AMERICAN HEALTH CONSULTANTS®

CONTRACEPTIVE TECHNOLOGY UPDATE®

A Monthly Newsletter for Health Professionals

INSIDE

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✔ ***STD Quarterly:*** Syphilis elimination efforts prove effective; clinic promotes HIV care in the community

✔ **2001 *CTU* Index**

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Organon launches NuvaRing, first combined contraceptive vaginal ring

Limited distribution now in effect — look to June 2002 for wider access

You review your patient's contraceptive history. A candidate for combined oral contraceptives (OCs), she has struggled with maintaining a daily pill regimen. What are her options for safe, effective birth control?

Add the NuvaRing combined contraceptive vaginal ring from West Orange, NJ-based Organon to the list of family planning options. The device, the first of its kind to be introduced in the United States, received approval from the Food and Drug Administration Oct. 3. U.S. women are the first to have access to the new method, confirms **Frances DeSena**, Organon spokeswoman. **(*Contraceptive Technology Update* reviewed the NuvaRing in the following issues: May 1998, p. 57; May 2001, p. 49; and August 2001, p. 88.)**

"For decades, there has been a limited choice in convenient, reliable, and reversible contraception in the U.S.," says **Wayne Shields**, president and CEO of the Washington, DC-based Association of Reproductive Health Professionals. "NuvaRing gives women

Did you receive the e-mail regarding NuvaRing approval?

As a subscriber to *Contraceptive Technology Update*, you should have received an e-mail on Oct. 5 giving you the news that the Food and Drug Administration had approved NuvaRing. We offered you a link to the *CTU* web site (www.contraceptiveupdate.com) that offered additional information and a photo. If you didn't receive the e-mail and would like to receive further news updates, please contact our customer service department at customerservice@ahcpub.com or at (800) 688-2421. Don't miss breaking news in the family planning field! ■

EXECUTIVE SUMMARY

The NuvaRing combined contraceptive vaginal ring from Organon has been approved. Flexible, transparent, and colorless, the NuvaRing is about two inches in diameter. It releases a continuous low dose of ethinyl estradiol and etonogestrel over 21 days.

- The woman inserts the ring, leaves it in for three weeks, and removes the device for one week during which she will have her period.
- Women who are candidates for combined oral contraceptives may be considered for NuvaRing.
- The drug is in limited distribution. Consumer launch is scheduled for mid-2002.

another safe, effective contraceptive option."

A flexible, transparent, colorless vaginal ring, the NuvaRing measures approximately two inches in diameter, with a cross-sectional diameter of about 1/8 inch. It releases a continuous low dose of the estrogen ethinyl estradiol and the progestin etonogestrel at an average rate of 0.120 mg of etonogestrel and 0.015 mg of ethinyl estradiol per day over a 21-day period of use. The woman inserts the ring in the vagina, leaves it in for three weeks, and then removes the device for one week during which she will have her menstrual period.

Since the NuvaRing is not a barrier contraceptive, its exact positioning within the vagina is not critical for its effectiveness. This ability for the woman to insert the device herself and rely on its effectiveness is a strong advantage to its use, says **Phyllis Marx**, MD, an independent investigator with the Chicago Center for Clinical Research and in private practice at Women's Health Group in Skokie, IL.

"Ultimately, all you have to do is to remember to put [the device] in and take it out, and that is only once a month for each of those things," Marx observes. "So for people who have trouble remembering [to take OCs], the NuvaRing is really an advantage."

Initial distribution of the drug is currently limited to 6,000 U.S. providers who are now enrolling in Organon's "premier provider" plan, says DeSena. **(Editor's note: Final details were under way as of *Contraceptive Technology Update's* press time.)** The company is distributing a limited number of rings to the enrolled providers while it expands its manufacturing capacity to deliver the new technology, she explains. Consumer launch of the prescription product is scheduled for mid-2002, says DeSena.

Provider inquiries about program enrollment may be directed to a toll-free number, (888) 427-1177. In addition, a company-sponsored web site, www.nuvaring.com, and toll-free telephone number, (877) NUVARING [(877) 688-2746] carry product information for patients and providers.

While a final price for the NuvaRing has not yet been set, company officials say cost of the device will be comparable to combined pill costs.

Clinical trials of the device were conducted in the United States, Canada, Europe, and Israel by Organon's parent company, NV Organon of the Netherlands. The company plans to introduce the NuvaRing in other countries, says DeSena.

In a one-year, multicenter study, 1,145 women were exposed to the vaginal ring for 12,109 cycles (928 woman-years).[1] Six pregnancies occurred during treatment, giving a Pearl Index of 0.65 (95% confidence interval 0.24-1.41). Cycle control was good, with rare irregular bleeding (2.6%-6.4% of evaluable cycles) and low withdrawal bleeding (mean duration 4.7-5.3 days) occurring in 97.9%-99.4% of evaluable cycles. Compliance to the prescribed regimen was high with criteria being fulfilled in 90.8% of cycles, report investigators.

The most common side effects reported by NuvaRing users are vaginal infections and irritation, vaginal discharge (leukorrhea), headache, weight gain, and nausea. The device does not protect against HIV infection and other sexually transmitted diseases.

Who is a candidate?

Any woman who currently is using combined OCs may use the NuvaRing, says Marx. **(Look at the box, p. 139, for a list of conditions that caution**

COMING IN FUTURE MONTHS

- Inform teens on proper condom use
- Tips on use of emerging contraceptives
- Update on the contraceptive patch
- Time to re-evaluate the diaphragm?
- Boost EC awareness: Providers share resources

against NuvaRing use.)

When talking with women about use of the NuvaRing, remind them that the NuvaRing is NOT:

- a pill;
- a barrier device (like a diaphragm);
- a method of preventing HIV infection or sexually transmitted diseases;
- a daily contraceptive method.

As with oral contraceptives, NuvaRing may increase the risk of blood clots, heart attack, and stroke. These risks indicate that women over age 35 who smoke should be discouraged from using the NuvaRing, exactly as they are advised not to use combined oral contraceptives or the combined injectable, Lunelle (Pharmacia Corp., Peapack, NJ), says **Robert Hatcher**, MD, MPH, professor of gynecology and obstetrics at Emory University School of Medicine in Atlanta.

Device is easy to use

The woman can insert the NuvaRing when she is lying down, squatting, or standing with one leg up. Holding the device between the thumb and index finger so that the opposite sides of the ring are pressed together, the NuvaRing is gently pushed into the vagina. The exact position of the ring is not important for it to work, according to the patient package insert.

Although some women may be aware of the NuvaRing in the vagina, most women do not feel it once it is in place, states the package insert. If the woman feels discomfort once the device is inserted, the NuvaRing probably is not inserted far enough into the vagina. According to the insert, there is no danger of the NuvaRing being pushed too far up in the vagina or getting lost; the device can be inserted only as far as the end of the vagina, where the cervix will block it from going any further.

Instruct on use

If NuvaRing is used according to package directions, the chance of getting pregnant is about 1%-2% a year, states the package insert. However, risks increase if the device is improperly used, the insert states. Pregnancy must be ruled out if the NuvaRing user:

- misses a menstrual period and the device was out of the vagina for more than three hours during the three weeks of ring use;
- misses a period and the user had waited longer than one week to insert a new ring;
- followed the package instructions, yet missed two periods in a row;
- left NuvaRing in place for longer than four weeks.

Problems with the NuvaRing are low, according to Organon. More than 90% of the women who completed the NuvaRing trials reported they were satisfied with the device at the end of the study.

"This is one of the few studies in which I have been involved where people have actually called back and tried to find out when [the method] is coming on the market because they had such success with it," says Marx. "They really liked it."

Who Should Not Use NuvaRing?

Patients should *not* use NuvaRing if they have any of the following conditions:

- pregnancy or suspected pregnancy;
- blood clots in the legs (thrombosis), lungs (pulmonary embolism), or eyes (now or in the past);
- chest pain (angina pectoris);
- heart attack or stroke;
- severe high blood pressure;
- diabetes with complications of the kidneys, eyes, nerves, or blood vessels;
- headaches with neurological symptoms;
- known or suspected breast cancer or cancer of the lining of the uterus, cervix, or vagina (now or in the past);
- unexplained vaginal bleeding;
- yellowing of the whites of the eyes or of the skin (jaundice) during pregnancy or during past use of oral contraceptives;
- liver tumors or active liver disease;
- disease of the heart valves with complications;
- need for a long period of bed rest following major surgery;
- an allergic reaction to any of the components of NuvaRing.

Source: NuvaRing patient package insert, Organon, West Orange, NJ.

Reference

1. Roumen FJ, Apter D, Mulders TM, et al. Efficacy, tolerability, and acceptability of a novel contraceptive vaginal ring releasing etonogestrel and ethinyl oestradiol. *Hum Reprod* 2001; 16:469-475. ■

Slow entry seen for mifepristone in 2001

Indications point to increased use in 2002

One year after the federal Food and Drug Administration (FDA) issued approval of mifepristone (Mifeprex, manufactured by Danco Laboratories LLC, of New York City), providers have moved cautiously in adding the medical abortion drug regimen to their practices.

A national survey of women's health care providers by the Menlo Park, CA-based Kaiser Family Foundation (KFF) finds that 6% of gynecologists and 1% of general practice physicians have provided this early nonsurgical abortion option since it became available.[1] The FDA issued approval of Mifeprex on Sept. 28, 2000, with drug shipments initiated in November 2000. Danco Laboratories holds an exclusive license from the New York City-based Population Council to manufacture, market, and distribute Mifeprex in the United States.

Gynecologists who perform surgical abortions are more likely to have used mifepristone, KFF survey findings indicate. To place these numbers in context, 27% of gynecologists report having performed surgical abortions within the last five years, including 10% who report doing so "routinely;" 1% of general practice physicians surveyed currently perform surgical abortions, explain KFF officials.[2] The national random-sample telephone survey was administered to 790 health care providers, including 595 gynecologists and 195 family practitioners, internists, and general practitioners.

EXECUTIVE SUMMARY

One year following the federal approval of mifepristone (Mifeprex, Danco Laboratories), few gynecologists and general practice physicians say they offer the drug, according to a new survey.

- Only 6% of gynecologists and 1% of general practice physicians have offered mifepristone. Gynecologists who provide surgical abortions are more likely to have provided mifepristone.
- An additional 16% of gynecologists and 7% of general practice physicians say they are "likely" to begin offering the drug.
- The National Abortion Federation offers presentations, a CD-ROM, and self-study courses on the use of mifepristone.

While the numbers may seem small, it is important to remember that it is yet early in the delivery of medical abortion in the United States and that only a relatively small percentage of physicians today perform surgical abortions, notes **Tina Hoff**, vice president of public health information and partnerships at the foundation.

Facilities that specialize in abortion services performed 70% of all abortions in the United States in 1996, the most recent year for which data are available.[2] According to Danco Laboratories statistics, physicians in 45 states and the District of Columbia offer mifepristone to their patients.

However, the number of medical abortion providers may be increasing in 2001. According to the KFF survey results, an additional 16% of gynecologists and 7% of the general practice physicians say they are "likely" to begin offering the drug in 2001.

Education is key

The Washington, DC-based National Abortion Federation (NAF) has made education a priority when it comes to the option of medical abortion. Since January 2000, NAF has educated more than 3,300 professionals in the administration of mifepristone, says **Vicki Saporta**, NAF executive director.

Provider education has been delivered at regional seminars and national medical meetings, says Saporta. The organization also is customizing inservice training for NAF members who need additional educational opportunities in order to provide the mifepristone regimen.

"We currently have about 200 of our 400 provider members offering mifepristone to women, and more are adding it to their services that they provide on a regular basis," says Saporta.

Educational videotapes, a continuing medical education self-study guide, and an educational CD-ROM are all part of NAF's efforts to deliver provider education in every desired format. Providers can visit the organization's web site, www.earlyoptions.org, to order materials and check the schedules for regional training sessions.

NAF has been equally aggressive in providing education on medical abortion to women, both through the earlyoptions.org web site and through a public service advertisement campaign launched in 14 national magazines, which reached some 70% of U.S. women ages 18-49, says Saporta.

A centerpiece of the education program has been NAF's toll-free hotline [(800) 772-9100], says Saporta. Since the FDA approval, phone lines

RESOURCES

For more information about Mifeprex, contact the Mifeprex hotline, (877) 432-7596 [(877) 4 Early Option]. Web: www.earlyoptionpill.com.

For more information on medical abortion, contact:

- **National Abortion Federation**, 1755 Massachusetts Ave. N.W., Suite 600, Washington, DC 20036. Fax: (202) 667-5890. NAF operates a hotline, (800) 772-9100, as well as a web site, www.earlyoptions.org.

have been filled with calls about the medical abortion method, she says.

"Now, about 40% of the calls we receive are from women who want more information about medical abortion," states Saporta. "They are very grateful to have a place they can call to get their questions answered and to get referrals to providers of quality care in their area."

Strides are being made

While medical abortion has not yet experienced wide acceptance from American women and their physicians, there has been some steady progress in the past 12 months, says **Eric Schaff**, MD, professor of family medicine at the University of Rochester (NY).

Newer regimens have become less expensive and simpler without loss of effectiveness, notes Schaff. Recent studies have shown that a 200 mg dosage of mifepristone is as effective as the currently approved 600 mg dosage, which makes the regimen less expensive; the vaginal route of misoprostol allows misoprostol to be taken from one to three days after mifepristone and extends the gestational age up to nine weeks; and misoprostol can be used at home, thereby safely avoiding an additional health care visit.[3]

Major health insurers, as well as several state Medicaid plans, including New York and California, have added coverage for mifepristone abortion, says Schaff. In addition, more U.S. women are learning about the abortion option through major public educational campaigns, and threats of restrictive legislation have not occurred, he observes.

"As barriers [such as] reimbursement and malpractice are addressed and the costs of the procedure decrease, mifepristone should become a standard option for early abortion, as we have seen in European countries," states Schaff.

References

1. Kaiser Family Foundation. *2001 National Survey of Women's Health Care Providers on Reproductive Health: Views and Practices on Medical Abortion.* Menlo Park, CA: September 2001.
2. Kaiser Family Foundation. Few offering mifepristone one year after FDA approval; indications that number may increase in next year. Press release. Sept. 24, 2001.
3. Newhall EP, Winikoff B. Abortion with mifepristone and misoprostol: Regimens, efficacy, acceptability, and future directions. *Am J Obstet Gynecol* 2000; 183(2 Suppl):S44-53. ■

Researchers eye Yasmin for treatment of PMS

Investigation is now under way in a large multicenter trial to determine if the newly approved oral contraceptive (OC) Yasmin is effective in treatment of premenstrual symptoms.

The clinical study of the drug, manufactured by Berlex Laboratories of Montville, NJ, seeks to confirm findings of a smaller-scale study that indicates the OC may be effective in easing the symptoms of premenstrual syndrome (PMS) and premenstrual dysphoric disorder (PMDD).[1]

Yasmin, a monophasic oral contraceptive, contains 0.03 mg of ethinyl estradiol and 3 mg of drospirenone, a new progestin. The Food and Drug Administration (FDA) approved it in May 2001 for contraceptive use. **(See the July 2001 issue of *Contraceptive Technology Update*, p. 73, for news of the regulatory approval, and *Contraceptive Technology Reports*, inserted in the September 2001 issue, for a clinical review of the drug.)**

EXECUTIVE SUMMARY

Research is under way in the potential use of the oral contraceptive (OC) Yasmin (Berlex Laboratories) for premenstrual symptoms.

- A small study indicates the OC may be effective in easing premenstrual syndrome (PMS) and premenstrual dysphoric disorder (PMDD). Results must be confirmed in a larger study, with the indication approved by the Food and Drug Administration.
- Sarafem (fluoxetine hydrochloride, marketed by Eli Lilly) is the first prescription medication with an approved indication for PMDD. The drug, a selective serotonin reuptake inhibitor, also is marketed as Prozac.

The FDA approved in July 2000 the selective serotonin reuptake inhibitor (SSRI) Sarafem (fluoxetine hydrochloride, marketed by Eli Lilly of Indianapolis) as the first prescription medication indicated for the treatment of PMDD. The drug also is marketed as Prozac, which has been in use for several years under approved indications for depression, obsessive-compulsive disorder, and bulimia.

While several studies have found that premenstrual symptoms are less severe among OC users than among other women, no OC currently carries an approved indication for relief of premenstrual symptoms.[2]

When premenstrual symptoms are severe enough to disrupt usual functioning and impact work and family, treatment is appropriate and will help the majority of those who suffer, reflects **Ellen Freeman**, PhD, research professor in the obstetrics and gynecology department in the University of Pennsylvania School of Medicine and co-director of the university's Division of Human Behavior and Reproduction. Freeman served as lead author of the small-scale Yasmin study. At this point in time, the SSRIs have produced the most evidence of efficacy, Freeman observes.

"Yasmin is a promising treatment for PMS which offers a different class of medication and provides contraception as well," says Freeman.

Look at study results

The small-scale double-blind study enrolled 82 women, ages 18-40, to evaluate the efficacy of Yasmin in the treatment of PMDD. Qualified volunteers with PMDD were randomized and treated with Yasmin or a placebo.

Study participants recorded their PMDD symptoms each day for a three-month period, using the Calendar of Premenstrual Experiences (COPE), a prospective inventory statistical tool designed by researchers at the Department of Reproductive Medicine at the University of California, San Diego, now standardized for use in PMS/PMDD studies. Overall, the Yasmin users showed greater reduction in the severity of symptoms than the placebo group for all symptoms rated on the COPE scale. The researchers noted statistically significant improvement with the contraceptive in symptoms such as acne, increased appetite, and food cravings. In addition, Yasmin was well tolerated, and reports of adverse events were typical of those associated with oral contraceptive use.

"All PMS symptoms assessed — both mood and physical — decreased more on the OC than on the placebo," states Freeman. "These were consistent results, although most differences were not statistically significant in a relatively small sample."

The multicenter trial now in progress is designed to confirm or refute these results, she notes.

Make the distinction

To qualify as PMS, symptoms must appear during the woman's luteal phase and decrease greatly or disappear with the onset of menstruation or shortly thereafter. Common PMS symptoms include, among others, abdominal bloating, irritability, mood swings, headache, weight gain, fatigue, food cravings, tension, and breast swelling.

For a PMDD diagnosis, the patient must have:

• five or more of the following symptoms during most menstrual cycles in the past year: irritability, tension, depressed mood, mood swings, decreased interest in usual activities, difficulty concentrating, lethargy, marked change in appetite, insomnia or hypersomnia, sense of being overwhelmed, and physical symptoms such as breast tenderness and bloating. One or more of these symptoms must be depressed mood, tension, mood swings, or irritability.

• a disturbance that significantly interferes with social or occupational functioning;

• symptoms that are not an exacerbation of another disorder, such as major depressive disorder.[3] **(The April 2001 issue of *CTU*, p. 37, carries a complete overview of PMS, PMDD, and treatments.)**

Studies showing that combination oral contraceptive pills have benefits beyond safe and effective contraception are powerful motivators for successful use, says **Steven Sondheimer**, MD, professor of obstetrics and gynecology at the University of Pennsylvania Medical Center and co-director of its Premenstrual Syndrome Treatment Program. "Yasmin is effective and safe contraception, and if it does not increase weight and helps premenstrual symptoms such as bloating, mood changes, and difficulty concentrating, many women will be grateful for these additional and important benefits," he notes.

References

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2. Blackburn RD, Cunkelman JA, Zlidar VM. Oral

Contraceptives — An Update. *Population Reports*, Series A, No. 9. Baltimore, Johns Hopkins University of Public Health, Population Information Program; Spring 2000.
3. Karpa K. For women only. *Drug Topics* 2001; 2:51. ■

'Spermistatics' may lead to new contraceptives

While research is still in the early stages, scientists at the University of Virginia Health System's Center for Recombinant Gamete Contraceptive Vaccinogens in Charlottesville have identified a class of molecules that may lead to new forms of contraceptives.

The scientists coined the word "spermistatic" in a just-published paper to indicate a class of molecules whose principal mechanism of contraceptive action takes place by agglutinating and coating sperm, rather than simply by direct membrane lysis, as is the case with detergent-based spermicides, says **John Herr**, PhD, center director and professor of cell biology at the university.[1]

Spermicides act by direct killing ("-cidal" activity), whereas a spermistatic may act by preventing the progression of sperm through the female tract and by blocking fertilization, even though the sperm may not be "dead" in a metabolic sense, Herr explains.

If such molecules could be proven safe and effective for human use, products using this novel technology would give women another option in female-controlled methods.

Spermicides have several advantages over other methods: They are controlled by women, have no systemic side effects, are available without prescription, and can be used with little advance planning, says **Elizabeth Raymond**, MD, MPH, associate medical director of the biomedical affairs division at Family Health International in Research Triangle Park, NC. However, according to the 1995 National Survey of Family Growth,[2] spermicides are used by a very small percentage (1.3%) of women at risk for unintended pregnancy.

The reason for the low usage is not known, says Raymond. One possibility is that women may understand that spermicides are not as effective at preventing pregnancy as other contraceptive methods, or perhaps they are simply not as aware of this class of methods, she observes.

"Introduction of a new spermicide might result in increased awareness about spermicides in general," says Raymond. "A new product would be especially desirable if it were more effective than existing products."

EXECUTIVE SUMMARY

Early research indicates that a class of molecules may lead to new forms of contraceptives.

- Scientists have coined the term "spermistatic" to define molecules that agglutinate and coat sperm, rather than direct membrane lysis, as is the case with detergent-based spermicides.
- Spermicides act by direct killing ("-cidal" activity), whereas a spermistatic may prevent the progression of sperm through the female tract and block fertilizations.
- Scientists are examining use of the new class of molecules in a cream or foam carrier for women.

Focus on sperm

University of Virginia researchers have discovered a unique carbohydrate epitope, sperm agglutination antigen-1 (SAGA-1), on the sperm surface, says Herr. The SAGA-1 epitope was present on all surface domains of the head and flagellum of the sperm, scientists report.

An extensive study of the tissue distribution of the SAGA-1 antigen revealed its specificity to the epididymis and sperm surface and revealed its complete absence in the female reproductive tract, Herr notes. This indicates that an antibody to SAGA-1 would not cross-react with female tract tissues, he explains.

"These properties, coupled to the need for new strategies for intravaginal contraceptives, led us to test if a miniantibody could be genetically engineered that would be active against the sperm surface and used as a topical reagent," states Herr.

The scientists developed a recombinant antisperm antibody (RASA), which they are now refining to render it theoretically less immunogenic in humans.

"It is not clear if RASA, which is based upon a murine immunoglobulin structure, will be seen as a foreign antigen by some women," says Herr. "To reduce this possibility, the framework regions of human immunoglobulins are being substituted for the murine framework regions of the RASA molecule."

The researchers are looking at the other half of the contraceptive coin and examining their

SAGA-1 findings to develop better treatments for immune-induced infertility.[3]

Delivery system eyed

By binding to the sperm surface, RASA monoclonal antibodies inhibit sperm penetration into cervical mucus, scientists theorize.

University of Virginia researchers are collaborating with Columbia, MD-based Novavax to examine the company's trilamellar liposomes as carriers for the new technology. The liposomes can be formulated as a cream or foam, says Herr. Preliminary studies have shown that this preparation inhibits sperm penetration into cervical mucus and immobilizes sperm over a wide range of pH concentrations.

References

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2. Abma JC, Chandra A, Mosher WD, et al. Fertility, family planning, and women's health: New data from the 1995 National Survey of Family Growth. National Center for Health Statistics. *Vital Health Stat* 23 1997 May; (19):1-114.

3. University of Virginia. University of Virginia Researchers find key to infertility problem. Press release. Charlottesville, VA; Aug. 5, 1999. Accessed at web: hsc.virginia.edu / newstips / Archives99 / infertility.html. ■

Check out these resources to expand access to ECs

Is expanding access to emergency contraceptives (EC) on your personal goal list for 2001? If so, take a look at the EC Materials Database, now available on the Emergency Contraception web site (www.not-2-late.com).

The database, developed by the American Society for Emergency Contraception (ASEC) and the Consortium for Emergency Contraception (CEC), provides descriptions of EC educational and promotional materials from the United States and abroad, including client materials, provider education and training resources, and media campaign materials, says **James Trussell**, PhD, professor of economics and public affairs, faculty associate of the Office of Population Research, and associate dean of the Woodrow Wilson School of Public and International Affairs at Princeton (NJ) University.

EXECUTIVE SUMMARY

Use the following resources for expansion of access to emergency contraception:

- The EC Materials Database provides descriptions of EC educational and promotional materials, including client materials, provider education and training resources, and media campaign materials. It is available on the Emergency Contraception web site (www.not-2-late.com).
- A just-published analysis of the collaborative practice program in Washington state indicates that getting emergency contraceptive pills directly from a pharmacist within 72 hours of having unprotected sex can reduce unintended pregnancies and save money for payers.

The database allows organizations to share and adapt information, ideas, and graphics related to emergency contraception's introduction and promotion. Materials are being added as they become available. When complete, the database will offer a comprehensive catalogue of available materials from around the world, including consumer educational materials; television, radio, and print media materials; medical guidelines; training curricula; and novelty items. Materials may be searched by type, language, target audience, target location, and sponsor organization.

ASEC and the CEC are committed to EC awareness. ASEC is a voluntary collaboration of organizations, founded in 1997, which promotes the option of emergency contraception for women. The CEC is an international-based collaboration committed to making a dedicated product for emergency contraception a standard part of reproductive health care around the world.

Pharmacist program eyed

EC proponents who are looking to establish collaborative practice agreements to expand EC availability in their states may wish to examine the findings in a just-published analysis of a pilot program launched in Washington state. **(See the August 1999 issue of *Contraceptive Technology Update*, p. 85, for an overview of the Washington state project. Also see the January 2001 issue, p. 1, for a report on other states' moves toward wider EC access.)**

The new study's results indicate that getting emergency contraceptive pills directly from a

pharmacist within 72 hours of having unprotected sex can reduce the number of unintended pregnancies and save money for public and private payers.[1]

"Health care decision makers proposing collaborative arrangements in other states can use this information to demonstrate how pharmacist-provision of emergency contraception can reduce unintended pregnancies and save costs," says **Kristin Marciante**, MPH, a member of the Pharmaceutical Outcomes Research and Policy Program within the Department of Pharmacy at the Seattle-based University of Washington. "Public and private insurers can use our findings in conjunction with other information to drive their health care coverage decisions."

Because cost plays an important role in health care decision making, researchers sought to determine the cost and outcomes of increasing access to emergency contraception through pharmacist provision relative to the cost and outcomes occurring in the absence of the pharmacy service, says Marciante. "Our goal was to provide information to insurers considering providing coverage for pharmacist-prescribed emergency contraception and to health care decision makers considering implementing collaborative arrangements in other states," she notes.

Look at the study

The study investigated the effect on the risk and cost of unintended pregnancies of emergency contraceptive pills obtained directly from a pharmacist. Researchers used a decision model to compare outcomes for private and public payers.

The estimate incidence of pregnancy was reduced from 4.9% to 1.8% for women who obtained emergency contraceptives from pharmacies rather than from a physician or clinic or not at all. Obtaining emergency contraceptive pills from a pharmacy, compared with obtaining them from a physician or clinic, resulted in a $158 [95% confidence interval (CI) = $76, $269] reduction in costs for private payers and a $48 [95% CI = $16, $93] reduction for public payers.

"Emergency contraception is an effective method of reducing unintended pregnancy; however, because it must be used within 72 hours of unprotected sex, access can be problematic," Marciante observes. "Pharmacist provision of emergency contraception can facilitate use of the regimen within the 72-hour window because pharmacies are typically open outside of regular business hours."

Reference

1. Marciante KD, Gardner JS, Veenstra DL, et al. Modeling the cost and outcomes of pharmacist-prescribed emergency contraception. *Am J Public Health* 2001; 91:1,443-1,445. ■

Find family planning info at government sites

Looking for federal family planning statistics? Need to research national reproductive issues, or learn more about contraceptives now under development? Take a look at the following sites:

1. National Institute of Child Health and Human Development. Web: www.nichd.nih.gov/.

The Bethesda, MD-based National Institute of Child Health and Human Development is part of the National Institutes of Health, U.S. Department of Health and Human Services. It provides a clearinghouse for information on health issues and publications related to research on women's health, with trained information specialists providing access to information and referral services. Information specialists are available to respond to inquiries Monday through Friday, 8:30 a.m. to 5 p.m. EST by calling the toll-free number, (800) 370-2943. Publications also may be searched at www.nichd.nih.gov/publications/pubs.cfm.

2. U.S. Agency for International Development. Web: www.usaid.gov/.

The Washington, DC-based U.S. Agency for International Development (USAID) is an independent federal government agency that receives overall foreign policy guidance from the federal secretary of state. Click on "Population, Health, and Nutrition" on the site's home page to go to its Population, Health, and Nutrition Center web page. Its "Links" section offers a good listing of international population web sites.

3. CONRAD Program. Web: www.conrad.org.

The CONRAD Program is dedicated to developing better, safer, and more acceptable methods of contraception that are especially suitable for use in developing countries. Established in 1986 at the

Eastern Virginia Medical School in Norfolk as a cooperating agency of the U.S. Agency for International Development, CONRAD concentrates its work on moving potential methods through Phase I and II clinical trials for safety and efficacy. Click on "Contraceptive Info and Related Links" to view its list of contraception and reproductive health web sites.

4. Office of Population Affairs. Web: http://opa.osophs.dhhs.gov/.

The Bethesda, MD-based Office of Population Affairs (OPA), within the Office of Public Health and Science of the Department of Health and Human Services, provides resources and policy advice on population, family planning, reproductive health, and adolescent pregnancy issues. OPA also administers two grant programs: the national Family Planning Program, authorized under Title X of the Public Health Service Act (PHSA), and the Adolescent Family Life Program, authorized under Title XX of the PHSA. Click on "Data and Statistics" for links to statistics for several family planning issues.

5. Center for Drug Evaluation and Research. Web: www.fda.gov/cder/.

The Rockville, MD-based Center for Drug Evaluation and Research (CDER), located within the Food and Drug Administration, ensures that safe and effective drugs are available to the American people. CDER's best-known job is to evaluate new drugs before they can be sold. Click on "Drug Approvals" on the site's home page to see a listing of all approved drugs during 1998-2001. Listings are sorted by product name. When the drug approval or tentative approval letter, labeling text, or review are available, a hyperlink posting date is issued, which allows you to view the source document.

6. MEDLINEplus. Web: medlineplus.gov/.

MEDLINEplus offers health information from the Bethesda, MD-based National Library of Medicine, the world's largest medical library. It offers extensive information from the National Institutes of Health and other sources on about 500 diseases and conditions, and also includes lists of hospitals and physicians, a medical encyclopedia and dictionaries, health information in Spanish, information on prescription and nonprescription drugs, health information from the media, and links to thousands of clinical trials.

7. Agency for Healthcare Research and Quality. Web: www.ahcpr.gov/.

The Rockville, MD-based Agency for Healthcare Research and Quality provides research that offers evidence-based information on health care outcomes; quality; and cost, use, and access. It is a Public Health Service agency in the Department of Health and Human Services. Click on "Women's Health" on the site's home page to go to a page focusing directly on women's health issues. ■

Future uncertain for state family planning waivers

By **Cynthia Dailard**
Senior Public Policy Associate
Alan Guttmacher Institute
Washington, DC

The Bush administration appears to be backpedaling from its decision in July 2001 to oppose expansions of state family planning programs under Medicaid. At that time, the Department of Health and Human Services (HHS) announced that it would no longer approve state applications for "1,115 waivers" to extend Medicaid coverage for family planning services to low-income individuals who would not otherwise meet a state's Medicaid eligibility criteria.

To gain approval, the administration said, states would instead have to provide coverage of a broad package of primary care services — a requirement that many states claimed was prohibitively expensive and would stand in their way of providing family planning services to low-income women in need of care.

Since 1993, 14 states have received approval from the federal government for demonstration projects allowing them to expand Medicaid coverage of family planning services. The earliest of these waivers allowed states to provide family planning services to low-income women enrolled in Medicaid for up to five years following the birth of a child, rather than the traditional 60-day postpartum period. More recent waivers allow states to provide family planning services to any woman with an income up to 200% of the federal poverty level. States with waivers in place include Alabama, Arizona, Arkansas, California,

Delaware, Florida, Maryland, Missouri, New Mexico, New York, Oregon, Rhode Island, South Carolina, and Washington.

According to data collected by the New York City-based Alan Guttmacher Institute, these family planning state expansions serve at least 1.3 million enrollees a year. Moreover, results from the earliest of these waivers show that in addition to being cost-effective, they successfully help low-income women to avoid unintended pregnancy and to properly space their births.

For example, California was able to avoid more than 100,000 unintended pregnancies between fiscal year 1998-99, resulting in a savings of more than half a billion dollars in public expenditures for medical care and social services (or $4.48 for every dollar invested). Additionally, in Rhode Island, the percent of Medicaid recipients with short interbirth intervals (who became pregnant within 18 months of having given birth) showed a significant drop.

Waivers challenged

Nonetheless, the administration in July announced that it would reject all pending applications for family planning waivers. In addition to Wisconsin's waiver request, signed by HHS Secretary Tommy Thompson while he was governor, states with pending applications included Colorado, Georgia, Kentucky, New York, Mississippi, North Carolina, and Virginia. The administration also announced that existing waivers, which typically last five years, would not be renewed.

Reaction to this policy change was swift on Capitol Hill. Within only a few days, Sen. Lincoln Chafee (R-RI), Rep. Nita Lowey (D-NY) and 23 of their colleagues introduced "The State Family Planning Empowerment Act" that would allow states to implement family planning expansions without applying to the federal government for a waiver.

Given the powerful results beginning to emerge from these programs, Chafee and Lowey argued that these expansions should no longer be considered demonstration projects that require federal approval, but instead should be an option readily available to all states. In September, a bipartisan group of senators wrote to Sens. Tom Harkin (D-IA) and Arlen Specter (R-PA), the chairman and ranking member of a Senate appropriations subcommittee, urging them to include language in pending legislation to fund HHS to facilitate states' ability to expand Medicaid coverage for family planning.

In response to this pressure, the administration appears to be easing its stance. While administration officials initially indicated that programs would have to include coverage of primary care *services*, it is now informing states that the primary care requirement can be met by including *referrals* for primary care. States will need to make formal

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CE/CME Questions

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

- Name the estrogen component in the NuvaRing combined contraceptive vaginal ring.
- State the U.S. brand name for mifepristone.
- Identify the progestin component in the combined oral contraceptive Yasmin.
- Give the drug used in treating syphilis in pregnant women.

21. What is the estrogen component used in the NuvaRing combined contraceptive vaginal ring?
    A. desogestrel
    B. mestranol
    C. gestodene
    D. ethinyl estradiol
22. What is the U.S. brand name for mifepristone?
    A. Cytotec
    B. Mifeprex
    C. Methergine
    D. Postinor
23. What is the name of the progestin in the oral contraceptive Yasmin?
    A. desogestrel
    B. gemeprost
    C. drospirenone
    D. gestodene
24. If syphilis is detected in a pregnant woman, which drug should be used for treatment?
    A. penicillin
    B. erythromycin
    C. azithromycin
    D. ceftriaxone

arrangements with community health centers to provide primary care services and will need to submit a letter of support from community health centers with their waiver application. Additionally, enrollees in the family planning program must be given information on how to access primary care services from community health centers.

A number of states have responded favorably to this requirement, now that they will not have to bear the cost of providing primary care services. At least some states have begun the process of revising their waiver applications to accommodate this new referral requirement. However, as of mid-October, the Bush administration had not yet approved a single waiver application, leaving at least some family planning advocates skeptical about the future of these important initiatives. ■

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QUARTERLY

Syphilis elimination program pays off: Lower congenital syphilis rates

Efforts must continue to reach elimination goals

Vigilance in detecting and treating primary and secondary syphilis in the United States is reaping rewards: The syphilis rate among infants in 2000 declined by 51% since 1997, the year before the Atlanta-based Centers for Disease Control and Prevention (CDC) launched its national syphilis elimination campaign.[1]

Cases of congenital syphilis (CS) in 2000 appeared in 155 counties, which represent only 5% of all counties in the United States.[1] A regional breakdown of CS indicates that rates were highest in the South, with congenital syphilis occurring in approximately 19 of every 100,000 live births. Rates in other regions were significantly lower.[1]

EXECUTIVE SUMMARY

The syphilis elimination campaign by the Centers for Disease Control and Prevention is making an impact: The syphilis rate among infants in 2000 declined by 51% since 1997.

- Rates of congenital syphilis (CS) closely follow trends in primary and secondary syphilis in women, as infants become infected during pregnancy or delivery. In 2000, infectious syphilis cases among women ages 15-44 dropped 38% from 1997.
- National goals are to reduce infectious syphilis cases to 1,000 or fewer annually and increase the number of syphilis-free counties to at least 90% by 2005.

Congenital syphilis is acquired when an infected pregnant woman transmits the infection to her fetus. Rates of congenital syphilis closely follow trends in primary and secondary syphilis in women, as infants become infected from their mothers during pregnancy or delivery. In 2000, 2,219 infectious syphilis cases among women of childbearing age (ages 15-44) were reported to the CDC, a 38% drop from 3,590 cases in 1997.[2]

Left untreated, up to 40% of congenital infections will result in infant death, says **George Counts**, MD, director of CDC's syphilis elimination activities. Infected children who are not treated may suffer neurological impairment, seizures, deafness, or bone deformities. If syphilis is detected in pregnant women, however, it can be treated with a single dose of penicillin, an inexpensive, widely available antibiotic that is effective and safe for mother and child, he notes.

While news of the reduction in CS rates has been hailed as an important milestone, there still is work to do to reach the national goals of reducing infectious syphilis cases to 1,000 or fewer annually and increasing the number of syphilis-free counties to at least 90% by 2005, say CDC officials.

Racial disparities eyed

The new CDC data indicate that despite signs of decline overall, minority groups, especially African-Americans, continue to

be disproportionately affected by syphilis.[2]

In 2000, the congenital syphilis rates were 49.3 cases per 100,000 live births for African-Americans, 22.6 cases per 100,000 live births for Hispanics, 13.2 cases per 100,000 live births for American Indians / Alaska Natives, 5.9 cases per 100,000 live births for Asian / Pacific Islanders, and 1.5 cases per 100,000 live births for whites.[1]

Progress is being made in impacting CS rates, according to CDC information. From 1997 to 2000, CS rates declined 59.7% for African-Americans, 58.3% for whites, 32.5% for Hispanics, and 29.8% for Asian / Pacific Islanders.[1] American Indians / Alaska Natives experienced a slight increase.[1]

In a 1998 national survey, only 85% of OB / GYNs reported routinely screening pregnant women for syphilis.[3] To combat congenital syphilis, the CDC recommends that health care providers test all women for syphilis during the early stages of pregnancy.[2] In areas where syphilis prevalence is high and for pregnant women at high risk, CDC recommends that providers test their patients early during pregnancy and twice in the third trimester, including once at delivery.

Because stillborn delivery can be due to syphilis infection, all women who deliver a stillborn infant after 20 weeks of gestation also should be tested for syphilis and treated if infected, according to the CDC.[2] Syphilis screening also should be offered in emergency departments, jails, prisons, and other settings that provide episodic care to pregnant women at high risk for syphilis.[1]

Focus on pilot programs

Syphilis elimination is defined as the absence of sustained transmission. When elimination goals are achieved, the occasional outbreaks can be identified quickly and contained, thus eliminating the risk of a new epidemic, explain CDC officials.

With syphilis rates at their lowest levels in U.S. history, the CDC moved forward in 1998 with its syphilis elimination program. **(See *Contraceptive Technology Update*'s September 1997 issue of *STD Quarterly*, "Syphilis hits 40-year low: Is elimination within reach?" p. 111, and p. 113, "What can turn the tide?")** The geographic concentration of disease provided public health officials an opportunity to build on current STD prevention and control efforts to combine intensified traditional approaches with innovative new ones, say CDC officials.

When the syphilis elimination plan was launched in 1998, the CDC targeted 31 sites with the highest levels of syphilis morbidity and awarded funding to establish local syphilis elimination plans, says Counts.

"What that tells us is that if you aggressively focus additional resources to a community, those that have strong community partnerships, you can make a bigger impact on decreasing the syphilis rate."

In addition to targeting those sites, the CDC designated three U.S. counties with high levels of syphilis as demonstration sites, Counts explains. The three sites — Marion County in Indiana, Wake County in North Carolina, and Davidson County in Tennessee — received additional funds to field-test the CDC's national plan, says Counts.

The demonstration sites focus on strengthening community involvement and partnership. The CDC is working closely with community partners and state and local governments to fortify programs in hardest-hit communities.

The partnerships are paying off, according to Counts. While the national primary and secondary syphilis rates fell by about 10% from 1999 to 2000, the rates among the three demonstration sites fell two to three times faster, he says.

"What that tells us is that if you aggressively focus additional resources to a community, those that have strong community partnerships, you can make a bigger impact on decreasing the syphilis rate," he notes.

For example, Davidson County has made great strides in attacking its syphilis rates through its jail-screening program. During a 14-month period, one-third of all new syphilis cases in the county were detected by screening metro jail inmates.[4]

According to **Chris Freeman**, program director for the STD / HIV program at the Metro Davidson County Health Department in Nashville, the county is using its "STD-Free" program to address

not only syphilis, but other sexually transmitted diseases (STDs) as well.

A community coalition approach, "STD-Free" brings together community members and health department personnel who subsequently are divided into five sections: education, which includes local schools; private providers and hospitals; community services, which includes social services and other allied personnel; religious- and faith-based; and correctional, which includes local law enforcement personnel. These groups meet on a regular basis to identify and address STD concerns.

"I think it has given the community some ownership of the problem, more so than just a health department problem," says Freeman. "Because of that, I think there's been more of a community awareness, a lot more community education, not necessarily by the health department staff, but by other members of the community that keep those issues out on everybody's radar screen."

Outreach screenings and educational sessions are used in the "STD-Free" approach, says Freeman.

"Any opportunity — health fairs, college meetings, or any type of gathering — is a great opportunity for us to set up a table or display so we can talk about STDs in Davidson County," notes Freeman.

Time for action is now

According to the CDC, the last U.S. syphilis epidemic peaked in 1990, with the highest syphilis rates in 40 years. Although infections have subsided to the lowest level since reporting began, syphilis rates tend to run in seven- to 10-year cycles, note CDC officials. Unless continued action is taken to eliminate the disease, the United States once again could experience a rise in syphilis rates.

The syphilis elimination activities and interventions now in place are assisting in reducing the prevalence of syphilis among women of reproductive age and, in turn, eliminating congenital syphilis. With early detection of maternal syphilis and treatment with safe, effective antibiotics, syphilis among infants can be eliminated, says the CDC.[1]

"If we fail to take advantage of this historic opportunity, the health of our families and our communities will continue to suffer," says Counts.

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Delivering HIV care: Take it to the community

How can quality of care for HIV-positive and AIDS patients be improved? For those in Robeson County, NC, a new community-based infectious disease clinic has eliminated a five-hour drive to facilities at University of North Carolina at Chapel Hill (UNC-CH).

Infectious disease experts at the UNC-CH School of Medicine started the clinic in January 2001 after examining the number of patients treated at the Chapel Hill-based facility, says **Charles van der Horst**, MD, UNC-CH professor

EXECUTIVE SUMMARY

The University of North Carolina at Chapel Hill School of Medicine has brought HIV/AIDS care to the community, with an infectious disease clinic in Robeson County.

- Ten percent of the Chapel Hill clinic patients were driving from Robeson County to receive care.
- A $100,000 grant was secured for the first year of operations. Medicaid, private insurance, Medicare, and the federal AIDS Drug Assistance Program cover indigent patients' costs.

of medicine and infectious diseases and medical director of the University of North Carolina AIDS Clinical Trials Unit. The AIDS Clinical Trials Unit conducts and develops research of HIV infection and its associated opportunistic infections and provides access to promising clinical protocols to persons living with HIV.

The Chapel Hill clinic follows 1,500 patients, says van der Horst. In examining its patient population, clinic officials determined that 10% of its patients were coming from Robeson County. The idea for initiating a community-based clinic came from UNC-CH providers' desire to locate services closer to those impacted by the HIV/AIDS epidemic.

"If you're a single mother, for example, who is infected with HIV, the virus that causes AIDS, you shouldn't have to drive so far for a 15-minute doctor's appointment, especially if you don't own a car," says van der Horst.

County hit hard

Robeson County, while not among North Carolina's most populous counties, has been disproportionately impacted by sexually transmitted diseases, including syphilis, states van der Horst.

High syphilis rates are of concern, since infection increases HIV transmission at least two- to fivefold, according to the Atlanta-based Centers for Disease Control and Prevention (CDC).[1] In 1998, Robeson County ranked 28th in the nation in new cases of infectious syphilis.[2] Half of its cases were among African-Americans, with 41% among Native Americans, according to the CDC.[2]

Special services offered

Providing care to HIV/AIDS patients requires specific services, says van der Horst. The skills needed to obtain and provide drugs, manage individual cases, and provide other services have made care a very specialized, complicated business, he notes. By developing a community clinic staffed with providers experienced with HIV/AIDS, patients now receive the services they need at a convenient location.

A $100,000 grant from the N.C. Department of Health and Human Services in Raleigh, made possible by federal monies from the Ryan White bill, were secured for the clinic's first year of operations. Medicaid, private insurance, Medicare and the federal AIDS Drug Assistance Program cover indigent patients' costs. The clinic also provides financial assistance to a few patients who need help with drug costs, van der Horst said.

Each week, Dickens Theodore, MD, or **Becky Stephenson**, MD, members of UNC-CH's department of medicine faculty, accompany UNC-CH family nurse practitioner Laurie Frarey, FNP, to Lumberton to see patients at the clinic. All services are HIV health care-related; no primary care is provided, says Stephenson.

The clinic has been promoted in the local paper and on UNC-TV, and case managers for the HIV-infected patients have notified the local providers, says Stephenson.

"We also had a reception with the local providers before we started," she notes. "The reception has been very positive."

The clinic's first patient was a newly diagnosed woman in the third trimester of pregnancy, says van der Horst. Knowing that a baby's life has been saved due to the clinic's care is "worth the whole grant," he says.

Making an impact

When adequate care for people with HIV infection is not readily available, treatment is often sought in local hospital emergency rooms, observes van der Horst. Such practice is detrimental to patients, since they present with more advanced symptoms, and costly for hospitals, since such care is often not reimbursed.

"This clinic, while a small and modest beginning, is really a landmark opportunity not only to provide compassionate, humane care for those who are often marginalized on the fringes of society, but also to help stop the spread of HIV," van der Horst said. "We hope that it will serve as a catalyst for local communities and medical centers to step forward and help out as well."

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CONTRACEPTIVE TECHNOLOGY UPDATE®
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Continuing Medical Education Test

JULY

1. What are the two hormones in the contraceptive injectable, Lunelle?
   A. norehisterone enanthate and estradiol valerate
   B. dihydroxyprogesterone acetophenide and estradiol enanthate
   C. dihydroxyprogesterone acetophenide and estradiol valerate
   D. medroxyprogesterone acetate and estradiol cypionate

2. According to the package insert, when should reinjections be given for Lunelle?
   A. every 28 days after the last day of a woman's menstrual period
   B. 11-13 weeks following the last injection
   C. every 28-30 days and no later than 33 days after the last injection
   D. every 35 days after the last injection

3. What six quality assurance tests are used at the manufacturing site to check the integrity of Planned Parenthood condoms?
   A. wet electrical test, dry electrical test, air burst test, water burst test, aging test, vacuum test
   B. wet electrical test, dry electrical test, air burst test, water burst test, aging test, tensile test
   C. wet electrical test, dry electrical test, viral impermeability test, water burst test, aging test, vacuum test
   D. wet electrical test, dry electrical test, air burst test, lubrication test, aging test, vacuum test

4. Which of the following is NOT a recommendation from the U.S. Preventive Services Task Force regarding chlamydia screening?
   A. Screen all women who are sexually active and age 25 or younger.
   B. Screen all women who have more than one sexual partner, regardless of age.
   C. Screen all women who have had a sexually transmitted disease (STD) in the past, regardless of age.
   D. Screen all men who have no symptoms.

AUGUST

5. What are the active ingredients in the oral contraceptive Cyclessa?
   A. ethinyl estradiol and levonorgestrel
   B. ethinyl estradiol and desogestrel
   C. ethinyl estradiol and norgestimate
   D. ethinyl estradiol and norethindrone acetate

6. What is the leading reason women discontinue hormone replacement therapy?
   A. nausea
   B. breast tenderness
   C. vaginal atrophy
   D. vaginal bleeding

7. What is the name of the contraceptive patch developed by R.W. Johnson Research Institute?
   A. Ortho Evra
   B. CombiPatch
   C. Esclim
   D. FemPatch

8. What is the name of the drug that, when used during pregnancy and the neonatal period, reduces the rate of mother-to-child HIV transmission by approximately two-thirds?
   A. stavudine
   B. ritonavir
   C. zidovudine
   D. nelfinavir

SEPTEMBER

9. Which benefit is NOT conferred by use of combined oral contraceptives?
   A. less iron deficiency anemia, due to lighter menstrual bleeding
   B. more regular cycles
   C. less dysmenorrhea
   D. protection from breast cancer

10. According to calcium guidelines from the National Academy of Sciences, what is the recommended daily calcium intake for adolescents?
    A. 1,000 mg of calcium each day
    B. 1,600 mg of calcium each day
    C. 1,500 mg of calcium each day
    D. 1,300 mg of calcium each day

11. What is the progestin in the emergency contraceptive pill Plan B?
    A. desogestrel
    B. norgestimate
    C. levonorgestrel
    D. gestodene

12. What is the progestin in the Mirena intrauterine system?
    A. levonorgestrel
    B. norgestimate
    C. desogestrel
    D. drospirenone

OCTOBER

13. What was one of the primary findings of Workshop Summary: Scientific Evidence on Condom Effectiveness for Sexually Transmitted Disease (STD) Prevention?
    A. The evidence is clear that condoms are effective against HIV and all forms of STDs.
    B. The evidence is clear that condoms are ineffective in preventing transmission of HIV but are effective in protection against other STDs.
    C. The evidence is clear that condoms are ineffective in preventing transmission of HIV and other STDs.
    D. The evidence is clear that correct and consistent use of condoms can reduce the risk of HIV/AIDS transmission, as well as reduce a man's risk of acquiring gonorrhea from a female partner.

14. What did the July 2001 scientific advisory from the American Heart Association state regarding the provision of hormone replacement therapy (HRT) for prevention of future coronary events in postmenopausal women with cardiovascular disease (CVD)?
    A. HRT should not be initiated for the prevention of future coronary events in postmenopausal women with CVD.
    B. HRT should be used for the prevention of future coronary events in postmenopausal women with CVD.
    C. Providers should use only estrogen replacement therapy for the prevention of future coronary events in postmenopausal women with CVD.

15. What was a key finding of a recently published analysis (Xu F, 2000) of a population-based STD registry in Washington state?
    A. Race/ethnicity was the strongest predictor for one and two or more repeat infections after controlling for the length of follow-up and other variables.
    B. Young age was the strongest predictor for one and two or more repeat infections after controlling for the length of follow-up and other variables.
    C. Coinfection with gonorrhea was the strongest predictor for one and two or more repeat infections after controlling for the length of follow-up and other variables.
    D. County of residence was the strongest predictor for one and two or more repeat infections after controlling for the length of follow-up and other variables.

16. According to the American College of Obstetricians and Gynecologists, when should providers screen nonpregnant women for intimate partner violence?
    A. Women should be screened only when they present with physical signs of abuse.
    B. Women should be screened only when family members are present with them in the examination room.
    C. Screening should occur at routine OB/GYN visits, family planning visits, and preconception visits.

NOVEMBER

17. What was an important outcome of a 2001 study (Hubacher D, et al, *N Engl J Med)* of copper T380A intrauterine device (IUD) users?
    A. Compared with women who had not used hormonal, intrauterine, or barrier contraception, use of a copper IUD was greatly associated with an increased risk of tubal infertility.
    B. Compared with women who had not used hormonal, intrauterine, or barrier contraception, use of a copper IUD was not associated with an increased risk of tubal infertility.
    C. Women who used the copper IUD had more incidents of chlamydia infection.

18. State an important finding from a 2001 study (Ness RB, et al, *Am J Obstet Gynecol),* which examined pelvic inflammatory disease (PID) risks in women using contraception.
    A. Neither recent oral contraceptive use nor barrier method use (condoms or other barrier methods) reduced the risk of upper genital tract disease among women presenting with signs and symptoms consistent with PID.
    B. Oral contraceptive use was associated with a lower risk for PID.
    C. Use of depot medroxyprogesterone acetate was associated with a higher risk for PID.

19. What are the standards for care for rape victims as established by the American Medical Association?
    A. Rape victims should receive a pregnancy test at the time of the initial emergency department visit.
    B. Rape victims should not receive emergency contraception at the time of the initial emergency department visit.
    C. Rape victims should receive a Pap smear at the time of the initial emergency department visit.
    D. Rape victims should be counseled about their risk of pregnancy and offered emergency contraception.

20. What is the State Children's Health Insurance Program (SCHIP)?
    A. targets children up to age 13 whose families earn too much to qualify for Medicaid but who cannot afford private health insurance
    B. offers general health care, but excludes reproductive health services, for children up to age 19 whose families earn too much to qualify for Medicaid but who cannot afford private health services
    C. targets children up to age 15 whose families earn too much to qualify for Medicaid but who cannot afford private health insurance
    D. targets children up to age 19 whose families earn too much to qualify for Medicaid but who cannot afford private health insurance

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21. What is the estrogen component used in the NuvaRing combined contraceptive vaginal ring?
    A. desogestrel
    B. mestranol
    C. gestodene
    D. ethinyl estradiol

22. What is the U.S. brand name for mifepristone?
    A. Cytotec
    B. Mifeprex
    C. Methergine
    D. Postinor

23. What is the name of the progestin in the oral contraceptive Yasmin?
    A. desogestrel
    B. gemeprost
    C. drospirenone
    D. gestodene

24. If syphilis is detected in a pregnant woman, which drug should be used for treatment?
    A. penicillin
    B. erythromycin
    C. azithromycin
    D. ceftriaxone

Contraceptive Technology Update
Continuing Education Evaluation

Please take a moment to answer the following questions to let us know your thoughts on the continuing education program. Place an "x" in the appropriate space **and return this page in the envelope with your test answer form. Thank you.**

For your reference, here is the stated purpose of *CTU:* To keep readers updated on clinical and regulatory developments in contraception so they can offer the latest products and information to their patients.

Did *Contraceptive Technology Update* enable you to meet the following objectives?

yes__ no__ 1. Are you able to identify clinical, legal, or scientific issues related to development and provisions of contraceptive technology or other reproductive services?

yes__ no__ 2. Are you able to describe how those issues affect service delivery and note the benefits or problems created in patient care in your practice area?

yes__ no__ 3. Are you able to cite practical solutions to problems and integrate information into daily practices, according to advice from nationally recognized family planning experts?

yes__ no__ 4. Did these objectives help accomplish the overall purpose of the program?

yes__ no__ 5. Were the teaching/learning resources effective for this activity?

6. How many minutes do you estimate it will take you to complete **this entire semester** (6 issues) activity? Please include time for reading, reviewing, testing, and studying the answer sheet, which you will receive with your certificate. One nursing contact hour equals 50 minutes._____ minutes

yes__ no__ 7. Were the test questions clear and appropriate?

yes__ no__ 8. Were the instructions clear and appropriate?

yes__ no__ 9. Were you satisfied with the customer service for the CE Program?

10. Do you have any general comments about the effectiveness of this CE Program?

Continuing Medical Education Survey

Contraceptive Technology Update

Currently accredited for approximately 9 continuing medical education hours per six-month semester.

Please take a moment to answer the following questions to let us know your thoughts on the continuing medical education program. Place an "X" in the appropriate space and **return this page in the envelope with your CME test answer form.** Thank you.

1. Did the program enable you to meet the objectives?
   Objectives:

- 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 note the benefits or problems created in patient care in your practice area;

- cite practical solutions to problems and integrate information into daily practices, according to advice from nationally recognized family planning experts.

   ☐ Yes ☐ No

2. Did the program meet your expectations as defined in the promotional literature?
   ☐ Yes ☐ No

3. Were the test questions well-written?
   ☐ Yes ☐ No

4. Was the test a fair assessment of the learning activity?
   ☐ Yes ☐ No

5. Were the tests graded and returned efficiently?
   ☐ Yes ☐ No

6. Did the program help improve your professional effectiveness?
   ☐ Yes ☐ No

If not, please explain.

_____

_____

_____

_____

_____

American Health Consultants® designates this continuing medical education activity for approximately 18 credit hours per year in Category 1 of the Physicians' Recognition Award of the American Medical Association. Each physician should claim only those hours of credit that he/she actually spent in the educational activity.

American Health Consultants® is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians. This CME activity was planned and produced in accordance with the ACCME Essentials.

CONTRACEPTIVE TECHNOLOGY UPDATE®
A Monthly Newsletter for Health Professionals

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