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Update your practice: Check new WHO Medical Eligibility Criteria

Review changes to ensure your contraceptive guidelines are current

By **Robert A. Hatcher**, MD, MPH
Senior Author, *Contraceptive Technology*
Professor of Gynecology and Obstetrics
Emory University School of Medicine
Atlanta

The new World Health Organization (WHO) Medical Eligibility Criteria (MEC) for Contraceptive Use are being released this spring. The changes made will dramatically affect the provision of contraceptives throughout the world.

Here are the 10 recommendations that have changed the most:

1. Continued use of an intrauterine device (IUD) by a woman diagnosed with pelvic inflammatory disease (PID).

Perhaps most important are the MEC for using an IUD in a variety of clinical situations. The new MEC suggest that an IUD may be left in place for a woman who already has an IUD and develops PID if her PID is treated *"using appropriate antibiotics. There is usually no need for removal of the IUD if the client wishes to continue its use"* (WHO:2, changed from a 4).[1]

EXECUTIVE SUMMARY

New guidance for family planning service delivery is offered in the World Health Organization Medical Eligibility Criteria for Contraceptive Use. The changes made will significantly affect provision of contraceptives throughout the world.

- Several of the changes in the guidelines address use of intrauterine devices in a variety of clinical situations.
- Other new recommendations address such contraceptive methods as spermicides, diaphragms, cervical caps, oral contraceptives, the transdermal contraceptive, and the contraceptive vaginal ring.

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Editor: **Rebecca Bowers**.
Vice President/Group Publisher: **Brenda Mooney**, (404) 262-5403, (brenda.mooney @thomson.com).
Editorial Group Head: **Valerie Loner**, (404) 262-5475, (valerie.loner@thomson.com).
Senior Managing Editor: **Joy Daughtery Dickinson**, (229) 551-9195, (joy.dickinson@thomson.com).
Production Editor: **Nancy McCreary**.

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Editorial Questions

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

(See four classifications of the WHO Medical Eligibility Criteria, below.) This change is based on three studies demonstrating that there is no difference in the clinical course of the PID whether the IUD is removed or left in place during treatment.[2]

The new WHO MEC continue to recommend that an IUD *not be inserted* for a woman seen with current PID; a woman with AIDS who is not clinically well on antiretroviral therapy; or a woman with a chlamydial infection, gonorrhea, or purulent cervicitis. All receive a 4 in the WHO MEC.

Women deemed at increased risk for sexually transmitted infections (STIs) received a 3 in the 2000 WHO MEC. If a woman is deemed to be at very high risk for gonorrhea or chlamydia, the condition remained classified as a 3. However, high risk for other STIs receives a 2 in the 2004 WHO MEC. Women at increased risk of STIs who already have an IUD moved from a 3 to a 2 in 2004.

Two other conditions may apply to the teenager wanting to consider IUD use. The 2004 and the previous WHO MEC recommend that a woman who is nulliparous may use an IUD and that a woman who is younger than 20 years of age may use an IUD.[3]

2. IUD insertion and continuation and HIV/AIDS.

Four Classifications of Medical Eligibility Criteria

- **World Health Organization (WHO):1.** A condition for which there is no restriction for the use of a contraceptive method. The method may be used in any circumstance.
- **WHO:2.** A condition for which the advantages of using the method generally outweigh the theoretical or proven risks. The method is generally or broadly usable.
- **WHO:3.** A condition for which the theoretical or proven risks usually outweigh the advantages, so the prospective user should be advised that another method would be preferable, but if she accepts the risks and the alternative methods cannot be used, the method may be used with caution and with additional care/follow-up.
- **WHO:4.** A condition that represents an unacceptable health risk. Do not use.

Source: Word Health Organization, Geneva.

The new MEC developed by experts working with WHO suggest that an IUD may be used:

- by a woman at high risk for HIV (WHO:2, changed from a 3);
- by a woman who is infected with HIV (WHO:2, changed from a 3);
- by a woman with AIDS (WHO:2, changed from a 3).

3. Hormonal contraceptives and HIV/AIDS.

In another decision related to HIV/AIDS, the Expert Working Group concluded that evidence does not support any restrictions on hormonal contraceptives for women at high risk of HIV or HIV infection, including those with AIDS. These health conditions remain category 1 for all hormonal methods.

4. Fibroids and IUD insertion.

The new MEC suggest that an IUD may be used by a woman with fibroids that do not distort the uterine cavity (WHO:1, changed from a 2).

5. Known thrombogenic mutations and use of pills.

The new criteria from WHO strongly discourage (WHO:4) the use of combined pills, patches, vaginal rings, and combined injectables for a woman known to have a thrombogenic mutation (Leiden mutation, prothrombin Factor, protein S, and protein C). However, the Expert Working Group specifically cautions that *routine screening is not appropriate because of the rarity of the condition and the high cost of screening. As for all the MEC, the classifications refer to known conditions and do not necessarily imply that screening is necessary or advisable*.[1] As testing becomes more readily available and cheaper, known thrombogenic disorders may become important reasons to avoid pill use.

6. Depressive disorders.

Past WHO MEC have not covered the initiation of contraceptives for women with depression. The October 2003 MEC meeting concluded there is no need for restriction on the use of combined or progestin-only hormonal contraceptives for women with depression (WHO:1). Conclusions could not be reached regarding postpartum depression or bipolar disorders because current evidence is inadequate.

7. Spermicides.

Spermicidal products containing nonoxynol-9 (N-9) should not be used by women at high risk for HIV (WHO:4, changed from 2), women who already are HIV-infected (WHO:4, changed from 2), or women with AIDS (WHO:4, changed from 2), according to the new MEC. Data on the use of spermicides from women using spermicides several times a day, usually sex workers, demonstrated a greater likelihood of developing an HIV infection than women having sex as often but not using a spermicide.[4] However, data among women having sex less frequently found an increased risk for becoming HIV-positive, but the increase was not statistically significant.[4] For women having sex less frequently than sex workers, the risk of developing HIV increased as the frequency of use of spermicides increased.

8. Diaphragms used with spermicides and cervical caps.

For women at high risk for HIV, women who are HIV-infected, or women with AIDS, the new WHO MEC recommend that diaphragms and cervical caps generally not be used (WHO:3, changed from 1).

9. Anticonvulsants.

The anticonvulsants phenytoin, carbamazepine, barbiturates, and primidone previously had received a 3 from the Expert Working Group for the use of combined pills, progestin-only pills, Norplant (Leiras Pharmaceuticals, Turku, Finland), Jadelle (Leiras Pharmaceuticals), and Implanon (Organon Pharmaceuticals, West Orange, NJ). They have received two additions: topiramate and oxcarbazepine. Depo-Provera (depot medroxyprogesterone acetate or DMPA, Pfizer, New York City) continues to receive a 1 for the use of all these anticonvulsants.

10. Griseofulvin.

Combined pills, the patch (Ortho Evra, Ortho-McNeil Pharmaceutical, Raritan, NJ), the vaginal ring (NuvaRing, Organon Pharmaceuticals, West Orange, NJ), and progestin-only pills receive a 2 rather than a 3 in the new WHO MEC if a woman is on griseofulvin.

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FDA approves HIV oral fluid-based test

Get ready to implement new advances in your clinical setting: The Food and Drug Administration (FDA) has approved the use of oral fluid samples with a rapid HIV diagnostic test kit to provide accurate screening in as little as 20 minutes. While there are three rapid HIV testing kits now on the market, the OraQuick Rapid HIV Antibody Test is the first to get clearance for use on oral fluid samples, which bypasses the need for needlesticks or fingerpricks for blood samples.

The FDA approved the original version of the test, known as the OraQuick Rapid HIV-1/2 Antibody Test (OraSure Technologies, Bethlehem, PA), in November 2002 for detection of HIV-1. **(*Contraceptive Technology Update* reported on the regulatory approval in the article, "Rapid HIV testing method approved — prepare now to apply new strategies," February 2003, p. 13.)** The FDA gave approval in early March 2004 for use of the blood test to test for HIV-2. The new oral fluid test has been approved for detection of HIV-1 only; however, OraSure may seek approval for HIV-2 detection in oral fluid samples as well, says **William Bruckner**, vice president of strategic marketing.

Unlike the fingerstick rapid HIV test, the new oral test cannot be performed outside of laboratories and physicians' offices, according to **Robert Janssen**, MD, director of the Atlanta-based Centers for Disease Control and Prevention's (CDC's) Division of HIV/AIDS Prevention.

"However, the availability of a saliva-based test is an advantage for those who don't like to have their finger pricked," says Janssen. "In addition, health care workers face a much lower risk of exposure to infectious diseases from oral fluid than from blood."

OraSure is in active talks with the FDA to expand the use of the test so it may be performed in a variety of health care settings, Bruckner reports. The company is seeking what is known as a CLIA (Clinical Laboratory Improvement Amendments of 1988) waiver. Many different types of health providers can use a test categorized as a waived test in many more health care settings.

Case in point: The OraQuick Rapid HIV-1/2 test now used on blood samples was classified as a waived test in January 2003; it is now in use at more than 180,000 U.S. sites, including outreach clinics, community-based organizations, and physicians' offices, according to OraSure.

How does it work?

To perform the OraQuick test on oral fluid samples, the person being tested for HIV-1 takes the device, which has an exposed absorbent pad at one end, and places the pad above the teeth and against the outer gum. After swabbing around the outer gums, both upper and lower, one time around, the tester then takes the device and inserts it into a vial containing a solution. In about 20 minutes, the test device will indicate if HIV-1 antibodies are present in the solution by displaying two reddish-purple lines in a small window on the device.[1]

Bruckner estimates cost of the new test to be between $10 and $12, comparable to that of lab-based tests. As with the OraQuick blood test, the new test can be stored at room temperature and requires no specialized equipment.

Other commercially available reactive rapid HIV tests include the Reveal Rapid HIV-1 Antibody Test (MedMira Laboratories, Halifax, Nova Scotia), approved by the FDA in April 2003, and the Uni-Gold Recombigen HIV Test (Trinity Biotech, Wicklow, Ireland), approved in December 2003. **(Information on the Reveal test was included in the article, "The war gears up against HIV: Scientists and providers seek enhanced prevention," in *STD Quarterly*, inserted in *CTU*, August 2003.)** The Recombigen test is used for detection of antibodies to HIV-1 in plasma, serum, and whole blood (venipuncture), while the Reveal test is used on serum and plasma. Both of these tests are categorized as moderate-complexity tests.

EXECUTIVE SUMMARY

The Food and Drug Administration has approved the use of oral fluid samples with a rapid HIV diagnostic test kit to provide accurate screening in about 20 minutes. While there are three rapid HIV testing kits now on the market, the OraQuick Rapid HIV Antibody Test is the first to get clearance for use on oral fluid samples, which bypasses the need for needlesticks or fingerpricks.

- The new test is approved for detection of HIV-1 in oral fluid samples.
- The manufacturer is seeking regulatory approval to expand the use of the test so it may be performed in a variety of health care settings.

RESOURCES

- **For more information on rapid testing**, visit the Centers for Disease Control and Prevention's web page, www.cdc.gov/hiv/testing.htm. Click on "Rapid HIV Testing" to review such resources as a CLIA Certificate of Waiver Fact Sheet, product insert sheets for rapid tests, and a link to CDC studies on rapid testing.
- **For more information on the OraQuick test**, contact: OraSure, 220 E. First St., Bethlehem, PA 18015. Telephone: (610) 882-1820. Fax: (610) 882-1830. E-mail: customerservice@orasure.com. Web: www.orasure.com.
- **Plan to participate in the 10th year of National HIV Testing Day**, scheduled this year for June 27. The annual campaign is organized by the Washington, DC-based National Association of People with AIDS (NAPWA-US) to encourage at-risk people to receive voluntary HIV counseling and testing. While the event falls on a Sunday this year, organizers encourage testing site participants to schedule events near June 27, if not on the date itself. To help plan and promote your testing event, visit the NAPWA-US web site, www.napwa.org, and click on "National HIV Testing Day." Download free posters, flyers, campaign kits, and handouts, all available in English and Spanish. For more information, contact the organization at nhtd@napwa.org.

All of the reactive rapid HIV tests require confirmatory testing, according to the CDC. The CDC confirmatory protocols recommend:

• confirmation of all reactive rapid HIV test results with Western blot or immunofluorescent assay, even if an enzyme immunoassay screening test is negative;

• follow-up testing for persons with negative or indeterminate confirmatory test results, with a blood specimen collected four weeks after the initial reactive rapid test result.[2]

Do you use rapid tests?

What's your approach to HIV testing? One-fourth of the approximately 900,000 HIV-infected people in the United States are not aware that they are infected, according to CDC estimates.[3] Around the world, that figure may be as high as 95%, according to the Geneva-based World Health Organization.[4] **(See the resource box above for information on rapid testing and National HIV Testing Day, June 27, 2004.)**

"I think that what we will find is that there are many people out there who have been at risk for HIV, but for whatever reason have not come in to be tested," says Bruckner. "With the availability of the first oral fluid rapid HIV test, those people are expected to come in and be tested, which will be a tremendous benefit." **(To get tips on providing rapid HIV tests, see the article, "Check counseling skills with rapid HIV tests," *CTU*, February 2003, p. 16.)**

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EC provision doesn't boost unprotected sex in teens

Does advance access to emergency contraception (EC) in adolescents lead to an increase in unprotected sex? Not according to findings from a newly published study, which indicate advance EC provision does not cause teens to have more unprotected intercourse or practice less consistent contraceptive use.[1] In addition, researchers found that teens who were provided EC in advance were more likely to use the pills in the first 12 hours after unprotected intercourse, when the drug is most effective.

Teens who were provided advance EC were not likely to discontinue ongoing contraception and were more likely to report condom use at the six-month follow-up, reports **Melanie Gold**, DO, associate professor of pediatrics at the University of Pittsburgh School of Medicine and lead author of the paper.

"We hypothesized that might be because girls who have EC in advance have their action plan," Gold observes. "They are in a preventive health mode, and so in addition to having their backup for unprotected sex, they are now more careful

EXECUTIVE SUMMARY

Advance emergency contraception (EC) provision does not cause teens to have more unprotected intercourse or practice less consistent contraceptive use, according to a just-published study.

- Teens who were provided EC in advance were more likely to use the pills in the first 12 hours after unprotected intercourse, when the pills are most effective.
- The Food and Drug Administration is reviewing the data and other information in considering a move to over-the-counter status for the levonorgestrel emergency contraceptive pill Plan B. The agency extended its review in February 2004 to analyze more information on teen use.

overall and work harder to make sure that their 'Plan A' is working."

The Food and Drug Administration (FDA) is reviewing these data, along with other information, in considering a move to over-the-counter status (OTC) for the levonorgestrel emergency contraceptive pill Plan B (Barr Laboratories, Pomona, NY). The agency announced in February 2004 it was extending its review of the company's request to analyze additional data on adolescent use submitted by Barr Labs and Plan B's former owner, Women's Capital Corp. of Washington, DC. **(*Contraceptive Technology Update* reported on the FDA's move in the article, "Bulletin: FDA delays decision on Plan B," March 2004, p. 25. *CTU* will keep readers posted on the FDA's actions. At press time, Barr Laboratories said it expected a decision regarding Plan B's OTC status within 90 days of the agency's original Feb. 20, 2004, review deadline.)**

Science given short shrift?

Advocates of EC OTC provision are concerned that the scientific evidence may not be given full weight in the decision on drug access. The editor of the *New England Journal of Medicine* and two members of the FDA advisory panel point to "political considerations" affecting the review extension in an April 2004 editorial published in the scientific journal.[2]

"Although the FDA is frequently criticized by politicians and others for being either too lenient or too tough . . . the integrity of the process has seldom been questioned," the editorial states. "To squander that trust by allowing political pressure to delay a decision to make safe and effective emergency contraception available over the counter seems to us a serious error."

To perform the adolescent study, researchers enrolled 301 female adolescents ages 15 to 20 between 1997 and 2001. Participants were provided education about emergency contraceptive pills (ECPs) and received monthly follow-up telephone calls to assess sexual activity and usage of various contraceptive methods.

Participants were followed for a period of six months and were randomized to receive emergency contraceptive education along with a package of ECPs or education only, with instruction on how to get the pills if they were needed. All participants were sexually active, with a mean age at first intercourse between 14 and 15 years.

At one-month interviews, teens who already had ECP packages were nearly twice as likely to use them, with 15% of the advance group reporting ECP use and 8% of the education-only control group reporting ECP use. By the final follow-up at six months, the differences between the groups had almost disappeared, with 8% of the advance group reporting ECP use, compared to 6% of the control group.[1]

EC safe for teen use

Is EC safe for use in adolescents? According to a small study in young teens, the drug is safe and well tolerated.[3]

Researchers found that teens were able to use the method correctly and that they experienced the same minor and transient side effects that adults experience, says **Cynthia Harper**, PhD, an assistant professor of obstetrics and gynecology at the University of California at San Francisco. The effect on the menstrual cycle for teens also was similar to that on adults, she states.

Until a decision is reached on OTC access for emergency contraception, providers should continue to offer advance EC to adolescent patients, says Gold. Discuss the expiration date for the drug, counsel teens to call for a prescription or another sample if they need it, and make sure teens understand that while EC may prevent unintended pregnancy, it does not provide protection against sexually transmitted diseases, she says. **(For more tips on providing EC, see the article, "Teens face obstacles when obtaining EC," *CTU*, April 2004, p. 41.)**

"Until we have methods which are 100% effective, I think we have to have back-ups," states Gold. "I always do advance [EC] provision."

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Research eyes IUS use for menstrual bleeding

Many women may experience excessive menstrual bleeding, but for those with extreme menstrual bleeding (menorrhagia), such blood loss often interferes with daily activities and can lead to anemia. Defined as total menstrual blood loss of more than 80 ml/cycle, menorrhagia affects 15%-20% of American women.[1]

As a clinician, you may opt to treat menorrhagia with nonsteroidal anti-inflammatory drugs, progestins, or oral contraceptives. However, if these approaches prove ineffective, women may seek endometrial resection or ablation or undergo a hysterectomy.[2]

Just-published research compares outcomes, quality-of-life issues, and costs of the levonorgestrel-releasing intrauterine system (LNG-IUS, Mirena, Berlex Laboratories, Montville, NJ) vs. hysterectomy in the treatment of menorrhagia.[3] While the Mirena IUS is approved solely for contraceptive use in the United States, several countries also have granted regulatory clearance for use of the device for treatment of menorrhagia. U.S. clinicians have used the Mirena IUS for this noncontraceptive approach on an off-label basis; however, the company is looking at an indication for the device. According to Berlex spokeswoman **Kimberly Schillace**, the company is in talks with the Food and Drug Administration to determine what would be required to obtain regulatory approval for the new indication.

Treatment of menorrhagia with the LNG-IUS is not new; it has been studied since the device's development, says **Elof Johansson**, MD, vice president of the New York City-based Population Council. The LNG-IUS was co-developed and tested by the Population Council and the Finnish pharmaceutical company Leiras. German pharmaceutical company Schering, Berlex's parent company, markets the device worldwide. Public health officials have looked at use of the device in developing countries, where an estimated 45% of nonpregnant women are considered anemic.[4] Use of the LNG-IUS offers a viable approach; women with menorrhagia using the device reported up to 96% reduction in blood loss at 12 months.[5]

EXECUTIVE SUMMARY

Menorrhagia, or extreme menstrual bleeding, affects 15% to 20% of American women. Nonsteroidal anti-inflammatory drugs, oral progestins, and oral contraceptives have been used to treat the condition; however, if these approaches prove ineffective, women may seek endometrial resection, ablation, or a hysterectomy.

- Several foreign countries have granted regulatory clearance for use of the levonorgestrel-releasing intrauterine system (LNG-IUS, Mirena, Berlex Laboratories, Montville, NJ) for treatment of menorrhagia. The manufacturer is looking at obtaining similar clearance in the United States.
- By providing improvement in patients' health-related quality of life at a relatively low cost, the LNG-IUS may offer a wider availability of choices for the patient and may decrease costs by preventing surgery, new research concludes.

Look at the study

In the new study, Finnish researchers evaluated the outcomes of 236 women with an average age of 43 years who were referred to five Finnish hospitals for treatment of menorrhagia between 1994 and 2002. The study participants were randomized to treatment with the LNG-IUS or hysterectomy, and they were monitored for five years.

Of the 117 women initially randomized to hysterectomy, intraoperative complications occurred in four women, and postoperative complications were noted in 33 (30%). Of the 117 participants who received LNG IUS insertion, 50 (42%) ultimately underwent hysterectomy. Of the 57 (48%) IUS recipients who continued with the IUS in place at five years, 75% reported amenorrhea or oligomenorrhea. Two women had the IUS removed after developing mood symptoms, one due to recurrent thromboembolic disease and one was due to a benign ovarian cyst. No expulsions or perforations were reported.

Notwithstanding the initial IUS recipients who ultimately underwent hysterectomy, the five-year overall costs were estimated to be substantially lower in the group randomized to IUS insertion. By providing improvement in patients' health-related quality of life at relatively low cost, the LNG-IUS may offer another choice for the patient and may decrease costs by preventing surgery, researchers conclude.

One limitation of the study is that it did not report on standardized pre-randomization assessment of the menorrhagia, says **Andrew Kaunitz**, MD, professor and assistant chair in the obstetrics and gynecology department at the University of Florida Health Science Center/Jacksonville. It would be important to know, for instance, what percentage of participants had been diagnosed with intramural fibroids, adenomysosis, or intracavitary lesions prior to randomization, he notes. This information may have provided insight into the reasons women ultimately underwent hysterectomy, he observes.

Weigh the options

In Kaunitz's practice, a growing number of patients with benign conditions associated with heavy bleeding are choosing to try the progestin-releasing IUS. Clinicians and patients should be aware, however, that use of this intrauterine device to treat menorrhagia represents off-label use and that expulsion rates have been observed to be higher in women with fibroids than in other women,[6] Kaunitz notes. Not all women with menorrhagia will achieve therapeutic success with an IUS, but the IUS does represent an office-based, minimally invasive approach to treatment, says Kaunitz.

"This study clarifies that use of the progestin-releasing intrauterine system indeed can successfully treat menorrhagia in a substantial proportion of women who otherwise will need surgical intervention," Kaunitz observes.

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Check new advances in natural family planning

Review the contraceptive options you currently discuss with your female patients. Where does natural family planning enter into the conversation?

You may want to include a discussion of the Standard Days Method (SDM). Defined as a fertility-awareness-based method, the SDM is appropriate for women with regular menstrual cycles between 26 and 32 days long. It identifies days 8-19 of the menstrual cycle as the "fertile window" — the days when pregnancy is very likely. To prevent pregnancy, a couple avoids unprotected intercourse during the 12-day fertile window by using a barrier method or abstaining from sex. About 500 women in Bolivia, Peru, and the Philippines participated in an efficacy trial

EXECUTIVE SUMMARY

Natural family planning options are expanding women's choices when it comes to contraception.

- The Standard Days Method fertility-awareness-based method is appropriate for women with regular menstrual cycles between 26-32 days long. It identifies certain days when pregnancy is very likely. To prevent pregnancy, a couple avoids unprotected intercourse during the "fertile window" by using a barrier method or abstaining from sex. A simple device, CycleBeads, helps couples use the method effectively.
- The TwoDay Method is a new approach to natural family planning. It uses a simple algorithm to help women identify when they are fertile, based upon the presence or absence of cervical secretions.

of the SDM; researchers determined a first-year pregnancy rate of 4.8% when the method was used correctly.[1] **(*Contraceptive Technology Update* reported on the method in the article, "Standard Days Method: Family planning option," October 2002, p. 114.)**

Researchers at Georgetown University's Institute for Reproductive Health in Washington, DC, have been involved in educating providers in the United States and abroad about SDM. Presentations were made at the 2004 conferences of *Contraceptive Technology* and the Washington, DC-based American College of Nurse-Midwives, and training sessions have been held by state health departments, Planned Parenthood affiliates, and the Oakland, CA-based Center for Health Training, says **Victoria Jennings**, PhD, director of the Institute for Reproductive Health.

To broaden access to provider training, the institute is implementing an on-line training module through its web site, www.irh.org. **(See resource box at right for registration information.)** The program is available free for a limited time, says Jennings.

Color-coded beads provide quick visual cue

To help couples learn and use the SDM effectively, the institute has developed a simple device known as CycleBeads. The device was introduced for retail sale in 2002; since that time, some 100,000 women around the globe use it, including 20,000 in the United States. Most women here buy the device on-line at its web site, www.cyclebeads.com, and it also is available from a growing number of health care providers and retail outlets. **(See resource box at right for ordering information.)** The web site also includes an easy screening tool to help women determine if the SDM is right for them.

The CycleBeads device consists of color-coded beads and a black ring on a circular chain, with each bead representing a day of the woman's cycle. The color of the beads provides a quick visual cue as to a woman's fertile and non-fertile days.

Researchers at the Institute of Reproductive Health are now looking at the TwoDay Method, which relies on a simple algorithm to help women identify when they are fertile, based upon the presence or absence of cervical secretions.

The TwoDay method was developed to address the need for a simple method based on secretions, says **Marcos Arevalo**, MD, MPH, assistant professor at Georgetown University and the institute's director of biomedical research. Researchers used computer modelings to distill information on women's secretions. The modeling confirmed that the mere presence of noticeable cervical secretions of any type, regardless of such characteristics as color, consistency, lubricity, and elasticity, was a very good indicator of fertility, explains Arevalo.[2]

Two questions help determine fertility

To use the method, Arevalo says a woman should check daily for secretions and ask herself two questions: "Did I notice any secretions today?" and "Did I notice any secretions yesterday?" If she notices secretions of any type "today" or "yesterday," the woman should consider herself fertile and should avoid unprotected intercourse that day if she does not want to become pregnant, explain Arevalo. If she notices no secretions on either day, then she is not fertile, he states.

The clinical trial of the TwoDay Method has been completed, with 450 women from five sites in Guatemala, Peru, and the Philippines using the method for up to one year. Researchers are encouraged by the results of the efficacy study,

RESOURCES

- **To register for the on-line SDM training offered by the Institute for Reproductive Health**, go to the institute's web site, www.irh.org, and click on "SDM Online Training for Health Professionals." The on-line training program takes approximately two hours to complete and offers up to 2.4 contact hours for health care professionals. The program is available free for a limited time. For more information on the program, contact: Institute for Reproductive Health, Georgetown University Medical Center, 4301 Connecticut Ave. NW, Suite 310, Georgetown, Washington, DC 20008. Telephone: (202) 687-1392. Fax: (202) 537-7450. E-mail: irhinfo@georgetown.edu.
- **The cost for one set of CycleBeads** is $12.95, plus $2.95 for shipping and handling. (New York residents also must include $1.12 for sales tax.) Payment may be made by check, money order, Visa, or MasterCard. CycleBeads may be ordered on-line at the web site www.cyclebeads.com, or via mail to Cycle Technologies, P.O. Box 250027, New York, NY 10025. Bulk pricing for 10 sets or more is available; e-mail info@cyclebeads.com for more information.

says Jennings. Results are scheduled to be published in fall of 2004.

How should clinicians evaluate these forms of natural family planning?

"They both have their strengths," observes Jennings. "The Standard Days Method is just so easy because it applies to everyone who uses this method [in that they] do exactly the same thing, and they know in advance every cycle what they are going to need to do. With the TwoDay Method, it gives people a little bit more information about their fertility."

Both methods are easy to teach, learn, and use, says Jennings. Their costs are low, and their flexibility allows couples to use them in a number of ways. Some people decide they will abstain during the women's fertile days, while some will choose to use a condom. Couples can use the methods to avoid pregnancy as well as to get pregnant, she explains.

Women who are choosing these methods have used another method in the past and have stopped using it due to dissatisfaction, or they have never used an effective method of family planning, says Jennings.

"In other words, it is not taking the satisfied pill user and substituting another method," she explains. "It really expands contraceptive choice and thereby expands the number of women who can find a method that can work for them."

References

1. Arevalo M, Jennings V, Sinai I. Efficacy of a new method of family planning: the Standard Days Method. *Contraception* 2002; 65:333-338.
2. Sinai I, Jennings V, Arevalo M. The TwoDay Algorithm: a new algorithm to identify the fertile time of the menstrual cycle. *Contraception* 1999; 60:65-70. ■

Abortion, breast cancer not linked, data say

A new analysis of worldwide evidence on the possible relation between breast cancer and previous spontaneous and induced abortions reaffirms earlier findings that pregnancies that end in abortion do not increase a woman's risk of developing breast cancer.[1]

The report on the meta-analysis "agrees exactly" with information presented at a March 2003 workshop held by the Bethesda-based National Cancer Institute (NCI), says **Leslie Bernstein**, PhD, professor of preventive medicine at the Keck School of Medicine, University of Southern California in Los Angeles.[2] **(*Contraceptive Technology Update* reported on the NCI workshop's findings in the article, "No link found between abortion, breast cancer," May 2003, p. 55.)** The report also concurs with a July 2003 committee opinion issued by the Washington, DC-based American College of Obstetricians and Gynecologists, which found no evidence supporting a causal link between induced abortion and subsequent development of breast cancer.[3]

The federal government had previously suggested that abortion might raise the risk of breast cancer. An NCI fact sheet on the issue was revised in November 2002 to say the evidence for a link between induced abortions and breast cancer was inconclusive. It was changed in May 2003 to

EXECUTIVE SUMMARY

Pregnancies that end in miscarriage or abortion do not increase a woman's risk of developing breast cancer later in life, new research indicates.

- An international research team evaluated information from 53 epidemiological studies from 16 countries, including previously unpublished data, in obtaining the finding.
- The new report concurs with information presented at a March 2003 workshop held by the National Cancer Institute (NCI) and falls in line with a similar July 2003 committee opinion issued by the American College of Obstetricians and Gynecologists.

COMING IN FUTURE MONTHS

- ■ Vasectomy update: Review new research
- ■ Condom counseling: top talking points
- ■ Lunelle: What's the status of the combined injectable?
- ■ Vaginal discharge: Check your diagnosis
- ■ Side effects and the Pill: management tips

reflect the findings of the March 2003 workshop. **(To access the fact sheet, "Abortion, Miscarriage, and Breast Cancer Risk Sheet," go to www.cancer.gov and click on "Cancer Information," "Prevention, Genetics, Causes," "Breast Cancer: Prevention, Genetics, Causes," then the publication title.)**

Currently, three states — Minnesota, Mississippi, and Texas — have laws in effect that require providers to counsel women on the purported abortion/breast cancer link, according to **Chinué Richardson**, public policy assistant at the Washington, DC, bureau of the Alan Guttmacher Institute. The information comes in state-directed counseling that is required prior to the abortion procedure. Women must wait 24 hours after receiving the counseling before having an abortion.[4]

Look at the findings

The new analysis came from an international collaboration of scientists, led by a team of researchers from the University of Oxford in England. The group focused on the "obvious need to consider completely and separately the studies with prospectively recorded information on previous induced abortions," explains Sir **Richard Peto**, FRS, professor of medical statistics and epidemiology at the University and co-author of the analysis.

The group re-analyzed original information from 53 epidemiological studies from 16 countries, including previously unpublished data. Relative risks of breast cancer (comparing the effects of having had a pregnancy that ended in an abortion with those of never having had that pregnancy) were calculated and stratified by study, age at diagnosis, parity, and age at first birth. Results of studies that used prospective information on abortion (recorded before the diagnosis of breast cancer) were considered separately from results of studies that used retrospective information (recorded after the diagnosis of breast cancer).

In reporting the relative risk (wherein a value of 1.0 or less indicates no adverse effect on the risk of developing breast cancer), the researchers found a 0.98 relative risk for women who have had a spontaneous abortion and a 0.93 relative risk for women who have had an induced abortion. The group plans to look at relevance of age and timings of any full-term pregnancies to breast cancer incidence in its next round of research, states Peto.

Why have some researchers linked abortion to an increased risk for breast cancer? According to the new analysis, studies of breast cancer with retrospective recording of induced abortion may have lead to "misleading results," perhaps because women who had developed breast cancer were, on average, more likely than other women to disclose previous induced abortions.[1]

Bernstein does not agree with that assessment. She says she believes well-designed case-control studies can yield the same level of data as cohort investigations. The key point for providers to take away from the new analysis is that the evidence showing that induced abortion is not associated with an increase in breast cancer risk is well established, she says.

References

1. Beral V, Bull D, Doll R, et al. Breast cancer and abortion: collaborative reanalysis of data from 53 epidemiological studies, including 83,000 women with breast cancer from 16 countries. *Lancet* 2004; 363:1,007-1,016.
2. National Cancer Institute. "Summary Report: Early Reproductive Events and Breast Cancer Workshop." Bethesda, MD; March 4, 2003. Accessed at: www.cancer.gov/cancerinfo/ere-workshop-report.
3. ACOG Committee on Gynecologic Practice. ACOG Committee Opinion. No. 285, August 2003: Induced abortion and breast cancer risk. *Obstet Gynecol* 2003; 102:433-435.
4. Gold RB. Review of key reproductive health-related developments in the states: 2003. *Guttmacher Report on Public Policy* 2003; 6:11-12. ■

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. The semester ends with this issue. You must complete the evaluation form included in this issue and return it in the provided reply envelope that is addressed "Education Department" to receive a certificate of completion. When your evaluation is received, a certificate will be mailed to you. ■

CE/CME Questions

[For details on *Contraceptive Technology Update*'s continuing education program, contact: Customer Service, Thomson American Health Consultants, P.O. Box 740056, Atlanta, GA 30374. Telephone: (800) 688-2421. Fax: (800) 284-3291. E-mail: customerservice@ahcpub.com. Web: www.ahcpub.com.]

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

- Identify clinical, legal, or scientific issues related to development and provision of contraceptive technology or other reproductive services. **(See "Research eyes IUS use for menstrual bleeding" and "EC provision doesn't boost unprotected sex in teens.")**
- Describe how those issues affect service delivery and note the benefits or problems created in patient care in the participant's practice area.
- Cite practical solutions to problems and integrate information into daily practices, according to advice from nationally recognized family planning experts. **(See "FDA approves HIV oral fluid-based test" and "Check new advances in natural family planning.")**

21. What forms of HIV is the new oral-fluid based test from OraSure Technology approved to detect?
A. HIV-1 only
B. HIV-2 only
C. HIV-1 and HIV-2
D. Subtype E only

22. What do findings from the study Gold MA, et al. *Pediatr Adolesc Gynecol* 2004; 17:87-96 indicate regarding emergency contraception (EC)?
A. Advance EC provision causes teens to have more unprotected intercourse.
B. Advance EC provision causes teens to practice less consistent contraceptive use.
C. Advance EC provision does not cause teens to have more unprotected intercourse or practice less consistent contraceptive use.
D. Advance EC provision causes teens to acquire more sexually transmitted diseases.

23. Menorrhagia is defined as:
A. Total menstrual blood loss of more than 200 ml/cycle.
B. Total menstrual blood loss of more than 40 ml/cycle.
C. Total menstrual blood loss of more than 60 ml/cycle.
D. Total menstrual blood loss of more than 80 ml/cycle.

24. What is the name of the device used to help couples achieve effective use of the Standard Days Method?
A. Mirena
B. Progestasert
C. CycleBeads
D. Essure

Answers: 20. A 22. C 23. D 24. C

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