AMERICAN HEALTH CONSULTANTS

CONTRACEPTIVE TECHNOLOGY UPDATE®

A Monthly Newsletter for Health Professionals

INSIDE

DECEMBER 2002

VOL. 23, NO. 12 (pages 133-144)

Family planning facilities meet the challenge of Lunelle syringe recall

Clinics scramble to issue alert, provide backup contraception

If a large segment of your patient population is using the monthly contraceptive injection Lunelle, chances are that the last few weeks have been filled with contacting patients, answering questions, and counseling on backup contraception after the manufacturer issued a voluntary recall of prefilled syringes of the product.

Pharmacia Corp. of Peapack, NJ, issued the recall on Oct. 10, 2002, due to what the company terms "a lack of assurance of full potency and possible risk of contraceptive failure."

As many as 100,000 women could be affected by the recall, according to the Food and Drug Administration.

The affected lots of the prefilled syringes were manufactured at a Pharmacia plant in Belgium and distributed in the United States, Puerto Rico, and the U.S. Virgin Islands during 2002. Pharmacia was alerted to the problem after a provider reported a prefilled syringe appeared suspect and testing indicated it might not have full potency.

Pharmacia has instructed providers who have administered Lunelle prefilled syringes to contact all patients and recommend the use of an additional barrier method of birth control, such as condoms, diaphragms, or spermicides for pregnancy prevention until they begin use of another form of hormonal birth control The company also is recommending that providers perform a pregnancy test for patients on Lunelle; Pharmacia is

Did you receive the e-mail about the Lunelle recall?

As a subscriber to *Contraceptive Technology Update,* you should have received an e-mail on Oct. 14 that gave you the news that Pharmacia Corp. had issued a voluntary recall of Lunelle prefilled syringes. If you'd like to receive future e-mails regarding news events about contraceptives, please contact customer service with your e-mail address. Customer service can be reached at (800) 688-2421 or customerservice@ahcpub.com. ■

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. Periodicals 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), $429. Approximately 18 nursing contact hours or Category 1 CME credits, $479; Outside U.S., add $30 per year, total prepaid in U.S. funds. Two to nine additional copies, $343 per year; 10 to 20 additional copies, $257 per year; for more than 20, call (800) 688-2421. **Back issues**, when available, are $67 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.

Editorial Questions

Questions or comments? Call **Joy Daughtery Dickinson** (229) 377-8044.

Statement of financial disclosure: Dr. Kaunitz (board member) discloses that he performs research for Barr Laboratories, Berlex, Galen, Lilly, Merck, National Institutes of Health, Organon, Parke Davis, Pfizer, Pharmacia, R.W. Johnson Pharmaceutical Research Institute, and Solvay. Kaunitz is a consultant for Barr Laboratories, Johnson & Johnson, Lilly, Organon, Pharmacia, and Proctor & Gamble. He is a stockholder in Johnson & Johnson, Ostex International, and Cytyc. Ms. Dominguez (board member) discloses that she is on the speaker's bureau for Ortho, Pfizer, Roche, and Organon. Ms. Wysocki (board member) discloses that she is on the speaker's bureau for Ortho-McNeil, Wyeth Ayerst Pharmaceuticals, Berlex, Organon, Pharmacia, Pfizer, and Bristol Myers Squibb. Dr. Nelson (board member) serves on the speaker's bureau for Berlex Laboratories, Gynetics, Eli Lilly & Co., 3M Pharmaceuticals, Ortho-McNeill, Organon, Parke-Davis, Pfizer, Pharmacia & Upjohn Co., and Wyeth Ayerst; she conducts research for Ortho-McNeil and Pharmacia & Upjohn. Dr. Rosenfield (board member) is a stockholder and board member of Biotechnology General Corp. Dr. Rosenberg (board member) is a consultant for Organon; serves on the speaker's bureau for Organon, Wyeth-Ayerst, and Parke-Davis; and conducts research for Organon, Wyeth-Ayerst, Ortho-McNeil, and Parke-Davis. Dr. Kaunitz (board member) conducts research for Merck, Pfizer, Pharmacia & Upjohn, RW Johnson Pharmaceutical Research Institute, and Solvay; he is a consultant for Ortho-McNeil, Parke-Davis, and Pharmacia & Upjohn; he is a stockholder in Johnson & Johnson; and does CME presentations and publications for Merck, Organon, Pharmacia & Upjohn, and Wyeth-Ayerst.

THOMSON
AMERICAN HEALTH CONSULTANTS

EXECUTIVE SUMMARY

Family planning providers have been busy contacting and counseling patients following the Oct. 10, 2002, voluntary recall of prefilled syringes of the combined injectable contraceptive Lunelle.

- Manufacturer Pharmacia Corp. issued the recall for all prefilled Lunelle syringes due to what the company terms "a lack of assurance of full potency and possible risk of contraceptive failure." As many as 100,000 women could be affected by the recall.
- Providers are complying with the company's instructions to contact all patients and recommend the use of an additional barrier method of birth control until they begin using another form of hormonal birth control.

providing free pregnancy test kits for use with these patients. **(See the resource box on p. 135 for contact information.)**

At *Contraceptive Technology Update* press time, affiliates of the New York City-based Planned Parenthood Federation of America (PPFA) were notifying all patients who had received at least one injection of Lunelle since January 2002, according to **Vanessa Cullins**, MD, MPH, MBA, PPFA vice president for medical affairs. What has been the immediate response from patients? According to Cullins, most women have been concerned upon learning about the recall.

"Most patients' immediate response is to learn what can they do to prevent unintended pregnancy and to ensure that they are not pregnant at the current time," she notes. While the manufacturer is providing free pregnancy test kits, each PPFA affiliate has been advised to make its own decision about charging fees, says Cullins.

PPFA affiliates have taken a three-pronged approach to notifying patients: first alerting those women who received a Lunelle injection in the past four to six weeks, then informing those who received a Lunelle injection in the past two to four months who could possibly be pregnant and may not know it, and then contacting those clients who used Lunelle sometime earlier in the year. **(See the box on p. 136 for talking points to use in discussions about Lunelle. Refer to the "Questions and Answers About the Voluntary Recall of Lunelle" handout inserted in this issue to answer patient questions about the recall. Use the documentation form inserted in this issue to chart client notification and visit information.)**

According to Pharmacia, vials of Lunelle are not affected by the recall. The concentration of estradiol cypionate and medroxyprogesterone acetate contained in the vials is sufficient to result in expected contraceptive efficacy, the company states. However, manufacture of vials had been temporarily halted about the time the prefilled syringes became available, so supply of vials is limited, says **Bryant Haskins**, Pharmacia director of communications for global supply.

PPFA is recommending that its affiliates refrain from use of the vials due to the supply issue. With the number of vials in limited supply, affiliates would have to devise criteria on who should receive the monthly contraceptive shots, as well as determine how to allocate stock, all of which could prove problematic, notes Cullins.

Continuing to use vials to keep women on Lunelle also may result in a possible quality perception problem, since most providers will have moved to take women off Lunelle completely due to the syringe recall and low supply of vials, notes the PPFA. Women who continue to get shots may perceive — incorrectly — that they are receiving "bad" product, because the prefilled syringes were recalled, notes the PPFA. The national organization suggests that affiliates who continue to supply Lunelle shots from vials have patients sign release forms noting that they have been informed that the vials are unaffected by the recall.

Negotiations are under way with Pharmacia as to what costs will be reimbursed as a result of the recall. The company has announced it will provide free pregnancy kits and condoms, in addition to reimbursement on returned product. **(See the resource box, above right, for contact information.)** In the meantime, PPFA is instructing its affiliates to keep a strict accounting of all expenses incurred due to the recall, including office visits, birth control methods dispensed, emergency contraceptive pills dispensed, and administrative and mailing costs.

What are the options?

Use of Lunelle has climbed since its spring 2001 U.S. introduction. Three-quarters of 2002 *CTU* Contraceptive Survey respondents indicated their facilities offer the contraceptive option, up 15% from the some 60% of respondents who gave similar answers in the 2001 survey.

Pharmacia has not set a time frame for reinstating the product, says **Caroline Bullock**, company spokeswoman.

"We want to bring it back, but right now we are focusing on eradicating the manufacturing issues," states Bullock. "We are working as hard and fast as we can to address them."

In the meantime, how should providers proceed with women who have been using Lunelle as their chosen method of contraception? Some women may opt to use oral contraceptives for a couple of months until the product is reinstated, observes **Susan Wysocki**, RNC, NP, president and chief executive officer of the Washington, DC-based National Association of Nurse Practitioners in Women's Health. As for condom use, she believes it is counterintuitive that those women who chose Lunelle for the convenience of a monthly injection would move toward the inconvenience of condoms.

Women who have chosen Lunelle for birth control have indicated their preference for highly effective, long-acting contraception, agrees **Andrew Kaunitz**, MD, professor and assistant chairman of the department of obstetrics and gynecology at the University of Florida Health Science Center in Jacksonville.

"I am therefore not sure that recommending that current Lunelle users should use backup barrier

RESOURCES

For more information on the Lunelle recall, providers can contact the Pharmacia medical information service, (800) 323-4204. Patients may call the Pharmacia patient information service, (888) 691-6813. In addition, information is posted on the product's web site, www.lunelle.com.

The company's letters to physicians, pharmacists, and wholesalers are available at the Food and Drug Administration Medwatch site, www.fda.gov/medwatch. Click on "Lunelle Monthly Contraceptive Injection." Instructions for returning recalled product are covered in the Oct. 10, 2002, "Dear Physician" letter from Pharmacia.

For questions regarding the return of recalled product, Pharmacia has instructed providers to contact Indianapolis-based NNC Group. Telephone: (866) 264-9233.

Pharmacia has announced it will supply condoms to providers to give to Lunelle patients free of charge, as well as free pregnancy kits for provider user. To request pregnancy test kits or condoms, providers should call (866) 264-9233.

Talking Points for Lunelle Recall

- Pharmacia, the manufacturer of Lunelle, is voluntarily recalling all prefilled syringes of Lunelle. The company is taking this step because a production error may have resulted in insufficient dosing.
- We are pleased that Pharmacia has taken a responsible, proactive approach to educating women and health care providers about the voluntary recall.
- The possible dosage issue is not dangerous to women. However, to reduce the risk of unintended pregnancy, Lunelle users also need to use a barrier method such as male or female condoms. They also should keep their next monthly appointment to receive counseling on other birth control options.
- Women have several other options for birth control. These include the ring, the patch and the intrauterine device — in addition to the Pill and condoms. Lunelle is expected to eventually return to the market.
- We are working closely with Pharmacia to notify Lunelle users and counsel them about their birth control options.
- Birth control is basic health care. It's not just good pregnancy prevention, it's good medicine.

Source: Adapted from information from Planned Parenthood Federation of America, New York City.

contraception until new supplies of Lunelle become available meets the contraceptive needs of all Lunelle users," comments Kaunitz.

Current Lunelle users affected by this recall also should be given the opportunity, following a negative urine pregnancy test, to immediately begin combination oral contraceptives or injections of depot medroxyprogesterone acetate (DMPA), he says. Inform potential users of combination OCs that scheduled withdrawal bleeding may not occur with the first pack of pills, Kaunitz advises.

Lunelle is expected to eventually return to the market.

"I do not believe that [the recall] is an indication that the method does not work," states says **David Archer**, MD, professor of obstetrics and gynecology and director of the Clinical Research Center at the Eastern Virginia Medical Center in Norfolk. "This is important to convey to the consumer." ■

Bone loss in DMPA users mostly reversible

Add just-published research to your counseling on Depo-Provera (depot medroxyprogesterone acetate or DMPA): Use of the injectable contraceptive is strongly associated with bone density loss; however bone loss appears to be largely reversible once the injections are stopped.[1]

Loss of bone density increases the risk for osteoporosis, a disease in which bones become fragile and are more likely to break. The new study findings indicate that women who used DMPA continuously for three years experienced about the same amount of bone loss as women who are breast-feeding or going through menopause. While the new research shows that the bone loss is largely reversible, providers should discuss the issue during contraceptive counseling with women with risk factors for osteoporosis, according to the Bethesda, MD-based National Institute of Child Health and Human Development (NICHD), which funded the research. Risk factors for osteoporosis include smoking, thin or small frame, prior broken bones, Caucasian or Asian ancestry, family history of osteoporosis, and diet low in calcium.

Since DMPA reduces estrogen levels, the study was proposed in 1993 in response to previous findings associating hypoestrogenic conditions with decreased bone density, as well as preliminary results suggesting that long-term DMPA users had lower bone density than nonusers,[2] states **Steven Kaufman**, MD, MS, a medical

EXECUTIVE SUMMARY

A new study confirms earlier reports that Depo-Provera (depot medroxyprogesterone acetate or DMPA) is strongly associated with bone density loss; however, the research indicates bone loss associated with DMPA use appears to be largely reversible once injections are stopped.

- Women with risk factors for osteoporosis (smoking, thin or small frame, prior broken bones, Caucasian or Asian ancestry, family history of osteoporosis, diet low in calcium) should discuss bone loss with their providers when considering DMPA.
- Research is under way on the impact of DMPA use in adolescents.

officer in the Contraception and Reproductive Health Branch of the NICHD.

"The method's popularity — it was being used at that time by more than 3.5 million women worldwide and had recently been licensed for use in the U.S. — made this an important question of potentially high public health significance," says Kaufman.

Since the Food and Drug Administration approved the method in 1992, use of DMPA, marketed in the U.S. by Pharmacia Corp. in Peapack, NJ, 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.[3]

To get a more in-depth look at the effect of DMPA in adolescents, researchers are continuing to study the effects of DMPA injections and other risk factors on bone density in this population, says **Delia Scholes**, PhD, associate scientific investigator with the Center for Health Studies at the Seattle-based Group Health Cooperative of Puget Sound and lead author of the current study. Investigators are completing 24-month follow-up visits for the adolescent prospective cohort study, she reports.

"The project will be completed early in 2003, and we will have 24-36 months of longitudinal follow-up on a group of 174 teens between the ages of 14 and 18," states Scholes. "Eighty-one of our participants were using DMPA, and 93 were not [our comparison group]."

For the just-published study, Scholes and her colleagues compared hip and spine bone density measurements from 440 women, ages 18-39, who were enrolled in Group Health Cooperative, a Seattle-based health plan. A total of 182 participants were using DMPA, and 258 comparable women were not. Bone density measurements were taken at the start of the study and at six-month intervals over the next three years.

Compared to nonusers, DMPA users had greater decreases in average bone density throughout the follow-up period. Women who used the contraceptive injection continuously experienced a loss of bone density at the hip of 1.12% per year compared with 0.05% per year among nonusers. Women who discontinued DMPA during the course of the study showed marked increases in bone density after discontinuation, although they recovered bone density at the hip more slowly than at the spine. By approximately 30 months after stopping DMPA, bone density values for most DMPA users were similar to those of nonusers.

The only exception occurred among women between the ages of 18 and 21, whose bone density values continued to lag behind those of nonusers even 2½ years after stopping Depo-Provera. The authors of the study attribute this finding to the 18-21 year-old users' large bone density deficits at the beginning of the study.

DMPA, which is given once every three months via injection, is relatively low cost, private, and easy to use, says Scholes. It is a popular choice among women for whom other types of contraception have not worked well, she adds.

The following steps may help women improve or maintain bone health, whether they are using Depo-Provera or not, says Scholes:

- obtain plenty of calcium;
- participate in weight-bearing exercise;
- don't smoke;
- limit consumption of caffeinated beverages and sodas.

Choosing a contraceptive involves a highly individualized set of decisions, observes Scholes. She hopes the findings will alert women and their providers to consider bone density when comparing the plusses and minuses of Depo-Provera.

"Although bone loss is one consideration, an unintended pregnancy has huge consequences in a woman's life as well," notes Scholes.

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. Abma JC, Chandra A, Mosher WD, et al. Fertility, family planning, and women's health New data from the 1995 ational Survey of Family Growth. *Vital Health Stat* 1997; Series 23(19). ■

OCs and weight gain: It's time to banish the myths

When reviewing birth control options with a teen-age female patient, she tells you that she doesn't want to use the Pill because it will make her gain weight. What do you tell her?

Share the following scientific findings from a new long-term study: Oral contraceptive (OC) use during adolescence is not associated with

EXECUTIVE SUMMARY

Four out of 10 women in a 2001 survey said weight gain is a reason to stop taking or avoid use of oral contraceptives (OC). Results of a new long-term study indicate that OC use during adolescence is not associated with weight gain or increased body fat.

- Yasmin from Berlex Laboratories has gained popularity among some women for its reputed ability to prevent weight gain.
- While the pill's progestin, drospirenone, has diuretic properties that influence the regulation of water and sodium levels in the body and may prevent bloating, Yasmin is not being studied for such an indication.

weight gain or increased body fat.[1]

Until now, most of the major research on the effects of pill use have looked at women ages 20 and older, says **Tom Lloyd**, PhD, professor of health evaluation sciences at the Penn State College of Medicine in Hershey, PA, and lead author of the research paper. The study provides new information about the effects of oral contraceptive use on adolescents and young women.

Why are the study results so important?

The No. 1 reason for women of all ages discontinuing OC use is the perception that they are gaining weight or getting fatter, notes Lloyd. **(Four out of 10 women in a 2001 survey said weight gain is a reason to stop taking or avoid the Pill. See "Women and weight gain: OCs are not the culprit," *Contraceptive Technology Update,* May 2002, p. 53.)**

"The operative word is perception," observes Lloyd. "In adult women, other works have shown that they do not gain weight or get fatter,[2-5] but this had not been illustrated and defined in teen women."

Look at the results

The research paper is the latest work drawn from the Penn State Young Women's Health Study, an ongoing observational study begun in 1990 with the enrollment of 112 healthy Caucasian female adolescents. The Penn State researchers continue to follow the natural progression of cardiovascular, reproductive, and bone health in this study population.

The OC study involved 66 females, 39 who used pills for a minimum of six months, were still users at age 21, and had used oral contraceptives for an average of 28 months. The 27 nonusers had never used OCs.

From ages 16-21, researchers took blood samples from the participants once a year to measure cardiolipoprotein levels. From ages 12.5-21, they took body composition measurements with dual energy X-ray absorptiometry. Participants filled out questionnaires with information about physical activity so that researchers could adjust results for body mass index and level of activity.

Results revealed that height, weight, body mass index, body fat, and most cardiovascular disease risk factors were similar for OC users and nonusers. Low-density lipoproteins, total cholesterol, and triglycerides were slightly higher in users than in nonusers, although still within the normal range.

No weight-loss OC

While no OC promotes weight gain, it is important to note that no OC promotes weight loss. Some providers report that women are requesting a particular pill, Yasmin, due to word-of-mouth reports that the OC will help them lose weight, or at least prevent them from gaining weight.

Yasmin, a monophasic birth control pill from Berlex Laboratories of Montville, NJ, is the first OC is the first to use the progestin drospirenone. Each package contains 21 active tablets with 3 mg of drospirenone and 0.030 mg of ethinyl estradiol and seven inert tablets. The pill gained Food and Drug Administration approval in May 2001. **(See "Oral contraceptive with unique progestin receives FDA approval," in *CTU,* July 2001, p. 73, for news of the regulatory approval, and the *Contraceptive Technology Reports,* "Evaluation of a new oral contraceptive progestogen, drospirenone with ethinyl estradiol," inserted in the September 2001 issue, for a clinical review of the drug.)**

In two European studies, Yasmin had a more favorable effect on body weight than a comparable OC, with mean body weight remaining lower in the Yasmin group.[6] In one study, there was a distinct weight decrease in Yasmin users over the whole treatment phase, with a less distinct decrease in the comparative group.[7] In the other study, the mean body weight per cycle in the Yasmin group was slightly below the baseline value throughout the study, with an increase in the comparison group from cycle 5 onward.[8]

The ethinyl estradiol in oral contraceptives can cause fluid retention, leading to weight increase in women sensitive to estrogen.[9] Theoretically,

the mild antimineralocorticoid properties of drospirenone help to counteract this effect and decrease the likelihood of weight gain.

Berlex Laboratories has no plans to market the drug for weight capabilities; the only studies now ongoing revolve around the drug's potential use for treatment of premenstrual symptoms, says **Kim Schillace**, the company's manager of public relations for female health care. **(Read about this research in "Researchers eye Yasmin for treatment of PMS," December 2001 *CTU,* p. 141.)**

"We have never marketed Yasmin as any kind of weight-loss method," says Schillace. "In fact, we are very concerned; we want people to know that it is not a weight-loss method."

References

1. Lloyd T, Lin HM, Matthews AE, et al. Oral contraceptive use by teenage women does not affect body composition. *Obstet Gynecol* 2002; 100:235-259.

2. Rosenberg M. Weight change with oral contraceptive use and during the menstrual cycle: Results of daily measurements. *Contraception* 1998; 58:345-349.

3. Reubinoff BE, Grubstein A, Meirow D, et al. Effects of low-dose estrogen oral contraceptives on weight, body composition, and fat distribution in young women. *Fertil Steril* 1995; 63:516-521.

4. Endrikat J, Müller U, Düsterberg B. A 12-month comparative clinical investigation of two low-dose oral contraceptives containing 20 mg ethinyl estradiol/75 mg gestodene and 30 mg ethinyl estradiol/75 mg gestodene, with respect to efficacy, cycle control, and tolerance. *Contraception* 1997; 55:131-137.

5. Redmond G, Godwin AJ, Olson W, et al. Use of placebo controls in an oral contraceptive trial: Methodological issues and adverse event incidence. *Contraception* 1999; 60:81-85.

6. Foidart JM. The contraceptive profile of a new oral contraceptive with antimineralocorticoid and antiandrogenic effects. *Eur J Contracept Reprod Health Care* 2000; 5 Suppl 3:25-33.

7. Huber J, Foidart JM, Wuttke W, et al. Efficacy and tolerability of a monophasic oral contraceptive containing ethinyl estradiol and drospirenone. *Eur J Contracept Reprod Health Care* 2000; 5:25-34.

8. Foidart JM, Wuttke W, Bouw GM, et al. A comparative investigation of contraceptive reliability, cycle control, and tolerance of two monophasic oral contraceptives containing either drospirenone or desogestrel. *Eur J Contracept Reprod Health Care* 2000; 5:124-134.

9. Krattenmacher R. Drospirenone: Pharmacology and pharmacokinetics of a unique progestogen. *Contraception* 2000; 62:29-38. ■

Condom errors common among college-age men

In discussing condom use, your college-age male patient tells you that he uses protection on a regular basis. But is he using condoms correctly?

Don't be surprised if he is not: Results from a small sample of sexually active heterosexual college men show that condom use errors are frequent.[1] While the researchers note that the findings cannot be generalized to a broader population, they say the results point to a clear need for better condom education and instruction.

"Assuming that the errors and problems are as common as we found here, I think the following step is to create an awareness among health professionals and health educators that there is a strong need to not just promote condom use, but promote their correct use," says the study's lead author, **Richard Crosby**, PhD, assistant professor of behavioral sciences and health education at the Rollins School of Public Health at Emory University in Atlanta.

The study, conducted from November 2000 through January 2001, explored condom use errors and problems among college men at Indiana University in Bloomington. Of 362 men, 158 met the study inclusion criteria, which included reported use of a condom for sex at least once in the past three months.

Here are some of the basic condom errors reported by the college age men:

- not checking the condom for visible damage (74%);
- not checking the expiration date (61%);
- not discussing condom use with their partner before sex (60%).

In addition, various technical errors were found,

EXECUTIVE SUMMARY

Many men in college do not use condoms correctly, according to results of a recent study. Such findings point to the need for better condom education and instruction, say the investigators.

- Common errors noted in the study included not checking the condom for visible damage, failure to check the expiration date, and not discussing condom use with the partner before sex.
- Many of the men reported putting on the condom after starting sex, not leaving a space at the tip of the condom, placing the condom incorrectly on the penis and then having to flip it over, and taking off the condom before sex was over.

including putting on the condom after starting sex (43%), not leaving a space at the tip of the condom (40%), placing the condom incorrectly on the penis and then having to flip it over (30%), and taking off the condom before sex was over (15%).

About 30% of study participants reported condom breakage, and 13% reported that the condom slipped off during sex. Such errors are not surprising since those who reported slippage or breakage also had significantly higher error scores, note researchers.

How can you help?

So how can you become a better condom coach? Crosby says that in his experience of working as a health educator, he has found that young men, as well as young women, are very receptive to open and honest discussions about sex. The key to such discussion is to keep it interactive and nonjudgmental, he stresses.

When discussing how to use a condom, keep in mind its context in use, advises **Jane Bogart**, MA, CHES, director of the Center for Health Promotion at New York University Health Center in New York City. Counsel men and women to practice putting the condom on in the dark to prepare them for actual use situations, she notes. Also, advise masturbating with a condom on, so that keeping an erection doesn't become an issue, she says.

Lubrication is a problem for many condom users, says Bogart. According to *A Pocket Guide to Managing Contraception*, plain condoms may decrease lubrication and provide less stimulation for the woman. If patients use latex condoms, be sure to advise on the need to use water-based, rather than petroleum-based, lubricants.

If your facility provides free or reduced-price condoms, check to see if a variety of styles are available. Advise clients that condoms come in a number of sizes and colors, so they should look for ones that are comfortable in fit and style, says Bogart.

Check the package

Before a condom is used, be sure to check its date, says Bogart. According to *A Pocket Guide to Managing Contraception,* the date on a condom may be its expiration date (marked as EXP) or a date of production.[2] If it is an expiration date, the condom must not be used beyond the stated date. If it is a date of production, the condom may be used for several years past the date: three years for spermicidal condoms, and five years for nonspermicidal latex condoms.[2]

Bogart says she'd like to see condom manufacturers add two features to condom packaging: instructions for use on the individual packages, and some form of identification to mark the right and wrong side of a condom. While some may argue that such instructions may be disregarded in the heat of the moment, she says some users may benefit from the reinforcing information.

"Sometimes when you open a condom, it is hard to tell which way is the right way and the wrong way on," she notes. "Even if it is something as simple as putting an arrow on the up side, or a dot on the right side, something you could physically feel or something that tells you the right side, it would be helpful."

References

1. Crosby RA, Sanders SA, Yarber WL, et al. Condom use errors and problems among college men. *Sex Transm Dis* 2002; 29:552-557.

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

Pill options expand with new, generic OCs

As 2002 comes to a close, get ready to add a new lower-dose version of a popular oral contraceptive (OC) to your list of pills, and look to the upcoming 2003 introduction of a generic form of a long-time Pill favorite.

You should see Ortho Tri-Cyclen Lo from Raritan, NJ-based Ortho-McNeil Pharmaceutical now on retail market shelves, says **Kellie McLaughlin**, director of global pharmaceutical communications for New Brunswick, NJ-based Johnson & Johnson, Ortho-McNeil's parent company. The pill, approved by the Food and Drug Administration (FDA) in August 2002, is a lower-dose form of Ortho Tri-Cyclen, the No. 1 prescribed birth control pill. **(Read more about the drug in "Ortho Tri-Cyclen first low-dose OC to be indicated for noncontraceptive use," *Contraceptive Technology Update,* March 1997, p. 25.)**

The new formulation provides a daily 25 mcg dose of estrogen for 21 days and three different doses of norgestimate (180 mcg daily / days 1-7; 215 mcg daily / days 8-14; 250 mcg daily / days 15-21).

EXECUTIVE SUMMARY

Family planners have seen expanded choices in oral contraceptives (OCs) in 2002; Ortho Tri-Cyclen Lo from Ortho-McNeil Pharmaceutical is the latest addition.

- The pill, approved by the Food and Drug Administration in August 2002, is a lower-dose form of the firm's popular Ortho Tri-Cyclen.
- Barr Laboratories has introduced six generic OC products in 2002 and will introduce its generic version of Ortho-McNeil's Ortho 7/7/7 in January 2003.

The last seven days contain no active ingredients.

Women are looking for a lower-dose pill, but one with excellent cycle control, says McLaughlin. Ortho Tri-Cyclen Lo offers such an option, she states.

In a multicenter study, researchers compared the contraceptive efficacy, cycle control, and safety of Ortho Tri-Cyclen Lo with another pill, Loestrin Fe 1/20 Loestrin (Pfizer, New York City).[1] Contraceptive efficacy was comparable for the two pills; the overall and method failure probabilities of pregnancy through 13 cycles were 1.9% and 1.5%, respectively, with Ortho Tri-Cyclen Lo, and 2.6% and 2.4%, respectively, with Loestrin Fe 1/20. Breakthrough bleeding and spotting were reported by a significantly lower percentage of participants in the Ortho Tri-Cyclen Lo group compared with the Loestrin Fe 1/20 group. Compliance and safety data were similar for the two regimens.

Look at generic options

The past year has seen a number of generic OC choices added to the contraceptive options list. Barr Laboratories of Pomona, NY, a specialty pharmaceutical company engaged in the development, manufacture and marketing of generic and proprietary pharmaceuticals, has introduced six generic products. Barr is set to debut its generic version of Ortho-McNeil's Ortho 7/7/7 in January 2003, says **Carol Cox**, company spokeswoman. She says three more generic pills also may be introduced in the new year.

Following are the company's 2002 additions, listed with their therapeutic equivalent products and manufacturers:

- Kariva (Mircette, Organon, West Orange, NJ);
- Lessina (Levlite, Berlex Laboratories, Montville, NJ);
- Portia (Nordette, Monarch Pharmaceuticals, Bristol, TN; Levlen, Berlex Laboratories; Levora, Watson Pharmaceuticals, Corona, CA);
- Enpresse (Triphasil, Wyeth-Ayerst, Philadelphia; Trivora, Watson; Tri-Levlen, Berlex Laboratories);
- Cryselle (Lo-Ovral, Wyeth-Ayerst; Low Ogestrel, Watson);
- Sprintec (Ortho-Cyclen, Ortho-McNeil Pharmaceutical).

The company previously introduced Apri, the therapeutic equivalent of Desogen (Organon) and Ortho-Cept (Ortho-McNeil) in 1999, and three products in 2001: Aviane (Alesse, Wyeth-Ayerst); Nortrel 1/25 (Ortho 1/35, Ortho-McNeil); and Nortrel 0.5/35 (Modicon-28, Ortho-McNeil).

The company plans to launch its generic version of the Ortho-Novum 7/7/7 pill in January 2003 operating under a nonexclusive license granted by Ortho-McNeil Pharmaceutical. The Barr Laboratories pill will be marketed under the name Nortrel 7/7/7.

Under the terms of an agreement reached in October 2001, Ortho-McNeil granted Barr a nonexclusive license effective Jan. 1, 2003, nine months before the patents protecting the product expire in September 2003. As part of the settlement, Barr acknowledged its infringement of, and the validity and enforceability of, the patent claims at issue in the case.

Is a four-periods-per-year pill on the horizon? The FDA accepted Barr Laboratories' New Drug Application for its proprietary pill, Seasonale, in August 2002. The company also is researching a similar extended-period pill, dubbed DP3, in a current Phase III trial, says Cox.

Barr Laboratories, in agreement with the Medical College of Hampton Roads, Eastern Virginia Medical School in Norfolk, are developing the pill. **(See article on Seasonale, "4-periods-per-year pill eyed for use in U.S. market," in *CTU*, May 1999, p. 51, and see "4-periods-per-year OC: Comparable to pill," August 2002 *CTU*, p. 87.)**

The Seasonale regimen is designed to reduce the number of withdrawal bleeds from 13 to four per year. Under its regimen, women take the OC for up to 84 consecutive days, followed by seven days of placebo. This pill-taking regimen contrasts with the majority of oral contraceptives, which are based on a regimen of 21 treatment days, followed by seven days of placebo.

In a multicenter trial, two versions of the Seasonale extended oral contraceptive therapy prevented pregnancy comparable to study drugs.[2]

The adverse profile of the Seasonale drug was similar to that of other oral contraceptives, study findings indicate.[2]

References

1. Hampton RM, Short M, Bieber E, et al. Comparison of a novel norgestimate/ethinyl estradiol oral contraceptive (Ortho Tri-Cyclen Lo) with the oral contraceptive Loestrin Fe 1/20. *Contraception* 2001; 63:289-295.

2. Anderson FD. Results from a multicenter, open-label, Phase III study of Seasonale, a novel 91-day extended oral contraceptive (OC). Presented at the 50th Annual Clinical Meeting of the American College of Obstetricians and Gynecologists. Los Angeles; May 2002. ■

Administration defunds U.N. Population Fund

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

This summer, the Bush administration officially announced it was cutting off all U.S. support for the United Nations Population Fund (UNFPA), the largest multilateral population assistance agency in the world. This decision was a major victory for anti-family planning members of Congress, who have long alleged that UNFPA's small program in China indirectly supports coercive practices sanctioned by the Chinese government as a result of its "one-child-per-family" policy. And it represents only the latest twist in a long-standing political saga that at times has placed the United States — the world's largest population assistance donor country — at odds with UNFPA.

Ironically, more than 30 years ago, the United States was a driving force behind the establishment of UNFPA, whose mandate is to "assist developing countries, at their request, in dealing with their population problems in the forms and means best suited to the individual countries' needs." The agency provides assistance in approximately 140 countries and supports the delivery of maternal and child health care and family planning services.

A major supplier of contraceptives around the world, UNFPA also devotes substantial resources toward preventing the spread of HIV/AIDS and other sexually transmitted diseases, addressing the unique reproductive health needs of young people, and enhancing the status of women. The agency provides no support for abortion services.

In the 1980s, opponents of population assistance latched onto UNFPA's small program in China as an excuse to defund the program. In 1985, they passed legislation, known as the "Kemp-Kasten," amendment that prohibits U.S. funding to any agency when there is a presidential finding that the agency directly or indirectly supports coercive abortion or sterilization. While the Reagan administration acknowledged that UNFPA's own program did not support abortion or coercion, it declared that the agency's very presence in China indirectly supported the country's coercive one-child-per-family policy. Deeming the agency guilty by association, President Reagan cut off all U.S. funding to UNFPA, thus punishing not only the China program but also the other countries where UNFPA worked.

U.S. funding was not restored until President Clinton took office in 1993 and determined that UNFPA did not indirectly or directly support coercion. Nonetheless, Congress ensured that strings remained attached: The U.S. contribution to UNFPA would remain in a separate account, none of which could be used in China. Moreover, for every dollar of non-U.S. funding spent by UNFPA in China, the U.S. contribution to the agency would be reduced by one dollar. This punishment applied to no other agency working in China and receiving U.S. support.

Suggesting that it looked at favorably on UNFPA, the Bush administration's fiscal year 2002 budget recommended $25 million for UNFPA. In support of this request, Secretary of State Colin Powell testified in Congress that UNFPA "does invaluable work through its programs in maternal and child health care, voluntary family planning, screening for reproductive tract cancers, breast-feeding promotion, and HIV / AIDS prevention." Congress would go beyond the president's request by setting funding for the program at $34 million.

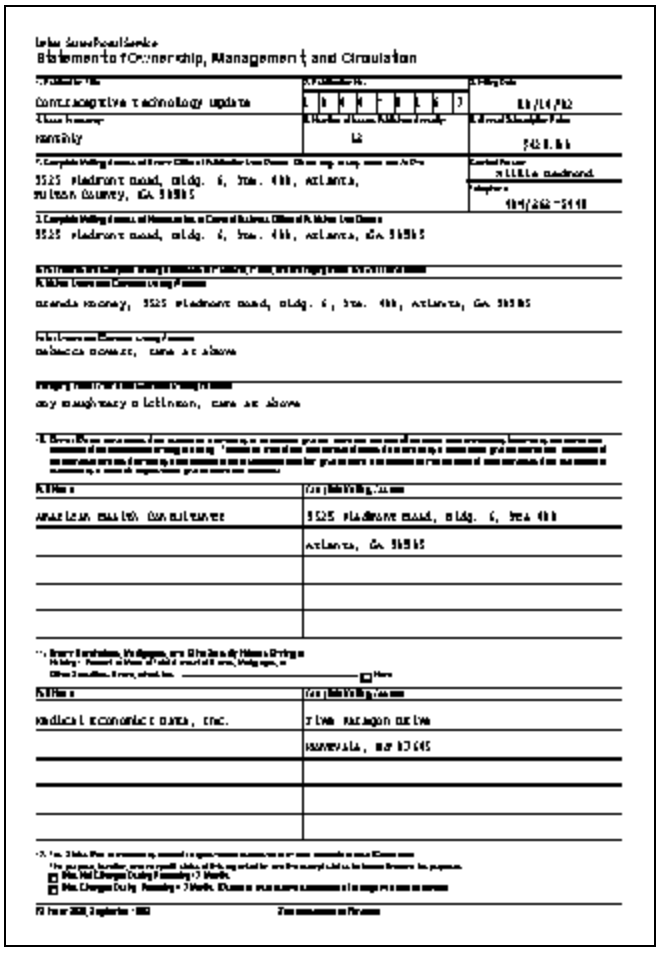
Conservative members of Congress, however, continued to insist that the Bush administration re-institute the funding ban, which prompted the White House to send a three-member fact-finding team to China to assess the situation. The team's report, issued in May, found no evidence that UNFPA is in violation of the Kemp-Kasten provision and recommended continued funding of the agency. Indeed, the program's supporters have long argued that it is a force for good in China and it serves as a model for providing family planning services on a voluntary basis.

Nonetheless, the administration succumbed to right-wing pressure when it notified Congress that it would withhold the $34 million from UNFPA.

The "evidence" cited as a violation of Kemp-Kasten is $200,000 (in non-U.S. funds) provided by UNFPA to the Chinese State Family Planning Commission, which fines Chinese couples that exceed their birth quotas. Thus, wrote the administration, the agency's funding "allows the Chinese government to implement more effectively its program of coercive abortion," even though, as the administration itself notes, "arguments can be made that UNPFA is undertaking good-faith educational and other efforts to improve the lives of the people of [China] and assist them in family planning decisions."

Sen. **Patrick Leahy** (D-VT), chairman of the Senate subcommittee responsible for funding UNFPA, deems the administration's position "an embarrassment and a travesty."

"It is ludicrous that because there is coercion in China — coercion we all know about and deplore — the administration is barring all U.S. support for use anywhere by the world's largest family planning organization . . . . UNFPA's mission is to promote alternatives to coercion and abortion and to prevent the spread of AIDS, and that is exactly what UNFPA should be doing [in China]," said Leahy. "We do not send foreign aid to countries that are doing everything right — we send it to try to make things better. That is also UNFPA's mission." ■



Statement of Ownership, Management and Circulation

Contraceptive technology update

monthly

12

$48.00

3525 Piedmont Road, Bldg. 6, Ste. 400, Atlanta, Fulton County, GA 30305

Jill Ellis Piedmont

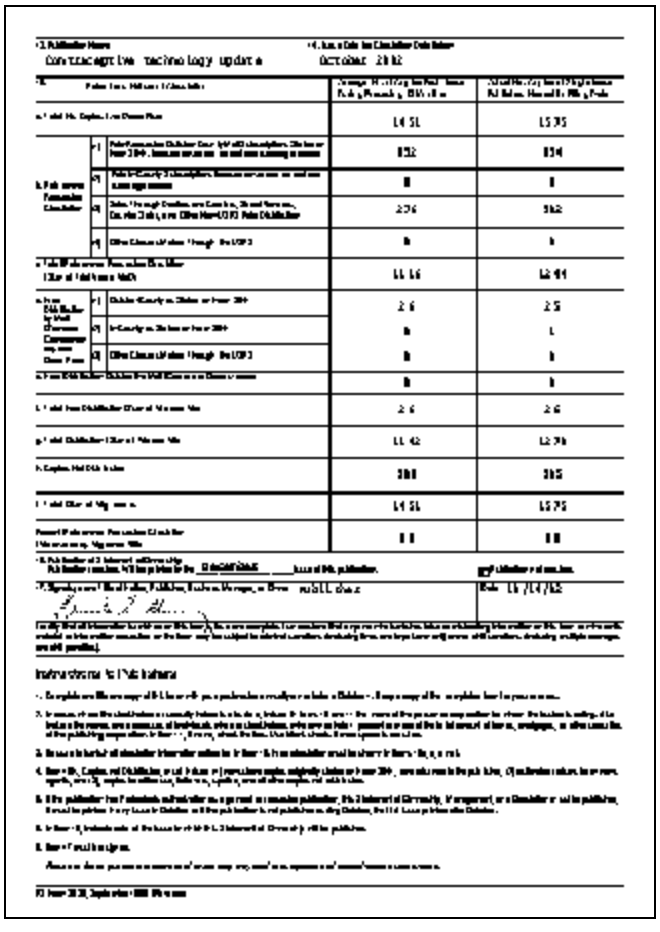
404/262-5410

3525 Piedmont Road, Bldg. 6, Ste. 400, Atlanta, GA 30305

Same as above

Same as above

American Health Consultants	3525 Piedmont Road, Bldg. 6, Ste 400 Atlanta, GA 30305
Medical Economics Data, Inc.	7 Live Paragon Drive Harrevala, NH 03045



Contraceptive technology update

October 2002

a. Total No. Copies (Net Press Run)		14 51	15 35
b. Paid and/or Requested Circulation	(1) Paid/Requested Outside-County Mail Subscriptions Stated on Form 3541. (Include advertiser's proof copies and exchange copies)	852	834
	(2) Paid In-County Subscriptions Stated on Form 3541 (Include advertiser's proof copies and exchange copies)	0	0
	(3) Sales Through Dealers and Carriers, Street Vendors, Counter Sales, and Other Paid Distribution Outside USPS	276	362
	(4) Other Classes Mailed Through the USPS	0	0
c. Total Paid and/or Requested Circulation (Sum of 15b (1), (2), (3), and (4))		11 16	12 01
d. Free Distribution by Mail (Samples, complimentary, and other free)	(1) Outside-County as Stated on Form 3541	2 6	2 5
	(2) In-County as Stated on Form 3541	0	0
	(3) Other Classes Mailed Through the USPS	0	0
e. Free Distribution Outside the Mail (Carriers or other means)		0	0
f. Total Free Distribution (Sum of 15d and 15e)		2 6	2 6
g. Total Distribution (Sum of 15c and 15f)		11 42	12 76
h. Copies Not Distributed		309	359
i. Total (Sum of 15g and h)		14 51	15 35
Percent Paid and/or Requested Circulation (15c / 15g x 100)		0 0	0 0

16. Publication of Statement of Ownership — Publication required. Will be printed in the 12/14/02 issue of this publication.

17. Signature and Title of Editor, Publisher, Business Manager, or Owner — Jill Ellis — Date 10/14/02

I certify that all information furnished on this form is true and complete. I understand that anyone who furnishes false or misleading information on this form or who omits material or information requested on the form may be subject to criminal sanctions (including fines and imprisonment) and/or civil sanctions (including multiple damages and civil penalties).

Instructions to Publishers

CE/CME Questions

To obtain CE or CME credit for this semester, please answer the questions published in the July-December 2002 issues, fill out the enclosed Scantron and CE/CME questionnaire, and submit them in the enclosed envelope. Please note: For the July 2002 issue, the questions should have been numbered 1-4.

For details 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: customer service@ahcpub.com. Web: www.ahcpub.com.

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

- State the reason for the October 2002 recall of Lunelle prefilled syringes.
- Identify the risk factors for osteoporosis.
- Name the progestin in the oral contraceptive Yasmin.
- State the proper type of lubrication for use with latex condoms.

21. Why did Pharmacia Corp. of Peapack, NJ, issue the Oct. 10, 2002, recall on Lunelle contraceptive injection prefilled syringes?

A. A lack of assurance of full potency and possible risk of contraceptive failure.
B. The syringe mechanism was found to be defective.
C. Some syringes were misfilled with a toxic substance.
D. Some syringes had been contaminated during the manufacturing process.

22. Which of the following is NOT a risk factor for osteoporosis?

A. Smoking
B. Thin or small frame
C. Diet low in calcium
D. African-American ancestry

23. What is the progestin contained in the oral contraceptive Yasmin?

A. Desogestrel
B. Drospirenone
C. Norgestimate
D. Norethindrone

24. What is the proper type of lubrication for use with latex condoms?

A. Either oil- or water-based lubrication
B. Only water-based lubrication
C. Only oil-based lubrication
D. Only silicone-based lubrication

This continuing education offering is sponsored by American Health Consultants® (AHC), 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 an approved provider by the California Board of Registered Nursing for approximately 18 contact hours (provider #CEP10864).

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. Each physician should claim only those hours of credit that he/she actually spent in the educational activity.

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

Contraceptive Technology Update *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.*

AMERICAN HEALTH CONSULTANTS

2002 SALARY SURVEY RESULTS

CONTRACEPTIVE TECHNOLOGY UPDATE®

A Monthly Newsletter for Health Professionals

Family planning providers hold the line on salaries in 2002

Slight increases reported, especially for nurse practitioners

Take a look at your paycheck; chances are if you are in the family planning field, it shows a slight increase from 2001.

The results reflect a continued trend of increases, particularly for nurse practitioners (NPs), who comprised the majority of survey responses. **(See "What is your salary level?" below.)** The survey was mailed in July 2002 to 1,236 readers and had a response of 131, for a response rate of 10.6%.

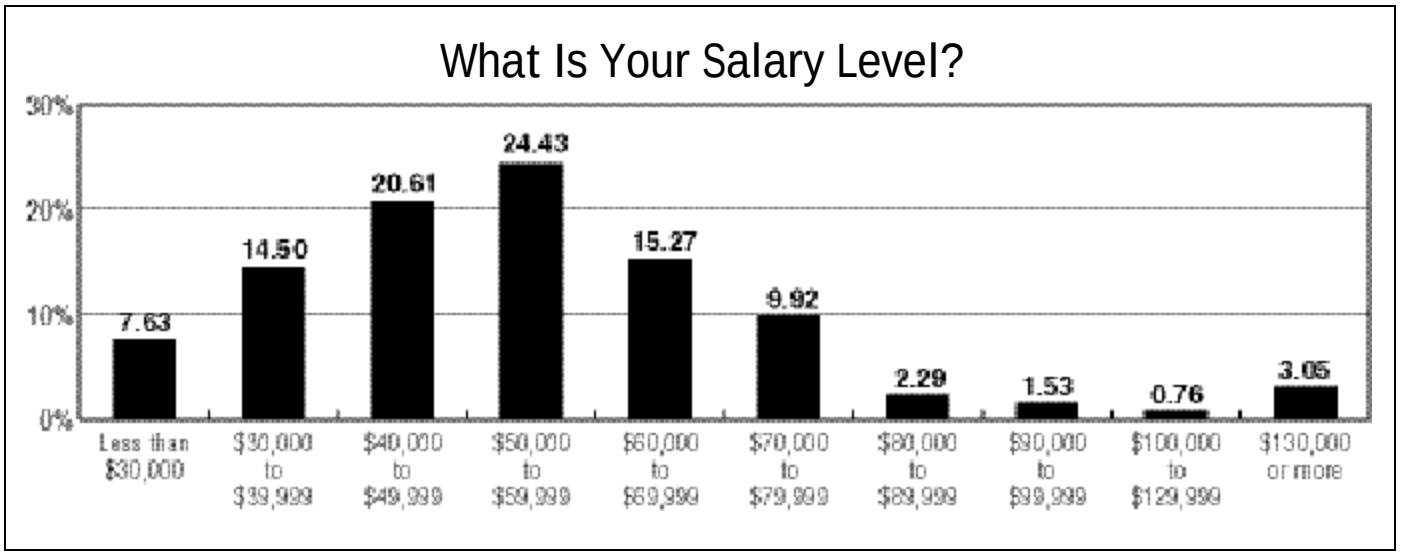
Average salary for NPs moved up to $55,710, rising from $53,043 in 2001. Median salary also increased: The 2002 figure was $55,313, compared to $48,333 in 2001.

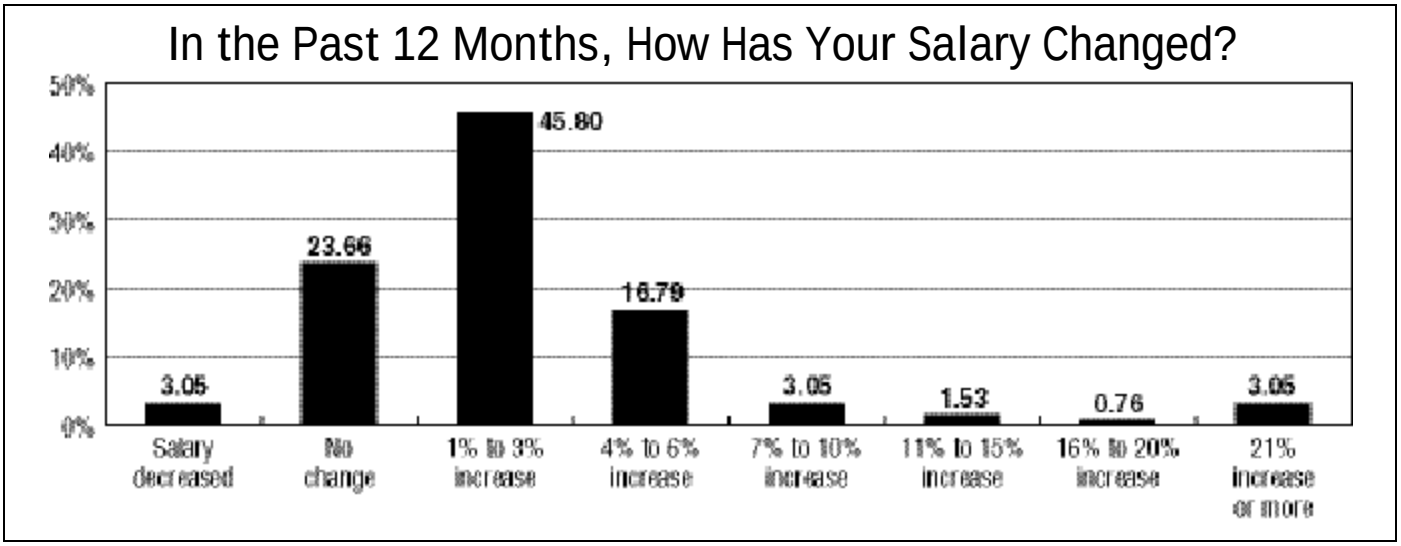
"My initial impression is that salaries appear to be going up, and I think that is terrific," observes **Susan Wysocki**, RNC, NP, president and chief executive officer of the Washington, DC-based National Association of Nurse Practitioners in Women's Health. "It is an improvement, but it is way below what we should be seeing for some of those people who are in the $30,000-$40,000 category."

While average salary for administrators/coordinators dipped slightly from 2001's $53,571 to $49,230 in 2002, their median salary rose from $47,857 in 2001 to $52,778 in 2002. The group represented 31.46% of 2002's total responses.

Look at national scene

While other national surveys of physicians show pay increases in the past year, industry





analysts note that physicians are having to work smarter, harder, and longer to maintain compensation levels.[1] Obstetricians/gynecologists (OB/GYN), who are among the hardest-hit by skyrocketing medical malpractice premiums, saw their salaries dip in six of the nine surveys monitored by *Modern Healthcare*, a national health care magazine.[2] Decreases as high as 8% have been reported; industry analysts point to a possible willingness by these specialists to accept lower salaries if their employers contribute to insurance costs.[2]

Malpractice issues are major ones for OB/GYNs: the Washington, DC-based American College of Obstetricians and Gynecologists (ACOG) issued a national "Red Alert" in May 2002 on the condition of obstetrical care, warning that without federal and state reforms, chronic problems in the nation's medical liability system could severely jeopardize the availability of physicians to deliver babies in the United States.

Salaries continue to trend upward for physician assistants, according to information from the American Academy of Physician Assistants in Alexandria, VA. Results of its 2002 salary survey show a median salary of $69,567; the median salary reported in 2001 was $65,177.

RN salaries going up

The demand for RNs in the hospital setting is impacting salary levels for such health professionals; according to the federal Bureau of Labor Statistics, median annual earnings of registered nurses were $44,840 in 2000, up from $40,690 in 1998.[3] The middle 50% earned between $37,870 and $54,000. The lowest 10% earned less than $31,890, and the highest 10% earned more than $64,360.

The United States is in the midst of a nursing shortage that is projected to intensify as baby boomers age and the need for health care grows, according to the Washington, DC-based American Association of Colleges of Nursing (AACN). While a 2001 AACN survey shows enrollment in generic (entry-level) baccalaureate programs in nursing increasing by 3.7% nationwide over 2000, enrollments in all programs were down 17% or 21,126 students from 1995. On average over the last five years, the number of enrollees and graduates from generic programs declined by 1,567 and 1,420 each year, respectively, according to the AACN.

What does it mean for you?

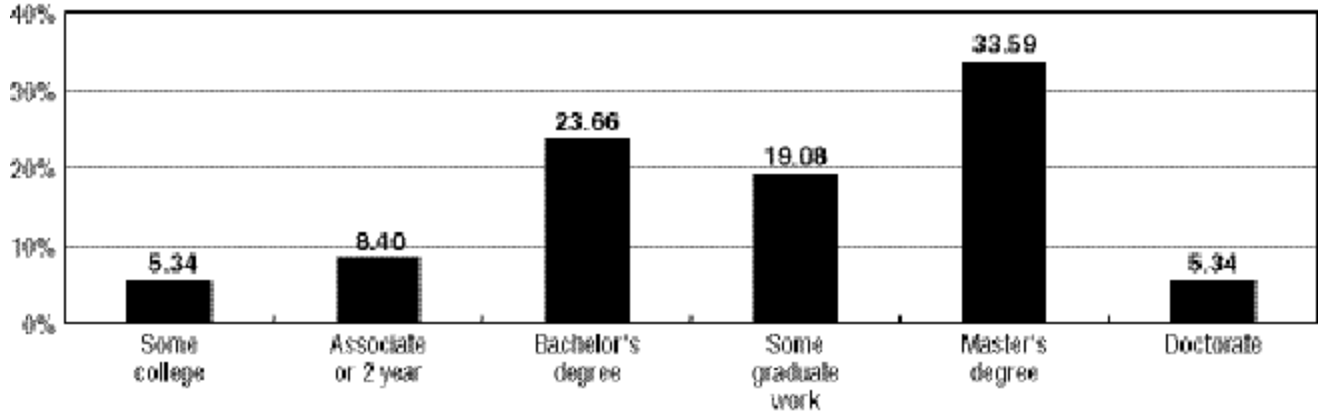
Challenges for one group of health professionals may translate into advantages for another. Pay may need to be increased for nurse practitioners in family planning facilities in some parts of the country if employers want to retain staff against the rising pay being offered to hospital-based RNs, notes Wysocki.

Marion McCartney, CNM, director of professional services for the Washington, DC-based American College of Nurse-Midwives (ACNM), says, "Things look promising, and with this physician malpractice crunch, I think nurse midwives, at least in some areas, will find even more places that are looking for someone to work in to supply the needs of the community."

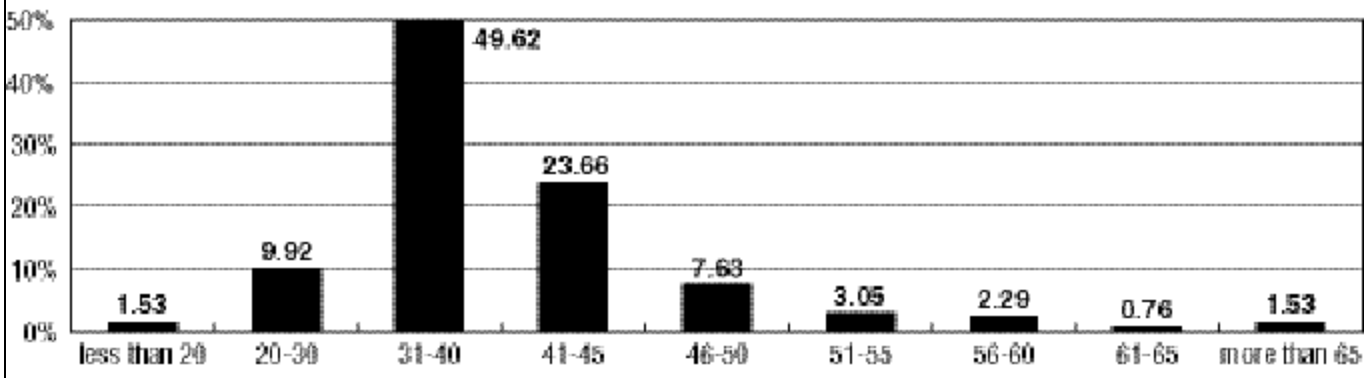
The shortage in RNs has not yet translated into the fields of advanced practice nurses, but problems

(Continued on page 4)

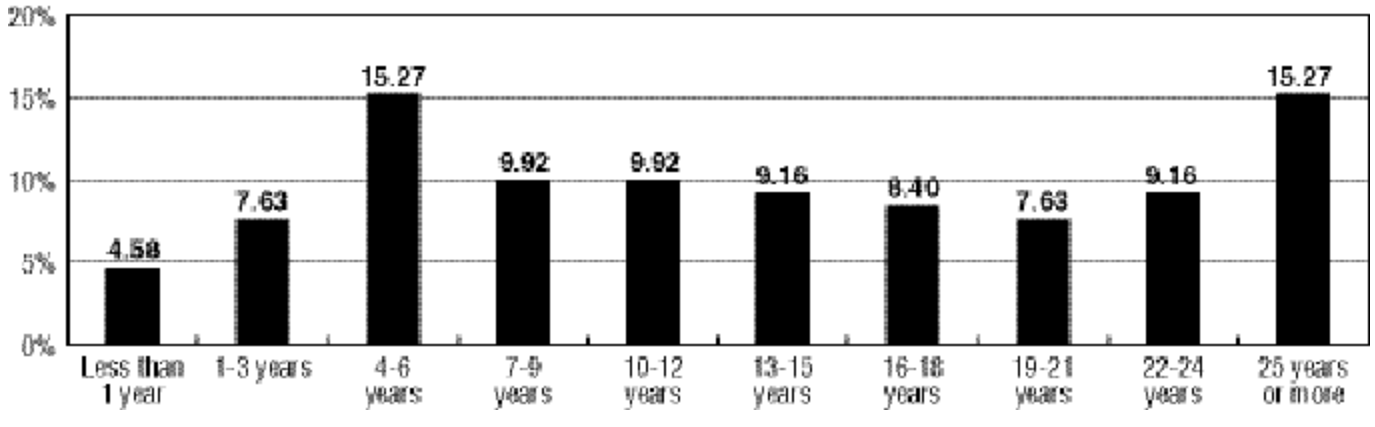
What is Your Highest Academic Degree?

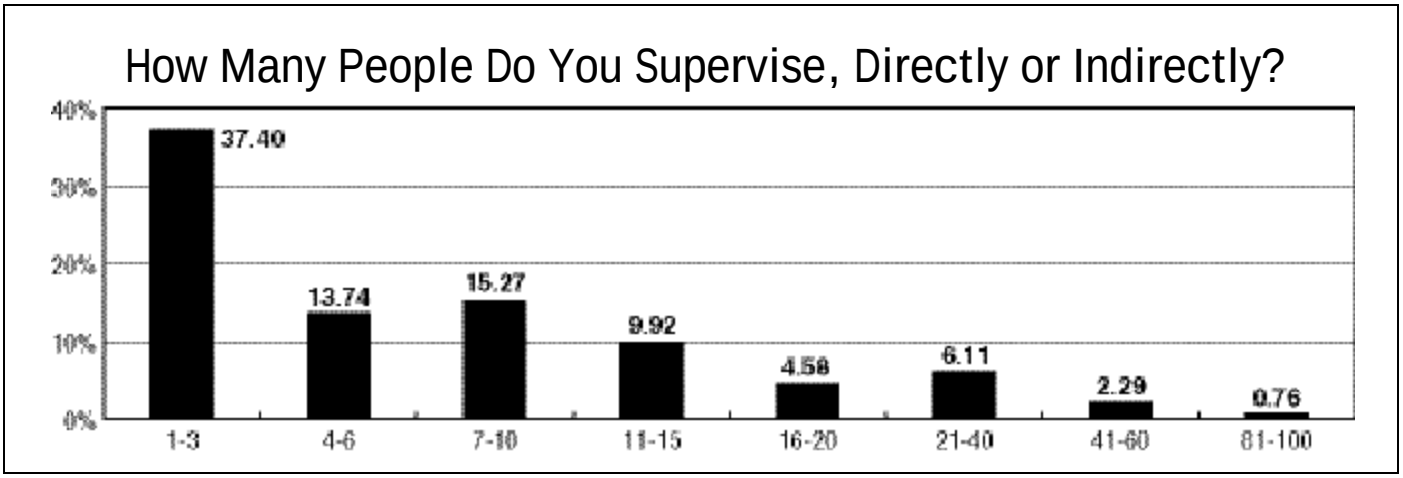


How Many Hours a Week Do You Work?



How Long Have You Worked in Positions with the Same or Similar Responsibilities as Your Current Position?





may be looming down the road, forecast Wysocki and McCartney.

NPs to be hit by shortage

Wysocki predicts that the nursing shortage will catch up with nurse practitioners in the next five or 10 years. The dearth of RNs in the pipeline will start to show then in terms of shortages among NPs, she believes.

"We don't see the graduate nurses for at least five years, until they apply to ACNM," says McCartney. "So we don't see a shortage right away, but we will probably see it in about five years, unless the situation is turned around."

A shortage could cause problems, since more patients are coming to rely on the value of advanced practice providers, notes McCartney.

"It is much more common for people to know someone or to have used a nurse-midwife themselves," says McCartney. "More and more people are aware that nurse-midwives work in hospitals, although still for a lot of people, that is out of their grasp."

Make your move

How can you make circumstances and professional expertise increase the numbers on your paycheck? The No. 1 recommendation is to ask for more money, because no one is going to give it to you until you do, says Wysocki.

"Ask how you might be able to participate in ways to increase your salary," notes Wysocki. "I think that it is important to recognize that salary and what is brought out into a clinical practice are related."

If you are an advanced practice provider, consider using the following questions, suggested by health care employment expert **Carolyn Buppert**, JD, of Annapolis, MD:

- What is the practice's collections rate?
- What is the average lag time between submission of claim and payment?
- Who negotiates the fee schedules with commercial insurers? Can I see the fee schedules?
- How many patients do you expect me to see per day?
- What is the average charge billed per visit by the physicians in the practice?
- What profit do you expect me to generate for the practice?
- What profit do you expect employee physicians to generate for the practice?[4]

Look at your productivity figures, and also analyze what goes into the formula for figuring your salary, suggests Wysocki. If your potential increase is based on your categorization, perhaps negotiate for a different and more lucrative, one, she states. Look at your options and the current job market, because opportunities do exist.

"There are a lot of jobs out there for nurse-midwives, but not always in the communities they want to work," says McCartney. "As many times as I hear of practices that are closing for nurse-midwives, I seem to get an equal amount of calls into this office with requests to fill positions."

References

1. Medical Group Management Association. *Physicians Saw Slight Increase in Compensation in 2001, but Gains to Disappear in 2002.* Press release. Denver; Aug. 5, 2002.

2. Romano M. Another good year. *Modern Healthcare* 2002; 32:29-31.

3. US Department of Labor. *Bureau of Labor Statistics. Occupational Outlook Handbook.* 2001-02 ed.

4. Buppert C. What's in a number? *Green Sheet* 2001; 3. Accessed at www.medscape.com/viewarticle/407069. ■

Questions and Answers about the Voluntary Recall of Lunelle

1. **Why is Lunelle being recalled?**
   In a small number of prefilled syringes, the amount of medication may be insufficient to protect against pregnancy. Even though this number is small, the manufacturer wants to make sure that all Lunelle users are protected against unintended pregnancy, so it has voluntarily recalled all current supplies.

2. **What is the risk to women who have recently received their monthly injection of Lunelle?**
   The risk for a very small number of users is unintended pregnancy. There are no other medical risks. These doses of Lunelle are not harmful. There was a production error, and it is possible that the amount of hormones may not be enough to protect against unintended pregnancy.

3. **What does a woman who is using Lunelle advised to do now?**
   Any woman who is currently using Lunelle is advised to immediately begin using a barrier method of birth control, in order to protect against unintended pregnancy. She can use latex condoms or female condoms. Condoms are over-the-counter and easy to get — they are available in most drug stores, grocery stores, and health centers.

4. **What would happen if a Lunelle user uses another hormonal method?**
   Another hormonal method can be used, but just as when starting any new hormonal method, there may be uncomfortable side effects, including nausea, vomiting, breast tenderness, headache, and breakthrough bleeding.

5. **Do Lunelle users have any other contraceptive options?**
   For the short term, a woman who is using Lunelle needs to use a barrier method: latex or female condoms. She should keep her next appointment with her clinician (when she would normally receive the next injection), and then discuss her long-term birth control options if she chooses to continue having vaginal intercourse while avoiding pregnancy. The methods she may want to consider include progestin-only injections (Depo-Provera), the Pill, the Ring, the Patch, the IUD, diaphragms or cervical caps, and fertility awareness methods, as well as latex or female condoms.

6. **Should a Lunelle user have a pregnancy test?**
   Even though there is only a very small chance that a Lunelle user may have become pregnant, a pregnancy test will be performed at her next scheduled appointment. Women who already had planned to discontinue Lunelle and do not have a visit scheduled in 3-4 weeks should make an appointment for a pregnancy test.

7. **Will Lunelle be available in the future?**
   The manufacturer, Lunelle users, and Planned Parenthood have confidence in this method of contraception, and they are looking forward to having it back on the market in a matter of months.

Lunelle Recall Documentation Form

Client Name _____ MR# _____

Date _____ Date of last intercourse _____ Date of last Lunelle injection _____

Check all that apply

- ☐ Client has been informed of the Lunelle recall and for the recommendation of immediate use of an over-the-counter barrier method with each act of intercourse
- ☐ Informed during in-office visit
- ☐ Informed via letter (see correspondence section of chart)
- ☐ Informed via phone
- ☐ Telephone attempt to inform was made
- ☐ Upon attempt to phone client, there was no answer
- ☐ Left message to have client call us
- ☐ Client verbalized understanding
- ☐ Pregnancy test was performed; results_____ Date performed_____
- ☐ ECP offered as protection if last date of intercourse was within 120 hours
- ☐ Client has chosen the following new contraceptive method _____

Comments:

_____

_____

_____

_____

_____

_____

Staff Signature/Title

Source: Planned Parenthood of Southeast Michigan, Detroit.

Contraceptive Technology Update
CE/CME Evaluation

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

In which program do you participate? ____ CE ____ CME

For your reference, here is the stated overall purpose of *Contraceptive Technology Update:* To provide current, practical information on contraceptive development and use, as well as other clinical, social, and legal issues encountered in the field of family planning and reproductive health.

Did *CTU* enable you to meet the following objectives?

yes __ no __1. Are you able to identify clinical, legal, or scientific issues related to development and provision of contraceptive technology or other reproductive services?

yes __ no __2. Are you able to describe how those issues affect service delivery and note the benefits or problems created in patient care in the participant's practice area?

yes __ no __3. Are you able to cite practical solutions to problems and integrate information into daily practices, according to advice from nationally recognized family planning experts?

yes ___ no __4. Were these objectives consistent with the overall goal of the newsletter?

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

yes __ no __6. Were the test questions clear and appropriate?

yes __ no __7. Were you satisfied with the customer service for the CE/CME program?

yes __ no __8. Do you have any general comments about the effectiveness of this CE/CME program? If so, please explain: _____

_____

_____

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 an approved provider by the California Board of Registered Nursing for approximately 18 contact hours per year (provider #CEP10864).

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 18 credit hours in Category 1 of the Physicians' Recognition Award of the American Medical Association. This activity was planned and produced in accordance with ACCME Essentials.

CONTRACEPTIVE TECHNOLOGY UPDATE®
A Monthly Newsletter for Health Professionals

2002 Index

When looking for information on a specific topic, back issues of Contraceptive Technology Update *newsletter, published by American Health Consultants, may be useful. To obtain back issues, go on-line at www.contraceptiveupdate.com. Your user name has been preset as your subscriber number on your mailing label. Your password is ctu in small letters, then your subscriber number again. Click on "archives." Nonsubscribers can purchase stories at www.ahcpub.com. Click on the section titled "e-solutions," and then "AHC Online." Under "Please select an archive, select* Contraceptive Technology Update." *Or contact our customer service department at P.O. Box 740060, Atlanta, GA 30374. Telephone: (800) 688-2421 or (404) 262-7436. Fax: (800) 284-3291 or (404) 262-7837. E-mail: customerservice@ahcpub.com.*

Sterilization

Women's health