiple subscriptions. For pricing information, call Steve Vance at (404) 262-5511. **Back issues**, when available, are \$75 each. (GST registration number R128870672.) **Photocopying:** No part of this newsletter may be reproduced in any form or incorporated into any information retrieval system without the written permission of the copyright owner. For reprint permission, please contact Thomson American Health Consultants. Address: P.O. Box 740056, Atlanta, GA 30374. Telephone: (800) 688-2421. World Wide Web: <http://www.ahcpub.com>.

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This publication does not receive commercial support.

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whether the woman has a plan for how she is going to use her method effectively, what that plan is, and how she is going to overcome barriers and solve problems," says Oakley, who has studied Pill use.<sup>4-7</sup>

Many women experience difficulty in taking the Pill correctly, according to results from the new survey.<sup>1</sup> To perform the analysis, researchers questioned 8,531 heterosexual men and women ages 16-40 years in 14 countries about their contraceptive use and experience. A previous survey shows that more than two-thirds of women regularly miss pills, and one in five pill users miss a pill every month.<sup>8</sup>

Problems with pill-taking can lead to fears. More than half of pill users and 40% of men whose partner used the Pill had thought they/their partner might be pregnant while on the Pill, according to results from the new survey.<sup>1</sup> Overall, 67% of women and 59% of men reported that pregnancy scares had a negative impact on their emotional life, rising to 72% and 67% respectively if their career was important to them. About 25% of women and men reported a negative impact on their work or studies, with figures rising to 34% and 42% respectively among respondents who said their career or studies were important to them.<sup>1</sup>

### Who can take OCs daily?

What are some ways to assess a woman's ability to take a pill every day? Findings from research performed by Oakley and family planning colleagues suggest that two of the most powerful predictors of those who especially need to be asked about future plans for effective use are:

- women who have had an abortion;
- women who are not especially strong in their resolve to avoid pregnancy for the next six months.

Contrary to many clinicians' beliefs, risky OC use is not necessarily related to socioeconomic status or age, says Oakley. Recent research confirms that compliance problems are common among all age groups, with 47% of women missing one or more pills per cycle and almost a quarter (22%) missing two or more pills per cycle.<sup>9</sup>

Help women to formulate a game plan for success with oral contraceptives, says Oakley. Help them to identify potential barriers and discuss how to solve such problems — use the following "problem areas" as discussion triggers:

- staying overnight at a friend or relative's house and forgetting to take her pill pack;
- forgetting to take a pill during a stressful

time at work or school;

- drinking too much or getting sick so that no protection is used or severe vomiting occurs;
- not having money to refill a prescription.

“Listening is such a powerful tool, and more of the provider-client/patient interaction needs to be focused on asking questions about how the future will unfold for the contraceptive user,” says Oakley.

### **Educate on side effects**

Aside from providing basic information about OCs, provide anticipatory guidance as part of the counseling process, says **Mimi Zieman, MD**, adjunct associate professor at Emory University in Atlanta. Although many women never experience adverse events related to Pill use, others may have episodes of breakthrough bleeding or may skip an entire period.<sup>10</sup>

“It is very important when a woman is starting oral contraceptives to know in advance what side effects she may have and the usual time course of those side effects, because many improve with time,” says Zieman. “The most important message is that if she is experiencing anything that she is worried about, or she doesn’t like, that she needs to call [the provider’s office] before just stopping using the method.”

Many teen OC users tend to skip pills, so anticipatory counseling also should include emergency contraception methods, use of backup contraceptives, and alternatives to sexual intercourse.<sup>10</sup>

Help patients to establish a regular pill-taking regimen, which may be cued to daily activities such as putting on earrings, brushing teeth, or showering. Another way women are reminding themselves to take their pill is by setting their cell phones to beep at a certain time each day. Research has looked at using daily e-mail reminders for pill-taking; 64% of women participating in the study said they found such reminders helpful.<sup>11</sup>

By gearing oral contraceptive counseling to a woman’s individual needs, clinicians can increase the likelihood that patients will adhere to the prescribed regimen, says Zieman.

“Today, there are so many formulations and so many delivery systems that we can really work to make people as satisfied as possible with their chosen method,” she states. **(Editor’s note: What is your guidance regarding missed pills? See upcoming issues of *Contraceptive Technology Update* for a review of current evidence.)**

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## **OCs associated with reduced risk of MS**

**F**indings from a new study indicate that use of oral contraceptives (OCs) may affect the development of multiple sclerosis (MS).<sup>1</sup> While the study provides support for the concept of hormonal influences in MS, more research is needed to demonstrate that the Pill can prevent the onset of the disease.

Approximately 400,000 Americans have MS, and every week about 200 people are diagnosed with the disease, according to the National Multiple Sclerosis Society in New York City.<sup>2</sup> A chronic, unpredictable disease of the central nervous system, MS is thought to be an autoimmune disorder. MS symptoms result when the immune system attacks myelin, the tissues surrounding the nerve fibers of the central nervous system.

Symptoms of MS are unpredictable and vary from person to person. They may include abnormal fatigue, episodes of numbness and tingling,

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Findings from a new study indicate that use of oral contraceptives (OCs) may affect the development of multiple sclerosis (MS). While the study provides support for the concept of hormonal influences in MS, more research is needed to demonstrate that the Pill can prevent the onset of the disease.

- Approximately 400,000 Americans have MS, and every week about 200 people are diagnosed with the disease.
- MS occurs twice as often in women as in men, and attacks are less likely during pregnancy. This finding is sparking research into the possible influence of sex hormones on the disease.

loss of balance and muscle, slurred speech, tremors, stiffness, and bladder problems.<sup>2</sup>

MS occurs twice as often in women as in men, and attacks are less likely during pregnancy. This finding is sparking research into the possible influence of sex hormones on the disease, says **Patricia O’Looney**, PhD, director of biomedical research programs at the National MS Society. “Our position in the past five to six years has been to encourage research in this area, to really accelerate the interest in the scientific community in trying to find more answers.”

Such advances are needed. In severe MS, people have symptoms on a permanent basis that may include partial or complete paralysis as well as difficulties with vision, cognition, speech, and elimination.<sup>2</sup>

When investigators began formulating the currently published research, there were only three studies assessing the association between OCs and MS,<sup>3,5</sup> says **Álvaro Alonso**, MD, PhD, a research fellow in the department of epidemiology at Harvard University’s School of Public Health in Boston and lead author of the study.

None of them found an important link, he observes. “However, two of them had a limited sample size, and the other was not well suited to assess the short-term effect of OCs on the risk of MS, given that the information on OC is gathered every other year.”

To conduct the current study, Alonso’s team analyzed women from the General Practice Research Database, which contains prospective health information on more than 3 million people in the United Kingdom who are enrolled with selected general practitioners. They identified 106 women younger than 50 years with definite or probable MS who

had been followed for at least three years before the onset of symptoms and compared the records with those of 1,001 women without the disease.

Researchers found that the risk of developing MS was 40% lower in women who had used oral contraceptives, compared with nonusers, during the previous three years. In addition, women in the study showed a higher risk of developing first symptoms of MS in the six months following a pregnancy.

“From the preventive point of view, it would be worthy to study the specific association of different types of OCs on the risk of MS,” says Alonso. “Our number of MS cases was not large enough to study separately different OCs.”

### Explore the differences

Understanding the increased incidence and prevalence of MS in women compared to men, along with differences in disease course and manifestations, can provide new information about MS, its cause, and even its treatment, says O’Looney.

Prior to 1998, the National MS Society supported fewer than five research and training grants with a gender focus; however by 2003, such projects accounted for some \$6.6 million in total expenditures, a 10-fold increase over pre-targeted funding. The society is cofunding projects with the National Institute of Allergy and Infectious Diseases to further look at sex differences in disease course, the immune system, brain tissues, hormonal influences, and response to infection.

One example of gender-focused research comes from Rhonda Voskuhl, MD, an associate professor in the department of neurology at the University of California at Los Angeles. In a small-scale, early-phase trial of the hormone estriol, Voskuhl’s team report that women with relapsing-remitting MS showed decreases in brain lesion activity and immune responses during treatment.<sup>6</sup> A larger study of the subject is planned, says O’Looney.

“The MS Society has always had interest in trying to understand why women develop the disease more frequently,” states O’Looney. “It wasn’t until we knew a little bit more about the immune system that we could try and tease away the differences that the hormones may play.”

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## At-home HIV test kit to undergo FDA review

Increasing access to HIV testing is a prevention priority in the United States. Health officials estimate more than 25% of those infected are transmitting HIV to others because they are unaware that they are infected.<sup>1</sup>

OraSure Technologies of Bethlehem, PA, is aiming at lowering those numbers. It intends to seek Food and Drug Administration (FDA) approval to sell its OraQuick ADVANCE test over the counter (OTC), reports **Jennifer Moritz**, company spokeswoman. The company made a presentation before the FDA's Blood Products Advisory Committee in November 2005 regarding such a potential product.

The OraQuick ADVANCE Rapid HIV-1/2 Antibody Test is the first and only FDA-approved rapid point-of-care test that provides results for

HIV-1 and HIV-2 with greater than 99% accuracy in as little as 20 minutes. It uses an oral fluid, fingerstick or venipuncture whole blood or plasma sample.<sup>2</sup> It received a CLIA (Clinical Laboratory Improvements Amendments of 1988) waiver in 2004 that allows the test to be used in a wide variety of settings, including outreach clinics, community-based organizations, and physicians' offices. (Read more about the test in the following *Contraceptive Technology Update* articles: "Rapid HIV testing method approved — prepare now to apply new strategies," February 2003, p. 13; FDA approves HIV oral fluid-based test, June 2004, p. 64; and "Broader access now available for HIV test," August 2004, p. 95.) The only other CLIA-waived rapid HIV diagnostic test is the Uni-Gold Recombigen (Trinity Biotech, Wicklow, Ireland); however, it is designed to test blood — but not oral fluid — samples.

There are no rapid at-home self-collection kits available in the United States. One home self-collection kit marketed by Home Access Health Corp. of Hoffman Estates, IL, is available on the U.S. commercial market; however, it calls for self-collection of a blood sample via finger prick, with the specimen mailed to a laboratory for analysis.

The OraQuick ADVANCE over-the-counter test would allow a person to swab his or her gums with a special swab to collect the oral specimen. The swab then would be placed in a holder, with results displayed 20 minutes later. The company does not yet have a projected price for the OTC kit, says Moritz.

### More people will know

If rapid self-testing were available, it would greatly improve access to acceptable HIV testing in this country, says **Freya Spielberg**, MD, MPH, assistant professor in the department of family medicine at the University of Washington in Seattle.

"We need to try different tactics to win the war against AIDS," she says. "The most powerful prevention strategy is knowledge of HIV infection."

Studies have shown that people who learn that they have HIV are much more likely to change sexual and drug use behaviors so that others will not become infected, as compared to studies that provide intensive or brief behavioral interventions to those at risk for acquiring HIV,<sup>3,4</sup> Spielberg maintains. Many people at risk do not seek testing in clinical settings because of fear, stigma, and inconvenience; an over-the-counter

### EXECUTIVE SUMMARY

OraSure Technologies intends to seek Food and Drug Administration (FDA) approval to sell its OraQuick ADVANCE HIV test over the counter.

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- There are no rapid at-home self-collection kits available in the United States. While there is one approved at-home collection kit, its specimens must be mailed to a laboratory for results.

HIV test would help to overcome some of these barriers, says Spielberg.

According to Spielberg's research of those at risk for the disease, those who had never tested before were significantly more likely to prefer home self-testing compared with other strategies.<sup>5</sup>

"People like that home self-tests would be completely anonymous and that they will get results right away; whereas, with home specimen collection, people are concerned that their tests will get lost in the mail, the wait for test results makes people anxious, and people don't like getting their results from someone on the telephone who could trace their call," she says.

With any advance in HIV testing strategies, concerns are raised about the safety of receiving HIV test results without face-to-face counseling, Spielberg observes. Results from home specimen collection post marketing studies indicate that people may be able to use such tests responsibly. Among 1,494 positive individuals diagnosed with HIV and provided with test results over the telephone, 88% accepted referrals or already had access to medical care.<sup>6</sup> The remaining 12% already were getting care for HIV.<sup>6</sup>

"When implementing over-the-counter HIV testing, it will be necessary to determine educational and counseling strategies that are necessary to ensure the tests are accurate and safe, and to ensure that people who receive preliminary positive results through rapid tests understand the need for confirmatory testing and have ready access to appropriate referrals," says Spielberg. "Advances in communication technologies make this quite feasible; if necessary, it will be possible to offer interactive computer consent and interactive risk-reduction counseling and referrals for people who want to use self-tests for HIV."<sup>7</sup>

OraSure plans to work with the FDA to develop directions for using the test, interpreting results, and finding appropriate care, says Moritz.

"We anticipate providing access through multiple channels for counseling, support and linkages to care, as well as counseling on how to properly conduct the test and interpret the results," she notes. "This could be accomplished by providing customers service and support through telephone and a web site, as well as establishing counseling options by telephone, web site, or in person through a local public health clinic."

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## Condoms protect against herpes, study shows

Results from a just-published study indicate that consistent use of condoms is associated with lower rates of infection with herpes simplex virus-2 (HSV-2) and should be routinely recommended.<sup>1</sup>

The 18-month study, which included 1,843 adults who had a sexually transmitted disease (STD) or four or more sexual partners in the last year, found that participants who used condoms at least three-quarters of the time were 25% less likely to acquire HSV-2 than others in the study.

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- The 18-month study, which included 1,843 adults who had a sexually transmitted disease (STD) or four or more sexual partners in the last year, found that participants who used condoms at least three-quarters of the time were 25% less likely to acquire HSV-2 than others in the study.
- The Food and Drug Administration has issued draft guidance for condom labeling. Some conservative groups have criticized claims concerning condoms' effectiveness against STDs.

## RESOURCE

To comment on the FDA guidance, *Class II Special Controls Guidance Document: Labeling for Male Condoms Made of Natural Rubber Latex (70 FR 69,156 [2005])*, submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852. Electronic comments may be submitted at [www.fda.gov/dockets/ecomments](http://www.fda.gov/dockets/ecomments). (Search for docket ID 2004N-0556.) All comments should be identified with the docket number 2004D-0555 and should be submitted by Feb. 13, 2006.

According to lead researcher **Anna Wald, MD, MPH**, professor of medicine at the University of Washington in Seattle, the analysis is one of the first studies to show that condoms can reduce the risk of HSV-2 transmission.

"It showed that condoms work for both men and women, and in the past, that has not been very clear," she says.

Strengths of the study include its multicenter design, the large number of carefully evaluated participants, and use of serologic measures for detection of infection, states **Edward Hook III, MD**, professor of medicine at the University of Alabama in Birmingham, in an accompanying commentary to the study.<sup>2</sup> "In the last two years, we have removed the question as to whether condoms prevent some of the most common STDs we see," he says. "That includes herpes, which affects 45 million Americans and for which there are a million new cases a year, as well as gonorrhea and chlamydia, which between the two of them, there are over 4 million new cases every year."<sup>3,4</sup>

### **Latex highly effective**

According to *Contraceptive Technology*, clinical studies have shown latex condoms to be highly effective against HIV infection, the most serious STD, and should be promoted to sexually active patients at risk for STDs for this reason alone.<sup>5</sup>

Most people have no signs or symptoms from HSV-1 and 2 infections; when signs do occur, they typically appear as one or more blisters around the genitals or rectum.<sup>6</sup> The blisters break, leaving tender ulcers that may take two to four weeks to heal the first time they appear. Another outbreak can occur weeks or months after the first, but usually is less severe and shorter in duration. While the infection can stay in the body indefinitely, the number of outbreaks tends to decrease over a period of years.<sup>6</sup>

Men and women who were involved in the condom study were participants in a study of a herpes vaccine that did not work. Investigators evaluated the participants 11 times over 18 months and collected information about sexual activity and frequency of condom use at each visit. Blood samples also were taken at each visit to check for HSV-1 and HSV-2 infection.

To conduct the analysis, investigators looked at the relationship between frequency of condom use and HSV infection. During the study, 118 of the 1,843 participants developed HSV-2 infection, and 19 developed HSV-1 infection. Participants reporting more frequent condom use were less

likely to develop HSV-2 infection than patients who reported less frequent condom use. The researchers found no association between frequency of condom use and HSV-1 infection; too few participants were exposed to the infection during the study to determine such a link, researchers note.<sup>1</sup>

### **FDA eyes new labeling**

The impact of condoms on STD prevention has been a source of ongoing debate. Some conservative groups have claimed that condoms are less than effective in STD protection. (**Read about the debate in *CTU*, October 2001, "Confused about condoms? It's the data, not condoms, that may be inadequate," p. 113.**)

The debate has flared with the Food and Drug Administration (FDA) issuance of a draft guidance for condom labeling. (Access the guidance on-line at [www.fda.gov/cdrh/comp/guidance/1548.pdf](http://www.fda.gov/cdrh/comp/guidance/1548.pdf). **See the resource box, above, to submit comments on the guidance.**)

The new research on HSV and condoms adds further scientific evidence to the effectiveness of condoms, says Hook.

"In the last year or two, we have had good, well-conducted, published studies and analyses that show that condoms prevent these very common STDs and adds assurance to what many clinicians already believe," states Hook. It also adds empirical evidence and scientific proof to demonstrate to those people who would argue whether condoms really work," he says.

Wald adds, "I think recommendations should be based on scientific evidence, and scientific evidence shows that condoms can reduce the risk of many STDs, including HSV."

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## Fatal infection caused death in Mifeprex cases

A just-published report in the *New England Journal of Medicine (NEJM)* finds that the deaths of four California women who took the abortion drug Mifeprex (mifepristone, Danco Laboratories, New York City) were linked to toxic shock caused by the bacterium *Clostridium sordellii*, but the risk of infection in conjunction with taking the drug is "low," state epidemiologists who reviewed the cases.<sup>1</sup>

About 510,000 women in the United States have used Mifeprex since it received Food and Drug Administration (FDA) approval in 2000. In

### EXECUTIVE SUMMARY

A just-published report finds that the deaths of four California women who took the abortion drug Mifeprex (mifepristone) were linked to toxic shock caused by the bacterium *Clostridium sordellii*.

- The risk of infection with taking the drug is low, the authors say.
- In July 2005, Mifeprex's safety labeling was revised and providers were alerted with an advisory highlighting the risk of sepsis or blood infection when undergoing medical abortion using Mifeprex and misoprostol in a manner not consistent with the approved labeling.

July 2005, the drug's safety labeling was revised and health care providers were alerted with an FDA public health advisory highlighting the risk of sepsis or blood infection when undergoing medical abortion using Mifeprex and misoprostol in a manner not consistent with the approved labeling. (*Contraceptive Technology Update* reported on the updated labeling in its October 2005 article, "Mifepristone label gets new safety information," p. 115.)

The new *NEJM* report and a companion commentary put into perspective the fact that *C. sordellii* infections are very rare and have been reported in the literature in obstetric and gynecologic circumstances including after childbirth, medical abortion, and other nonpregnancy-related conditions, says **Cynthia Summers, DrPH**, Danco Laboratories' director of marketing and public affairs. The commentary was written by Michael Greene, MD, professor of obstetrics, gynecology, and reproductive biology at Harvard Medical School and director of obstetrics at Massachusetts General Hospital, both in Boston.

"I think it is clear after reading both pieces that medical abortion is a safe and important option for women who are facing an unintended pregnancy," states Summers. "It is associated with the same risks as a natural miscarriage and is many times safer than carrying a pregnancy to term."

The new report found no direct link between the deaths of the four women, who received prescriptions at different California clinics between 2003 and 2005. It also found that the drugs they received came from different manufacturing lots.

One common element in all four deaths was the fact that the women used intravaginal administration of misoprostol in the medical abortion regimen, which differs from the FDA-approved regimen. The FDA-approved regimen calls for the following administration:

- Day One: Three tablets of 200 mg Mifeprex orally at once.
- Day Two: Two tablets of 200 mcg misoprostol orally at once.
- Day 14: The patient must return to confirm that a complete termination has occurred.

### Look for symptoms

*Clostridium sordellii* is a gram-positive, toxin-forming anaerobic bacteria. To improve diagnosis and therapy, clinicians should be aware of the distinctive features of toxic shock syndrome associated with such infection, including:

- tachycardia;
- hypotension;
- edema;
- hemoconcentration;
- profound leukocytosis;
- and absence of fever.

Health care providers should report to their state or local health department any cases of toxic shock syndrome occurring after an abortion or associated with pregnancy, say state epidemiologists in the *NEJM* report.<sup>2</sup>

“Be vigilant for atypical presentations of endometritis,” suggests **Vanessa Cullins**, MD, MPH, vice president for medical affairs at Planned Parenthood Federation of America in New York City. “See a woman immediately for clinical evaluation if her clinical course does not seem typical.”

The Mifeprex web site, [www.earlyoptionpill.com](http://www.earlyoptionpill.com), offers prescribing information, a medication guide, and a patient agreement that reflects the new information on *Clostridium sordellii* toxic shock

syndrome, says Summers. All of these materials describe the symptoms that patients and providers should look for and advise patients to call their provider right away if they experience any of those symptoms, she notes.

Many unanswered questions remain, says Summers. “Danco is still working closely with the FDA, CDC and other medical experts to try and understand the circumstances surrounding these events, and we fully support ongoing investigation and discussion of *Clostridium sordellii* infections in general, including the infections in the four women who died after medical abortion,” states Summers.

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## Why is the IUD Number One?

By **Robert Hatcher**, MD, MPH  
Professor, Gynecology and Obstetrics  
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*Contraceptive Technology Update*  
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**W**hat is the most commonly used reversible contraceptive in the world? It is the intrauterine device (IUD).<sup>e</sup>

There are several reasons the IUD tops the list. IUDs are effective, safe, convenient, cost effective, and fully reversible.<sup>1</sup> A single decision can lead to five to 10 (or more) years of extremely effective and very safe contraception AND at any time, it may be removed for a woman to become pregnant. Continuation rates for IUDs, 78%-81% at one year, are 10%-25% higher than for pills, patches, rings, depot medroxyprogesterone acetate (DMPA, Depo-Provera, Pfizer, New York City), or condoms.<sup>2</sup>

In the United States, there now are two IUDs: the Copper T-380 (ParaGard, Duramed Pharmaceuticals, Woodcliff Lake, NJ) and the levonorgestrel IUD (Mirena, Berlex, Montville, NJ). Good news: From 1995 to 2002, the use of an IUD tripled, according to data in the 1995 and 2002 National Surveys of Family Growth.<sup>3</sup> Bad news: Only 2%

of women now use IUDs in our country.<sup>3</sup>

Most women wanting an intrauterine device can use either the Copper-T or the Mirena IUDs. Women who can use either IUD include women who want:

- **Long-term contraception from a single decision.**

Women who wish to use a contraceptive that is extremely effective, very safe, and very convenient can consider an IUD, where there is nothing to do at the time of intercourse or even at daily, weekly, monthly, or three-month intervals.

- **Reversible contraception.**

Women who want to be able to have a baby in the future can look to the IUD as a potential method.

- **Contraception with the highest level of patient satisfaction.**

Women who use IUDs represent the highest percent of patients who are “very” or “somewhat” satisfied with their method.

Patients with the following medical conditions also can consider either form of intrauterine contraception:

- anemia;
- diabetes;
- cervical intraepithelial neoplasia;
- HIV (this category includes women who are HIV-infected, at high risk for HIV, or who have AIDS, but are clinically well on antiretroviral therapy);
- previous pelvic infection that was three

months or more in the past<sup>4</sup>;

- use of antibiotics (anti-tuberculosis drugs or griseofulvin) that decrease the Pill's effectiveness;
- use of anti-seizure medication that decreases the Pill's effectiveness.

Women who wish to use a contraceptive that dramatically reduces the risk of an ectopic pregnancy should definitely look to the IUD; the absolute risk of ectopic pregnancy is approximately one per 1,000 person years and is less than half the risk for women using no contraception.<sup>5,6</sup>

### **Which IUD is best?**

Consider the following parameters when helping women select the proper form of intrauterine contraception. Women who might be best served by choosing the levonorgestrel IUD are those who have:

- painful or heavy periods;
- dysfunctional uterine bleeding;
- anemia;
- uterine fibroids;
- endometriosis;
- cyclic premenstrual symptoms (if related to prostaglandin release);
- Wilson's disease (a very rare disease of copper metabolism);
- need for the lowest hormone level of all hormonal methods;
- minimal concern when provided information about the possibility of amenorrhea<sup>7</sup>;
- need for a postmenopausal progestin to protect against endometrial cancer.

Which women might be best served by choosing the ParaGard IUD? Consider the Copper-T for those women who have:

- reason to avoid using any hormone at all;
- desire to avoid irregular bleeding and spotting;
- desire to avoid missing periods (amenorrhea);
- desire for the most years of contraceptive protection (10-12 years);
- current or past occurrence of breast cancer;
- severe (decompensated) cirrhosis;
- active viral hepatitis;
- desire for IUD insertion just after delivery of

placenta;

- need for the most effective emergency contraceptive available.

Although U.S. women who use the IUD love it, not many use it. This is most unfortunate. The percentage of women using an IUD tripled from 1995 to 2002.<sup>3</sup> Perhaps IUD use in the United States will catch up to IUD use in the rest of the world in the not-too-distant future.

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## **Drug label information moves to the Internet**

In preparing for a counseling session on contraceptives, you decide to review labeling for a number of birth control pills. How can you be sure you have the most up-to-date information in your files?

### **COMING IN FUTURE MONTHS**

■ Expand EC access in your practice

■ Microbicide update: What's in the pipeline?

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■ Talk with patients about trichomoniasis

Look to the Internet. By 2007, all prescription drug labeling will be available on DailyMed, a new federal interagency on-line health information clearinghouse operated by the National Library of Medicine at [dailymed.nlm.nih.gov](http://dailymed.nlm.nih.gov). Similar product information also will be available in the future through the Food and Drug Administration (FDA) web site, [facts@fda.gov](mailto:facts@fda.gov), which is envisioned as a comprehensive internet resource for one-stop access for information about all FDA-regulated products.

At press time, FDA officials were to begin loading label information on the DailyMed site for some 9,000 drugs as of January, says **Lisa Stockbridge**, FDA spokeswoman. The project is scheduled for completion by January 2007, says Stockbridge. According to the FDA, future additions to the DailyMed site will include labels for biologics (such as vaccines), medical devices, veterinary drugs, and some food products.

### ***New format in use***

Drug manufacturers are now required to submit prescribing and product information to the FDA in a new format known as structured product labeling (SPL).

The new format is designed to provide accurate, up-to-date drug information using standardized medical terminology in a readable, accessible format. Using embedded computer tags, the prescribing and product information in the SPL format can be electronically managed, allowing a user to search for specific information. These tags can instruct computers to read specific sections of a drug label including product names, indications, dosage and administration, warnings, description of drug product, active and inactive ingredients, and how the drug is supplied.

### ***Reducing errors***

Health care providers should be able to quickly search and access specific information they need before prescribing a treatment, which will result in fewer prescribing errors and better informed decision-making, according to the FDA. By using the SPL format, the FDA hopes to improve the drug labeling review process so it can provide immediate access to the most recent information about medications to providers and patients. Updated product labels will be posted on the DailyMed site within one business day of an approval action by FDA. ■

## **On-line reports available for *CTU* subscribers**

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### **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.
- **Describe** how those issues affect service delivery and the benefits or problems created in patient care in the participant's practice area.
- **Integrate** practical solutions to problems and information into daily practices, according to advice from nationally recognized family planning experts.

5. What is the typical use failure rate for oral contraceptives?
  - A. 4%
  - B. 6%
  - C. 7%
  - D. 8%
6. What are the two CLIA (Clinical Laboratory Improvements Amendments of 1988) waived rapid tests for HIV?
  - A. OraQuick ADVANCE and Uni-Gold Recombigen
  - B. OraQuick ADVANCE and Reveal Rapid HIV-1 Antibody Test
  - C. Uni-Gold Recombigen and Reveal Rapid HIV-1 Antibody Test
  - D. Reveal Rapid HIV-1 Antibody Test and Single-Use Diagnostic System for HIV-1
7. What is the approved dosing regimen for misoprostol in the mifepristone/misoprostol regimen for medical abortion?
  - A. Three tablets of 200 mcg misoprostol orally at once on Day Five
  - B. Two tablets of 200 mcg misoprostol orally at once on Day Two
  - C. Two tablets of 200 mcg misoprostol administered intravaginally on Day Two
  - D. One tablet of 200 mcg misoprostol orally at once on Day Five
8. What is a symptom of genital herpes?
  - A. Proctocolitis
  - B. Homogeneous, white noninflammatory discharge
  - C. One or more blisters around the genitals or rectum
  - D. Diffuse yellow-green discharge

**Answers: 5. D; 6. A; 7. B; 8. C.**

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