

# CONTRACEPTIVE TECHNOLOGY

## U P D A T E ®

A Monthly Newsletter for Health Professionals

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### INSIDE

- **Yasmin:** 13 conditions that preclude use ..... 75
- **New OC:** Six drugs to check prior to use ..... 75
- **Lunelle:** Pilot pharmacy project expands access ..... 77
- **Condoms:** Planned Parenthood debuts brand ..... 78
- **Emergency contraception:** Raising awareness in New York City ..... 80
- **Chlamydia:** Review screening recommendations ..... 81
- **CTUpdates:** New pill pack designs introduced ..... 83
- **Inserted in this issue:**  
Education and Training Fax-back Survey

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## Oral contraceptive with unique progestin receives FDA approval

*Drospirenone, ethinyl estradiol combined in new monophasic, Yasmin*

**A**dd another oral contraceptive (OC) to the list of choices for American women: Yasmin, a monophasic birth control pill from Berlex Laboratories of Montville, NJ.

Developed by Berlex Laboratories' parent company, Schering AG of Berlin, the OC is the first to use the progestin drospirenone. The pills will be packaged with 21 active tablets, each containing 3 mg of drospirenone and 0.03 mg of ethinyl estradiol, and seven inert tablets.

Yasmin was approved by the Food and Drug Administration on May 11. At press time, the new OC was scheduled for market delivery by mid-June, according to **Julie Mandell**, Berlex Laboratories spokeswoman. According to Berlex Laboratories, more than 500,000 European women now are using the OC. Yasmin already is available in the Netherlands, Germany, and other European countries.

"The second- and third-generation progestins we have seen in recent years are derivatives of norgestrel or norethindrone acetate," observes **Susan Wysocki**, RNC, NP, president and CEO of the

### CE/CME questions enclosed

**B**eginning this month, *Contraceptive Technology Update* will print BCE/CME questions in each issue (**see p. 84**). At the end of the six-month semester, we'll include a Scantron form and envelope in the issue so that you can answer the questions and return the answers to us. This change means you'll need to keep your issues for at least six months so that you can refer to those issues and write down your answers when you receive your answer sheet. Also, if you already are a participant in our CE/CME program, you'll find the test for the previous semester enclosed in this issue. If you have any questions, please contact Joy Daughtry Dickinson, Senior Managing Editor, at [joy.dickinson@ahcpub.com](mailto:joy.dickinson@ahcpub.com). Telephone: (229) 377-8044. ■

## EXECUTIVE SUMMARY

Yasmin, a monophasic oral contraceptive (OC) from Berlex Laboratories, now is available in the United States. With 0.03 mg of ethinyl estradiol, the OC contains 3 mg of drospirenone, a new progestin.

- While initial research suggests Yasmin might provide relief from physical and emotional symptoms associated with the menstrual cycle, these effects must be confirmed in placebo-controlled comparative studies.
- Yasmin's antimineralcorticoid activity influences the regulation of water and electrolyte balance, which might increase potassium levels. Women with kidney, liver, or adrenal disease should not take Yasmin, and those who take drugs that increase potassium levels should consult with their health care provider before initiating use.

Washington, DC-based National Association of Nurse Practitioners in Women's Health. "Drospirenone is in its own class," she adds.

While initial research suggests Yasmin may provide relief from common physical and emotional symptoms associated with the menstrual cycle, such as negative moods, water retention, and increased appetite, these effects must be confirmed in placebo-controlled comparative studies.<sup>1</sup> The drug currently is labeled for no other indication other than contraception; however, the company is studying Yasmin for other potential benefits beyond birth control, confirms Mandell.

### Look at new progestin

Drospirenone is derived from 17alpha-spirolactone. To understand its unique characteristics, review the following explanation of progesterone's impact in the menstrual cycle:

In the second half of a normal menstrual cycle, progesterone levels rise. Progesterone binds to its specific receptor, but also to the mineralocorticoid receptor, acting as a mineralocorticoid antagonist.

Natriuresis (loss of sodium in the urine) is

slightly enhanced in the luteal phase and, as a reflection of the negative sodium balance, plasma renin and aldosterone rise by 20%-50%. This rise prevents further sodium loss.

Synthetic progestins, whether they are derivatives of 17alpha-hydroxyprogesterone or 19-nortestosterone, lack the antimineralcorticoid effect of natural progesterone. Ethinyl estradiol, as the estrogenic component of combined OCs, is a sodium-retaining drug. This effect mainly is due to a significant increase of the hepatic synthesis of renin substrate (angiotensinogen). Even with low-dose OCs, systolic and diastolic blood pressure might be slightly raised in susceptible individuals.<sup>2</sup>

However, the relationship between drospirenone's progestogenic and its antimineralcorticoid potency almost is identical to that of natural progesterone.<sup>2</sup>

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.<sup>3</sup> In one study, there was a distinct weight decrease in Yasmin users over the entire treatment phase, with a less distinct decrease in the comparative group.<sup>4</sup> 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 five onward.<sup>5</sup>

### Impact on weight gain?

Yasmin represents an interesting addition to existing OC options because of the suggestion that antimineralcorticoid activity may improve symptoms associated with the late portions of the cycle (or in this case, OC use), remarks Michael Rosenberg, MD, MPH, clinical professor of obstetrics and gynecology at the school of medicine and adjunct professor of epidemiology at the school of public health, both at the University of North Carolina at Chapel Hill, and president of Health Decisions, a Chapel Hill private research firm specializing in reproductive health.

For most women, there is a cyclic gain of about

## COMING IN FUTURE MONTHS

■ Evra contraceptive patch: New efficacy data on tap

■ Challenge: Hispanic teen pregnancy rates

■ Microbicide update: When will products reach women?

■ Counsel women on perimenopause

■ Recognize signs of female sexual dysfunction

one pound during the first half of each OC cycle and the loss of the same amount over the latter half, which probably reflects fluid retention.<sup>6</sup> However, the bloating that is commonly experienced toward the end of each cycle is probably related to estrogen as well as progestin, along with timing, says Rosenberg.

### ***Look at efficacy rates***

A randomized, open-label, 13-cycle study was conducted at 80 European centers, assessing contraceptive reliability, cycle control, blood pressure, body weight, adverse events and skin condition during 13 cycles of OC use and at follow-up.<sup>4</sup> Two pills were used in the trial: Yasmin and Marvelon (NV Organon, Oss, The Netherlands), a 30 mcg ethinyl estradiol/0.15 desogestrel pill marketed by Organon US as Desogen.

The 2,069 women who started the study were assigned to two groups; 1,657 women received Yasmin, and 412 received Marvelon. A total of 1,615 women completed the 13 cycles plus follow-up, providing data for over 23,000 evaluable cycles.

Eleven pregnancies occurred during treatment, with only one (which occurred in the Yasmin group) unable to be ascribed to user failure or interaction with other factors.

### ***26-cycle study completed***

A separate multicenter, open-label, randomized study was carried out in 26 European centers, using Yasmin and Marvelon.<sup>5</sup> Contraceptive efficacy, cycle control, and tolerance (including body weight, blood pressure, and heart rate) were assessed over 26 cycles, plus a three-month follow-up period.

Of the 900 women who were randomized, 887 started treatment and 627 completed the 26 cycles plus follow-up (310 in the Yasmin group and 317 in the Marvelon group). Both OCs were found to be effective with regard to contraceptive reliability, and cycle control was good. Researchers reported six pregnancies (three in each group), but none were considered to have been the result of method failures.

An American open-label, multicenter investigation of the drug was conducted to evaluate the efficacy, safety, and cycle control of Yasmin.<sup>7</sup> In this study, 326 women were evaluated, and 220 (67%) completed all 13 treatment cycles. One subject became pregnant during the study. The year-long study used the Pearl index (the number of

## **Who Should Not Use Yasmin?**

Women who have the following:

- renal insufficiency;
- hepatic dysfunction;
- adrenal insufficiency;
- thrombophlebitis or thromboembolic disorders;
- past history of deep-vein thrombophlebitis or thromboembolic disorders;
- cerebral-vascular or coronary-artery disease;
- known or suspected carcinoma of the breast;
- carcinoma of the endometrium or other known or suspected estrogen-dependent neoplasia;
- undiagnosed abnormal genital bleeding;
- cholestatic jaundice of pregnancy or jaundice with prior pill use;
- liver tumor (benign or malignant) or active liver disease;
- known or suspected pregnancy;
- heavy smoking (> 15 cigarettes per day) and over age 35.

Source: Yasmin Prescribing Information, Berlex Laboratories, Montville, NJ.

## **Drugs to Check Prior to Yasmin Use**

- nonsteroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen (Motrin, Advil) and naprosyn (Aleve), when taken long-term and daily for treatment of arthritis or other problems;
- potassium-sparing diuretics such as spironolactone;
- potassium supplementation;
- ACE (angiotensin converting enzyme) inhibitors such as Capoten (captopril, Bristol-Myers Squibb Co., Princeton, NJ), Vasotec (enalapril, Merck & Co., West Point, PA), and Zestril (lisinopril, Zeneca Pharmaceuticals, Wilmington, DE);
- angiotensin-II receptor antagonists such as Cozaar (losartan potassium, Merck & Co.), Diovan (valsartan, Novartis Pharmaceuticals Corp., East Hanover, NJ), and Avapro (irbesartan, Bristol-Myers Squibb Co.);
- heparin.

Source: Yasmin Prescribing Information, Berlex Laboratories, Montville, NJ.

unintended pregnancies divided by the number of woman-years of exposure to risk of pregnancy) to measure contraceptive efficacy. The uncorrected Pearl index was 0.406 based on one pregnancy in 3,201 cycles of 326 women; the corrected Pearl index was 0.407 based on 3,192 cycles. The pregnancy ratio, based on 220 women completing 13 cycles without the use of alternative contraception, was 0.455.

In all, 20 women discontinued participation in the study because of adverse events. The most frequently reported events leading to discontinuation included emotional lability, nausea, dysmenorrhea, intermenstrual bleeding, and depression. Only one woman discontinued due to weight gain.

### **Review candidacy for OC**

Yasmin's antimineralcorticoid activity influences the regulation of water and electrolyte balance in the body, which may increase potassium levels in some patients. **Therefore, it is recommended on the package insert that women with kidney, liver, or adrenal disease should not take Yasmin, because this antimineralcorticoid activity could cause serious heart and health problems. (Other conditions that preclude use are listed in the box on p. 75, upper right.)**

If women are currently on daily, long-term treatment for a chronic condition with any of the medications listed in the box (**p. 75, bottom right**), discuss with them whether Yasmin is the right OC for them. If they do choose the OC, the package insert states that they should have their potassium level checked during the first month of OC use.

Women and health care providers will welcome the addition of a new contraceptive product that has great efficacy and might address some of the troublesome symptoms of PMS, predicts **Linda Dominguez**, RNC, NP, assistant medical director of the Albuquerque-based Planned Parenthood of New Mexico. However, a careful history of other medication use that impact potassium levels will be critical, given that the population providers serve is aging and might be taking drugs for associated health problems, she observes.

Many clinicians might be reluctant to prescribe Yasmin for two reasons, observes **Andrew Kaunitz**, MD, professor and assistant chair in the obstetrics and gynecology department at the University of Florida Health Science Center/Jacksonville. First, in contrast with other OCs formulated with widely used and studied progestins,

### **SOURCES AND RESOURCES**

For more information on Yasmin, contact:

- **Susan Wysocki**, RNC, NP, National Association of Nurse Practitioners in Women's Health, 503 Capitol Court N.E., Suite 300, Washington, DC 20002. E-mail: NPWHDC@aol.com.
- **Michael Rosenberg**, MD, MPH, Health Decisions, 1512 E. Franklin St., Suite 200, Chapel Hill, NC 27514.
- **Linda Dominguez**, RNC, NP, Planned Parenthood of New Mexico, 719 San Mateo N.E., Albuquerque, NM 87108. Telephone: (505) 265-5976.
- For more information on Yasmin, providers should call Berlex Laboratories' toll-free product information line, (888) BERLEX4 [(888) 237-5394]. Consumers who would like to learn more about Yasmin should visit its web site, [www.yasmin.com](http://www.yasmin.com), or call the toll-free number (866) YASMIN1 [(866) 927-6461] to receive a complimentary, informational product brochure by mail.

experience to date is limited with drospirenone. Second, the list of concomitant medications that should be checked prior to prescribing complicates what is, for existing OCs, a relatively simple prescribing process, he notes.

### **References**

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# Pilot pharmacy program gives injections a shot

Women who use Lunelle (Pharmacia Corp., Peapack, NJ) might have more options in getting their monthly contraceptive injections outside clinic walls if a pilot program proves successful. The Easy Access Sites for You (EASY) program developed by Pharmacia Corp. allows druggists at select local pharmacies to administer the monthly shots, once the woman has received her prescription from her health care provider.

"Given our busy lives, having to go to one particular site every month within a window of two to five days can be difficult for a lot of women," says **Sharon Schnare, RN, FNP, CNM, MSN**, women's health consultant and clinician with the Seattle King County Health Department in women's and adolescent health care and the International District Community Health Center in Seattle. "This program is going to be a win-win situation for a lot of people."

Female consumers who go to pharmacy chain stores to do their shopping and take care of their errands will benefit, since they will have access to birth control injections, as well as a host of other services, says **Kristin Elliott**, Pharmacia Corp. spokeswoman. Pharmacists, who already are offering vaccinations and flu shots, will be able to add another service to their line of care, she notes.

## A look at the program

Currently, 30 states allow druggists to administer injections in the pharmacy. (See list, p. 78.)

### EXECUTIVE SUMMARY

Access to the new Lunelle Monthly Contraceptive Injection might be expanded if an innovative pilot program proves successful. The Easy Access Sites for You (EASY) program allows druggists at select local pharmacies to administer the monthly shots, once the woman has received her prescription from her health care provider.

- Pharmacia Corp. launched the program this spring in participating Seattle pharmacies in the Fred Meyer chain of multidepartment stores, as well as in the Amarillo, TX, Walgreen's drug store. Other sites will be added.
- At this point in time, 30 states allow druggists to administer injections in the pharmacy.

Pharmacia Corp. launched the program this spring in participating Seattle pharmacies in the Portland, OR-based Fred Meyer chain of multidepartment stores. The participating pharmacies offer a private area where women can receive the injections and ask questions about the method.

The EASY program also is in Walgreen's in Amarillo, TX, states Elliott. Pharmacia Corp. is talking with other pharmacies in several states, and company officials hope to expand the pilot program, she reports. As more women take advantage of the service, the company anticipates rolling it out nationally later this year, says Elliott.

The cost of the monthly shots, on average, is about the same as a pack of birth control pills: \$20-\$30, Schnare estimates. Pharmacies participating in the EASY project might charge an additional \$10 for the injection, about the same amount billed in a provider's office, she notes.

There is no need to perform weight checks or measure blood pressure with injection visits.<sup>1</sup> The process can be as quick and easy as receiving an allergy shot.

## Access aids women

Administering injections is not a new concept for Washington pharmacists, who have been giving immunizations for some time now, says **Rod Shafer, RPh**, CEO of the Washington State Pharmacists Association in Seattle. The association already offered a training session on injections; it just added a component on Lunelle when the EASY project was launched, he notes.

Many family planners may recognize the Washington state pharmacists' group from its involvement in the groundbreaking provider/pharmacist emergency contraceptive (EC) collaborative project. (See *Contraceptive Technology Update*, June 1998, p. 79, for an overview of the project, which allows pharmacists to prescribe EC under prescriptive authority of health care providers.)

"We, as an association, have very serious concerns in the area of unintended pregnancy and the kinds of costs that it puts on society, not to mention the individuals involved," states Shafer. "We have been very supportive of pharmacists getting involved, including the emergency contraception project, and we feel that this program is just an extension of that, providing ready access to a relatively new form of birth control that should be very useful."

Each dose of Lunelle Monthly Contraceptive Injection contains 25 mg of the progestin medroxyprogesterone acetate and 5 mg of the estrogen estradiol cypionate. The intramuscular injections can only be effective if women receive their injections at the proper times. According to the package insert, Lunelle injections must be given monthly, every 28-30 days and no later than 33 days after the last injection. (*A Pocket Guide to Managing Contraception* [Nelson AL, Hatcher RA, Zieman M, et al. Bridging the Gap Foundation; 2000] advises that patients return in 28 days, plus or minus five days [23-33], for reinjections. *Contraceptive Technology Reports* [inserted in the March 2001 issue of CTU] advises that subsequent injections should be given within 28-30 days of the preceding injection, although they may be administered as early as 23 days and as late as 33 days.)

### Keep eye on 'window'

Keeping women in the "window" for re-injections is a prime objective for family planning providers. Adding pharmacists to the list of those who can administer the injections expands women's options, says Schnare.

To help women remember when to receive their Lunelle injections each month, women can register to receive an e-mail reminder notification through the web site [www.lunelle.com](http://www.lunelle.com). Pharmacia Corp. is developing in-store promotional materials for use by participating pharmacies, as well as information for providers to use in counseling women

## States that Allow Druggists to Give Injections

- Alabama
- Alaska
- Arkansas
- California
- Colorado
- Delaware
- Georgia
- Illinois
- Idaho
- Indiana
- Iowa
- Kansas
- Kentucky
- Michigan
- Mississippi
- Missouri
- Nebraska
- New Mexico
- Nevada
- Ohio
- Oklahoma
- Oregon
- South Carolina
- South Dakota
- Tennessee
- Texas
- Utah
- Virginia
- Washington
- Wisconsin

## SOURCE AND RESOURCES

For more information about in-pharmacy Lunelle injections, contact:

- **Rod Shafer**, RPh, Washington State Pharmacists Association. E-mail: [rshafer@u.washington.edu](mailto:rshafer@u.washington.edu).

For more information on Lunelle, including full prescribing information, visit [www.lunelle.com](http://www.lunelle.com) or [www.birthcontrolresources.com](http://www.birthcontrolresources.com). Physician and pharmacist information on Lunelle is available by calling (800) 253-8600, extension 38244.

The Washington, DC-based National Association of Nurse Practitioners in Women's Health is offering a continuing education module on Lunelle in its ongoing *New Option in Hormonal Contraception* series. The Continuing Education Committee of the National Association of Nurse Practitioners in Women's Health has approved the activity for 1.8 contact hours, which includes 1.2 contact hours of pharmacology. Visit the association's web site at [www.npwh.org](http://www.npwh.org); click on "continuing education."

about the EASY project option.

During their training sessions, pharmacists are given information on Lunelle so they may effectively answer women's questions about the method, says Elliott.

"They become comfortable in knowing what to expect when a woman comes in and what are the commonly asked questions and concerns, so they can be better counselors," Elliott states. "They also find out when they need to go back and involve the provider."

### Reference

1. National Association of Nurse Practitioners in Women's Health. *New Option in Hormonal Contraception. Monthly Combination Contraceptive Injection*. Web: [www.npwh.org/Lunelle/aboutlunelle.htm](http://www.npwh.org/Lunelle/aboutlunelle.htm). ■

## Planned Parenthood develops its own condom

There will be 25 million advertisements carrying the message of Planned Parenthood Federation of America next year, but don't look on billboards or in magazines. Instead, check the wallets, purses, and nightstands of sexually

## EXECUTIVE SUMMARY

The Planned Parenthood Federation of America has just launched its own line of condoms. The organization expects to distribute more than 25 million condoms in the next year.

- Two styles now are available: a lubricated latex condom and a spermicidal latex condom. Future choices include two flavored styles, honeydew and raspberry, and two colored condoms, red and green.
- Each condom wrapper bears a toll-free number [(800)-230-PLAN (7526)] to reach the nearest Planned Parenthood health center, where users can get reproductive health information or make a confidential appointment.

active Americans for condom packages bearing the New York City-based group's logo and toll-free telephone number.

Planned Parenthood Federation of America has introduced its own private-label condom brand. With 127 affiliates operating 875 health centers nationwide, the organization expects to distribute more than 25 million condoms in the next year.

Each condom wrapper bears a toll-free number [(800)-230-PLAN (7526)] to reach the nearest Planned Parenthood health center, where users can get reproductive health information or make a confidential appointment.

"The Planned Parenthood name tells you it's a condom you can trust," says **Gloria Feldt**, president of the national organization. "And the toll-free number gives users an immediate connection to the full range of services and information people need to stay healthy and make their own responsible choices."

### Tests ensure quality

Condoms are an important defense against sexually transmitted diseases and unintended pregnancy, so it is important that the quality of the product is maintained at a high level, says **Dixie Newman**, RN, BSN, former vice president of patient services at Planned Parenthood of San Diego and Riverside Counties and now affiliated with the national organization.

Planned Parenthood has contracted with Malaysian condom manufacturer L.S. Rubber Co. for the private-label condoms, says Newman. Six quality assurance tests are performed at the manufacturing site, with a separate test performed

here in the United States.

Every condom on the manufacturing line goes through a wet electrical test, whereby electricity is passed through the latex to detect any weak areas or holes, Newman states. Once condoms move from the manufacturing line, a dry electrical test also checks each one for similar defects. Different lots of condoms are sampled for the air burst test and the water burst analysis. The air burst test uses air pressure to test the tensile strength of the latex, while the water burst test looks for holes in the product, says Newman.

Different product lots also are sampled for the aging test, which places packaged condoms inside a closed container. The container is then heated to a very high temperature for different lengths of time. The condoms are removed from the container and tested to make sure that the heat in the aging process did not cause the latex to break down, explains Newman. The package integrity of the condom wrapper is tested in a separate vacuum analysis.

### Consumers drive options

The first two styles in the Planned Parenthood line include a lubricated latex condom and a nonoxynol-9 spermicidal latex condom. Two flavored condoms, honeydew and raspberry, are the next styles to arrive in Planned Parenthood clinics, says Newman. Two colored condoms, red and green, will follow next, she reports.

Focus groups, comprised of Planned Parenthood patients, were involved in the development of the products, says Newman.

"We feel really fortunate that we, as a non-profit, are saying to our clients and patients, 'Tell us what you want; give us your feedback on what you want in a condom,' because we want to see broad public access of this product," says Newman. "They are really driving the styles and the feel of the condom."

Planned Parenthood Mar Monte in San Jose, CA, the largest Planned Parenthood affiliate, worked closely with a group of Fresno commercial sex workers in gathering acceptability information on the condoms, says **Lynn Fielder**, MA, MPH, vice president of medical services. The

### SOURCE

- **Susan Alocco**, Planned Parenthood Federation of America. E-mail: PPCONDOM@PPFA.ORG.

affiliate provides HIV education and other services to the workers, so it enlisted their help in evaluating the products.

"Very favorable reviews came back from them, so we're excited about that," says Fielder. "All around, the reviews have been excellent, the feedback has been really good, and I think we're excited about having the first Planned Parenthood product available to our clients."

Many Planned Parenthood affiliates are participating in a free distribution of the new condoms, which is advertised on the condom page of the Planned Parenthood web site ([www.plannedparenthood.org/condom](http://www.plannedparenthood.org/condom)). Since different affiliates receive various funding sources for condom supplies, there is no one set charge for the condom, explains Newman.

With the toll-free telephone number plainly visible on every condom wrapper, Planned Parenthood officials see an excellent opportunity to fulfill its mission of ensuring broad public access to reproductive health care, says Newman.

"They are the only product on the market that has aftercare built into it," observes Fielder. "If the condom breaks or comes off, a woman can call the 800 number and be connected to one of our clinics and get emergency contraception. The full circle of care is tremendously exciting." ■

## New York program boosts EC awareness

Radio spots, posters, drink coasters in restaurants and bars, and subway advertisements are making sure it's no accident that New Yorkers know about access to emergency contraception (EC). Using a media campaign revolving around the theme, "Accidents Happen," Planned Parenthood of New York City (PPNYC) has launched an intensive three-month media campaign to highlight the availability of EC at its three city clinics.

Advertising has been a proven factor in guiding women to the clinics for EC services, says **Joan Malin**, CEO of the Planned Parenthood affiliate. In 1998-99, the organization advertised its EC services and saw an increase in the number of women coming in for such care, she notes.

"In the year 2000, we did 4,500 visits for EC, and that was an increase of 40% in 1999, and a 70% increase from 1998," states Malin. "Clearly by advertising and spreading the word, women

## EXECUTIVE SUMMARY

With the theme, "Accidents Happen," Planned Parenthood of New York City has launched a three-month media campaign to highlight the availability of emergency contraception (EC) at its three city clinics.

- Advertising has been a proven factor in guiding women to the clinics for EC services. In the year 2000, the agency recorded 4,500 visits for EC, an increase of 40% from 1999 figures and a 70% increase from 1998.
- The campaign uses radio spots, posters, drink coasters in restaurants and bars, subway advertisements, and slides in movie theaters.

are getting the messages that these services are available, which is terrific."

The campaign kicked off in late April with radio spots featured on local stations. Developed by the national Planned Parenthood Federation of America in New York, the radio spots are voiced by Grammy-winning artists Dice Raw and Scratch from The Roots and Lilith Fair founder Sarah McLachlan. A Spanish-language advertisement also is being aired on a local Hispanic station.

PPNYC placed framed posters advertising EC in restrooms in more than 100 restaurants and bars in New York City from late April through June and distributed drink coasters promoting EC in participating restaurants and bars. Subway advertisements were posted from May through June.

### *Get the message out*

By using the national Planned Parenthood advertising materials and localizing them with the PPNYC logo and address, the New York organization is able to direct its dollars toward placement of the advertisements, says Malin.

"As it is, it is going to cost us over \$100,000 to do this program, but it would be far more if we had to go out and actually engage these services," states Malin.

The campaign will end with placement of movie slides promoting the EC awareness campaign in theaters in Brooklyn, the Bronx, and Harlem communities during the summer.

"We're hoping that this gets the message out that this service is here and can make a critical difference," says Malin.

Women who contact PPNYC directly through its confidential appointment and information hotline

## RESOURCES

For more information on Planned Parenthood of New York City's emergency contraception program, contact:

- **Jini Tanenhaus**, PA-C, Planned Parenthood of New York City, (212) 274-7200.

For more information on the affiliate, visit its web site at [www.pppny.org](http://www.pppny.org).

[(212) 965-7000], or through the national Planned Parenthood's toll-free number [(800) 230-PLAN (7526)] can receive information about EC, says **Jini Tanenhaus**, PA-C, associate vice president for the Clinician Training Initiative at PPNYC. If women have had unprotected intercourse in the last 72 hours, they are advised to come into one of the affiliates' three clinics for care.

Following a medical assessment, women are given Plan B (Women's Capital Corp., Bellevue, WA) at the clinic, as well as a written prescription for Preven (Gynétics, Belle Mead, NJ) as a prophylactic measure for future use, says Tanenhaus.

"Everyone who comes in who doesn't have some type of permanent method of birth control [such as an intrauterine device, contraceptive injectable, or contraceptive implant] gets offered a prescription for EC so they can have it at home in their medicine cabinet to use," states Tanenhaus.

PPNYC is evaluating the possibility of performing EC medical assessments over the telephone to further enlarge access to the pregnancy prevention method, says Tanenhaus. (See *Contraceptive Technology Update*, June 2001, p. 67, for information on two Planned Parenthood affiliates that are offering such services.)

"It is a bit of a logistical problem in terms of working it out, but we hope to do that in the future," Tanenhaus states. "Women could just get an assessment over the telephone, we could read them the consent information, and then call or fax in a prescription."

### Fact sheets and web help educate

All three PPNYC centers are open Tuesday through Saturday and offer EC services, says Malin. But when women call over the weekend, they are directed to the Margaret Sanger clinic on Monday for what is known as "EC Day"; the other two clinics, Boro Hall Center in Brooklyn and the Bronx Center, are closed on Mondays. Fact sheets

and brochures in each clinic give further details on EC, as does the affiliate's web site, [www.pppny.org/homepage.html](http://www.pppny.org/homepage.html).

When women come in for EC services, it gives Planned Parenthood providers an opportunity to talk about family planning and the need for planning before any "accidents," says Malin. The awareness campaign is just one more step in letting women know about the availability of EC.

"Widespread use of EC could prevent half of all unintended pregnancies and half of all abortions," states Malin. "In New York City alone, with increased availability and public awareness, EC could potentially eliminate 100,000 unintended pregnancies and up to 50,000 abortions a year." ■

## Task force calls for chlamydia screening

More providers are joining the battle against the silent spread of chlamydia infection with the recommendation from the third U.S. Preventive Services Task Force that primary care clinicians screen all sexually active women ages 25 and younger, as well as older women at risk, as part of regular health care visits.

The task force, a panel of independent, private-sector experts in prevention and primary care, made its recommendation after concluding that there is good scientific evidence that routine screening and treatment could reduce serious consequences of chlamydia in women. The task

### EXECUTIVE SUMMARY

Primary care clinicians should screen all sexually active women ages 25 and younger, as well as older women at risk, for chlamydia as part of regular health care visits.

- The U.S. Preventive Services Task Force made the recommendation after reviewing evidence that routine chlamydia screening and treatment can reduce chlamydia's impact on women.
- Clinicians should screen all women, whether they are pregnant, if they are sexually active and age 25 or younger; have more than one sexual partner, regardless of age; have had a sexually transmitted disease in the past, regardless of age; or do not use condoms consistently and correctly, regardless of age.

force, which is sponsored by the Rockville, MD-based Agency for Healthcare Research and Quality, systematically reviews the evidence of effectiveness of a wide range of clinical preventive services to develop recommendations for preventive care in the primary care setting.

The task force recommends that primary care clinicians routinely screen all women, whether they are pregnant, if they:

- are sexually active and age 25 or younger;
- have more than one sexual partner, regardless of age;
- have had a sexually transmitted disease (STD) in the past, regardless of age;
- do not use condoms consistently and correctly, regardless of age.

The task force made no recommendation for or against screening women older than age 26 who are not otherwise at risk. There was not enough evidence to recommend screening men who have no symptoms, members concluded.

Data indicate that many women are not being screened for the STD. According to a recent physician survey, only 32% said they would screen an asymptomatic sexually active teen-age girl for chlamydia as part of a routine gynecologic examination.<sup>1</sup> A 1997 study of four major U.S. health plans indicated that only 2%-42% of sexually active females ages 15-25 had been screened for chlamydia.<sup>2</sup>

### **Most show no symptoms**

Each year, an estimated three million women and men contract chlamydia, states **Janet Allan**, PhD, RN, CS, dean and professor in the School of Nursing at the University of Texas Health Science Center at San Antonio and vice chair of the task force. Chlamydia often is a silent disease; most women show no symptoms for six months or longer, she states.

"If it goes untreated, chlamydia can cause serious health problems such as pelvic inflammatory disease [PID], infertility; and if you are pregnant, it may cause preterm delivery," states Allan. "Babies born to women with chlamydia can develop eye infections and pneumonia; chlamydia can also cause tubal pregnancies, which can be fatal to the pregnant woman."

Chlamydia can be treated with antibiotics and treatment is 100% effective, Allan observes. Identified by a culture or a urine test, screening costs range from \$30-\$100, depending on whether a pelvic examination is included, with insurance

usually covering screening and treatment, she says.

Allan urges women at risk for the disease to be proactive in screening. Chlamydia now is the most common bacterial STD in the United States, according to the Atlanta-based Centers for Disease Control and Prevention. "Early detection of this disease is the most effective way to prevent serious health problems," she advises.

Chlamydia screening of sexually active young women ages 15-25 now is one of the performance measures included in the Washington, DC-based National Committee for Quality Assurance's Health Plan Employer Data and Information Set (HEDIS). HEDIS is the most widely used system for assessing managed care performance. The performance measure was added in 2000. (**Contraceptive Technology Update** reported on the addition of the performance measure in its February 2000 issue, p. 17.)

According to the organization's 2000 report, baseline results for the screening measure indicate room for improvement: Chlamydia screening rates for women ages 16-20 and 21-26 averaged 19% and 16%, respectively.<sup>3</sup>

Routine chlamydia screening of sexually active women 15-25 years of age has health and cost benefits, according to research supported by the Agency for Healthcare Research and Quality.<sup>4</sup> The review revealed that screening 100% of sexually active women ages 18-24 would prevent an estimated 140,113 cases of PID each year and result in a savings of \$45 for every woman screened.

With the advent of nucleic acid amplification tests, screening for chlamydia now is easier to perform because tests can be performed on urine samples, says **Rita Mangione-Smith**, MD, MPH, assistant professor of pediatrics at University of California Los Angeles. (See the cover story in the February 2001 *STD Quarterly supplement* inserted in *CTU* for an up-to-date review of nucleic acid amplification tests.)

"The technology still is not widely available, but it is becoming much more so now that it is a [HEDIS] performance measure that health plans are going to be measured on," observes Mangione-Smith. "The health plans will make sure that they have the technology in place to do it."

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## SOURCE

For more information on chlamydia screening, contact:

- **Rita Mangione-Smith, MD, MPH, Assistant Professor of Pediatrics, University of California Los Angeles.** E-mail: ritams@ucla.edu.

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# CTUPDATES

News ■ Resources ■ Events

## New designs added to Ortho Personal Paks

Two new designs have been added to the Ortho Personal Pak, Raritan, NJ-based Ortho-McNeil Pharmaceutical's unique line of birth control pill dispensers.

The designs, fuchsia daisy and leopard print, have been available since May 1 for users of Ortho Tri-Cyclen, a norgestimate/ethynodiol monophasic oral contraceptive (OC), and Ortho-Cyclen, a norgestimate/ethynodiol monophasic OC.

The Personal Paks, which also are available in colors of lapis, jade, onyx, and sapphire, complement the Ortho Dialpak pill dispenser, the pink-beige compact women receive with their prescription. The "any-day" start feature of the compact allows women to work with clinicians in choosing their start date, and the one-way dial, single-hole dispenser and clearly numbered pills and days of the week aid in pill taking.

In a recent survey of women who use the Dialpak, half of the respondents said they were more likely to take their birth control on time as a result of using the compacts. Many women are

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Editor: **Rebecca Bowers**.

Vice President/Group Publisher: **Brenda Mooney**, (404) 262-5403, (brenda.mooney@ahcpub.com).

Editorial Group Head: **Valerie Loner**, (404) 262-5475, (valerie.loner@ahcpub.com).

Senior Managing Editor: **Joy Daughtry Dickinson**, (229) 377-8044, (joy.dickinson@ahcpub.com).

Production Editor: **Nancy McCreary**.

### Editorial Questions

Questions or comments?

Call **Joy Daughtry Dickinson**, (229) 377-8044.

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## CE/CME Questions

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

- Identify the two hormones in the contraceptive injectable Lunelle. (See "Pilot pharmacy program gives injections a shot" in this issue.)
- Identify when re-injections should be given for Lunelle. (See "Pilot pharmacy program gives injections a shot.")
- Name six quality assurance tests are used at the manufacturing site to check the integrity of Planned Parenthood condoms. (See "Planned Parenthood develops its own condom.")
- Identify the recommendations from the U.S. Preventive Services Task Force regarding chlamydia screening. (See "Task force calls for chlamydia screening.")

1. What are the two hormones in the contraceptive injectable Lunelle?
  - A. norehisterone enanthate and estradiol valerate
  - B. dihydroxyprogesterone acetophenide and estradiol enanthate
  - C. dihydroxyprogesterone acetophenide and estradiol valerate
  - D. medroxyprogesterone acetate and estradiol cypionate
2. According to the package insert, when should re-injections be given for Lunelle?
  - A. every 28 days after the last day of a woman's menstrual period
  - B. 11-13 weeks following the last injection
  - C. every 28-30 days and no later than 33 days after the last injection
  - D. every 35 days after the last injection
3. What six quality assurance tests are used at the manufacturing site to check the integrity of Planned Parenthood condoms?
  - A. wet electrical test, dry electrical test, air burst test, water burst test, aging test, vacuum test
  - B. wet electrical test, dry electrical test, air burst test, water burst test, aging test, tensile test
  - C. wet electrical test, dry electrical test, viral impermeability test, water burst test, aging test, vacuum test
  - D. wet electrical test, dry electrical test, air burst test, lubrication test, aging test, vacuum test
4. Which of the following is NOT a recommendation from the U.S. Preventive Services Task Force regarding chlamydia screening?
  - A. Screen all women who are sexually active and age 25 or younger.
  - B. Screen all women who have more than one sexual partner, regardless of age.
  - C. Screen all women who have had a sexually transmitted disease (STD) in the past, regardless of age.
  - D. Screen all men who have no symptoms.

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