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AMERICAN HEALTH CONSULTANTS

IN THIS ISSUE

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More women know about emergency contraception, but can they get it?

New Mexico, Hawaii latest states to offer pharmacist provision of EC

The word is getting out about emergency contraception (EC). A just-released national survey reports that two-thirds of women ages 18-44 are aware that there is something a woman can do to prevent pregnancy in the few days following sexual intercourse.[1] However, barriers still exist to EC access. The survey results indicate only 6% of women report ever using the pregnancy prevention method.

Reproductive health advocates in New Mexico and Hawaii have moved forward in eliminating some of the physical obstacles to EC by amending legislation to allow pharmacists to offer direct provision of the method. Now women in those two states will be able to go directly to participating pharmacists for EC rather than waiting to call a clinician.

Five states now allow pharmacist provision of EC; Washington state led the way in 1998, followed by California and Alaska in 2002. **(Review *Contraceptive Technology Update* coverage of these events in the following issues: August 1999, p. 85; January 2001, p. 1; and March 2002, p. 25.)**

"New Mexico now has some of the broadest privileges to be granted

EXECUTIVE SUMMARY

New Mexico and Hawaii are the latest states to amend legislation to allow pharmacists to offer direct provision of emergency contraception (EC).

- New Mexico pharmacists have independent prescriptive authority to write prescriptions for EC.
- Hawaiian pharmacists have patterned their approach after the Washington state model, which uses collaborative practice.
- The states join Alaska, California, and Washington state in expanding access to the method.

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to pharmacists to provide emergency contraception," says **Linda Dominguez**, CNP, assistant medical director of Planned Parenthood of New Mexico in Albuquerque.

The New Mexico program is indeed different from other states' approaches to EC provision, agrees **Diana Koster**, MD, vice president of medical affairs and medical director of Planned Parenthood of New Mexico.

"It's not a collaborative practice," she states. "It's prescriptive authority for pharmacists."

Effective May 15, 2003, all requirements were met to allow pharmacists with training to prescribe EC, reports **Dale Tinker**, executive director of the Albuquerque-based New Mexico Pharmaceutical Association. The association has worked with the Albuquerque-based New Mexico Department of Health and the San Francisco-based Pharmacy Access Partnership, which helped spearhead similar legislation in its state, in developing the New Mexico program.

Hawaii governor Linda Lingle signed legislation on June 24 to allow collaborative practice provision of EC, and the state board of pharmacy has initiated discussion to begin implementation of the program, says **Annelle Amaral**, director of public affairs for Planned Parenthood of Hawaii in Honolulu. The bill was before the legislature for two years and passed in the second year, she notes.

Paving new ground

To enact the New Mexico law, proponents had to go to the state legislature to modify the pharmacy practice act, Koster explains. The act was modified for independent practice under protocols approved by the boards of pharmacy, medical examiners, and nursing, she states. The prescriptive authority is extended for two purposes: vaccines and EC. *(Review the statute, rules, protocols, and EC forms at the New Mexico Pharmaceutical Association web site; go to www.nm-pharmacy.com/pharmacist_rx_protocol.htm.)*

"We have a statewide protocol [for EC] for everybody in the state; it is the public health department's protocol, with some modifications," states Koster. "So everybody in the state essentially — all of Planned Parenthood, all public health, and all pharmacists — will be doing EC the same way."

Hawaii has opted for the collaborative practice route rather than extending independent prescriptive privileges to pharmacists, states Amaral. Proponents patterned legislation and protocols on the Washington state experience

and had several public briefings and discussions with Washington state officials in developing the Hawaii protocol, she explains.

Training is key

New Mexico pharmacists must successfully complete an EC training course prior to providing the drug therapy. The training includes current standards for prescribing EC drug therapy, as well as information on identifying indications for EC use; interviewing patients to establish the need for EC; counseling patients regarding safety, efficacy, and potential adverse effects; evaluating medical profiles for drug interaction; referring patients for follow-up care with a primary health care provider; providing informed consent; and managing records of adverse events, including identification, appropriate response, documentation, and reporting.

More than 70 pharmacists have received the complete EC training, and about 40 have completed part of the training, says Tinker. About 40 pharmacy technicians also have taken the training so they can better support the efforts of pharmacists, he notes.

Training of pharmacists began prior to enactment of the legislation, explains Koster. The New Mexico legislature operates alternating years of a short session, so it took until 2003 for the legislation to receive final approval, she notes.

More than 80 Albuquerque-based University of New Mexico College of Pharmacy students have received the training, since EC provision will now be part of the PharmD curriculum, says Tinker. Since EC provision now is part of the College of Pharmacy educational program, EC now will be seen as standard of practice for pharmacists in New Mexico, notes Koster.

An EC visit represents an opportunity not only to solve the immediate crisis, but also to do some better planning for the future in terms of a more effective method or re-education about the right way to use a method, she states. Pharmacists have been very interested in the contraceptive-counseling component of the training, she reports.

In Hawaii, the need for pharmacist training in EC provision is great; just 6% of pharmacists report they have received EC training within the past five years, reports Amaral. In a survey conducted by the Honolulu-based Healthy Mothers, Healthy Babies Coalition of Hawaii, 94% of the pharmacists surveyed had not received recent certified EC training from the Chicago-based American College of Pharmacy Education. About two-thirds of the pharmacists indicated an interest in receiving EC training. At press time, plans were in motion for the Honolulu-based Hawaii Pharmacists Association to host a statewide pharmacist training session, she says.

Getting the word out

Due to funding issues, the New Mexico pharmaceutical association has no way to notify the public about pharmacist provision of EC, except to encourage pharmacist prescribers to get listed on the Emergency Contraception Hotline, (888) NOT-2-LATE, and its companion web site, www.not-2-late.com. However, this may be set to change, says Koster; one foundation has pledged funding for a public awareness campaign, and proponents are seeking further monies to get out the word about EC.

Such awareness is important, says Koster, because many people continue to confuse EC with mifepristone, the abortion drug.

In a 2001 national survey, more than four in 10 (43%) of women who had heard of mifepristone said — incorrectly — that it is the same thing as EC.[2]

Planned Parenthood of Hawaii is working with a consortium of people representing the Board of Pharmacy, the Board of Medical Examiners, the University of Hawaii School of Medicine, the Department of Health, Kaiser-Permanente, Hawaii Medical Service Association, and others to develop a statewide coordinated EC public education plan, says Amaral.

With pharmacists now joining clinicians in providing EC, more barriers to accessing the method will fall, say proponents. While clinicians can continue to provide advance supplies of EC to patients, the addition of pharmacists adds another link to the EC access chain.

"New Mexico is a geographically large state with many medically underserved areas and a high rate of unintended pregnancy," reports Dominguez. "Pharmacists will be an important link in the effort to provide this critical service."

References

1. Henry J. Kaiser Family Foundation / *SELF* magazine. *National Survey of Women on their Sexual Health.* New York City; June 2003.

2. Henry J. Kaiser Family Foundation. *National Survey of Women's Health Care Providers and the Public: Views and Practices on Medical Abortion*. Menlo Park, CA; September 2001. ■

Check Nortrel stock — Barr Labs issues recall

If you have any patients who use 28-day packages of Nortrel 7/7/7 oral contraceptives (OCs), be sure your clinic has initiated its patient notification plan following the July 9, 2003, voluntary recall issued by the pill's manufacturer, Barr Laboratories of Pomona, NY.

Three lots, which total about 470,000 packages, are involved in the recall: 290122001, 290122002, and 290122003. The lot numbers should appear in a window labeled "LOT" on the upper right-hand corner of the backside of the package. Any Nortrel 7/7/7 28-day product that does not have a number in that location also is subject to the recall; no other lots of Nortrel or other Barr OC products are affected by the recall.

The recall was issued by the manufacturer after it received two reports that color-coded tablets in the blister card packaging of the product were reversed, which caused the white placebo row to be in the first row labeled "start," rather than in the last row labeled "week 4." The lot number and expiration date were not visible on the back of these two cards, states the company.

Nortrel 7/7/7 28-day pills are packaged in a blister card containing four horizontal rows of seven tablets each, with each row representing one week of tablets. The top row contains yellow tablets, followed by rows of blue, peach, and white tablets. The colored tablets contain the active hormonal ingredients of ethinyl estradiol and norethindrone; the white tablets are placebos that contain no active ingredient.

The company has strived to be proactive in issuing the recall, says **Anna Manno**, communications associate for Barr Laboratories. The federal Food and Drug Administration has been notified of the recall, and the company has reviewed all manufacturing and packaging processes related to the product. According to a press release issued by the company, the mispackaging was an isolated incident limited to the lots in question, and corrective actions have been taken.

Product recalls of the Norplant contraceptive implant in 2000 and the Lunelle contraceptive injection in 2002 caused headaches for many family planning clinics; the Nortrel 7/7/7 recall may not have appeared as urgent, observes **Michael Rosenberg**, MD, MPH, clinical professor of obstetrics and gynecology and adjunct professor of epidemiology at the University of North Carolina at Chapel Hill and president of Health Decisions, a private research firm specializing in reproductive health.

Results from prior *Contraceptive Technology Update* (*CTU*) contraception surveys bear out this observation. While the brand equivalent, Ortho 7/7/7 (Ortho-McNeil Pharmaceutical, Raritan, NJ) was once a popularly prescribed pill, its dominance waned following the introduction of lower-dose OCs. A total of 12% of *CTU* readers named Ortho 7/7/7 as their No. 1 pill for 21-year-old women in 1996; however, by 1999, that number had decreased to 5%. Ortho 7/7/7 has failed to chart in subsequent *CTU* surveys. Barr Laboratories introduced its version of the pill in January 2003.

Check patient guidance

Women who are using Nortrel 7/7/7 28-day packages should be instructed to carefully check their blister cards and take the following steps:

- If their blister card contains out-of-sequence tablets, women should continue taking the pills, and return the product to their pharmacist for a replacement blister card. Barr Laboratories will replace any out-of-sequence blister card at no additional cost and also will cover the cost of a pregnancy test for any woman who purchased and used a blister card with out-of-sequence tablets.
- If their blister card contains the correct sequence of tablets, women should continue taking the product.
- Women who are not certain whether their blister card contains the correct sequence of tablets should contact Barr Laboratories or their

EXECUTIVE SUMMARY

Barr Laboratories of Pomona, NY, has issued a product recall of three lots of its Nortrel 7/7/7 28-day packages of oral contraceptives.

- The recall is issued for the following lot numbers: 290122001, 290122002, and 290122003. The lot numbers should appear in a window labeled "LOT" on the upper right-hand corner of the backside of the package. Any Nortrel 7/7/7 28-day product that does not have a number in that location also is subject to the recall.
- The recall was issued after the company received two reports that color-coded tablets in the blister card packaging of the product were reversed, causing the white placebo row to be in the starting row, rather than the final fourth row.

pharmacist immediately, but should continue taking the product until otherwise instructed by their provider or pharmacist.

• Women who believe they may have previously taken Nortrel 7/7/7 28-day from an out-of-sequence blister card and who are concerned about pregnancy or irregular bleeding should consult their provider for further instructions.

To receive reimbursement for the reasonable and customary cost of a pregnancy test, the patient must provide proof that she is or was in possession of one of the effected lots of product or a copy of her prescription from her pharmacist, and a copy of the receipt for the pregnancy test. This information should be mailed to Barr Laboratories, Attention: Drug Information, Two Quaker Road, Box 2900, Pomona, NY 10970.

More information on the recall and the reimbursement process is available by call the company's information department at (800) 222-0190, ext. 33302. ■

Low-dose OCs not linked with stroke risk

EXECUTIVE SUMMARY

Findings from a new study indicate that use of oral contraceptives (OCs) containing 50 mcg estrogen or less do not appear to appreciably raise the risk of ischemic stroke in healthy women.

- Researchers found that women who reported currently using pills with fewer than 50 mcg estrogen seemed to be at no greater risk of ischemic stroke. In addition, there was no association between the number of years a woman had taken OCs and the risk of stroke.
- Factors associated with an increased risk of ischemic stroke were a history of hypertension, transient ischemic attack, previous myocardial infarction, or diabetes mellitus; family history of stroke; and smoking more than 20 cigarettes per day.

Findings from a new Australian study indicate that use of modern, low-dose oral contraceptives (OCs) containing 50 mcg estrogen or less do not appear to appreciably raise the risk of ischemic stroke in healthy women.[1]

Early evidence in the mid-1970s linked OC use to increased risk for stroke; however, studies with low-dose pills in the 1980s and 1990s have suggested less overall risk.[2] Despite the data, uncertainly about stroke risk associated with pill use has remained, says **Sasitorn Siritho**, MD, who served as a stroke research fellow at the National Stroke Research Institute in Melbourne, Australia, where the current research was conducted. Ischemic stroke is the type of stroke in which a blood clot blocks an artery supplying the brain.

"This study is important as another piece of data about low-dose oral contraceptives and ischemic stroke," observes **Diana Petitti**, MD, MPH, director of research and evaluation for Pasadena-based Kaiser Permanente Southern California, a group-practice health maintenance organization. "Data from U.S. studies[3,4] found no increase in the risk of ischemic stroke in current OC users; whereas studies done by the World Health Organization (WHO), the Transnational Study and, more recently, the Risk of Arterial Thrombosis in Relation to Oral Contraceptives (RATIO) study[5,6,7] all reported increases in the risk of ischemic stroke in current OC users." **(Review research highlights in previous *Contraceptive Technology Update* articles: "Ischemic stroke risk low for OC users," April 1998, p. 47; "Low-dose OCs don't increase stroke risk," December 1996, p. 148.)**

Petitti, who has conducted research on the subject, says her assessment of the literature now leads her to believe that use of low-estrogen dose oral contraceptive in women without hypertension does not increase the risk of ischemic stroke, with the risk slightly elevated in women who are heavy smokers. She also sees no documented differences in the risk of stroke between users of low-estrogen formulations with different progestins.

Look at the study

In the new study, researchers at four large Melbourne, Australia, hospitals matched 234 women ages 15-55 who had a stroke between 1984 and 1996 to 234 women recruited from the same geographic areas as the stroke patients. Detailed personal interviews were conducted, including family medical histories and lists of previous and current medications.

Researchers found that women who reported currently using pills with fewer than 50 mcg of estrogen seemed to be at no greater risk of ischemic stroke. In addition, there was no association

between the number of years a woman had taken OCs and the risk of stroke. Although the odds ratio of stroke was 1.76 for women who used low-estrogen pills, that number did not reach the level of statistical significance, researchers report.

Factors associated with an increased risk of ischemic stroke were a history of hypertension, transient ischemic attack, previous myocardial infarction, or diabetes mellitus; family history of stroke; and smoking more than 20 cigarettes per day.

What's the next step?

The next step in research should focus on the risk of stroke in women using newer generation of pills, says Siritho. Researchers in the Australian study were unable to describe which of the drugs that contained 50 mcg ethinyl estradiol also contained varying doses of norethindrone, lynestrenol, and ethynodiol diacetate.

The question of differences in stroke risk between low-estrogen OCs containing different progestins is an important one, Petitti agrees.

"A possible reason for the difference between the WHO/European studies and the U.S. studies is that there is a difference in the risk of stroke between low-estrogen OCs with levonorgestrel compared with those containing progestins that are in the estrane class," observes Petitti. "In the WHO and European studies, the use of low-estrogen OCs with an estrane was very infrequent, whereas these OCs are commonly used in the U.S."

Further research is needed to examine stroke risks in women with migraines, says Siritho. Several studies have found that OC users with a history of migraine are two to four times more likely to have an ischemic stroke than nonusers with a similar medical history. [3,8]

The increased risks involved with combined pill use and migraines with focal neurologic symptoms led the WHO in 2000 to revise its medical eligibility criteria to state that combined oral contraceptives should not be initiated in women of any age with the medical condition.[9]

According to the www.managingcontraception.com web site organized by Tiger, GA-based Bridging the Gap Foundation, focal neurologic symptoms include spots in front of one's eyes, blurred vision, loss of vision (or partial loss of vision), weakness in an arm or a leg, slurred speech or an aura (sense) before headache onset that such pain is oncoming.[10] Alternative contraceptive options for these women include progestin-only methods such as the mini-pill and quarterly contraceptive injection.[10]

References

1. Siritho S, Thrift AG, McNeil JJ, et al. Risk of ischemic stroke among users of the oral contraceptive pill: The Melbourne Risk Factor Study (MERFS) Group. *Stroke* 2003; 34:1,575-1,580.

2. Thorogood M. Stroke and steroid hormonal contraception. *Contraception* 1998; 57:157-167.

3. Schwartz SM, Petitti DB, Siscovick DS, et al. Stroke and use of low-dose oral contraceptives in young women: A pooled analysis of two U.S. studies. *Stroke* 1998; 29:2,277–2,284.

4. Petitti DB, Sidney S, Bernstein A, et al. Stroke in users of low-dose oral contraceptives. *N Engl J Med* 1996; 335:8-15.

5. WHO Collaborative Study of Cardiovascular Disease and Steroid Hormone Contraception. Ischaemic stroke and combined oral contraceptives: Results of an international, multicentre, case-control study. *Lancet* 1996; 348:498-505.

6. Heinemann LA, Lewis MA, Spitzer WO, et al. Thromboembolic stroke in young women: A European case-control study on oral contraceptives: Transnational Research Group on Oral Contraceptives and the Health of Young Women. *Contraception* 1998; 57:29-37.

7. Kemmeren JM, Tanis BC, van den Bosch MA, et al. Risk of Arterial Thrombosis in Relation to Oral Contraceptives (RATIO) study: Oral contraceptives and the risk of ischemic stroke. *Stroke* 2002; 33:1,202-1,208.

8. Chang CL, Donaghy M, Poulter N, et al. Migraine and stroke in young women: Case-control study. *BMJ* 1999; 318:13-18.

9. World Health Organization, Department of Reproductive Health and Research. *Medical Eligibility Criteria for Contraceptive Use*. Second ed. 2000. Accessed at /www.who.int/reproductive-health/publications/RHR_00_2_medical_eligibility_criteria_second_edition/rhr_00_2_acknowledgments.html.

10. Hatcher RA. "I stopped pills because of migraine headaches — what next?" *Questions and Answers.* Accessed at www.managingcontraception.com/cgi bin/mc_qna_news.cgi?cmd=show_item&id=547. ■

New reports spark more questions on HT risks

Just-published papers in the *Journal of the American Medical Association* add to heightened concern regarding hormone therapy (HT).[1,2] One report suggests that estrogen plus progestin HT use heightens the risk for breast cancers, which are diagnosed at a more advanced stage compared with placebo use, and increases the frequency of abnormal mammograms.[1]

The second paper, which focuses on long-term HT use among older women, indicates that

EXECUTIVE SUMMARY

New information on the use of estrogen plus progestin hormone therapy (HT) and the link to breast cancer risk are leading to more questions about use of the drug therapy.

- An update of information released from the Women's Health Initiative suggests that HT use heightens the risk for breast cancers, which are diagnosed at a more advanced stage compared with placebo use, and increases the frequency of abnormal mammograms.
- Another paper, which focuses on long-term HT use among older women, indicates that combination therapy poses an increase in breast cancer risk, regardless of the pattern of progestin use.

combination therapy poses an increase in breast cancer risk, regardless of the pattern of progestin use.[2]

How are clinicians interpreting these data? Much of the reaction is in response to the first report, which updates results from the original Women's Health Initiative (WHI) data released in 2002.[3] Many are puzzled by findings, which seem to contradict earlier studies of the subject.

"The Collaborative Report, for example, found that among a reanalysis of 57 studies (52,705 cancers vs. 108,411 controls) that cancers diagnosed while a woman was on HT were better differentiated, had less lymph involvement;[4] overall, the Collaborative Report contradicts what was found in the WHI," observes **Susan Wysocki**, RNC, NP, president and chief executive officer of the Washington, DC-based National Association of Nurse Practitioners in Women's Health (NPWH). "Clearly, we need to know more about what these disparities are about."

Wulf Utian, MD, PhD, executive director of the Cleveland-based North American Menopause Society (NAMS), says that the WHI report's finding of delay in diagnosis and increased size of tumor, does need further examination; however, there was no increase in mortality, he notes.

To help clinicians sort through the data, NPWH will offer two sessions focusing on hormone therapy at its October 2003 annual meeting. NAMS will address the data in a report on postmenopausal HT use from its 2003 HT Advisory Panel. Results will be issued at the September 2003 NAMS Annual Meeting in Miami Beach and posted on its web site, www.menopause.org. **(Check the resource box on p. 104 for information on both conferences.)**

"There may be a small increase in breast cancers with estrogen-progestin therapy, or this treatment stimulates pre-existing tumors to grow," comments **Leon Speroff**, MD, professor of obstetrics and gynecology at Oregon Health Sciences University in Portland. "I don't believe it is appropriate to discard the large body of literature indicating that tumors in hormone users are better-differentiated, lower grade and stage disease, with better outcomes."

Look at the research

The WHI report is an updated analysis of data that show that after an average of 5.6 years, 245 of the 8,506 women on combination therapy and 185 of the 8,102 women on placebo developed breast cancer. Of the total cancers, 349 cases were invasive, a type of breast cancer with a greater chance of spreading to other parts of the body.

The breast cancers in the estrogen plus progestin group had similar characteristics to those in the placebo group; however, the tumors in the combination HT group tended to be larger and more advanced. More women had abnormal mammograms in the estrogen plus progestin group (9.4%) compared to the placebo group (5.4%); this pattern continued until the study ended.[1]

Women in the WHI study received placebo or combined conjugated equine estrogens (0.625 mg / d) plus medroxyprogesterone acetate (2.5 mg / d), manufactured as Prempro (Wyeth Pharmaceuticals, Collegeville, PA).

Keep in mind that the WHI report demonstrated there was no increase in the risk of invasive breast cancer until after five years of use, points out **Anita Nelson**, MD, professor in the obstetrics and gynecology department at the University of California in Los Angeles (UCLA) and medical director of the women's health care clinic and nurse practitioner training program at Harbor-UCLA Medical Center in Torrance. Never-users had no increase in breast cancer risk over the control group for the full five years; it was only the women who had used HT before they entered the study who had any increase in risk, she observes.

David Archer, MD, professor of obstetrics and gynecology and director of the Clinical Research Center at the Eastern Virginia Medical Center in Norfolk, sees the report as a recapitulation of the data that were issued in 2002, with two new points: increased mammographic density and

RESOURCES

The National Association of Nurse Practitioners in Women's Health's (NPWH) annual conference will be held Oct. 15-18, 2003, in Savannah, GA. Registration costs for NPWH members: $315 for early registration (postmarked by Aug. 29); $365 for regular registration (postmarked by Oct. 1). Nonmember registration is $390. Registration may be entered on-line at www.npwh.org; also the registration form may be printed and mailed to RSG Consulting, 75 Dogwood Road, Cortlandt Manor, NY 10567, or fax to (914) 734-8055 (credit card registrants only). For more information on the conference, contact: Alyssa Arceneaux, NPWH, 503 Capitol Court N.E., Suite 300, Washington, DC 20002. Telephone: (202) 543-9693, ext. 1. Email: info@npwh.org.

The North American Menopause Society's annual meeting is scheduled for Sept. 17-20, 2003, in Miami Beach, FL. Registration costs are $545 for members; $645 for nonmembers. All registration fees must be received by Sept. 3; after that date, participants must register at the conference. Visit the NAMS web site, www.menopause.org, for more information.

increased size of tumor.

"Mammographic density should not delay diagnosis of breast lesions, and tumor size is not as important as nodal involvement," he comments.

What will be the outcome for hormone therapy in light of the new data?

"I think the bottom line, at the moment, is that we will see a tendency toward the same history as we saw with oral contraceptives of reducing dosages in anticipation that lower doses may have the same symptom efficacy but have lower risk profiles," observes Utian.

References

1. Chlebowski RT, Hendrix SL, Langer RD, et al. Influence of estrogen plus progestin on breast cancer and mammography in healthy postmenopausal women. The Women's Health Initiative Randomized Trial. *JAMA* 2003; 289:3,243-3,253.

2. Li CI, Malone KE, Porter PL, et al. Relationship between long durations and different regimens of hormone therapy and risk of breast cancer. *JAMA* 2003; 289:3,254-3,263.

3. Writing Group for the Women's Health Initiative Investigators. Risks and benefits of estrogen plus progestin in healthy postmenopausal women: Principal results from the Women's Health Initiative randomized controlled trial. *JAMA* 2002; 288:321-333.

4. Collaborative Group on Hormonal Factors in Breast Cancer. Breast cancer and hormone replacement therapy: Collaborative reanalysis of data from 51 epidemiological studies of 52,705 women with breast cancer and 108,411 women without breast cancer. *Lancet* 1997; 350:1,047-1,059. ■

Diabetics present contraceptive dilemmas

The next patient in your exam room is a 32-year-old woman with type 2 (adult onset) diabetes. While she is obese, she does not smoke, and her chart shows no evidence of hypertension, nephropathy, or retinopathy. What birth control options can you offer her?

With type 2 diabetes becoming more prevalent in young women due to obesity, clinicians will be seeing an increase in similar scenarios, predicts **Sarah Freeman**, PhD, FNP, clinical professor in the Nell Hodgson Woodruff School of Nursing at Emory University in Atlanta and director of its family and women's health nurse practitioner programs. Freeman will present on care of diabetic women at the October 2003 annual meeting of the Washington, DC-based National Association of Nurse Practitioners in Women's Health. **(See resource box, left, for conference information.)**

The Atlanta-based Centers for Disease Control and Prevention (CDC) classifies diabetes and obesity as "twin epidemics"; a 2003 CDC study shows a 61% increase in diagnosed diabetes and a 74% spurt in obesity from 1991 to 2001.[1]

According to the Washington, DC-based

EXECUTIVE SUMMARY

With type 2 (adult onset) diabetes becoming more prevalent in young women due to obesity, clinicians need to review appropriate contraceptive options for such women.

- Use of combination OCs by diabetic women should be limited to those who do not smoke, are younger than 35, and are otherwise healthy with no evidence of hypertension, nephropathy, retinopathy, or other vascular diseases, according to the Washington, DC-based American College of Obstetricians and Gynecologists.
- Clinicians should encourage diabetic women to use a highly effective method of birth control. While expectant mothers with diabetes can and do have normal, healthy pregnancies and deliveries, they are at greater risk for complications, as are their infants.

American College of Obstetricians and Gynecologists (ACOG), use of combination OCs by diabetic women should be limited to those who do not smoke; are younger than 35; and are otherwise healthy with no evidence of hypertension, nephropathy, retinopathy, or other vascular diseases.[2] This same line of thinking may be extended to the transdermal contraceptive and the contraceptive vaginal ring as well, advises **Andrew Kaunitz**, MD, professor and assistant chair in the obstetrics and gynecology department at the University of Florida Health Science Center/Jacksonville. Kaunitz aided in the development of the 2000 ACOG practice bulletin that reviewed hormonal options for women with coexisting medical conditions.

"In the absence of data suggesting otherwise, it indeed makes sense to treat all combination methods similarly with respect to vascular disease risk factors," he states.

What contraceptive options are available for older diabetic women and those with hypertension, coronary artery disease, nephropathy, retinopathy, peripheral, or other vascular disease?

According to Kaunitz, appropriate contraceptive options include progestin-only methods, such as depot medroxyprogesterone acetate injections (DMPA or Depo-Provera, Pharmacia Corp., Peapack, NJ) and mini-pills, and intrauterine devices, including the ParaGard Intrauterine Copper Contraceptive (also known as the TCu-380A; Ortho-McNeil Pharmaceutical, Raritan, NJ) and the Mirena levonorgestrel intrauterine system (Berlex Laboratories, Montville, NJ).

Barrier methods represent an acceptable option for women with all classes of diabetes, says Freeman. Keep in mind that use of such methods must be correctly and consistently used to achieve the level of efficacy needed for women who may face health risks should an unintended pregnancy occur.

Contraception is key

Effective contraception is an important part of the medical management of diabetic women of reproductive age.[3] Although expectant mothers with diabetes can and do have normal, healthy pregnancies and deliveries, they are at greater risk for complications such as preeclampsia, cesarean section, and infections.[4] Pregnancy also can aggravate common diabetic complications such as retinopathy and nephropathy.[5]

Diabetes' effect on pregnancy outcome also can impact the child. Infants of diabetic women are at higher risk of congenital malformations, premature birth, stillbirth, and abnormally large body size.[3] Children of diabetic women also have a higher risk of becoming diabetic during their lives.[3]

"The stress of pregnancy can make the disease worse; so if you go into pregnancy, you are liable to come out of it with more damage than you went into it with," comments Freeman. "So, if women do not want to become pregnant, it is really important that we give them an effective method of contraception."

For women who have completed their families, sterilization should be discussed as a contraceptive option, says Freeman. Pregnancy can be problematic in diabetic women who already have vascular disease, such as nephropathy or retinopathy.[3] If sterilization is chosen, the procedure should be conducted when the diabetic condition is under control; additional medical support may be necessary when sterilizing diabetics with vascular complications.[3]

Review the options

Early studies demonstrated that high-dose OCs impaired carbohydrate metabolism; however, today's combined low-dose OCs have little or no impact on carbohydrate metabolism.[6] In addition, OCs do not increase a woman's chance of developing type 1 or type 2 diabetes.[7] Women with gestational diabetes also do not appear to be at

Teach diabetic patients to know their 'ABCs'

- **A is for A_{1C}.**
  The A_{1C} test — short for hemoglobin A_{1C} — measures your average blood glucose (sugar) over the last three months.
  Suggested target: below 7.
- **B is for blood pressure.**
  High blood pressure makes your heart work too hard.
  Suggested target: below 130/80.
- **C is for cholesterol.**
  Bad cholesterol, or low-density lipoprotein (LDL), builds up and clogs your arteries.
  Suggested LDL target: below 100.

Source: Adapted from National Diabetes Education Program. *Be Smart About Your Heart. Control the ABCs of Diabetes: A_{1C}, Blood Pressure, and Cholesterol.* November 2001. Accessed at: www.ndep.nih.gov.

increased risk of developing type 1 or type 2 diabetes mellitus from combined pill use.[8]

Intrauterine devices are considered safe for diabetic women, with or without vascular disease.[3] As with healthy women, intrauterine devices should be offered to those in monogamous relationships, since those at risk of sexually transmitted infections may be at increased risk for pelvic inflammatory disease following device insertion.[3]

For women with diabetes who do not have vascular disease, the Geneva-based World Health Organization (WHO) says that with DMPA injections, "the advantages generally outweigh theoretical or proven disadvantages," and the method may be provided.[9] The WHO advises caution, however, in providing DMPA to diabetic women with nephropathy, retinopathy, or neuropathy; these women should be carefully monitored for adverse effects, it notes.[9]

It is important to monitor diabetic patients' blood pressure, weight, and lipid status, part of what the National Diabetes Education Program terms the "ABCs" (A_{1C}, blood pressure, and cholesterol) throughout the duration of contraceptive use as standard practice in managing the diabetic condition, says Freeman. **(See chart on p. 105.)**

"Blood pressure is the one that is most critical to deal with, especially since we are getting more evidence that uncontrolled blood pressure may not be a good choice with hormonal contraception,"[10] states Freeman. **[Review web-based resources on diabetes; see the resource box, right.** Are you looking for information on contraception and coexisting medical conditions? Please send your topic suggestions to Rebecca Bowers, Editor, *Contraceptive Technology Update,* P.O. Box 740056, Atlanta, GA 30374. Fax: (404) 262-5447. Or e-mail Joy Daughtery Dickinson, Senior Managing Editor, at joy.dickinson @ahcpub.com.]

RESOURCES

For more information on diabetes, review information at the National Diabetes Education Program web site, www.ndep.nih.gov. The web site, a joint program of the Bethesda, MD-based National Institutes of Health and the Atlanta-based Centers for Disease Control and Prevention, offers several patient education materials that may be ordered or freely printed using documents posted in Adobe Acrobat Portable Document Format. Those with multicultural populations may be especially interested in the brochure, "*Take Care of Your Heart. Manage Your Diabetes*," which is available in 15 Asian American and Pacific Islander languages, as well as Spanish. Order forms may be printed from the web site, then mailed to National Diabetes Education Program, One Diabetes Way, Bethesda, MD 20892-3600, or faxed to (301) 907-8906.

References

1. Mokdad AH, Ford ES, Bowman BA, et al. Prevalence of obesity, diabetes, and obesity-related health risk factors, 2001. *JAMA* 2003; 289:76-79.

2. Kaunitz AM. The use of hormonal contraception in women with coexisting medical conditions. ACOG Practice Bulletin No. 18: *Clinical Management Guidelines for Obstetrician-Gynecologists;* 2000.

3. Rivera R. Diabetic women need effective contraception. *Network* 1999; 19:9-10.

4. National Center for Chronic Disease Prevention and Health Promotion. *Diabetes and Women's Health Across the Life Stages: A Public Health Perspective;* 2001. Accessed at: www.cdc.gov/diabetes/pubs/women/index.htm#2.

5. Wysocki S, Schnare SM. *Current Advances In Oral Contraceptives*. Accessed at: www.npwh.org/Oral-Contraception/.

6. Contraception for women with diabetes. *Contraception Report* 2000; 11:10-14.

7. Hannaford PC, Kay CR. Oral contraceptives and diabetes mellitus. *BMJ* 1989; 299:1,315-1,316.

8. Kjos SL, Shoupe D, Douyan S, et al. Effect of low-dose oral contraceptives on carbohydrate and lipid metabolism in women with recent gestational diabetes: Results of a controlled, randomized, prospective study. *Am J Obstet Gynecol* 1990: 163:1,822-1,827.

9. World Health Organization, Department of Reproductive Health and Research. *Medical Eligibility Criteria for Contraceptive Use*. Second ed.; 2000. Accessed at www.who.int/reproductive-health/publications/RHR_00_2_medical_eligibility_criteria_second_edition/rhr_00_2_acknowledgments.html.

10. Lubianca JN, Faccin CS, Fuchs FD. Oral contraceptives: a risk factor for uncontrolled blood pressure among hypertensive women. *Contraception* 2003; 67:19-24. ■

COMING IN FUTURE MONTHS

- Smoking and OC use: New data are in
- Contraceptive advertising: Is it on target?
- Help women deal with Pill side effects
- Migraines and contraception: What are the options?
- Barrier contraception: Look for future methods

CTUPDATES
News ■ Resources ■ Events

New video reviews teen birth control options

Do you work with an adolescent population? A new educational video, "It's Your Choice: Birth Control for Teens," presents unbiased information about all current and upcoming methods of contraception as well as abstinence.

Contraceptive options reviewed in the 30-minute video include new methods such as the transdermal contraceptive and the contraceptive vaginal ring, as well as future methods such as the Implanon single-rod contraceptive implant and the two-rod contraceptive implant, says producer **Marsha Gelt**, MPH, of the Oakland, CA-based Center for Health Training.

Information is presented by peer educators, with real life interviews of teens giving their opinions and experiences about these methods. Intended for use in schools, youth groups, and in-clinic education, the video also includes an accompanying discussion guide.

Cost of the video is $30; shipping and handling is included in the price for up to four videos. Those ordering five or more videos should call the center's Seattle office at (206) 447-9538 for shipping and handling charges. Go to www.centerforhealthtraining.org to download an order form and send it with a check or agency purchase order to Center for Health Training, 1809 Seventh Ave., Suite 400, Seattle, WA 98101. Check the web site in October to order an updated version of the 1999 staff training video, "Contraceptive Choices: What Your Clients Need to Know." Cost for the training video will be $35; same shipping and handling guidelines apply. ▼

NAMS issues revised menopause guidelines

Help women better understand the physical and emotional changes that accompany menopause with information presented in the updated edition of the *Menopause Guidebook* issued by the Cleveland-based North American Menopause Society (NAMS).

The book reviews a broad range of topics related to menopause, including perimenopausal changes, birth control, premature menopause, and treatment options, such as lifestyle changes, prescription remedies, nonprescription therapies, and complementary and alternative medicine approaches. The guidebook also examines such postmenopausal health concerns as heart disease, osteoporosis, and cancer.

Now in its third edition, the book presents current information based on recent scientific advances, including findings from the Women's Health Initiative, updated Food and Drug Administration labeling for hormones, and new menopause-related treatments. A Spanish edition will soon be posted on the NAMS web site, www.menopause.org.

Preview the *Menopause Guidebook* on the NAMS web site. A printed copy can be ordered as part of a "MenoPak" of consumer information on the NAMS web site or by calling its toll-free, automated consumer request line, (800) 774-5342. The MenoPak is free, but there is a $5 shipping/handling fee (U.S. and Canada). Individual guidebooks can be purchased for $20, including shipping and handling; bulk orders also are available. Use the order form located on the web site; mail payment to NAMS, P.O. Box 94527, Cleveland, OH 44101. ■

CE/CME instructions

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

CE/CME Questions

After reading this newsletter, the participant will be able to:

- Identify clinical, legal, or scientific issues related to development and provisions of contraceptive technology or other reproductive services. **(See "Check Nortrel stock, Barr Labs issues recall," "New reports spark more questions on HT risks," and "Low-dose OCs not linked with stroke risk" in this issue.)**
- 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 "Diabetics present contraceptive dilemmas.")**

9. What oral contraceptive was the focus of a July 2003 three-lot recall by its manufacturer, Barr Laboratories?

A. Kariva
B. Lessina
C. Portia
D. Nortrel 7/7/7

10. What is an ischemic stroke?

A. It is the kind of stroke in which a blood clot blocks an artery supplying the brain.
B. It is the kind of stroke that occurs when a blood vessel in the brain ruptures.
C. It is an impediment to circulation that deprives the heart of adequate blood supply.
D. Is the kind of stroke in which a blood clot blocks an artery supplying the lungs.

11. What was the result of the 2003 paper published by Chlebowski RT, et al., in regard to hormone therapy (HT)?

A. Use of HT decreases the risk for breast cancers.
B. Use of HT heightens the risk for breast cancers, which are diagnosed at a more advanced stage compared with placebo use, and increases the frequency of abnormal mammograms.
C. Women who use HT who do develop breast cancer have more defined tumors that are easily detected by mammograms.
D. Women who use HT who do develop breast cancer have a higher cure rate than women who have never used HT.

12. According to guidelines issued by the American College of Obstetricians and Gynecologists, use of combination OCs by diabetic women should be limited to those who:

A. Are younger than 35 and are otherwise healthy with no evidence of hypertension, nephropathy, retinopathy, or other vascular diseases.
B. Do not smoke, are younger than 40, and are otherwise healthy with no evidence of hypertension, nephropathy, retinopathy, or other vascular diseases.
C. Do not smoke, are younger than 35, and are otherwise healthy with no evidence of hypertension, nephropathy, retinopathy, or other vascular diseases.
D. Do not smoke, are younger than 35, and have well-controlled hypertension.

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

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