AMERICAN HEALTH CONSULTANTS

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A Monthly Newsletter for Health Professionals

INSIDE

■ **Inserted in this issue:**
— Lunelle patient handout

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2002 Contraception Survey

Family planning facilities embrace contraceptive patch, vaginal ring

Patch, ring offer convenience, but price may restrict access

Your patient is a young woman who says she needs reliable birth control, but states her busy schedule makes it hard to remember to take a daily pill. What are the options you offer?

If your list includes two new options, the contraceptive patch and the vaginal ring, you join the majority of respondents to the 2002 *Contraceptive Technology Update* Contraception Survey. About 58% said they already were offering the Evra patch (Ortho-McNeil Pharmaceutical, Raritan, NJ) and the NuvaRing vaginal ring (Organon, West Orange, NJ) or would be implementing their use by the end of the year.

Ortho Evra and NuvaRing use is just beginning in the practice of **Carrie Hrubala**, CNM, a certified nurse-midwife at Women's Health Care of Trumbull, CT. She reports no initial problems with patients using the methods, and she soon will be seeing women for follow-up.

"We have both Evra and NuvaRing; young women are more interested in the patch," says **Suzanne Schmidt**, CRNP, a nurse practitioner at Pacific Coast Women's Health in Encinitas, CA. "I'm disappointed that NuvaRing has not been as enthusiastically embraced."

EXECUTIVE SUMMARY

Two new birth control methods — the contraceptive patch and the vaginal ring — became available in 2002, and about 58% respondents to the 2002 *CTU* Contraceptive Survey say they have added the options to their practice.

- While the contraceptive patch and ring offer convenient birth control, some family planning providers say price may restrict their access.
- Three-quarters of 2002 survey respondents say their facilities also offer the combined injectable contraceptive, up 15% from similar responses in the 2001 survey.

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THOMSON
AMERICAN HEALTH CONSULTANTS

Three-quarters of 2002 *CTU* survey respondents say their facilities are offering the contraceptive injectable Lunelle (Pharmacia Corp., Peapack, NJ), which entered the U.S. market in spring 2001. This figure represents a 15% jump from the some 60% of respondents who gave similar answers in the 2001 survey.

Lunelle has been a very popular option for patients seen by **Kerry Raghib**, CNM, MSN, a certified nurse-midwife at Trinity Medical Center, Medical Arts Clinic in Minot, ND. However, she is curious about its continued popularity following introduction of the contraceptive patch and vaginal ring, since the injectable method requires a monthly office visit.

Schmidt's facility has very few Lunelle users. "It's a pain for them to get in each month," she says. "Several have asked if they could get several [doses] and have their partners inject them."

Review of the methods

Who can use these new methods? Women who are candidates for the Pill also may be considered for the Evra patch, NuvaRing vaginal ring, and the Lunelle combined hormonal injectable contraceptive. **(See the patient handout on Lunelle inserted in this issue, and look for handouts on Evra and NuvaRing in future issues.)** Those with contraindications should seek another method.

Each Ortho Evra patch contains 150 mcg of the progestin norelgestromin and 20 mcg of the estrogen ethinyl estradiol. In clinical trials, researchers found the contraceptive patch comparable to a combination pill in terms of contraceptive efficacy and cycle control.[1] In the efficacy trial, the most common adverse events resulting in discontinuation were application site reactions, nausea, emotional lability, headache, and breast discomfort.[2]

A patch is worn for one week at a time and is replaced on the same day of the week for three consecutive weeks. The fourth week is "patch-free." Women can wear the patch on one of four areas of the body: the buttocks, abdomen, upper torso (front and back, excluding the breasts), or upper outer arm.

A flexible, transparent, colorless vaginal ring, the NuvaRing measures approximately 2 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.

Survey Profile

A total of 374 providers participated in the 2002 *Contraceptive Technology Update* Contraception Survey, which monitors contraceptive trends and family planning issues among readers. Results were tallied and analyzed by American Health Consultants in Atlanta, publisher of *CTU* and more than 100 other resources.

About 65% of responses came from nurse practitioners or registered nurses. Physicians represented 21% of the responses, with allied health professionals and health educators comprising about 3% of the response group. About 11% listed other professions. Some 86% of respondents identified themselves as care providers, with nearly 8% involved in administration.

More than one-third of the respondents said they were employed at public health facilities, with about 31% working in private practice settings. About 10% listed student health centers as their place of employment, with some 13% working in hospitals. The remaining 11% reported employment in other settings.

When it comes to location of their employment, 37% said they worked in an urban setting. About 31% said they were employed in a suburban facility, while 29% listed a rural location. ■

Clinical trials have shown effectiveness rates for the ring to be similar to oral contraceptive pills.[3] The most common side effects reported by NuvaRing users are vaginal infections and irritation, vaginal discharge (leukorrhea), headache, weight gain, and nausea.

Women begin using NuvaRing on or before the fifth day of their menstrual period. To use NuvaRing, a 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.

The Lunelle combined hormonal injectable method has contraceptive benefits similar to the Pill, yet offers women the convenience of once-a-month dosing. Each 0.5-cc aqueous solution of Lunelle contains 5 mg estradiol cypionate and 25 mg medroxyprogesterone acetate.

Clinical trials have shown effectiveness rates for the combined injectable contraceptive to be similar to oral contraceptive pills.[4] Side effects include altered menstrual bleeding, weight change, and fluid retention.

The first injection of Lunelle is given within the first five days of the menstrual period, then is repeated monthly every 28-33 days, and no later than 33 days after the last injection. **(Obtain in-depth coverage of these options in the *Contraceptive Technology Reports* supplements inserted in *CTU*; check the May 2002 issue for "A Transdermal Delivery System Examined: Ethinyl Estradiol and Norelgestromin for Contraception," the February 2002 issue for "The Vaginal Contraceptive Ring — Efficacy, Caution, and Instructions," and the March 2001 issue for "Lunelle: Evaluation of a New Monthly Contraceptive Injection for U.S. Women.")**

Price may be a problem

While family planning providers say they like the convenience afforded by the contraceptive patch and vaginal ring, they are concerned that price may prove to be a problem for some of their patients.

"We do not currently offer NuvaRing," notes **Michele Van Vranken**, MD, medical director of the Annex Teen Clinic and West Suburban Teen Clinic in Minneapolis. "We depend on discounted prices to provide options, and the company making NuvaRing is not offering one at this point."

The Washington, DC-based National Family Planning and Reproductive Health Association (NFPRHA) has launched a public campaign to seek increased funding for the federal Title X program, the only federal program that provides categorical funding for family planning. While NFPRHA has negotiated a reduced Title X price for Ortho Evra and is working on similar pricing for NuvaRing, more dollars will be needed to aid family planning clinics in adding these new methods. **(See August 2002 *CTU*, p. 85, "Will rising prices limit the options for patients at family planning clinics?")**

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Pill still is popular family planning option

More contraceptive choices for women mean increased competition for the Pill, but the method continues to be favored by many family planning patients.

Oral contraceptives (OCs) continue to be the No. 1 choice with patients, says **Karin Rohn**, FNP, a nurse practitioner at Tuolumne County Health Department in Sonora, CA. She estimates 50% or more of her patients leave the office each month with pill prescriptions.

About 42% of 2002 survey respondents agree with Rohn, with half or more of their patients using OCs. While that number is significant, it represents a drop from 2001's 53% figure and is the lowest amount in the 50% plus category since the question was first posed in 1998.

About 38% of 2002 survey responses say 26%-50% of patients use pills, and 16.7% indicate that 11%-25% of patients choose OCs. About 3% of responses note pill use in 10% or less of their patient population.

"All of our methods have been slowly increasing, including OC users, due to gradual increases in the number of clients we are seeing," states **Michele Van Vranken**, MD, medical director of the Annex Teen Clinic and West Suburban Teen Clinic in Minneapolis.

Pill use has stayed about the same for patients of **Carrie Hrubala**, CNM, a certified nurse-midwife at Women's Health Care of Trumbull, CT. She estimates half of her patients are using birth control pills.

While **Helen Cook**, ARNP, a nurse practitioner at Franklin County Health Department in Appalachicola, FL, says half of her patients leave each month with pill prescriptions, that number has not increased in the past year.

"A few more are requesting intrauterine devices," says Cook. "The newer methods are not available in our clinics yet."

EXECUTIVE SUMMARY

Oral contraceptives (OCs) continue to represent a popular family planning option for women, say respondents to the 2002 *Contraceptive Technology Update* Contraception Survey.

- Survey responses show that Ortho Tri-Cyclen continues as the leading choice as the top nonformulary and formulary selections for a 21-year-old nonsmoking woman.
- Survey participants named Alesse as the preferred OC for older nonsmoking women.
- About 36% of survey respondents say they prescribed OCs specifically for one noncontraceptive benefit: prevention of cancer of the ovary.

Tri-Cyclen top choice

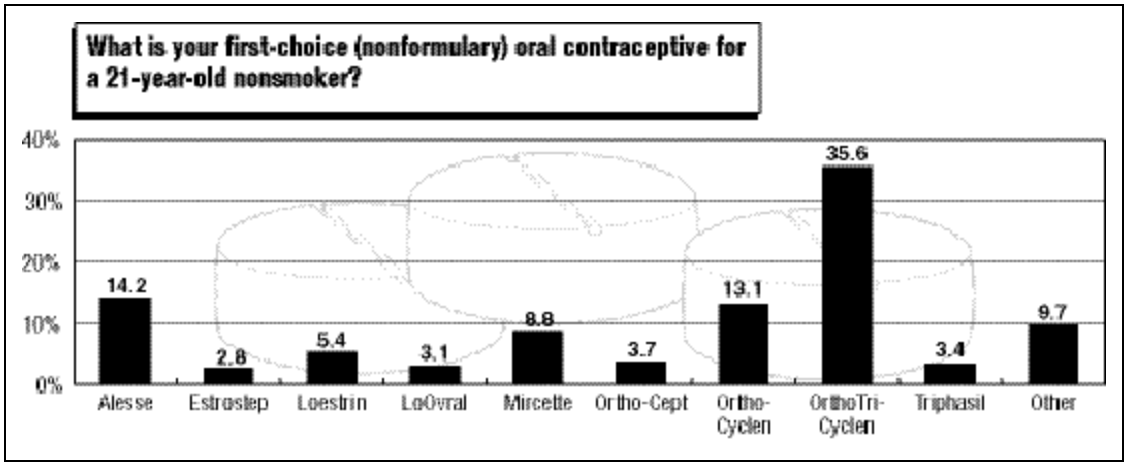
Ortho Tri-Cyclen, a 35-mcg ethinyl estradiol phasic pill marketed by Ortho-McNeil Pharmaceuticals of Raritan, NJ, continues as the leading choice as the top nonformulary and formulary selections for a 21-year-old nonsmoking woman, which marks five years of dominance in the survey responses. **(See chart on first-choice nonformulary OC for a 21-year-old nonsmoker, p. 125.)** About 36% of respondents in the 2002 survey say Tri-Cyclen is their top nonformulary choice, and when bound by program formularies, 37.2% of 2002 responses list the OC as the No. 1 choice. The findings showed a slight decrease from 2001's responses, where 37.4% chose the pill as the top nonformulary OC, and 39.5% named it the leading formulary selection.

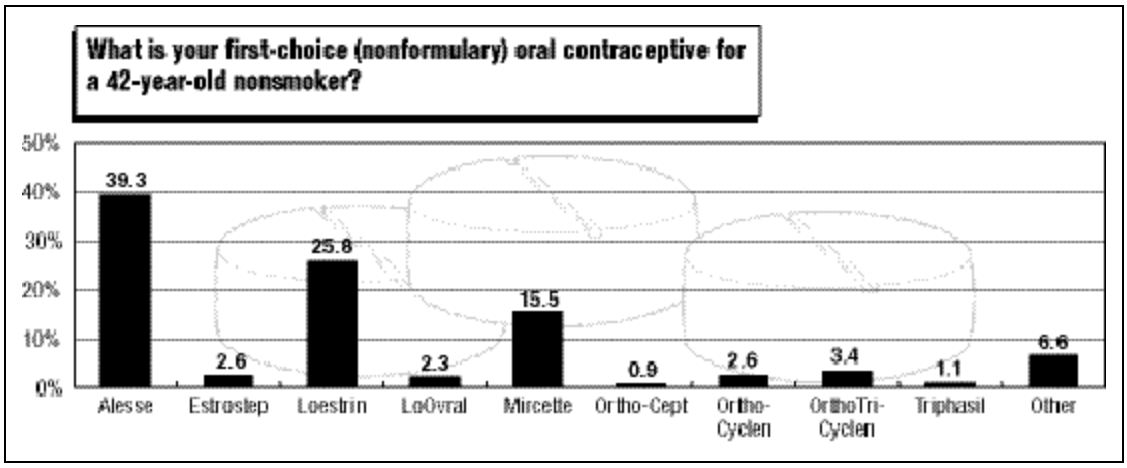
"Ortho Tri-Cyclen is on our formulary and is popular with the teens because of the company's marketing to that group of clients," says Cook. "Teens often come in requesting that particular OC, especially the ones with acne problems."

What OC for older women?

For the second year, *CTU* survey respondents named Alesse, a monophasic 20-mcg pill from Wyeth-Ayerst Laboratories of Philadelphia, as the preferred OC for older nonsmoking women. About 39% of responses listed the pill as their leading choice, a drop from its 52% ranking in 2001.

Loestrin, a monophasic 20-mcg pill from Pfizer of New York City, was named by almost 26% as their leading choice in the 2002 poll, up from 14.5% in 2001. About 15% named Mircette from Organon of West Orange, NJ, as their top choice,





a slight increase from 12.1% in 2001. The pill offers 21 days of 150-mcg desogestrel/20-mcg ethinyl estradiol, two days of placebo pill, followed by five days of 10-mcg ethinyl estradiol. **(See chart on first-choice nonformulary OC for a 42-year-old nonsmoker, above, bottom chart.)**

When discussing OC use with women, you discuss the side effects, such as spotting, breast tenderness, and headaches, but do you mention the noncontraceptive benefits? The Pill provides protection against benign breast disease, ectopic pregnancy, salpingitis, dysmenorrhea, and iron deficiency anemia, in addition to its effectiveness in pregnancy prevention.[1]

According to the 2002 *CTU* Contraception Survey, more providers say they are recommending pills to women specifically to reduce their risk of cancer of the ovary. Almost 36% of survey respondents indicated they prescribed pills based on patient history of ovarian cancer risk, up from 2001's 33.9% figure.

Such noncontraceptive benefits are included as a part of the general discussion with every OC patient, says **Maria Mangini**, PhD, CNM, FNP, a nurse practitioner in private practice in Berkeley, CA.

Julie O'Neill, CNM, a certified nurse midwife at Mount Timpanogos Women's Healthcare in Pleasant Grove, UT, says she uses pills for a number of noncontraceptive indications, including perimenopausal symptoms; heavy, painful menstrual periods; and premenstrual syndrome.

"When women ask for birth control, we mention the added benefits of OCs, and we have a handout on lowering the risk of ovarian cancer," says O'Neill. "We also mention it specifically to women who have family history of ovarian cancer."

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More women moving to intrauterine device use

Boosted by the 2000 introduction of a new intrauterine device (IUD), participants in the 2002 *Contraceptive Technology Update* Contraception Survey say they are seeing increased interest in the long-acting family planning method.

When *CTU* quizzed readers on device insertions and removals in the 2001 survey following the introduction of the Mirena levonorgestrel intrauterine system (IUS) [Berlex Laboratories, Montville, NJ], about 56% of respondents said they had inserted no devices in the past year. About 31% indicated they had inserted one to 10 devices, and

EXECUTIVE SUMMARY

More women are moving to use of intrauterine devices (IUDs), according to participants in the 2002 *Contraceptive Technology Update* Contraception Survey. In 2001, 56% said they had inserted no devices; in 2002, that number dropped to 45%, and about 7% indicated they placed 25 or more devices, which is double the rate noted in 2001.

- New publications underscoring the safety of he IUD, as well as the introduction of the levonorgestrel intrauterine system, have prompted the uptick in use.
- The levonorgestrel intrauterine system offers noncontraceptive benefits, which offer new avenues for its use.

13.1% said they had performed more than 10 insertions. About 3% reported more than 25 insertions.

In the 2002 survey, the number reporting no insertions dropped to 45%, with increases seen in all other categories. Just more than 7% of respondents said they had inserted 25 or more devices, doubling the rate from 2001. Device removals also increased slightly from 2001 numbers; 54% of survey respondents reported they had removed one to five devices in 2002, compared to 47.5% in 2001.

To help providers get up to speed, the Washington, DC-based Association of Reproductive Health Professionals added 20 additional sessions in 2002 for its *New Developments in Contraception: Counseling and Insertion Training Featuring the Levonorgestrel Intrauterine System.* The program was presented in 153 accredited continuing medical education sessions in 2001; more than 4,300 health care providers participated in the program.

According to **Julie O'Neill**, CNM, a certified nurse-midwife at Mount Timpanogos Women's Healthcare in Pleasant Grove, UT, providers are seeing more use of the Mirena and the Paragard Intrauterine Copper Contraceptive (Ortho-McNeil Pharmaceutical, Raritan, NJ; also known as the Copper T380A).

"It is just a matter of the word getting out that both are good options," says O'Neill. "We have a very low-risk population of mostly couples that are mutually monogamous and who have had children."

New publications underscoring the safety of IUDs[1,2] as well as the availability of the levonorgestrel intrauterine system (IUS), appear to be increasing interest in and use of IUDs, states **Andrew Kaunitz**, MD, professor and assistant chair in the obstetrics and gynecology department at the University of Florida Health Science Center/Jacksonville. **(*CTU* reported on the publications in its November 2001 article, "Are you concerned about infection, infertility risks with IUD? You can relax"; see p. 125.)**

When it comes to contraceptive use of IUDs, Kaunitz says two categories of potential candidates come to mind:

- women who are referred for tubal sterilization;
- women in their mid-30s who use oral contraceptives and smoke, and need to switch to a method medically appropriate for this clinical context.

ParaGard compares to sterilization

For women considering sterilization, remember that the ParaGard IUD is labeled for 10 years of protection and has been shown to be effective up to 12 years,[3] comparable to that of surgical sterilization, says Kaunitz. The Mirena IUS has been approved for five years of use in the United States.

According to *A Pocket Guide to Managing Contraception*,[4] use the "PAINS" mnemonic to teach early IUD warning signs:

- **P**eriod late (pregnancy); abnormal spotting or bleeding;
- **A**bdominal pain, pain with intercourse;
- **I**nfection exposure (sexually transmitted infection); abnormal vaginal discharge;
- **N**ot feeling well, fever, chills;
- **S**tring missing, shorter or longer.

The levonorgestrel IUS has important noncontraceptive and off-label applications, according to a new review of the device.[5] Kaunitz reports more women in his practice are considering use of the device for such applications as:

- treatment of menorrhagia stemming from fibroids, or following endometrial biopsy or sonohysterogram;
- treatment of peri- and postmenopausal vasomotor symptoms in those who have problems with systemic doses of progestins.

Recent research points to use of the levonorgestrel IUS in prevention of endometrial polyps in breast cancer survivors taking tamoxifen.[6] In the randomized British clinical trial, researchers enrolled menopausal breast cancer survivors with an intact uterus who had received tamoxifen for more than one year. Participants underwent baseline hysteroscopy and endometrial sampling, with

levonorgestrel-releasing IUDs insertions given to half of the women. Participants had follow-up hysteroscopy and endometrial sampling, with IUD removal, at 12 months. At the end of the study, four new polyps were noted in the non-IUD group; in contrast, no participant wearing an IUD was noted to have developed a new polyp.

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More providers offer emergency contraception

EXECUTIVE SUMMARY

Access to emergency contraception (EC) continues to grow: More than 80% of respondents to the 2002 *CTU* Contraception Survey say their facility prescribes EC on site and provides emergency contraceptive pills at any time.

- The majority of providers say they use Plan B, with about 15% using Preven. About 20% continue to use oral contraceptives for EC.
- Use of intrauterine devices for EC remains low: more than 80% said they performed no insertions for EC in 2002.

More providers are offering emergency contraception (EC), and more women are seeking prescriptions for it, say respondents to the 2002 *Contraceptive Technology Update* Contraception Survey. Just more than 81% said their facility prescribes EC on site and provides emergency contraceptive pills (ECPs) at any time, a slight increase from 2001's 80.6% number.

"Our numbers have definitely increased over the past year," reports **Michele Van Vranken**, MD, medical director of the Annex Teen Clinic and West Suburban Teen Clinic in Minneapolis. "Word gets out by clients talking to each other and by health educators giving talks about birth control options to schools and community groups."

Male patients have proven to be a valuable asset in spreading the word about EC, says **Jane Newhard-Parks**, FNP, MSN, a nurse practitioner at Student Health Services at California State University, Hayward. Information on the method is presented in talks to men, she notes. Posters on EC are displayed in the student health center, and handouts are distributed at every gynecological and sexually transmitted disease exam, she says.

What do you prescribe?

Two dedicated EC products are available in the United States: Plan B from Women's Capital Corp. and Preven from Gynétics of Belle Mead, NJ. About 66% of respondents to the 2002 survey say they use Plan B, up from 62.5% in 2001. About 15% report use of Preven; about 11% noted such use in 2001. About 20% said they issued oral contraceptives for EC, down from the 25.6% number in 2001.

Plan B is the preferred ECP at Pacific Coast Women's Health in Encinitas, CA, says **Suzanne Schmidt**, CRNP, a nurse practitioner at the facility. EC information is available in every exam room and Schmidt says she offers a prescription to all annual exam patients.

When discussing EC use, remember to note that some women experience temporary side effects with EC, which may include nausea, vomiting, lower abdominal pain, fatigue, headache, dizziness, and breast tenderness.[1] For advance prescriptions of EC, advise women who use a combined OC product for EC to purchase a long-lasting antiemetic and keep it next to their ECPs.[2]

Use of the Copper T380A intrauterine device (IUD) [marketed in the United States as the Paragard Intrauterine Copper Contraceptive by Ortho-McNeil Pharmaceutical, Raritan, NJ] for emergency contraception remains low, report respondents to the 2002 survey. About 83% reported no insertions for EC purposes, compared to 88.5% in 2001. About 9% said they inserted one to five IUDs, similar to 2001 numbers. A total of 4%

reported more than 15 insertions, up from 1% in 2001.

According to *A Pocket Guide to Managing Contraception,* a copper IUD can be inserted following the usual procedures within five days of unprotected or inadequately protected intercourse.[2] It may be used up to eight days after intercourse, if ovulation is known to have occurred three days or more after the unprotected sex. This form of EC is more frequently used outside the United States, where method costs are lower and IUD candidate restrictions are less stringent.

In the United States, use of the IUD for EC is generally restricted to use by women who intend to continue to use the IUD as an ongoing method of contraception. When discussing this option with patients, allow them to make the choice when it comes to IUD insertion, the book advises.[2]

More women need information about EC, according to a recent poll on the subject. In a July 2002 survey "likely voters" conducted for the Reproductive Health Technologies Project (RHTP) of Washington, DC, more than 60% of respondents said they do not know of a product or drug that has been proven effective in preventing pregnancy if used within the first few days after unprotected sex or contraceptive failure. When asked to specify an EC product, almost one-third of respondents who said they knew of such a product identified it as "RU-486," indicating EC is often mistakenly confused with other drugs.

Sen. Patty Murray (D-WA) and Rep. Louise Slaughter (D-NY) have introduced the Emergency Contraception Education Act (S1990 and HR3887), which will authorize funding for the Atlanta-based Centers for Disease Control and Prevention and the Washington, DC-based Health Resources and Services Administration to develop and distribute information on EC to the public and to health care providers. The legislation has been referred to health-related committees.

RHTP survey respondents say they support the government's role in educating the public about emergency contraception. Once informed about EC, 72% said they favored legislation aimed at expanding public health information about EC and its availability. Such information should be broadly available to the general public and to all women of childbearing age, including teen-agers, they affirmed.

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How are OCs used? Readers offer views

When it comes to oral contraceptives (OCs), what are the options when it comes to new mothers who are breast-feeding and older women smokers?

Think about your practice, and check your response against the views recorded in the results of the 2002 *Contraceptive Technology Update* 2002 Contraception Survey.

The majority of *CTU* 2002 survey respondents say they will not provide pill prescriptions for older women who smoke 10 cigarettes a day. For women ages 35-39, about 74% say they will not supply OCs, and for women ages 40 and older, the number climbs to 88.2%. These findings are in line with 2001 survey responses.

Helen Cook, ARNP, a nurse practitioner at Franklin County Health Department in Appalachicola, FL, says her decision to deny OCs is based on state protocols for women who smoke ages 35 and older. As options, she discusses Depo-Provera injections, intrauterine contraception, barrier methods, and sterilization. For women who still desire to continue OCs following the counseling, Cook's facility offers a smoking cessation program.

According to the Geneva-based World Health Organization (WHO), for women age 35 and older who smoke 20 or fewer cigarettes per day, use of OCs is not generally recommended unless other, more appropriate methods are not available or acceptable. For those in the same age bracket who smoke more than 20 cigarettes per day, OCs are not to be used.[1]

Nursing moms and pills?

When do you initiate combined pill use for a new mother who chooses not to breast-feed? About 46% of 2002 *CTU* survey respondents say they would prescribe OCs four to six weeks postpartum, an increase over 2001's 40.2% level. About 28% say they would initiate OCs one to three weeks postpartum, with about 11% providing pills upon hospital

EXECUTIVE SUMMARY

When it comes to oral contraceptives (OCs) for older women who smoke, the majority of participants in the 2002 *CTU* Contraception Survey said they will not write pill prescriptions.

- About 46% say they would prescribe OCs four to six weeks postpartum for new nonbreast-feeding mothers. For new mothers who wish to breast-feed, 44.4% say they would begin progestin-only pills at four to six weeks postpartum.
- For women who report nausea with prior pills, about half of 2002 respondents say they would prescribe Alesse, a 20-mcg pill.

discharge. About 8% would start pills at first menses, with about 6% using other approaches. These views are consistent with those reported in the 2001 survey.

For new mothers who wish to breast-feed, 44.4% of respondents say they would begin progestin-only pills (POPs) at four to six weeks postpartum, up from the 38% figure recorded in the 2001 survey. A total of 26% note they would initiate POPs at one to three weeks postpartum. About 21% would initiate POP use at hospital discharge, with fewer 1% starting mini-pills at first menses. About 8% say they would use other approaches.

According to the WHO guidelines, women who are not breast-feeding can begin combined OCs after the second to third postpartum week.[1] If women choose to breast-feed and use progestin-only pills, the POPs may be started after six weeks postpartum, the WHO guidelines recommend.[1]

For women who have experienced bothersome nausea on previous OCs, but can't remember the brand name of the pill used, almost half (49.7%) of the respondents to the 2002 *CTU* survey say they would prescribe Alesse, a monophasic 20-mcg pill from Wyeth-Ayerst Laboratories of Philadelphia.

Loestrin 1/20, a 20-mcg monophasic pill from Pfizer of New York City, increased its second place share in the 2002 survey, moving from 13.2% in 2001 to 20.2% in 2002. Mircette from Organon of West Orange, NJ, a pill with a unique dosing schedule (21 days of 150-mcg desogestrel/20-mcg ethinyl estradiol, two days of placebo pill, followed by five days of 10 mcg ethinyl estradiol) moved up to the third place, with 10.2% of responses. Less than 5% of respondents had named Mircette in the 2001 poll.

Cook offers the following approach if a patient says she experienced nausea with previous OCs:

- Take a detailed history about the nausea and when she experienced it.
- Educate the patient. Discuss the fact that nausea often decreases after the first couple cycles of OCs.
- Inform the patient that nausea is common when women double up on missed OCs, so it is important that pills are taken consistently.

Since most patients who take a 20-mcg OC have fewer problems with nausea, Cook says she starts her patients with her facility's formulary drug, which is Alesse.

In your written patient instructions, do you recommend that women who continue pills after developing vomiting or diarrhea use a backup contraceptive until their next period? About 72% of 2002 survey respondents provide such information, a slight decrease from 2001's 78.4% figure.

Reference

1. World Health Organization. *Improving Access to Quality Care in Family Planning: Medical Eligibility Criteria for Contraceptive Use.* Geneva: WHO, Family and Reproductive Health; 1996. ■

What is your practice when it comes to DMPA?

A young female patient says she's interested in using the contraceptive injectable Depo-Provera (depot medroxyprogesterone acetate or DMPA, marketed in the United States by Pharmacia Corp., Peapack, NJ). Do you inform her of the potential for diminished bone mass that has been linked with use of this method?

More than half (55%) of participants in the 2002 *Contraceptive Technology Update* Contraception Survey said they only inform patients of this possible side effect, a slight increase from the 52.9% figure recorded in 2001. About 27% said they used other strategies, such as discussing calcium supplementation, compared with 31.2% in 2001. About 5% indicated they inform patients of the potential risk, and either prescribe estrogen replacement therapy or oral contraceptives (OCs) to supplement low estrogen levels in DMPA users. About 12% said they take no precautions in this area, similar to the 10.6% 2001 figure.

Just-published research, however, may influence your practice. The prospective study, which

EXECUTIVE SUMMARY

More than half of respondents to the 2002 *Contraceptive Technology Update* Contraception Survey say they only inform patients about the potential diminished bone loss that has been linked to use of Depo-Provera (depot medroxyprogesterone acetate or DMPA).

- New research indicates that use of the drug is strongly associated with bone density loss. However, researchers note bone loss associated with DMPA use appears to be largely reversible once the injections are stopped. The impact of DMPA use on bone health in adolescent users is being examined.
- Advise patients on the important of calcium supplementation and regular exercise to maintain bone health.

enrolled women from a Washington state health maintenance organization, compared hip and spine bone density measurements taken in 182 reproductive-age women ages 18-39 receiving DMPA injections to those of 258 comparable women not receiving the drug. Researchers made bone density measurements at the start of the study and repeated them every six months for up to three years.[1]

Use of DMPA is strongly associated with bone density loss, echoing earlier reports,[2,3] the study findings indicate. However, researchers note bone loss associated with DMPA use appears to be largely reversible once the injections are stopped.

When it comes to use of DMPA in adolescent women, long-term impact on bone mineralization is not known. Researchers who examined DMPA use among the women in the Washington state health maintenance organization have begun studying a group of adolescent users to determine the effect of the injection's use in this age group.

Such information is of great interest to family planning providers. About 95% of respondents to the 2002 *CTU* survey say they would provide DMPA to teens, slightly less than 2001's 97% response.

Since the Food and Drug Administration approved the method in 1992, DMPA use has grown among adolescent users. While about half of teens report use of OCs, and a third say they use condoms, about 10% record use of DMPA.[4]

Many teens try DMPA and stop after a few shots due to weight gain, says **Kerry Raghib**, CNM, MSN, a certified nurse-midwife at Trinity Medical Center, Medical Arts Clinic in Minot, ND. According to *A Pocket Guide to Managing Contraception*, providers can use a "teachable moment" to help patients examine options to combat weight gain:

- Eat less. Small, frequent meals help some to lose weight.
- Exercise more.
- Find patterns of eating and exercise you enjoy.
- Call Overeaters Anonymous, a free source of support.
- Drink 10 glasses of water daily.[5]

Many 2002 *CTU* survey participants say they advise the importance of calcium supplementation and weight-bearing exercise for good bone health. Women ages 19-50 should get at least 1,000 mg of calcium daily, and teens ages 14-18 should get 1,300 mg, according to *Building Strong Bones: It Takes a Lifetime*, a new patient education brochure from the Washington, DC-based Association of Reproductive Health Professionals (ARHP). **(Review the brochure on ARHP's web site at www.arhp.org/bone health and see the resource box, above.)**

RESOURCE

To order a free copy of the brochure *Building Strong Bones: It Takes a Lifetime*, contact: Association of Reproductive Health Professionals (ARHP). Telephone: (202) 466-3825. E-mail: arhp@arhp.org. Providers may order up to 25 brochures free of charge; orders above that number are 10 cents each for ARHP members, 15 cents each for nonmembers, plus shipping charges of $3 for 25, up to a maximum of $10.

References

1. Scholes D, LaCroix AZ, Ichikawa LE, et al. Injectable hormone contraception and bone density: Results from a prospective study. *Epidemiology* 2002; 13:581-587.

2. Cundy T, Evans M, Roberts H, et al. Bone density in women receiving depot medroxyprogesterone acetate for contraception. *BMJ* 1991; 303:13-16.

3. Cundy T, Cornish J, Evans MC, et al. Recovery of bone density in women who stop using medroxyprogesterone acetate. *BMJ* 1994; 308:247-248.

4. 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. *Vital Health Stat* 1997; Series 23, Number 19.

5. Hatcher RA, Nelson AL, Zieman M, et al. *A Pocket Guide to Managing Contraception*. Tiger, GA: Bridging the Gap Foundation; 2001. ■

Thumbs down to Pill's over-the-counter access

Respondents to the *Contraceptive Technology Update* 2002 Contraception Survey continue to affirm their stance for continued prescription-only status for the Pill.

The 2002 survey statistics show 63% of respondents against over-the-counter (OTC) access — a virtual standstill from 2001's 62.9% figure.

Having to renew their pill prescription is one way women will come in for a Pap and breast exam, says **Kerry Raghib**, CNM, MSN, a certified nurse-midwife at Trinity Medical Center, Medical Arts Clinic in Minot, ND.

"If they could get OCs [oral contraceptives] over the counter, we might not be able to give this yearly physical and education," she comments. "Also, smokers older than 35 and others who have contraindications to the Pill would be able to get them without problems."

Suzanne Schmidt, CRNP, a nurse practitioner at Pacific Coast Women's Health in Encinitas, CA, says she would like to see OCs move to OTC status.

"I truly believe fewer unwanted pregnancies would occur and therefore fewer children in homes that are not emotionally equipped to meet the huge demands of proper parenting," she states.

However, Schmidt says she would support the move only with addition of heightened consumer education, periodic blood pressure checks, and awareness of warning signs.

EC may have more support

Providers may be more supportive of moving emergency contraception (EC) to OTC status. The Chicago-based American Medical Association and the Washington, DC-based American College of Obstetricians and Gynecologists have approved resolutions supporting expanded access for the method.

When EC is only available by prescription, women face more barriers to accessing it and are thus more likely to take the pills later, states a recent *New England Journal of Medicine* "Sounding Board" article.[1]

While EC is effective at preventing pregnancy if taken within 72 hours of sexual intercourse, the pills are most effective when taken as early after unprotected sex as possible.

At press time, Women's Capital Corp. of Washington, DC, is proceeding with its efforts to move its levonorgestrel emergency contraceptive pill, Plan B, to OTC status. **(*CTU* reported on the status of the project in the article, "OTC access sought for emergency contraception," August 2002, p. 89.)**

Women's Capital Corp. officials were scheduled to meet with the Food and Drug Administration (FDA) in late September 2002 to discuss its data supporting its submission for OTC status, reports **Sharon Camp**, PhD, company president and chief executive officer.

"We want to establish that the planned submission will be adequate for the FDA and that the timetable for amendments is acceptable," states Camp. "If the meeting goes well, we would hope to submit the application within four to six weeks."

EXECUTIVE SUMMARY

Sixty-three percent of respondents to the Contraception Survey say that pills should retain their prescription-only status.

- While providers may be hesitant in moving oral contraceptives (OCs) to over-the-counter (OTC) status, they may be more supportive of moving emergency contraception to OTC status.
- Two organizations have approved resolutions supporting expanded access. Women's Capital Corp. is moving forward in its request to have Plan B switched to OTC status.

Reference

1. Grimes DA. Switching emergency contraception to over-the-counter status. *N Engl J Med* 2002; 347:846-849. ■

COMING IN FUTURE MONTHS

- ■ Intrauterine devices: Review the options
- ■ Oral contraceptives: New pills on the way
- ■ OC complications: Tips on how to tackle them
- ■ Nursing shortage: Is it impacting your clinic?
- ■ Teens and parental consent: What's the status in your state?

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

- State when women should begin using the NuvaRing contraceptive vaginal ring. **(See "Family planning facilities embrace contraceptive patch, vaginal ring" in this issue.)**
- Give the definition of the "S" component of the "PAINS" mnemonic used in teaching the intrauterine device's early warning signals. **(See "More women moving to intrauterine device use.")**
- Identify the possible side effects of emergency contraceptive pills. **(See "More providers offer emergency contraception.")**
- * Give the daily amount of calcium recommended for women ages 19-50. **(See "What is your practice when it comes to DMPA?")**

17. When should women begin using NuvaRing?
A. Anytime during the month
B. Only on the first day of their menstrual period
C. Five days following the last day of their menstrual period
D. On or before the fifth day of their menstrual period

18. What does the "S" stand for in the "PAINS" mnemonic used in teaching the intrauterine device's early warning signals?
A. Shortness of breath
B. Sensitivity to light
C. String missing, shorter or longer
D. Soreness in flank

19. Which of the following is NOT a possible side effect of emergency contraceptive pills?
A. Nausea
B. Vomiting
C. Vaginal discharge
D. Fatigue

20. According to the Association of Reproductive Health Professionals patient education brochure *Building Strong Bones: It Takes a Lifetime,* what is the recommended calcium guideline for women ages 19-50?
A. At least 1,000 mg of calcium daily
B. At least 1,300 mg of calcium daily
C. At least 1,500 mg of calcium daily
D. At least 1,800 mg of calcium daily

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Lunelle: Combined Injectable

WHAT ARE COMBINED INJECTABLES?
Combined injectables are an injection of estrogen and progestin that you get once a month. Lunelle, manufactured by Pharmacia Inc., was approved as a monthly injectable and was made available in the United States as of June 2000. Lunelle should not be confused with the every-three-month injections of Depo-Provera. The progestin in Lunelle works by stopping ovulation so that an egg is not released, making cervical mucus thicker so that sperm cannot get through, and changing the lining of the uterus so that implantation of the fertilized egg in the uterine wall does not occur.

WHAT ARE THE ADVANTAGES?
- Excellent cycle control after first few cycles. Compared to Depo-Provera, Lunelle offers a woman a more regular bleeding pattern, and you keep normal estrogen levels.
- A single injection gives you one month of contraception. There's nothing to worry about at the time of intercourse.
- Privacy is a major advantage. No one has to know you are using this method, although a woman does need to return to a clinic each month.
- Fertility comes back quickly. You can get pregnant within an average of three months after stopping Lunelle, compared to about 10 months after stopping Depo-Provera.
- No known increased risk of breast cancer.

WHAT ARE THE DISADVANTAGES?
- You must return to the clinic for reinjection every 28 (plus or minus five) days, unless you learn how to inject yourself, and your clinician is willing to provide you with six to 12 injections.
- You may not like repeated injections.
- Expensive in some clinics.
- Not ideal if you're breast-feeding.
- May cause breast tenderness.
- Causes some weight gain, but less weight gain than Depo-Provera.
- Causes some menstrual irregularity, but much less than with Depo-Provera.

WHERE CAN I GO TO GET STARTED ON LUNELLE INJECTIONS?
You can get Lunelle injections from your clinician, health department, or family planning clinic. Most clinics provide the first shot when a woman has her period or within seven days after the start of her period.

WHAT IF I HAVE SEX AND I AM LATE FOR MY SHOT?
Be sure to use condoms or another birth control method.

WHAT IF I HAVE SEX AND DON'T USE BIRTH CONTROL?
Did you know that for 72 hours after sex, you can take emergency contraceptive pills to avoid becoming pregnant? AND for five to seven days after sex, you can have an IUD put in, so you won't become pregnant? Not all clinicians know about this. If you want more information or would like the phone numbers of clinicians near you that prescribe emergency birth control, call the toll-free number: (888) NOT-2-LATE or (800) 584-9911. Some of these sources of help are free. PLAN B is the emergency contraceptive pill that causes the least nausea, the least vomiting and has the lowest failure rate.

CHOICES: Preparation of this material was not supported by funds from a pharmaceutical company. This information is not copyrighted, and may be copied or adapted without asking permission. rah, llb: 09/20/02; (404) 616-3709 or (706) 782-6038; These brief descriptions of contraceptive options are available from the Bridging the Gap Foundation by printing them directly from this web site. Lengthier descriptions of these options may be found in *A Personal Guide to Managing Contraception for Women and Men,* which may be ordered by calling (404) 373-0530.

FYI: "CHOICES" is a special section of this web site. Each brief description of a contraceptive may be copied and provided to individual patients or classes.

Source: Managing Contraception, Tiger, GA. Web site www.managingcontraception.com.