AMERICAN HEALTH CONSULTANTS®

CONTRACEPTIVE TECHNOLOGY UPDATE®

A Monthly Newsletter for Health Professionals

INSIDE

1999 *Contraceptive Technology Update* Contraception Survey

■ **Norplant:** Implant use remains low 101
■ **Challenges:** Exploring options for smokers, new mothers, nausea sufferers 102
■ **OCs:** Readers offer insights into use 105
■ **Teens:** Dealing with DMPA, dysmenorrhea. . . 106
■ **Emergency contraceptive pills:** Moving into the mainstream 108
■ **Providers voice concerns:** Alternative medicine, DMPA costs. 110

■ **CTUpdates:** Register for fall *Contraceptive Technology* conference 111

SEPTEMBER 1999

VOL. 20, NO. 9 (pages 97-112)

American Health Consultants® is A Medical Economics Company

1999 Contraception Survey

Pills remain the top choice among reversible contraceptive options

OCs offer effective, convenient, and accessible birth control

The advent of the new millennium brings along one constant from the past: Oral contraceptives (OCs) remain the leading choice of reversible contraception for American women. More than 60% of providers who participated in the 1999 *Contraceptive Technology Update* Contraception Survey say 50 or more women leave their offices each month with pill prescriptions in hand. **(See chart, p. 98.)**

"I think our number of OC patients has increased over the last few years, especially as more perimenopausal women are accepting them for relief of symptoms," notes **Ann Tyree**, FNP-C, family nurse practitioner at Beach Physicians and Surgeons in Huntington Beach, CA.

When it comes to prescribing pills for an older nonsmoking woman, survey respondents named Alesse, a 20 mcg pill manufactured by Wyeth-Ayerst Laboratories of Philadelphia, and Loestrin, offered in both 20 and 30 mcg strengths from Parke-Davis of Morris Plains, NJ, as top choices. **(See chart, p. 99.)**

And for young nonsmoking women, Ortho Tri-Cyclen, a 35 mcg triphasic pill from Ortho-McNeil Pharmaceuticals of Raritan, NJ, continues

Alert: Levonorgestrel ECP gets FDA approval

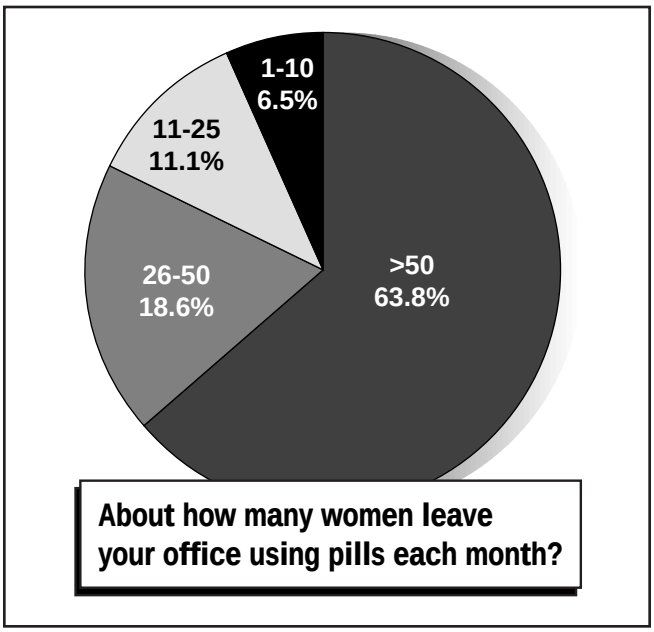
As *Contraceptive Technology Update* went to press, the Women's Capital Corporation of Seattle was preparing its new levonorgestrel-only emergency contraceptive pill (ECP), Plan B, for U.S. shipment. Interest in a dedicated progestin-only product has grown since a 1998 international study showed that the levonorgestrel pills are more effective and have fewer side effects than the current regimen using combined oral contraceptives for emergency contraception.

For more information on Plan B, as well as other emergency contraception news, turn to the story on p. 108. ■

its 1998 position as the leading choice for oral contraceptives. **(See chart, p. 100.)**

Why Ortho Tri-Cyclen? It offers efficacy, few complications, few side effects, and easy-to-use packaging, says **Jonathan Weiner**, MD, an OB/GYN in private practice in Fresno, CA.

Providers named Ortho Tri-Cyclen first whether or not they were bound by formulary constraints; 47% rated it as first choice in a non-formulary situation, and 32% named it No. 1 when prescribing under formulary restrictions. While nonformulary numbers rose from 44% in 1998, formulary numbers fell from the 41% reported last year.



EXECUTIVE SUMMARY

The power of the Pill remains strong as American women continue to use oral contraceptives (OCs) for effective birth control.

- Ortho Tri-Cyclen, a 35-mcg triphasic pill from Ortho-McNeil Pharmaceuticals of Raritan, NJ, again leads as providers' first choice for young nonsmoking women. Alesse, a 20 mcg OC from Wyeth-Ayerst Laboratories of Philadelphia, and Loestrin, offered in both 20 and 30 mcg strengths from Parke-Davis of Morris Plains, NJ, are top picks for use in older nonsmoking women.
- Providers remain opposed to OCs offered as over-the-counter drugs. While 30% say they would support the move, up from 22% in 1998, 70% believe pills should remain prescription-only.

Ortho Tri-Cyclen offers a graduated dose of the progestin norgestimate (180 mcg the first seven days, 215 mcg the next seven days, and 250 mcg the next seven days) and a constant 35 mcg dose of ethinyl estradiol.

Ortho-McNeil launched a powerful consumer advertising campaign for the OC following its 1997 federal Food and Drug Administration (FDA) approval as an effective treatment for acne in women seeking contraception. **(For additional information about the FDA approval, see *CTU*, March 1997, p. 25.)** Providers say the marketing message is getting through to young women, who often request the pill by name. "Being advertised to improve acne has really increased the demand for this pill in our clinic," says **Lorraine Charvet**, NP, OB/GYN nurse practitioner at the Anchorage (AK) Health Department's family planning clinic.

Ortho-Cyclen, an Ortho-McNeil pill with 35 mcg ethinyl estradiol and 0.25 mg norgestimate, shared top second-choice pill selection standing with Ortho-Tri-Cyclen in the nonformulary category. It followed Ortho Tri-Cyclen in the second-choice formulary category.

OCs benefit aging women

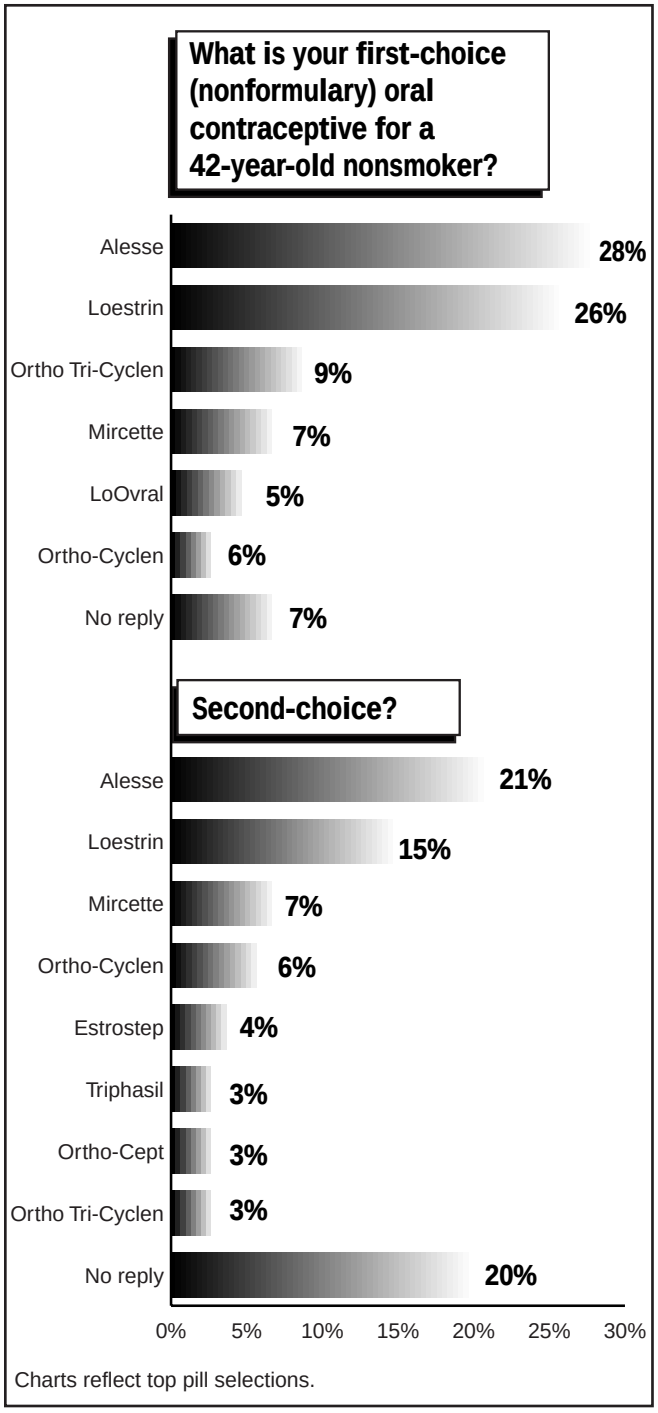
More than 60% of survey respondents named a 20 mcg pill as their top choice for older nonsmoking women. Alesse and Loestrin maintained their leading positions as top pills in this category from the previous year's survey.

"I have probably 10 or 12 women on Alesse," reports **Judy Lee**, ARNP, women's health nurse practitioner at Gateway District Health Department in Owingsville, KY. "It helps them through the perimenopausal stage."

Ortho Tri-Cyclen and newcomer Mircette, a 20 mcg pill with a shortened hormone-free interval from Organon of West Orange, NJ, also were listed as OC choices for older women. **(Mircette entered the U.S. market in mid-1998, after results were tabulated for the 1998 *CTU* survey. For details, see *CTU*, July 1998, p. 85.)**

Research has established that OCs protect women against dysmenorrhea and menorrhagia, menstrual cycle irregularities, iron deficiency anemia, ectopic pregnancy, pelvic inflammatory disease, ovarian cysts, benign breast disease, endometrial cancer, and ovarian cancer.[1]

In addition to these noncontraceptive health



benefits, OCs have proven valuable in the management of a variety of gynecologic disorders, including dysfunctional uterine bleeding, persistent anovulation, premature ovarian failure, functional ovarian cysts, pelvic pain (including secondary dysmenorrhea), mittelschmerz (ovulatory pain), endometriosis, and the control of bleeding in women with blood dyscrasias.[1]

Providers are moving toward prescription of OCs specifically for noncontraceptive benefits. About one-third of providers participating in the 1999 *CTU* Contraception Survey say they or colleagues at their facility recommended pills in the last year to women specifically to decrease their risk of ovarian cancer. One-quarter of those responding to the 1998 survey indicated they would do so.

At Gateway District Health Department, providers present a "pro and con" approach to birth control, pointing out the risks and benefits of each method, says Lee. For women who have a family history of ovarian cancer, the role of OCs in reducing such risks represents a very appealing option, she notes.

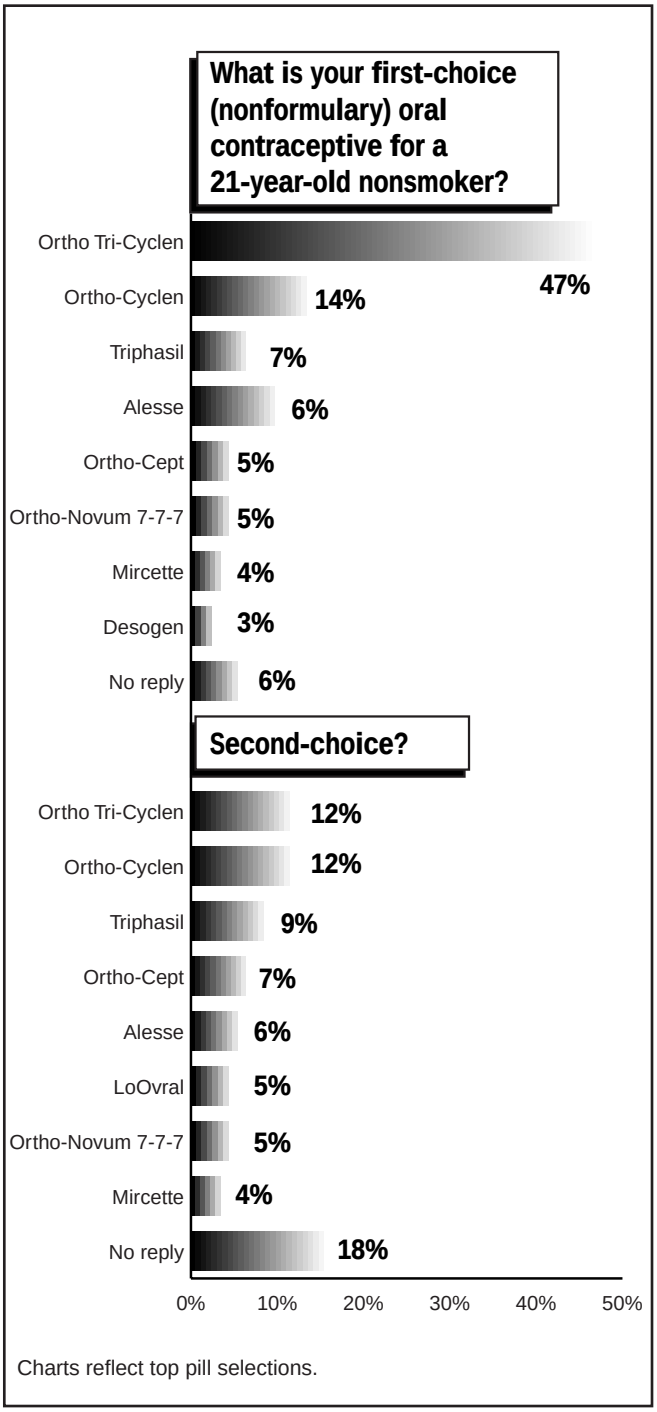
"I find the fact that one-third of clinicians specifically prescribed pills in the past year to decrease women's risk of ovarian cancer promising," comments **Robert A. Hatcher**, MD, MPH, professor of obstetrics and gynecology at Emory University in Atlanta and chairman of the *CTU* editorial advisory board. "Now if women knew enough about pills to request pills for the prevention of ovarian cancer, this number would approach 100%."

No go for over-the-counter OCs

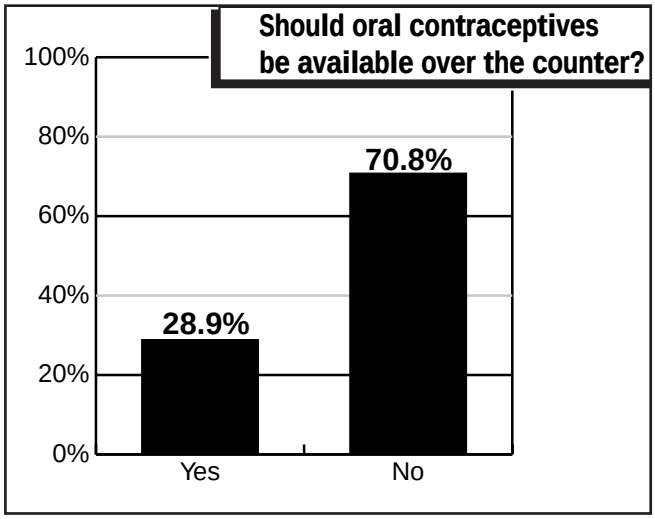
Despite their comfort level with the current formulations of combined OCs, the majority of survey respondents say they are yet unwilling to see OCs offered as an over-the-counter (OTC) drug. Nearly 30% of those participating in the 1999 survey say they would support the move, up from 22% in 1998. **(See chart, p. 100.)** Still, providers continue to hesitate to see women receive pills without medical assessment.

It is more complicated to take OCs for contraception than it is to take Tylenol for pain, and the contraindications for OCs are more serious, according to **Grace Miyazaki**, NP, family nurse practitioner at South Texas Family Planning and Health Corp. in Corpus Christi, TX. Many noncompliant women may cause themselves harm taking OCs without being medically evaluated, she says.

"There also is no solid standard system to deal with side effects and complications — i.e. who do you call if you experience a problem?" she asks. "Many people do not have a doctor to fall back on. Would companies dispensing OTC OCs have a hotline?"



Charts reflect top pill selections.



Survey profile

A total of 370 providers participated in the 1999 *Contraceptive Technology Update* Contraception Survey, which monitors contraceptive trends and family planning issues. Results were tallied and analyzed by American Health Consultants in Atlanta, publisher of *CTU* and more than 80 other medical newsletters and sourcebooks.

About 80% of responses came from nurse practitioners or registered nurses. Physicians represented about 10% of the responses, and 10% listed other professions. About 85% of respondents were listed as care providers, with nearly 10% involved in administration.

More than 41% work in public health facilities, while about 21% work in private practice settings. About 11% are employed in student health centers, and about 12% work in hospitals. The remaining 15% work in other settings. About 42% of respondents work in urban facilities and about 31% in rural settings. About 24% of survey respondents said they worked in a suburban setting. ■

By making OCs easily available for the patient, however, more women could protect themselves from the health risks associated with unintended pregnancies, says **Amador Ramirez**, MD, medical director of the Barren River District Health Department in Bowling Green, KY.

Some patients are afraid to come for an examination because they have misconceptions about Pap smears, states Ramirez, who sees a large number of patients of Vietnamese, Laotian, Cambodian, and Bosnian descent. By offering pills OTC, it would cover those women who do not use pills because they are afraid of the physician's office, he says.

"It oversimplifies the arguments for and against putting the pill over-the-counter, but in one sense, the pro-OTC argument is a public health argument — for the general good, by increasing the number of women using the pill — whereas the argument for maintaining medical

provision focuses on the good for the individual user," comments **Linda Potter**, DrPH, of Family Health Research in Princeton Junction, NJ. "At the same time, ignoring any other arguments, family planners have no data on the relative effectiveness of the two sources for protecting women against pregnancy."

Reference

1. Kaunitz AM. Oral contraceptive health benefits: Perception versus reality. *Contraception* 1999; 59 (1 Suppl):29S-33S. ■

Norplant: Use remains low, providers report

With a single decision, a woman can elect to have up to five years of effective contraception with the Norplant implant. Since it is coitus-independent, Norplant offers an excellent form of contraception for women who have difficulty remembering to use a birth control method at the time of intercourse or to take a daily pill.[1]

Despite its benefits, use of the implant system, marketed by Wyeth-Ayerst Laboratories of Philadelphia, lags in the United States. More than 70% of providers who responded to the 1999 *Contraceptive Technology Update* Contraception Survey say they inserted no implants during the past year. This represents a slight increase from 1998, when 68% reported no insertions. **(See charts at right.)**

Levels of insertion were consistent with 1998 figures:

- About 16% of providers reported one to five insertions, compared with 18% in 1998;
- 6.5% noted six to 10, the same as in 1998;
- 3.4% indicated 11 to 25, slightly less than the 5% in 1998;
- 1.6% said they inserted 25 or more implants. In 1998, that figure was 4%.

Joanne Shope, FNP, family nurse practitioner at El Dorado County Health Department in South Lake Tahoe, CA, says that while Norplant use decreased for a few years, she is now seeing a resurgence of interest. "I continue at 30 to 50 insertions per year," she notes. "Removals continue about the same level [11 to 25] — probably half at five years, and half for other reasons."

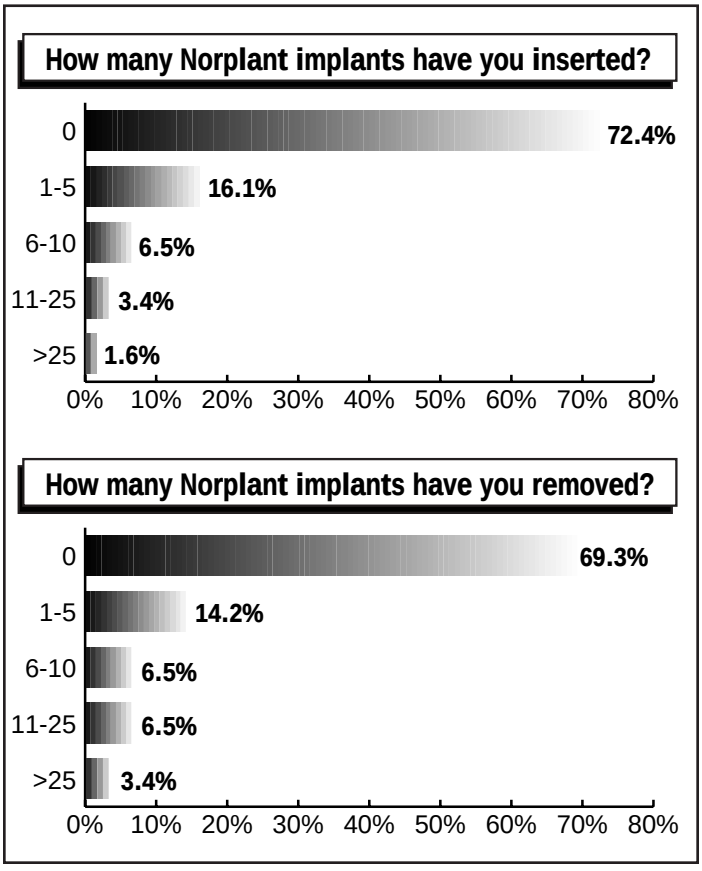
Interest in Norplant has increased over the past year at the Anchorage (AK) Health Department, says **Lorraine Charvet**, NP, OB/GYN nurse practitioner, who performed six to 10 insertions during the last year. "I'm not sure if it is real interest or because the community is aware that the Norplant system in our clinic is available on a sliding fee scale," she comments.

Levels of Norplant removals appear to be slowing, according to *CTU* survey results. Almost 70% of providers say they removed no implants in the last year, compared with 62% in 1998.

Fourteen percent said they removed one to five implants, compared with 12% in 1998. Six percent noted six to 10 removals, slightly below 1998's 9% figure. The largest decrease was seen in the 11 to 25 removal category: 6% in 1999, half of 1998's 12% level. Three percent said they removed 25 or more implants, compared with 5% in 1998.

Reference

1. Hatcher RA, Trussell J, Stewart F, et al. *Contraceptive Technology*. 17th ed. New York City: Ardent Media; 1998. ■



Consider the options in providing OCs

Take a look at the next three women scheduled to enter your examination room:

• a former patient, a 37-year-old who wants contraceptives but is a heavy cigarette smoker;

• a new patient, a 28-year-old new mother;

• and a walk-in patient, a 23-year-old who has used pills in the past but had problems with nausea.

What approaches do you use? Respondents participating in the 1999 *Contraceptive Technology Update* Contraception Survey offer their insights into how providers may address these daily challenges of providing patient care in the family planning setting.

Providers who see women ages 35 and above agree: Oral contraceptives and smoking do not mix. Responses to the 1999 *CTU* survey fall in line with previous years' findings, as 67% say they would not prescribe to women ages 35 to 39 who smoke 10 cigarettes a day; that percentage in 1998 was 65%. In the case of women ages 40 and above, the majority of providers again concur that OCs are contraindicated: 88% say they would not prescribe, compared with 1998's 87% figure. **(See chart at right.)**

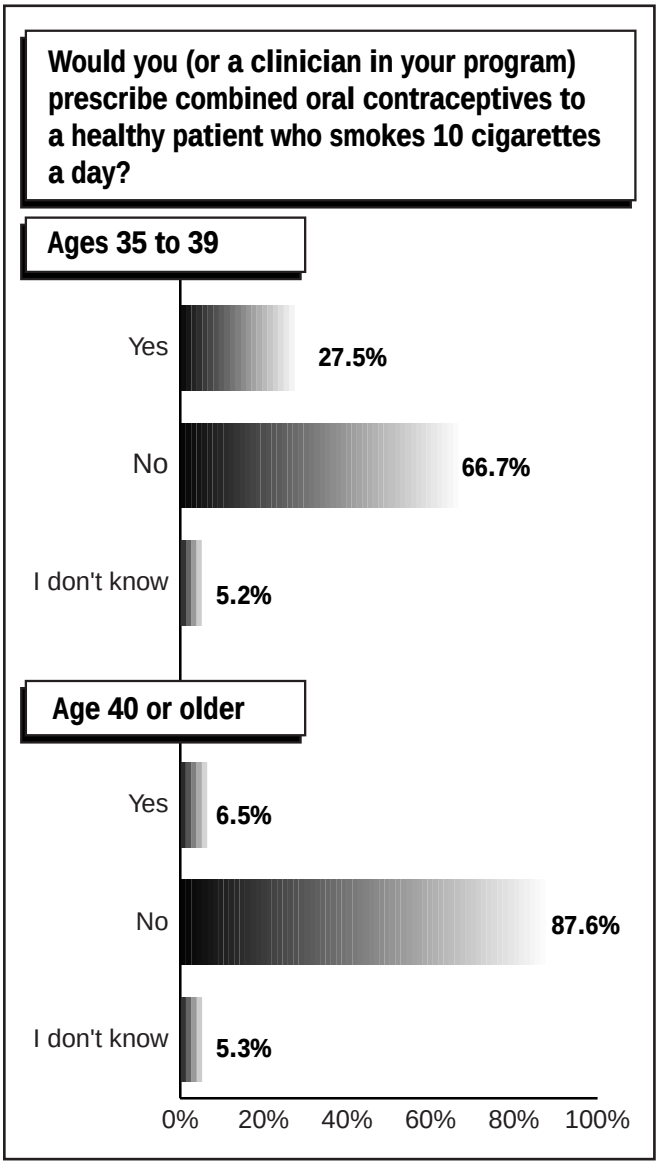
EXECUTIVE SUMMARY

Respondents to the 1999 *Contraceptive Technology Update* Contraception Survey offered their views on three contraception challenges: older women who smoke, new mothers, and women who have experienced nausea with previous oral contraceptives (OCs).

- Patients older than 35 who smoke 10 or more cigarettes per day are not offered combined OCs by most survey respondents.
- About half (41%) of survey respondents say they would initiate combined OC use three to six weeks postpartum. For women who choose to breast-feed, 42% say they would begin progestin-only pills at four to six weeks postpartum.
- Providers name Alesse, manufactured by Wyeth-Ayerst Laboratories of Philadelphia, as their top pill for women who have experienced nausea on previous OCs.

According to the Geneva, Switzerland-based World Health Organization's (WHO) "Medical Eligibility Criteria for Starting Contraceptive Methods," OCs for female smokers ages 35 and above rank in the "WHO 3" category, which is described as follows: "Should not be used unless a doctor or nurse makes a clinical judgment that the client can safely use it. Theoretical or proven risks usually outweigh the advantages of the method. Method of last choice, for which regular monitoring may be needed."[1]

Providers at Shenandoah Valley Medical Center in Martinsburg, WV, follow the WHO guidelines, reports **Marianne Fisher Vandiver**, PA-C, certified physician's assistant. "We try to stick as much as we can to those [guidelines], so some of those women are on progestin-only methods," she notes.

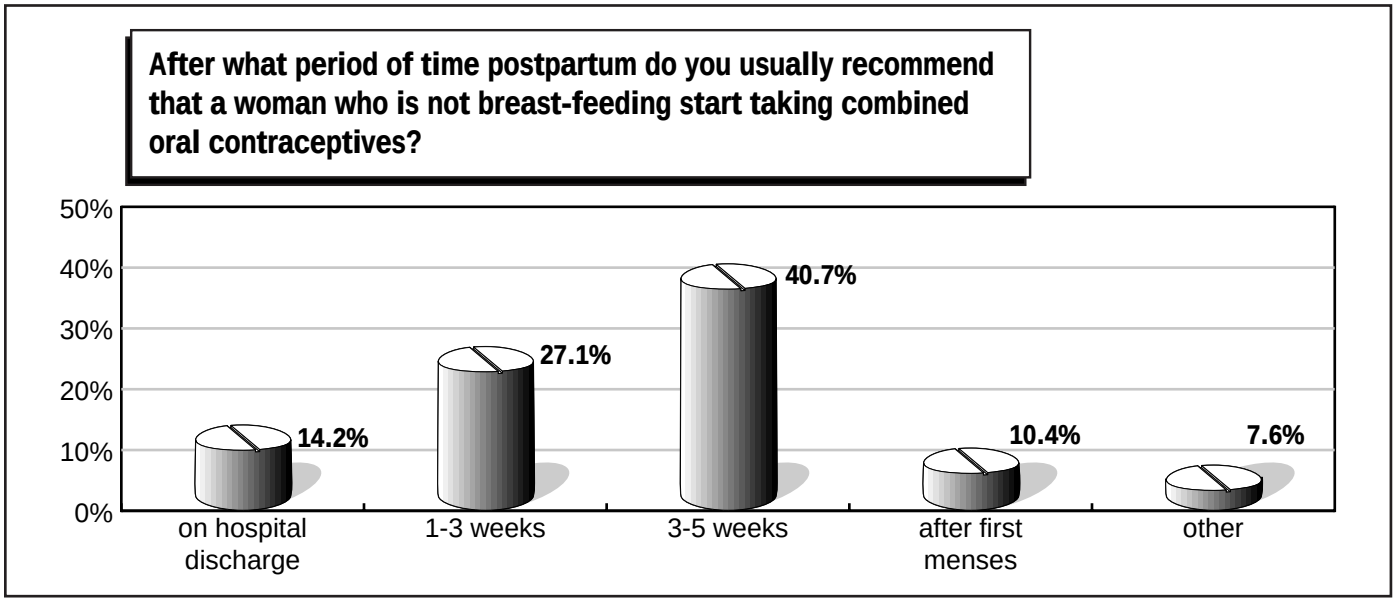


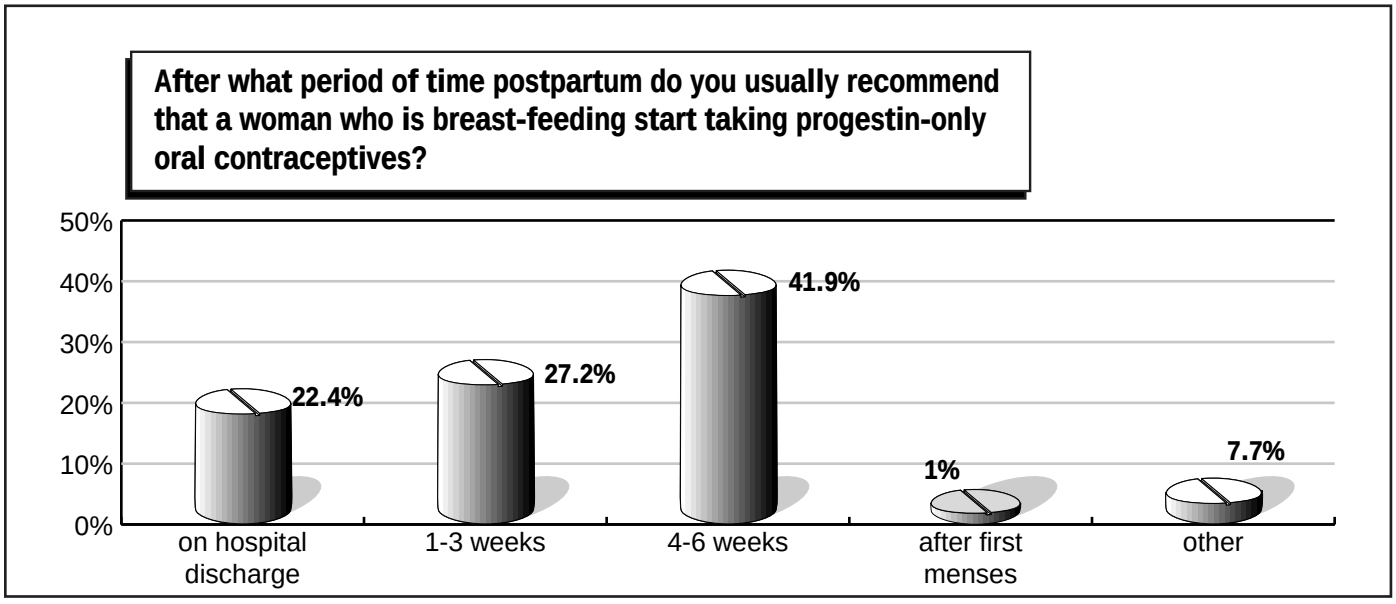
"We generally also discuss surgical sterilization if they really don't want to have kids, and we try to get them to stop smoking."

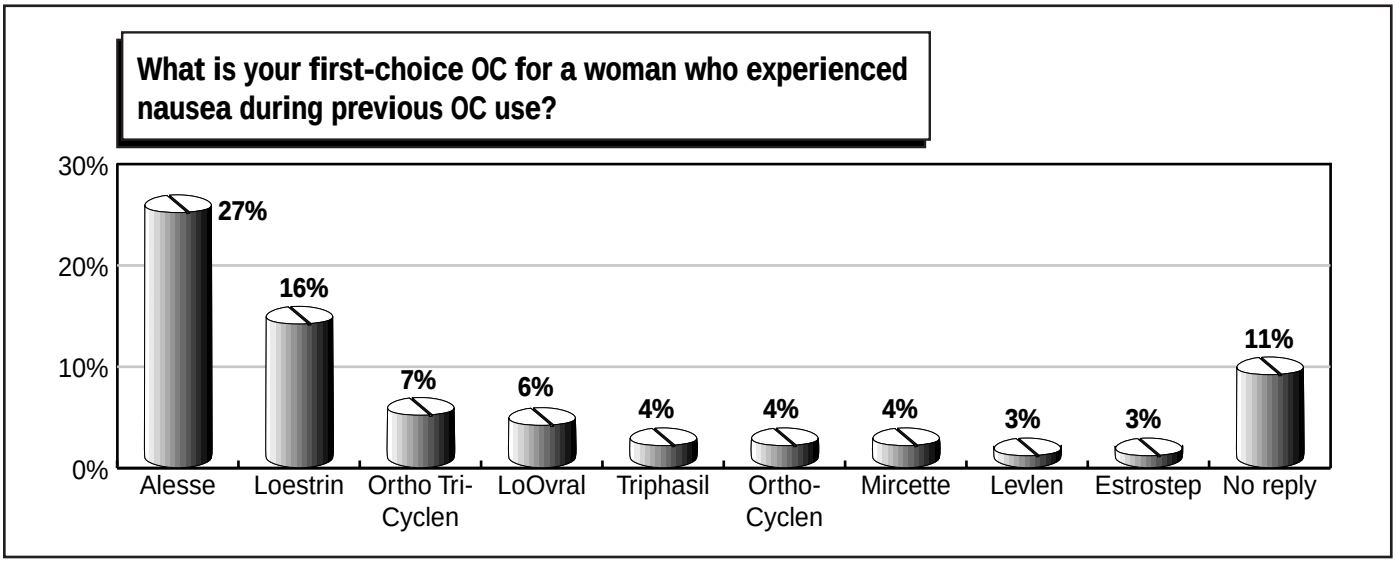
When you would begin combined OC use for new mothers who are not breast-feeding? About half (41%) of survey respondents say they would initiate use three to six weeks postpartum, up from 32% in 1998. For women who choose to breast-feed, 42% say they would begin progestin-only pills at four to six weeks postpartum. **(See charts, below.)**

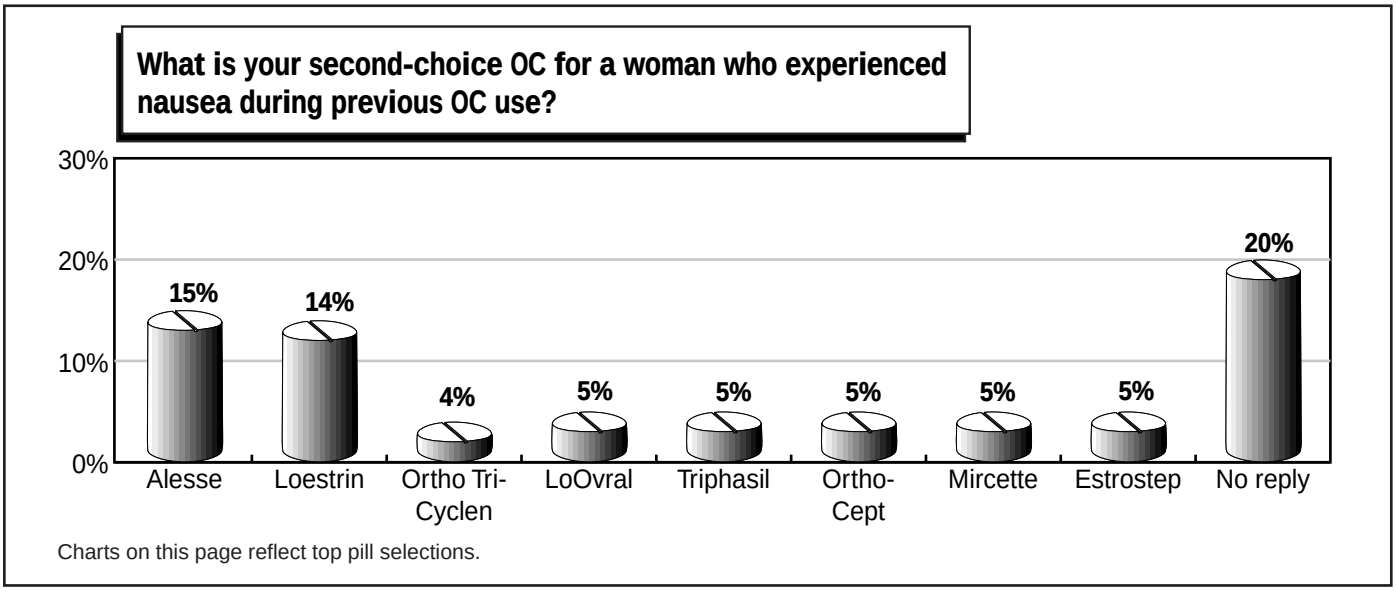
Package labeling for combination OCs suggests not initiating OCs until one month or more postpartum, notes **Andrew Kaunitz**, MD, professor and assistant chair of the department of OB/GYN at the University of Florida Health Sciences Center in Jacksonville. According to Kaunitz, several issues determine when it is appropriate to start combination OCs in this setting:

- Combination OCs reduce the quantity of mother's milk; thus, their use is not appropriate in the first month postpartum in nursing mothers.
- The puerperium is a time of hypercoagulability. Starting combination OCs immediately postpartum could place new mothers at an unnecessary increased risk of thromboembolism.
- In non-nursing women, the earliest ovulation can occur is 27 days postpartum.









Charts on this page reflect top pill selections.

• Many couples resume sexual relations within two to three weeks postpartum.

Given each of these observations, an appropriate time to initiate combination OCs in non-nursing women is on the first Sunday after the infant is 2 weeks old, notes Kaunitz. This avoids starting the OCs immediately postpartum during the period of greatest puerperal hypercoagulability and ensures effective ovulation suppression before any possibility that ovulation has occurred.

At the University Medical Center in Jacksonville, FL, providers have moved routine postpartum visits, including cesarean and postpartum tubal sterilization wound checks, to three weeks postpartum rather than the traditional six-week visit, Kaunitz reports.

At three weeks postpartum, women can arrange to begin OCs, depot medroxyprogesterone acetate injections, Norplant implants, or intrauterine devices before there is any chance they may have conceived, he notes.

Which pill for nausea?

What is your next move when a patient says she has used pills in the past and can't remember which brand but knows she had problems with nausea?

More than 40% of the *CTU* Contraception Survey respondents say they prescribe a 20 mcg pill for these patients. Providers pick Alesse, a 100 mcg levonorgestrel/20 mcg ethinyl estradiol OC manufactured by Wyeth-Ayerst Laboratories

of Philadelphia, as their first- and second-choice pill in this category. **(See charts, p. 104.)**

Ortho Tri-Cyclen, a 35-mcg triphasic pill from Ortho-McNeil Pharmaceuticals of Raritan, NJ, fell from first to second place in the first-choice category, while Loestrin, a pill manufactured in both 20 and 30 mcg strengths from Parke-Davis of Morris Plains, NJ, rose to second place in the second-choice category.

"Nausea from OCs is usually related to estrogen dosage," notes **Jonathan Weiner**, MD, an OB/GYN in private practice in Fresno, CA, commenting on his choice of OC. "Alesse is a low-dose estrogen formulation."

Reference

1. Technical Guidance/Competence Working Group and World Health Organization/Family Planning and Population Unit. Family planning methods: New guidance. *Population Reports.* Series J, No. 44. Baltimore: Johns Hopkins School of Public Health, Population Information Program; October 1996. ■

How to use OCs? Readers offer insights

When it comes to initiating oral contraceptive (OC) use, 70% of providers responding to the 1999 *Contraceptive Technology Update* survey say they prefer to start patients the Sunday after the beginning of the menstrual cycle. This compares with readers' 1998 response, in which 78% indicated a preference for this initiation method.

"I think they like the Sunday start better than the others," says **Debbie Freels**, MSN, certified nurse midwife at University Physicians Clinic, Boonville, and clinical instructor of nursing at the University of Missouri-Columbia. "I actually don't even counsel about other ways, just because it seems to be the easiest."

According to *Contraceptive Technology*, OCs can be started on the:

- first day of menstrual bleeding;
- first Sunday after menstrual bleeding begins;
- day of office visit, if pregnancy is excluded and there has been no unprotected sex since the last menstrual period.[1]

Freels, who sees many adolescents in her practice, says that educating patients on other methods has not proven as easy as the "Sunday start."

"It seems to work really well, she notes. "I get a fairly good amount of compliance, and the questions I get are always appropriate. When I get questions, it's not that they started it incorrectly. It is about other issues, such as they forgot what to do if they missed a couple of pills."

Vomiting and diarrhea info

Do you provide written recommendations that women who continue pills after developing vomiting or diarrhea use a backup method of contraception until their next period? While the majority of survey respondents (56%) say they do offer written instructions, the gap between pro and con is narrowing: 43% say they do not. Respondents were split 68% pro and 32% con in the 1998 survey.

"They are helpful in general about 50% of the time," says **Susan Skotleski-Krum**, MSN, CRNP, nursing instructor at Lycoming College in Williamsport, PA, who uses written instructions with patients she sees at the college's health center and local family planning agencies. "Patients either lose them, or when the problem arises, they don't remember what you told them and are too embarrassed to call."

Written instructions on use of backup contraceptives is recommended as a precautionary measure at South Texas Family Planning and Health Corp. in Corpus Christi, TX, reports **Grace Miyazaki**, NP, family nurse practitioner. No known actual cases have been reported if patients did not comply and pregnancy occurred, she notes.

For patients who experience vomiting or diarrhea, *Contraceptive Technology* offers the following patient instructions:

- If you vomit within two hours of taking a pill, take another pill from a separate pill pack as soon as you feel better. Make sure you always have extra pills on hand for situations like this.
- If you have severe diarrhea or vomiting for more than 24 hours, keep taking your pills on schedule, if you can. During the time you are ill and for seven days after you feel better, use a backup contraceptive or abstain from sexual intercourse.

• If your illness caused you to miss any pills from the third week (pills 15 to 21), do not take your usual week off of hormonal pills (do not take the reminder pills in the 28-day pack). Start a new pack of pills immediately.[1]

Reference

1. Hatcher RA, Trussell J, Stewart F, et al. *Contraceptive Technology*. 17th ed. New York City: Ardent Media; 1998. ■

Providers offer views on treatment of teens

For many family planning providers, adolescents represent a significant portion of their patient population. The 1999 *Contraceptive Technology Update* Contraception Survey explored two issues associated with adolescent reproductive health care: use of Depo-Provera (depot medroxyprogesterone acetate, or DMPA), a progestin-only contraceptive injectable, and treatment of dysmenorrhea.

Since DMPA, manufactured by Pharmacia and Upjohn of Bridgewater, NJ, obtained federal Food and Drug Administration approval in 1992, it has gained acceptance among contraceptive users, particularly among adolescents. It is estimated that 15% of teens ages 15 to 17 use DMPA.[1] "It is very, very popular with our teens," says **Amador Ramirez**, MD, medical director of the Barren River District Health Department in Bowling Green, KY. "We have over 250 patients on Depo right now."

While the effects of DMPA on bone growth and mineralization in adolescents are not yet fully understood, survey respondents say they are willing to prescribe the injectable for young teens. Ninety-six percent of 1999 respondents are in favor of such a practice, up slightly from 93% in 1998. **(See chart, p. 107, bottom left column.)**

"Depo is very popular among teens in our area, not so much with the college age, because they can't get it over the summer without a second exam at home," notes **Susan Skotleski-Krum**, MSN, CRNP, nursing instructor at Lycoming College in Williamsport, PA, who sees patients at the college health center and at local family planning agencies. "College students also are planning to get married out of school, and they worry about when their period will come back, so they tend to stick with the pill. But Depo has been great for teens."

EXECUTIVE SUMMARY

Adolescents make up a large segment of many family planners' practices. *Contraceptive Technology Update* surveyed providers on two important teen issues: use of Depo-Provera (DMPA), the progestin-only injectable manufactured by Pharmacia and Upjohn of Bridgewater, NJ, and treatment of primary dysmenorrhea.

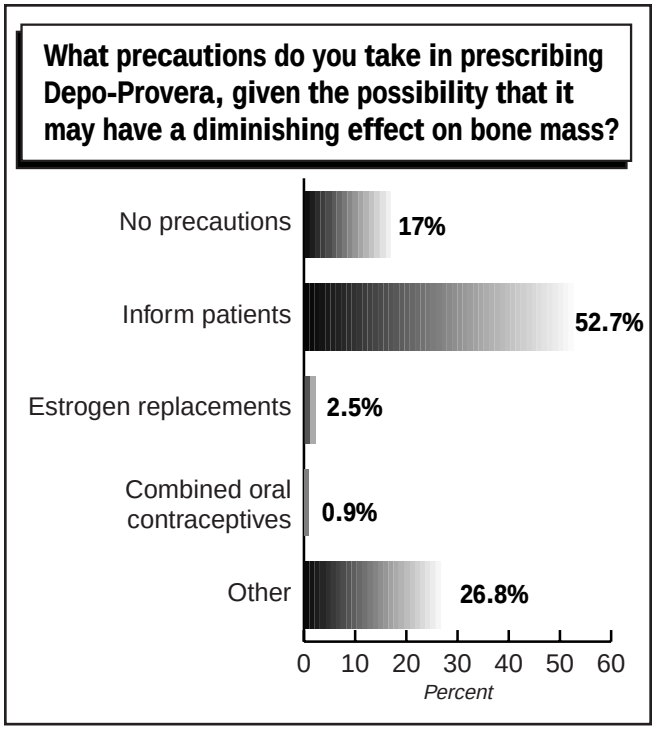
- Almost all readers responding to the survey say they are willing to prescribe DMPA for young teens. More than 50% say they inform patients about the potential risk for decreased bone density, an issue that is under continued research.
- The majority of providers surveyed say they use a combination of oral contraceptives and prostaglandin inhibitors for the treatment of primary dysmenorrhea in teens who are not sexually active.

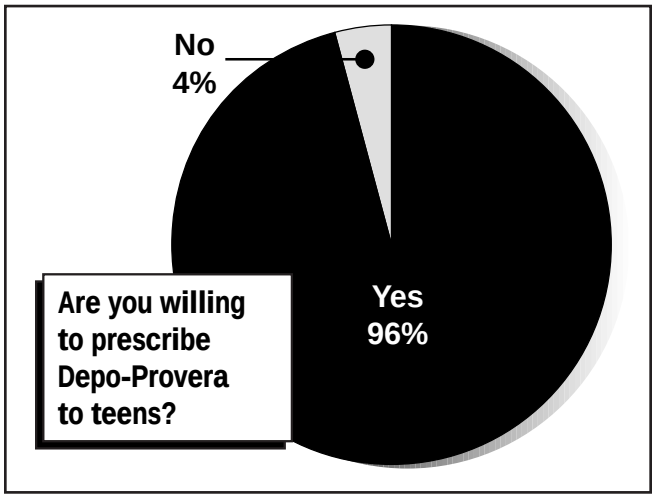
Calcium, exercise urged

Half of adult bone mass is acquired during adolescence, with the most rapid gains in bone mineralization between ages 11 and 14.[2] Questions about the use of DMPA center around research indicating that users of DMPA may develop decreased bone density.[3] A subsequent study of some of the original DMPA users who discontinued the method found that bone density tended to increase after the method was stopped.[4]

Until research further clarifies the issue, the majority of survey respondents say they will inform patients of this possible side effect. A total of 53% of readers now inform patients, compared with 63% who said they would do so in 1998. Twenty-seven percent said they take another type of precaution, compared with 19% in 1998, and 17% indicated they do nothing, up slightly from 15% in 1998. **(See chart, p. 107, top left column.)**

Providers use a variety of approaches. About 37% recommend calcium supplementation, and 26% call for increased calcium and weight-bearing exercise. Other responses include combining calcium supplementation and vitamin D and providing education on smoking cessation.

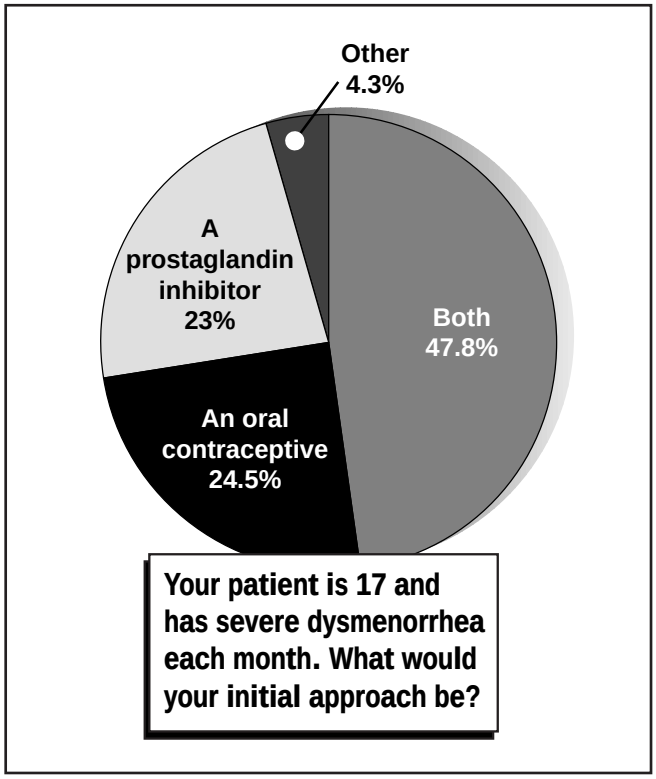




Patricia Carrick, FNP-C, clinic coordinator at Beaverhead Family Planning Clinic in Dillon, MT, says she informs patients about the potential side effect and prescribes 1,000 mg to 1,500 mg calcium, as well as vitamin D. "We also discuss the importance of exercise and diets," Carrick notes. "It is still a poor substitute for good old estrogen, and I am concerned."

What is your initial approach when a 17-year-old presents with severe menstrual cramps but says she is not sexually active and does not plan to be within the next year?

Almost half (48%) of respondents to the 1999 survey say they would prescribe both OCs and a prostaglandin inhibitor. About 35% said they would use a combination approach in 1998. In 1999, about one-quarter would begin with an OC alone, while 23% would use a prostaglandin inhibitor. **(See chart, above.)**



The use of both OCs and a prostaglandin inhibitor represents a complementary strategy for targeting the underlying problem of primary dysmenorrhea, according to *Contraceptive Technology*.[5] OCs tend to decrease menstrual cramps and pain, including symptoms that have been resistant to therapy with prostaglandin inhibitors alone.

References

1. Kaiser Family Foundation. *Fact Sheet: Contraceptive Use.* Menlo Park, CA: Kaiser Family Foundation; June 1997.

2. Nelson AL. Hormonal influences on young bones: When should we worry? Presented at *Contraceptive Technology* Conference, Washington, DC, and San Francisco, March 1998.

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

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

5. Hatcher RA, Trussell J, Stewart F, et al. *Contraceptive Technology*. 17th ed. New York City: Ardent Media; 1998. ■

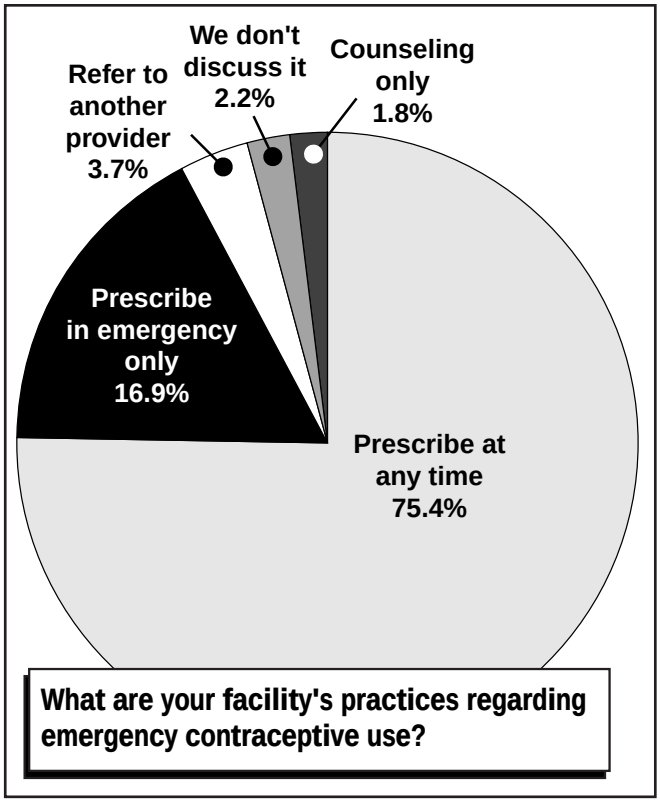
Emergency contraception use up — new ECP arrives

Get ready for increased interest in emergency contraception as the first progestin-only dedicated emergency contraceptive pill (ECP) enters the U.S. market. With Food and Drug Administration (FDA) approval now in hand, the Women's Capital Corp. of Seattle is moving ahead with shipments of Plan B, its levonorgestrel-only product.

Providers have been looking forward to the U.S. introduction of a progestin-only product since an international study showed the levonorgestrel-only method was more effective and resulted in fewer side effects than the combination regimen now in use.[1] **(Read more about the study results in the November 1998 issue of *Contraceptive Technology Update*, p. 143.)**

Awareness of ECPs has grown following the 1998 U.S. market introduction of the Preven Emergency Contraceptive Kit. Marketed by Gynétics of Belle Mead, NJ. Preven was the first dedicated ECP product to be released in the United States. **(See *CTU*, November 1998, p. 141, for further coverage of Preven's introduction.)**

Women's Capital Corp. is taking a different marketing and distribution approach to emergency contraception than Gynétics, which also is developing a progestin-only product. **(For more on the progestin-only products, see *CTU*, March 1999, p. 28.)**



Company president **Sharon Camp**, PhD, says Women's Capital Corp. plans to market and distribute Plan B to those facilities and providers who prescribe and dispense on-site. The 1999 *CTU* Contraception Survey shows that the number of these providers is growing: Three-quarters of survey respondents report their facilities prescribe emergency contraceptive pills (ECPs) on site and provide them at any time, up from 62% in 1998. **(See chart, above.)**

"We are an outgrowth of a private / public consortium, so we have a very strong public-sector focus," she says of the initial move not to market to retail pharmacies. "Our focus is on existing ECP providers / dispensers, such as Planned Parenthood affiliates, major Title X programs, and college / university student health centers."

By keeping its focus on such facilities, Women's Capital Corp. sees Plan B's chief competitors as those oral contraceptives (OCs) now determined by the FDA to be safe and effective for emergency contraception use. The challenge for Plan B is to be competitively priced because

EXECUTIVE SUMMARY

Plan B, the new levonorgestrel-only emergency contraceptive pill (ECP) from Women's Capital Corp. of Seattle, enters the U.S. market at a time when more providers say they are prescribing emergency contraception.

- Three-quarters of participants responding to the 1999 *Contraceptive Technology Update* Contraception Survey say their facilities prescribe ECPs on site and provide them at any time.
- The Preven Emergency Contraceptive Kit, marketed by Gynétics of Belle Mead, NJ, has made inroads with providers since its 1998 U.S. introduction. The company also is pursuing approval of a progestin-only ECP.
- Clinicians continue to use certain oral contraceptives (OCs) determined to be safe and effective for emergency contraception use. Lo-Ovral, manufactured by Wyeth-Ayerst of Philadelphia, was the most-named OC for this purpose.

Information Resources for Emergency Contraception

• **Are you providing emergency contraception?** Get listed on the Emergency Contraceptive Hotline (1-888-NOT-2-LATE) and the Emergency Contraception Web site (http://opr.princeton.edu/ec/). The Hotline is completely automated and available 24 hours a day in English and Spanish. Callers can listen to pre-recorded information about emergency contraceptive methods available in the United States and receive the names, telephone numbers, city, and state of five providers located near them.

The same information is available through the Web site. A provider sign-up form can be downloaded from the Emergency Contraception Web site or received by writing to the Emergency Contraception Hotline, 21 Prospect Ave., Princeton, NJ 08544-2091.

• **Interested in developing collaborative practice agreements with pharmacists to expand ECP access?** Explore the "EC Tools" page at the Seattle-based Program for Appropriate Technology Web site. All information presented at the workshop is available at the site: www.path.org/html/ec_tools.htm.

• **Is your institution interested in hosting an "Emergency Contraception: Train the Trainer" visiting faculty lecture this year?** Go to the Washington, DC-based Association of Reproductive Health Professionals' Web site to learn more about the program. The program is designed to provide accredited continuing medical education on emergency contraception to reproductive health and other primary care clinicians. The Web site also includes Power Point slides, which are updated continually to reflect the latest information. Web: www.arhp.org/ec/.

• **Gauge understanding of emergency contraception with the "Sex and Sensibility IQ Test."** It's offered at the Web site for the Alexandria, VA-based American Medical Women's Association. "Sex and Sensibility" is the Association's public education campaign to increase understanding of emergency contraception's role in comprehensive sexual health planning. The "IQ Test" is designed to help people assess their current knowledge and learn more about emergency contraception. Web: www.amwa-doc.org/ec.htm. ■

many facilities get bulk discount rates for OCs, says Camp.

1999 *CTU* survey results show that family planners are using Preven and the OCs approved by the FDA for ECP use. Lo-Ovral, a 30 mcg pill from Wyeth-Ayerst of Philadelphia, was the OC most frequently named for use as an ECP by survey respondents. Providers also used two Wyeth-Ayerst products: Nordette, a 30-mcg pill, and Ovral, a 50-mcg OC; and the Preven kit.

Preven has just received FDA approval of revised product labeling, says **Sherry Bump**, Gynétics executive director of marketing. The labeling change, which eliminates the "Black Box Warning" from the package, represents a reduction in the weight of the warnings of potential serious side effects. Black Box Warnings are used by the FDA to highlight areas of concern regarding side effects for which the FDA requires special note.

"This change puts the benefits and risks of emergency contraception in perspective," says Bump. "Additionally, removal of the Black Box Warning eliminates substantial restrictions on the company's ability to communicate directly to the consumer and to the medical professional."

This decision should help to accelerate the process of building awareness of emergency contraception and its availability in the United States, she notes.

More women are getting the message about emergency contraception, report participants in the 1999 *CTU* Contraception Survey. "We are listed on the [Emergency Contraception] Web site for ECPs," says **Lois Wessel**, FNP, director of primary care at Washington (DC) Free Clinic. "We started last fall, and our number has increased." **(The resource listing at left explains how your facility can be listed on the Web site.)**

The number of women seeking ECPs also has increased at Beaverhead Family Planning Clinic in Dillon, MT, says **Patricia Carrick**, FNP-C, clinic coordinator. "We try to give information on ECPs to all patients who are on oral contraceptives, using condoms, or using no method," she says.

Reference

1. Task Force on Postovulatory Methods of Fertility Regulation. Randomised controlled trial of levonorgestrel versus the Yuzpe regimen of combined oral contraceptives for emergency contraception. *Lancet* 1998; 352:428-433. ■

Alternative medicine, DMPA costs top concerns

What are the challenges facing women's health care facilities today? According to those participating in *Contraceptive Technology Update*'s 1999 Contraception Survey, providers are moving to fast to educate themselves about the use of complementary and alternative medicine and deal with the budget crunch brought on by the rise in use of the contraceptive injectable Depo-Provera (depot medroxyprogesterone acetate, or DMPA).

More than half of survey respondents responded "yes" to the question, "Is the use of alternative medicine by patients becoming a concern in their practice or facility?" That number has risen from the 28% level reported in 1998.

According to many survey respondents, the survey words "a concern" should be replaced by "accepted" because both patients and providers are expressing interest in alternative therapies.

"I would not classify it as a concern; patients and professionals are looking at alternative medicine," says **Deborah Mathis**, MSN, CRNP, women's health coordinator at the University of Pennsylvania Student Health Center in Pittsburgh. "We have always discussed vitamin and mineral supplements to supplement other treatments, and we have had inservices and individual learning / readings that co-workers share."

A number of facilities are encompassing alternative therapies in their practice, say survey respondents. About one-third of those who indicate use of such therapies say they are including herbal medicine, with 20% including massage therapy.

The Washington (DC) Free Clinic now offers acupuncture, reports **Lois Wessel**, FNP, director of primary care. There is a waiting list to see the acupuncturist, she notes.

"We are trying to educate ourselves and recommend those practices supported by either an extensively documented history of success or well-designed studies," says **Patricia Carrick**, FNP-C, clinic coordinator at Beaverhead Family Planning Clinic in Dillon, MT. "We try to maintain an open attitude and invite our patients to share their experiences so we can learn, too."

A 1997 national telephone survey of randomly selected households, mirroring a similar survey performed in 1991, showed that use of at least one of 16 alternative therapies increased from 33.8% in 1990 to 42.1% in 1997.[1] The therapies showing the most increase in use included herbal medicine, massage, megavitamins, self-help groups, folk remedies, energy healing, and homeopathy. The probability of users visiting an alternative medicine practitioner increased from 36.3% to 46.3%, according to survey results.

"As [midwives], we look at alternative therapies, because we tend to draw [those] who want alternative therapy," says **Debbie Freels**, MSN, certified nurse midwife at University Physicians

EXECUTIVE SUMMARY

Getting up to speed on complementary and alternative medicine and balancing the rising demand for Depo-Provera (DMPA) against finite budgets are two challenges faced by today's family planning facilities.

- More than half of *Contraceptive Technology Update* readers say use of alternative therapies by patients is a concern, up from less than 30% in 1998. Several facilities are encompassing alternative therapies, including herbal medicine and massage therapy.
- Almost one-quarter of providers say clinic cost considerations come into play when starting patients on DMPA. Many clinics are making hard choices as they find themselves caught between finite contraceptive budgets and escalating demands for the injections.

COMING IN FUTURE MONTHS

- Any link between heart attack and oral contraceptives?
- Late-night clinic meets women's health needs
- Patterns of sex partner selection influence gonorrhea, chlamydia risk
- New condom designs to enter market
- Cervical cancer vaccine shows promise

Clinic in Boonville, MO, and clinical instructor of nursing at University of Missouri at Columbia. "The people I notice that for are mostly menopausal-aged women, but I have had a few pregnant women, too."

One finding from the 1997 telephone survey remains consistent with its earlier 1990 predecessor: More than 60% of patients who used alternative therapies did not disclose this information to their regular physicians.[1]

"We are trying to be very open-minded about it, because it is really important that they let us know exactly what they are taking," says **Judy Lee**, ARNP, women's health nurse practitioner at Gateway District Health Department in Owingsville, KY. "I try to approach it [by asking] 'Are you using any herbal medications?' then explain why I'm asking, because some of them become very defensive. It doesn't make any difference, but I want to make sure that anything we prescribe isn't going to cause an interaction problem."

Almost one-quarter of providers say clinic cost considerations come into play when starting patients on DMPA. As previously reported in *CTU*, many clinics are having to make hard choices as they find themselves caught between finite contraceptive budgets and escalating demands for the injections. **(For details, see *CTU*, January 1998, p. 1.)**

To meet the DMPA demand, Beaverhead Family Planning Clinic charges one flat fee for patients 19 years old and above and offers a sliding fee for younger patients, says Carrick.

Sometimes the restrictions set by certain managed care organizations also come into play, notes **Ann Tyree**, FNP-C, family nurse practitioner at Beach Physicians and Surgeons in Huntington Beach, CA.

"I have to write for authorization from the [health maintenance organization] for Depo, because they won't give it unless I have good documentation that the patient can't take oral contraceptives for some reason," Tyree explains. "The fact that it might be a better choice for this particular patient, or that the patient wants that method, does not matter."

Reference

1. Eisenberg DM, Davis RB, Ettner SL, et al. Trends in alternative medicine use in the United States, 1990-1997. Results of a follow-up national survey. *JAMA* 1998; 280:1,569-1,575. ■

CTUPDATES

News ■ Resources ■ Events

Contraceptive Technology fall conference on tap

Make plans now to attend the *Contraceptive Technology* "Quest for Excellence" conference Oct. 27-29 at the Sheraton Colony Square Hotel in Atlanta.

Sponsored by Contemporary Forums of Dublin, CA, the conference will offer the latest information on contraceptive technology research, examine new findings in menopause management, and review clinical management

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

Subscriber Information

Customer Service: (800) 688-2421 or fax (800) 284-3291, (customerservice@ahcpub.com). Hours of operation: 8:30 a.m.-6 p.m. Monday-Thursday; 8:30 a.m.-4:30 p.m. Friday, EST.

Subscription rates: U.S.A., one year (12 issues), $369. Approximately 18 nursing contact hours or Category 1 CME credits, $419; Outside U.S., add $30 per year, total prepaid in U.S. funds. One to nine additional copies, $295 per year; 10 to 20 additional copies, $221 per year. Call for more details. **Back issues**, when available, are $62 each.(GST registration number R128870672.) **Photocopying:** No part of this newsletter may be reproduced in any form or incorporated into any information retrieval system without the written permission of the copyright owner. For reprint permission, please contact American Health Consultants®. Address: P.O. Box 740056, Atlanta, GA 30374. Telephone: (800) 688-2421. World Wide Web: http://www.ahcpub.com.

This continuing education offering is sponsored by American Health Consultants, which is accredited as a provider of continuing education in nursing by the American Nurses Credentialing Center's Commission on Accreditation. In addition, American Health Consultants is an approved provider by the California Board of Registered Nursing for approximately 18 contact hours (provider #CEP10864).

Opinions expressed are not necessarily those of this publication. Mention of products or services does not constitute endorsement. Clinical, legal, tax, and other comments are offered for general guidance only; professional counsel should be sought for specific situations.

Editor: **Rebecca Bowers**.
Group Publisher: **Brenda Mooney**, (404) 262-5403, (brenda.mooney@medec.com).
Executive Editor: **Park Morgan**, (404) 262-5460, (park.morgan@medec.com).
Managing Editor: **Joy Daughtery Dickinson**, (912) 377-8044, (joy.daughtery@medec.com).
Production Editor: **Terri McIntosh**.

Editorial Questions

Questions or comments?
Call **Joy Daughtery Dickinson** (912) 377-8044.

strategies of challenging complications in women's health. An "Adolescent Health Care" preconference will convene on Oct. 27 and will provide information on adolescent gynecology, pregnancy prevention strategies, contraceptive challenges, and eating disorders.

A special dinner and presentation on the benefits and risks of oral contraceptives also will be held on Oct. 27. Continuing medication education credits are available.

For additional information on the conference, contact: Contemporary Forums, 11900 Silvergate Drive, Dublin, CA 94568-2257. Telephone: (925) 828-7100, ext. 0. E-mail: hlth@cforums.com. Web: www.cforums.com.

The early conference registration fee (on or before Sept. 15) is $355 for MDs / DOs; $255 for nurses, physician assistants, residents, and other health professionals; and $175 for full-time students. The early preconference registration fee is $145. ■

CE objectives

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

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

- Identify clinical, legal, or scientific issues related to development and provisions of contraceptive technology or other reproductive services.
- Describe how those issues affect service delivery and note the benefits or problems created in patient care in 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 "Consider options in providing OCs," p. 102, and "How to use OCs? Readers offer insights," p. 105.) ■

This continuing education offering is sponsored by American Health Consultants®, which is accredited as a provider of continuing education in nursing by the American Nurses Credentialing Center's Commission on Accreditation. American Health Consultants® is accredited by the Accreditation Council for Continuing Medical Education to sponsor CME for physicians. American Health Consultants® designates this continuing medical education activity for approximately 18 credit hours in Category 1 of the Physicians' Recognition Award of the American Medical Association. This CME activity was planned and produced in accordance with the ACCME Essentials. In addition, American Health Consultants® is an approved provider by the California Board of Registered Nursing for approximately 18 contact hours (provider #CEP10864).

Contraceptive Technology Update *is endorsed by the National Association of Nurse Practitioners in Women's Health and the Association of Reproductive Health Professionals as a vital information source for health care professionals.*

NATIONAL ASSOCIATION NPWH National Association of Nurse Practitioners in Women's Health

A • R • H • P
Association of Reproductive Health Professionals