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INSIDE

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Emergency contraception is gaining momentum from local to national levels

Agency sees fivefold increase in EC use through educational efforts

Emergency contraception (EC) may once have been "the nation's best-kept secret," but a continued commitment to increasing public awareness is about to change its status.

The Washington, DC-based American College of Obstetricians and Gynecologists (ACOG) is moving to put emergency contraceptive pills in the medicine cabinets of every U.S. woman. In a letter directed mailed in March 2002 to the group's 40,000 member physicians, ACOG president Thomas Purdon, MD, urged advance prescription for the method. Sample letters also were issued at the same time to help members request that local pharmacies stock EC.[1]

On Capitol Hill, Sen. Patty Murray (D-WA) and Rep. Louise McIntosh Slaughter (D-NY) have introduced the Emergency Contraception Education Act to educate health care providers and the public about EC. The legislation is part of a growing effort to make sure women and health care providers know that there is a backup birth control method available in the United States.

At *Contraceptive Technology Update* press time, EC advocates were poised to kick off a national "Back Up Your Birth Control" campaign

EXECUTIVE SUMMARY

The push to increase access to emergency contraception (EC) is gaining momentum, as evidenced by the following:

- Two Capitol Hill legislators have introduced the Emergency Contraception Education Act to educate health care providers and the public about the method.
- U.S. women are being reminded to "back up their birth control" through a nationwide public awareness campaign.
- Through in-house education efforts, Planned Parenthood of Minnesota/ South Dakota clinics have seen a fivefold increase in the use of EC pills in the last three years.

to increase awareness about EC. **(Read more about the campaign in the February 2002 issue, p. 18, in the article, "Make EC the focus during March campaign"; also visit the campaign web site, www.backupyourbirthcontrol.org and click on "For Providers/Pharmacists" to download a patient information brochure, fact sheet, and poster on EC.)**

"If we want to reduce unintended pregnancies, we need to get serious about giving women options — and that includes emergency contraception," states **Kirsten Moore**, president of the Washington, DC-based Reproductive Health Technologies Project, which is coordinating the "Back Up" campaign. "Too many women don't know that they can get a dose of EC and keep it in their medicine cabinets just in case."

Commitment to education is what it takes to increase EC access, agrees **Sally Ward**, RN, clinical services director of the St. Paul, MN-based Planned Parenthood of Minnesota/South Dakota. She credits in-house patient education as an important facet of the campaign behind a fivefold increase in the use of EC pills in the last three years at the Planned Parenthood affiliate's clinics.[2]

Why the push for EC? Experts estimate that widespread use of the method could prevent as many as half of the 3 million unintended pregnancies in the United States each year.

The Emergency Contraception web site, www.not-2-late.com, touts its effectiveness. On average, if 100 women have unprotected intercourse once during the second or third week of their cycle, eight will become pregnant. Following treatment with combined emergency contraceptive pills (ECPs), two will become pregnant, representing a 75% reduction in the risk of pregnancy. When progestin-only ECPs are used, one will become pregnant, representing an 89% reduction in the risk of pregnancy.[3,4]

Open avenues of access

How can your clinic boost access to EC services? Take a look at how Planned Parenthood of Minnesota/South Dakota achieved its results, and look at avenues of access in your community:

- **Give advance prescriptions.**

The EC program is part of Planned Parenthood of Minnesota/South Dakota's comprehensive and limited services to women, says Ward. Clinicians provide a refillable EC prescription for all female patients who want it, with the prescriptions good for up to one year.

Prescriptions are filled in-house in the clinics, says Ward. While clinicians would be willing to write prescriptions to outlying pharmacies, the limited availability of dedicated EC product in Minnesota and South Dakota makes filling outside clinic walls problematic, she notes. Until more pharmacies stock EC products, the clinics will continue to fill the prescriptions, says Ward.

- **Get the word out.**

Use every available moment to educate patients about EC. Planned Parenthood of Minnesota/South Dakota uses its automated telephone hold and after-hours messages to educate about EC. When patients check in at any of the affiliate's clinic front desks, they receive an information sheet on emergency contraception, says Ward. A comprehensive women's health brochure, also distributed to all patients, covers EC in addition to such issues as contraception, breast self-exams, and sexually transmitted diseases. Posters on EC are displayed in each of the affiliate's 24 clinics. **(See resource box on p. 51 to order copies of the affiliate's printed material.)**

To date, Planned Parenthood of Minnesota/South Dakota has not used paid advertising to promote its EC services. How has it been so effective in getting the word out? Ward credits the clinic's internal marketing and patient education efforts.

"We know from our patient evaluation of services that the majority of patients hear about us from friends or families, so educating our patients tends to educate our communities as well," she says. "I think whereas it is not always the same person coming back, the word has gotten out from us talking with the women as they present to the clinics."

- **Make EC available.**

COMING IN FUTURE MONTHS

- Boost access to reproductive health care for men
- Update on ciprofloxacin-resistant gonorrhea
- Identify barriers to STD care in managed care organizations
- Review contraceptive counseling in gauging Pill's effectiveness
- Research takes another look at vasectomy reversal

RESOURCES

For more information on the Planned Parenthood of Minnesota/South Dakota emergency contraception program, contact Sally Ward, RN, at sward@ppmsd.org.

The Planned Parenthood of Minnesota/South Dakota Resource Center offers a brochure, *Emergency Contraception,* product No. PMOR019. Standard unit price is 40 cents; if more than 200 units, 35 cents; if more than 500 units, 32 cents. Add 15% for shipping and handling; orders under $25 must be prepaid with a check or credit card. Order from the affiliate's web site, www.ppmsd.org; click on "Online Store." Orders also may made by contacting:

- **The Resource Center**, 1200 Lagoon Ave., Department 300, Minneapolis, MN 55408. Telephone: (612) 823-6568. Fax: (612) 825-3522.

Many of Planned Parenthood of Minnesota / South Dakota's clinics are open on Saturday, so Sunday is the only day patients do not have EC access, says Ward. The clinic's telephone after-hours message reminds patients that they have up to 72 hours from the act of unprotected intercourse to use EC and instructs them to call back on Monday. Patients are getting the message; a clinic usually fields 15-20 EC requests on a Monday morning, says Ward.

• Look outside the clinic.

Do you know if EC is available outside your clinic walls, such as in hospital emergency departments? A 2001 survey of 137 Minnesota hospitals conducted by the St. Paul-based Minnesota National Abortion Rights Action League (NARAL) found that fewer than half of the hospitals surveyed would provide EC to survivors of rape.[5] ***(CTU* reported on emergency department EC access in November 2001, p. 129, "Is EC available in your local emergency room?")**

Since that time, the NARAL affiliate has worked with Minnesota Sen. Deanna Weiner (DFL) to hammer out a nonlegislative compromise with the Minnesota Hospital and Healthcare Partnership to ensure that the facts about EC are given to every sexual assault survivor who presents at a hospital emergency department, says **Timothy Stanley**, MPA, executive director of Minnesota NARAL.

Working with Planned Parenthood of Minnesota / South Dakota and the Minnesota Coalition Against Sexual Assault, Minnesota NARAL is putting together an EC information sheet that will be placed inside "rape kits" that are given to each sexual assault survivor, says Stanley. The kits are given to women to use after receiving medical treatment and include items such as sweat clothes and toiletries.

"The timeline is a little sketchy, but I think it is reasonable to assume that the EC info should be in the kits before spring," reports Stanley. "Also, the Minnesota Hospital and Health Care Partnership said they would work with all of us to provide training to hospital staff and allow us to test the efficacy of this agreement with some kind of random site visits."

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3. Task Force on Postovulatory Methods of Fertility Regulation. Randomised controlled trial of levonorgestrel vs. the Yuzpe regimen of combined oral contraceptives for emergency contraception. *Lancet* 1998; 352:428-433.
4. Trussell J, Rodriguez G, Ellertson C. Updated estimates of the effectiveness of the Yuzpe regimen of emergency contraception. *Contraception* 1999; 59:147-151.
5. Minnesota National Abortion Rights Action League. *Access in Crisis: The Continuing Decline of Hospital-Based Reproductive Health Services in Minnesota*. St. Paul; 2001. ■

Reach college students with information on EC

When it comes to providing access to emergency contraception (EC), is your local college student health center passing the grade?

A report published by the New York City-based National Abortion and Reproductive Rights Action League of New York (NARAL / NY) reveals that almost half (42%) of college health centers in New York State do not provide students with emergency contraception, with 60% of those facilities failing to provide quality referrals to EC services.[1] And of those health centers that do offer EC, 41% are closed throughout the weekend when EC may be most in demand. (Highlights of the report are available on the NARAL / NY web site, www.naralny.org.)

Why is it so important to reach college students?

EXECUTIVE SUMMARY

Advocates of emergency contraception (EC) are targeting college students, a group at particular risk for contraceptive failure and unintended pregnancy.

- Almost half of college health centers in New York state don't provide students with EC, with 60% of those facilities failing to provide quality referrals for EC services. About half of the centers that do offer EC are closed throughout the weekend, when EC may be most in demand.
- The progestin-only Plan B EC pill is being marketed in college newspaper ads and male pinup posters. The campaign is targeting 30 campuses in 10 states.

College-age women have the highest rate of unintended pregnancy of any group in the country. For every 1,000 women ages 18-19, about 105 experience an unintended pregnancy; among women ages 20-24, the rate is 96 out of every 1,000.[2]

The NARAL/NY report is allowing the organization to initiate dialogue with college administrators about EC services, says **Sara Sills**, EC campaign coordinator. Such communication has been beneficial because it has identified potential problems such as noncoverage on the weekend, she notes.

The dialogues also have allowed the organization to provide EC education, Sills notes. For example, physician exams are not necessary prior to EC prescription, so school health centers should not have to bring students in and have them charged for the extra service, Sills explains.

"This is teaching schools how they can make the process easier, because it [EC] is safe," states Sills.

NARAL/NY also is working with college groups to start grass-roots campaigns on EC advocacy, says Sills. It has developed a student action guide to help groups develop goals and implement campaigns.

"We may go back and look at the [report] data again, but I definitely would like to spend some time using the data that we have to change the policies, then coming back later and seeing if that had worked," notes Sills.

Posters heat interest

Women's Capital Corp. of Washington, DC, marketers of the levonorgestrel emergency contraceptive pill (ECP) Plan B, is using a combination of college newspaper ads and male pinup posters to get the word out on EC. According to **Sharon Camp**, PhD, company president, the marketing campaign is targeting 30 campuses in 10 states (Arizona, California, Massachusetts, Michigan, New York, North Carolina, Oregon, Pennsylvania, Texas, and Washington) and Washington, DC. **(See the resource box on p. 53 to order posters.)**

The ads and posters feature photographs of male models in a tongue-in-cheek take-off on male pinup posters. One poster features "Damian" with the headline, "A Renaissance Guy, A Deep Thinker, An Ancient Soul, A Walking Sperm Factory," while another highlights "Ernesto," with the headline, "Of All The Things You'd Love To Hear Him Whisper In Your Ear, 'Oops — The Rubber Broke' Isn't One Of Them." Both bear the tagline, "Accidents happen . . . that's why there's morning-after contraception," and direct readers to the Plan B web site, www.go2planB.com, or the Emergency Contraception Hotline, (888) NOT-2-LATE, for more information about the pills.

Posters give the campaign a long "shelf life," giving the company the biggest bang for its limited marketing budget, explains Camp. The company will reach 2.24 million students through the campaign, with a media buy of just $300,000, she states. The campaign will alternate the ads and posters on a monthly schedule through the end of the school year.

Providers should note that these are not drug ads, says Camp. They provide no information about Plan B; they only direct women to two sources of comprehensive information and networks of providers, she explains.

"Under FDA [Food and Drug Administration] guidelines, we cannot advertise Plan B without providing most of the information on the package insert," Camp comments. "We thought it unlikely that young women would hang the Plan B package insert in their dorm rooms."

Pinups pique interest

Student response to the campaign has been great, says Camp. "Even the guys are hanging up the male hunks, although they apparently have covered them with graffiti," she observes. "College women are plastering dorm rooms with them."

The ads also have generated some opposition from older adults, says Camp. Several schools have declined to accept them, and the company has received comments from four people who thought the ads "objectified men," promoted promiscuity, or "stereotyped Latino men as oversexed," with the

RESOURCE

To order copies of the Women's Capital Corp. posters, call (800) 330-1271, or e-mail llind@go2planb.com. There is no charge.

last comment referencing the "Ernesto" model, she notes.

"The campaign satirizes the popular hunk poster," says Camp. "It takes a realistic approach to women's sexuality, but then turns the corner to promote a message of sexual responsibility."

The idea behind the ads and posters is to keep information about EC, including the hotline number and the Plan B web site, in front of women for months so they can find the information they need when they need it, Camp says.

"We thought the best way to do this would be to give students something they would want to hang on the wall," she states.

References

1. National Abortion and Reproductive Rights Action League of New York. Emergency Contraception 101: The Availability of Emergency Contraception (EC) at College Health Centers in New York State. Accessed at www.naralny.org.

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'Graying' providers: Will abortion care be limited?

Take a look at the results of a just-released survey of practicing members of the Washington, DC-based National Abortion Federation (NAF), the professional organization of abortion providers in North America.[1] The majority of surveyed abortion providers is at least 50 years old, and nearly one-third is over age 55, according to the survey findings. Does the "graying" of skilled practitioners raise concerns about the future availability of abortion?

The National Abortion Federation first identified this threat to women's access to abortion more than a decade ago, says **Vicki Saporta**, executive director of the organization. In 1990, NAF convened a symposium, "Who Will Provide Abortions?" to address the growing shortage of health care providers offering such services. NAF's Access Initiative Project was specifically created to pursue the recommendations that grew out of that symposium, Saporta comments.

NAF established the Berkeley, CA-based Medical Students for Choice to educate and involve a new generation of physicians in the provision of abortion services, notes Saporta. The student organization has more than 4,000 members at more than 100 campuses across the country, she reports.

The Access Initiative project is working to integrate abortion care into obstetrics/gynecology (OB/GYN) residency training and has developed curricula for residency programs, a "values clarification" module for physicians and residents, and a comprehensive textbook on abortion practice, reports Saporta. The project also has organized Clinicians for Choice, which identifies pro-choice advanced practice clinicians who are committed to advocating for the full spectrum of women's reproductive health care within their professions, she reports.

The project's physician clearinghouse helps physicians who want training or would like to perform abortions to connect with a facility that is providing this service, says Saporta. NAF also conducts workshops to pair residency training programs with NAF member clinics willing to be training sites in areas where training opportunities are otherwise lacking.

Commitment to increasing education on the residency level is an important aspect of enlarging the provider pool, agrees **Steve Lichtenberg**, MD, MPH, medical director of Family Planning Associates Medical Group Limited of Illinois and a

EXECUTIVE SUMMARY

The "graying" of America's surgical abortion providers is evidenced by results of a survey of members of the National Abortion Federation. Most providers are at least age 50, and nearly one-third is over age 55.

- Medical Students for Choice has more than 4,000 members at more than 100 campuses to educate and involve a new generation of physicians in providing abortions.
- The addition of the mifepristone/misoprostol regimen to abortion services may add to the number of providers. A 2002 survey will include questions on medical abortion practice.

RESOURCE

For more information on abortion, contact:
- **National Abortion Federation**, 1755 Massachusetts Ave., N.W., Suite 500, Washington, DC 20036. Telephone: (202) 667-5881. Fax: (202) 667-5890. Web: www.prochoice.org.

clinical instructor in obstetrics and gynecology at Northwestern University Medical School, both based in Chicago. Lichtenberg, who serves as lead author of the recently published survey results, says residency programs are being encouraged by the Washington, DC-based American College of Obstetricians and Gynecologists to make elective clinical courses for abortion training.

Medical abortion eyed

How will the 2000 addition of mifepristone (Mifeprex, Danco Laboratories, New York City) impact the number of U.S. abortion providers? **(See the *Contraceptive Technology Reports* supplement, "Gauging the Effectiveness of Mifepristone and Misoprostol," inserted in the February 2001 issue of *Contraceptive Technology Update* for more information on the medical abortion regimen.)**

"Over time, medical abortion holds the promise of expanding access to abortion services for women, says Saporta. "Some health care providers who do not provide surgical abortion services are already offering medical abortion services to their patients."

NAF is working to ensure that those providers who want to add medical abortion to their practices have all the necessary information through its provision of educational materials and seminars.

"Of the 3,400 health care professionals who have attended our educational programs, many do not currently perform abortions and are interested in possibly adding medical abortion to their practices," reports Saporta. "Over time, we expect more clinicians to offer medical abortion as more women request this safe abortion option."

Medical abortion now constitutes 3%-5% of first-trimester abortions in the United States, Lichtenberg estimates. It is yet to be seen whether that number will increase, but the regimen holds the possibility of increasing access to early abortion, he believes. Lichtenberg and his co-authors will conduct a second survey in 2002 that will include information on medical abortion services.

What is the role of the midlevel practitioner in increasing access to abortion services?

"We have found that there is enormous interest among advanced practice clinicians in providing their patients with a full range of reproductive health care, including abortion," says Saporta. "In fact, across the country, advanced practice clinicians are currently providing medical abortion services to women under the supervision of a physician."

NAF is encouraging interested clinicians to seek training and become more involved in the provision of surgical and medical abortion care, including pregnancy options counseling, assisting in abortion service delivery, and post-abortion care, as allowed within the professional standards and regulations of their state, says Saporta.

"We know that with proper training, these clinicians are capable of providing patients with safe, high-quality, first-trimester medical and surgical abortion care," she notes.

Reference

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Get ready to add new contraceptive options

The next few months will be exciting ones for family planning providers as two new contraceptive methods, the contraceptive vaginal ring and the birth control patch, are set to hit pharmacy shelves.

The first half of 2002 is the projected entry date for the Ortho Evra transdermal contraceptive from Ortho-McNeil Pharmaceutical of Raritan, NJ, according to **Kellie McLaughlin**, director of global pharmaceutical communications for New Brunswick, NJ-based Johnson & Johnson, Ortho-McNeil's parent company.

Organon of West Orange, NJ, anticipates the launch of the NuvaRing combined contraceptive vaginal ring by July 2002, says **Nancy Alexander**, PhD, Organon's director of contraception.

There are some fast facts that providers will need to know to incorporate these methods in their practices.

The NuvaRing and the Ortho Evra offer the

EXECUTIVE SUMMARY

The contraceptive vaginal ring and the transdermal contraceptive are scheduled to arrive on U.S. pharmacy shelves by midsummer. Both are in nonpill form, which may be desirable for patients who have trouble with daily pill taking.

- The Ortho Evra is a thin, beige patch that delivers the progestin norelgestromin and the estrogen ethinyl estradiol. It is worn for one week at a time and is replaced on the same day of the week for three weeks. The fourth week is patch-free.
- The NuvaRing is a small, flexible, transparent ring that releases a continuous low dose of the progestin etonogestrel and ethinyl estradiol. It is inserted in the vagina, where it remains for three weeks, and then it is removed for one week.

convenience of effective birth control in a nonpill form, which may be desirable for those patients who have trouble with daily pill-taking. Cost for both methods is expected to be comparable to that of oral contraceptives.

The Ortho Evra is a thin, beige patch that delivers continuous levels of the progestin norelgestromin and the estrogen ethinyl estradiol through the skin and into the bloodstream. It is worn for one week at a time and is replaced on the same day of the week for three consecutive weeks. The fourth week is patch-free. **(For more on the Evra patch, see *Contraceptive Technology Reports* enclosed in this issue.)**

The NuvaRing is a small, flexible, transparent ring that releases a continuous low dose of the progestin etonogestrel and ethinyl estradiol. It is inserted in the vagina, where it remains for three weeks, and then is removed for one week. **(Get in-depth information on the NuvaRing; read the *Contraceptive Technology Reports* "The Vaginal Contraceptive Ring — Efficacy, Caution, and Instructions" inserted in the February 2002 issue of *CTU.)***

Points for discussion

McLaughlin suggests including the following talking points about Ortho Evra in your contraceptive options discussion:

• It combines the effectiveness of the Pill with convenient once-a-week dosing.

• Ortho Evra offers women an easy-to-use, weekly, noninvasive form of reversible birth control that does not require frequent trips to the doctor, surgical procedures, or daily dosing.

• The birth control patch allows the hormones to enter into the bloodstream through the skin, which may help loss of doses due to vomiting and diarrhea.

• Ortho Evra allows a slow, steady stream of hormones to enter the body over time.

Patch systems are widely used and efficient methods for delivering a variety of drugs and hormones, notes McLaughlin. While Ortho Evra represents the first contraceptive transdermal system, other medications that are available in patch form include hormone replacement therapy, smoking cessation, motion sickness treatment, chronic pain alleviation, hypertension treatment, and angina prophylaxis.

A hormone-releasing vaginal ring has been used for hormone replacement therapy, but the NuvaRing represents the first contraceptive vaginal ring. It has an outer diameter of 2 inches and a cross-sectional diameter of $^1/_8$ inch. Women can easily insert and remove NuvaRing by using their fingers to press the sides of the ring together and gently push it into or remove it from the vagina. The exact positioning of the NuvaRing within the vagina is not critical for it to work since it is not a barrier contraceptive; therefore, it cannot be incorrectly inserted. Although some women may be aware of the ring in the vagina, most women do not feel it once it is in place.

Support material on way

A variety of tools, such as brochures, posters, and other printed materials, will be made available to clinicians once Ortho Evra and the NuvaRing are launched. Until materials are ready, providers and consumers are directed to product web sites, www.orthoevra.com and www.nuvaring.com.

About 7,000 health care providers have had the opportunity to provide a small number of patients with free NuvaRings up until the official product launch, reports Alexander. The Premier Program has proven successful in introducing the new method; however, enrollment now is closed, says Alexander.

Samples, whether medicated or not, can be used as effective teaching tools in the office when introducing new methods, says **Andrew Kaunitz**, MD, professor and assistant chair in the obstetrics and gynecology department at the University of Florida Health Science Center / Jacksonville.

With a transdermal system, Kaunitz works with the patient by allowing her to apply a patch

and ask questions about the method. With the vaginal ring, his routine is to insert a ring in the office. He then allows the medical assistant to remain in the exam room with the patient to review inserting and removing the ring until the patient reaches a comfort level with the method.

"Hopefully, wide availability of sample patches and rings will facilitate this approach to patient education regarding these important new contraceptives," states Kaunitz. ■

New treatment option for trichomoniasis?

The next patient in your exam room is a young woman who has a frothy, yellow-green vaginal discharge with a strong odor. She reports discomfort during intercourse and urination. What's your initial diagnosis and plan of treatment?

If trichomoniasis is your call following a vaginal culture or wet mount, you have just diagnosed another case of the most common curable sexually transmitted disease (STD) in young, sexually active women. An estimated 5 million new cases occur each year in women and men, according to the Centers for Disease Control and Prevention (CDC).

Oral therapeutic options are limited to one drug: metronidazole (Flagyl, G.D. Searle & Co., Chicago), a first-generation 5-nitroimidazole. The CDC recommends 2 g orally in a single dose; an alternative regimen is 500 mg twice a day for seven days.[1]

Metronidazole has proved to be an effective drug for most cases of trichomoniasis. In randomized clinical trials, the recommended metronidazole regimens have resulted in cure rates of approximately 90%-95%.[1]

EXECUTIVE SUMMARY

Trichomoniasis is the most common curable sexually transmitted disease (STD) in young, sexually active women. An estimated 5 million new cases occur each year in women and men.

- While most cases are easily treated with metronidazole, reports of resistant cases have led to the U.S. research of tinidazole as a drug option.
- Tinidazole has been available in Europe for several years. The drug is under development by an Illinois company for introduction in the United States.

Resistance is a problem

But what are your options when you encounter a patient with recalcitrant trichomoniasis? Clinical treatment failures and in-vitro resistance to metronidazole have been reported.[2] Since trichomoniasis is not a reportable disease and culture specimens routinely are not obtained for diagnosis, the prevalence of metronidazole-resistant strains is not known.[2]

Treatment of patients with metronidazole-refractory vaginal trichomoniasis constitutes a major therapeutic challenge, and treatment options are extremely limited, says **Jack Sobel**, MD, professor of medicine and chief of the division of infectious diseases at Wayne State University in Detroit.

Sobel has published initial research of tinidazole, a second-generation 5-nitroimidazole, for treatment of metronidazole-resistant vaginal trichomoniasis.[3] His research reports a cure rate of 22 (92%) of 24 patients with refractory trichomoniasis who were treated with high doses of oral and vaginal tinidazole.

While tinidazole has been available in Europe for a number of years, it has not been marketed in the U.S. However, the drug now is under development by an Arlington Heights, IL, company, Presutti Laboratories, for introduction in the United States.

"As no other alternative therapy to metronidazole for trichomoniasis exists in the U.S., we feel that there is a medical need that tinidazole can fill," says **Dawn Flynn**, company vice president. "We plan to seek [Food and Drug Administration] approval for tinidazole."

Understand the STD

Trichomoniasis is caused by the single-celled protozoan parasite *Trichomonas vaginalis*. According to the CDC, the vagina is the most common site of infection in women, while the urethra is the most common site of infection in men. Women may have a frothy, yellow-green vaginal discharge with a strong odor, irritation, and itching in the genital area, and discomfort during intercourse and urination. Most men with trichomoniasis do not have signs or symptoms; those who do may have an irritation inside the penis, mild discharge, or slight

burning after urination or ejaculation. Symptoms usually appear within five to 28 days of exposure in women.

Trichomoniasis is a concern in pregnant women since it may cause premature rupture of the membranes and preterm delivery. The genital inflammation caused by the STD also might increase a woman's risk of acquiring HIV infection if she is exposed to the virus.

Treat the infection

When discussing treatment with your female patients, explain the importance of treating their male partners as well. Tell them that a man, who may never have symptoms or whose symptoms have stopped, can continue to infect a female partner until he has been treated. Therefore, plan to treat both partners at the same time to eliminate the parasite. The CDC recommends that persons being treated for trichomoniasis should avoid sex until treatment is completed and they have no symptoms. Patients should be instructed not to consume alcoholic beverages during metronidazole treatment and for at least three days afterward because abdominal cramps, nausea, headaches, and flushing may occur.

Trichomoniasis usually can be cured with the regimens recommended by the CDC. If treatment failure repeatedly occurs, the CDC advises treatment with a single 2-g dose of metronidazole once a day for three to five days. Patients with culture-documented infection who do not respond to such therapy should be managed in consultation with an expert; such consultation is available from the CDC.

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3. Sobel JD, Nyirjesy P, Brown W. Tinidazole therapy for metronidazole-resistant vaginal trichomoniasis. *Clin Infect Dis* 2001; 33:1,341-1,346. ■

Will Congress move on abstinence-only efforts?

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

In his fiscal year 2003 budget request to Congress, President George W. Bush proposed increasing funding for abstinence-only education by 33%, for an overall funding level of $135 million. The president has justified this request on the notion of "parity" — that the federal government should be spending the same amount on abstinence-unless-married education as it spends on providing contraceptive services to teens.

This funding would be tied to the federal government's stringent definition of abstinence education, which condemns sex outside of marriage — for people of any age. It also prohibits any positive discussion of contraception (in effect allowing discussion only of failure rates) and, among other things, requires programs to teach that sex outside of marriage has harmful physical and psychological effects.

This definition was first enacted — very quietly — as part of the 1996 welfare reform law. It now applies to two other, newer federal programs that also support abstinence-unless-married education. **(See the February 2001 issue of *Contraceptive Technology Update*, p. 22, "What's the next move in abstinence-only efforts?")** But with Congress poised to reauthorize the welfare law this year, the content of this federal definition and the $50 million in annual funds for abstinence-unless-married education housed in the welfare law are likely to receive more scrutiny than ever before.

Parity argument flawed

While the president's proposal will certainly strengthen the hands of conservatives seeking to protect the 1996 welfare language, the parity argument unfairly compares apples and oranges by equating funding for *education* programs and funding for *medical services* delivered under Medicaid and Title X of the Public Health Service Act.

Medicaid is the health insurance program for the nation's poorest Americans and reimburses physicians and other health care providers for rendered services. Title X supports the delivery of a broad range of contraceptives and related health services to low-income Americans at 4,500 family planning clinics nationwide. These services include Pap smears; breast exams; screening and treatment for sexually transmitted diseases; and screening for hypertension, diabetes, and anemia.

A more appropriate comparison, if one is to be made, is between what the federal government is spending on abstinence-unless-married education and what it may be spending on more comprehensive sexuality education that includes discussion of abstinence and contraception. But there currently is no federal program devoted to supporting more comprehensive sexual education.

Recent research, moreover, highlights the importance of providing teens with information about contraception and abstinence and sheds light on the factors responsible for recent declines in teenage pregnancy and interventions that work:

• Three-quarters of the decline in teen pregnancy between 1988 and 1995 was due to improved contraceptive use among sexually active teens; only one-quarter was due to increased abstinence.[1]

• While more comprehensive sexuality education programs can help teens to delay sexual activity and to reduce the number of partners and increase contraceptive use among sexually active teens, there is no reliable evidence to date supporting the effectiveness of abstinence-only education.[2]

• Programs that encourage students to take a virginity pledge promising to abstain from sexual activity until marriage can help some teens to delay the initiation of intercourse. Yet teens who break their pledge are less likely than those who never pledged in the first place to use contraception once they become sexually active.[3]

• Developed countries that have lower rates of teen-age pregnancy than the United States tend to provide comprehensive sexual information in schools.[4] U.S. policy, in contrast, exclusively promotes abstinence, and this country has among the highest teen pregnancy rates of any developed country.

Fortunately, some members of Congress have responded to this research by introducing legislation they hope will influence the debates over welfare reform and abstinence-only education.

The Family Life Education Act, introduced by Rep. Barbara Lee (D-CA) in December on a bipartisan basis, would provide $100 million annually to the states to fund more comprehensive sexual education that discusses abstinence and contraception. Also in December, Rep. Jane Harman (D-CA) introduced the Preventing Teen Pregnancy Act, which provides $20 million annually in federal funding for direct grants to organizations that replicate programs that have been scientifically proven to delay teen's initiation of sex, reduce their sexual risk-taking practices, or reduce teen pregnancy. Finally, Rep. Ben Cardin (D-MD) introduced his own comprehensive welfare reform proposal that contains significant funding to support and replicate best practices to reduce teen pregnancy.

Whether these or similar proposals ultimately will be incorporated into any welfare reform legislation signed into law by the president, or whether U.S. policy will continue to emphasize abstinence-unless-married education, remains to be seen.

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CTUPDATES
News ■ Resources ■ Events

Plan B seeks OTC status in Canada

The Plan B brand of emergency contraceptive pills soon may be available direct from Canadian pharmacists if the green light is given

by government regulators.

Women's Capital Corp. (WCC) of Washington, DC, marketer of the Plan B brand of emergency contraceptive pills, and Paladin Labs of Montreal, the Canadian distributor of the drug, have submitted an application to Health Canada to grant nonprescription status to the product. The application also is cosponsored by the Society of Obstetricians and Gynecologists of Canada and the Canadian Pharmacists Association, both based in Ottawa. WCC and Paladin Labs have asked for priority review that would allow for Canadian approval in less than a year.

Plan B is available only by prescription in most of Canada, although it is available without a prescription in British Columbia and Quebec. ***(Contraceptive Technology Update* included information on the British Columbia program in its article, "Emergency contraception: Direct from the pharmacist," January 2001, p. 1.)**

The company also plans to submit a U.S. application for nonprescription status to the Food and Drug Administration (FDA) in summer of 2002 following the completion of a clinical study. The study mimics actual over-the-counter (OTC) distribution at research sites in five U.S. cities: Houston; Boston; Phoenix; Grand Rapids, MI; and Seattle. The FDA is continuing to review a separate petition for OTC distribution of emergency contraception filed in February 2001 by some 70 medical and advocacy organizations. **(See the *CTU* article, "Emergency contraception: Going over the counter?" in the February 2001 issue, p. 17.)** ▼

See Planned Parenthood web site for teen games

Searching for a way to reach teens with an educational reproductive health message? Check out the seven new animated quiz games now offered on the www.teenwire.com web site, sponsored by the New York City-based Planned Parenthood Federation of America.

The site provides teens with honest and accurate sexual health and relationship information. The games address a variety of topics in a fun and creative way, which include body image, sexually transmitted infections, birth control, HIV, sexual assault, abstinence, and sexual orientation. Visitors may access the games by going to the "Now Playing" section and clicking on "Games." ■

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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 Daughtery Dickinson**, (229) 377-8044, (joy.dickinson@ahcpub.com).
Production Editor: **Nancy McCreary**.

Editorial Questions

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

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CE/CME Questions

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

- Give the effectiveness rates for combined and progestin-only emergency contraceptive pills (ECPs). (See "Advocates push for increased access to emergency contraception" in this issue.)
- Cite the dosing schedule for Ortho Evra. (See "Get ready to add new contraceptive options.")
- Name the drug currently indicated for initial treatment of trichomoniasis. (See "New treatment option for trichomoniasis?")
- State the possible symptoms of gonorrheal infection in women. (See "Research underscores need for increased STD screening.")

17. What are the effectiveness rates for combined and progestin-only ECPs?

A. combined ECPs, 75% reduction in the risk of pregnancy; progestin-only ECPs, 89% reduction in the risk of pregnancy
B. combined ECPs, 89% reduction in the risk of pregnancy; progestin-only ECPs, 75% reduction in the risk of pregnancy
C. both combined ECPs and progestin-only ECPs, 89% reduction in the risk of pregnancy
D. both combined ECPs and progestin-only ECPs, 75% reduction in the risk of pregnancy

18. What is the dosing schedule for the Ortho Evra transdermal contraceptive?

A. It is worn one day at a time and is replaced at the same time of day for three consecutive weeks. The fourth week is patch-free.
B. It is worn for one week at a time and is replaced on the same day of the week for three consecutive weeks. The fourth week is patch-free.
C. The same patch is worn for three consecutive weeks. The fourth week is patch-free.
D. It is worn for one week at a time and is replaced on the same day of the week. There is no patch-free week.

19. What is the drug currently indicated by the Centers for Disease Control and Prevention for initial treatment of trichomoniasis?

A. doxycycline
B. clindamycin
C. ampicillin
D. metronidazole

20. What are the possible symptoms of gonorrheal infection in women?

A. single or multiple vesicles on the genitalia
B. excessive or malodorous discharge
C. painful or burning sensation when urinating and a vaginal discharge that is yellow or occasionally bloody
D. skin eruptions, urticaria, arthritis

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Contraceptive Technology Reports

A supplement to *Contraceptive Technology Update* **May 2002, BB #S02103**

Introduction

The most common form of contraception used by women is an oral tablet consisting of an estrogen and a progestin. The oral contraceptive, which consists of various doses of ethinyl estradiol and a progestational agent, is widely used by women throughout the world. There have been few, if any, attempts to develop new and innovative methods of hormonal contraception in recent years. There has been an increasing interest in delivering hormonal contraceptives using implantable, injectable, transvaginal, or transdermal routes. Each of these approaches has advantages and disadvantages. Perhaps the major advantage of an injectable, implantable, and even a transdermal delivery system is the lowered motivation required by the consumer when using the product. It should be noted that injectable and implantable contraceptive methods require a health care provider. Transdermal contraception only requires a motivated consumer for its use. The frequency of required consumer action with other contraceptive methods varies from daily, monthly, and quarterly to every five years. In comparison, the transdermal system requires consumer action once a week. Clinical trial data indicate that compliance, meaning perfect use of the method, was 88%-91% with the transdermal system.[1]

Compliance, as measured by appropriate use of the transdermal contraceptive, was better than an oral contraceptive, specifically in younger women between ages 18 and 28.[1] Compliance improves with age and, of course, this is due to multiple factors involved in the individual's life and lifestyle.

The transdermal contraceptive delivery system now available contains ethinyl estradiol and norelgestromin (Ortho Evra/Evra, Johnson & Johnson Pharmaceutical Research and Development, Raritan, NJ). This is the only transdermal hormonal method currently available for contraception.

A Transdermal Delivery System Examined: Ethinyl Estradiol and Norelgestromin for Contraception

Author: **David F. Archer, MD,** Director, Clinical Research Center, The Jones Institute for Reproductive Medicine, The Department of Obstetrics and Gynecology, Eastern Virginia Medical School, Norfolk.

Peer reviewer: **Kirtly Parker Jones, MD,** Professor, Vice Chair for Educational Affairs, Department of OB/GYN, University of Utah Health Sciences Center, Salt Lake City.

Pharmacokinetics and Pharmacodynamic Profile

The delivery of progestins across the skin has been fraught with difficulty. The problem has been finding an appropriate formulation to deliver sufficient quantities of the progestin required for an effective contraceptive.[2] Norethindrone acetate is available as a hormone replacement therapy delivery system, but it has not been developed as a contraceptive.[3] Levonorgestrel has been found to be capable of being delivered across the skin in concentrations that could be contraceptive.[2, 4-11] At the present time, no transdermal system delivering levonorgestrel or norethindrone acetate used for contraception is commercially available in the United States, although there is clinical development of these steroids.[12]

The pharmacokinetic profile of the transdermal ethinyl estradiol /norelgestromin (EE/NEGL) shows comparable area under the curve concentrations of both steroids to that achieved for these hormones with an oral contraceptive, Ortho-Cyclen (Ortho-McNeil Pharmaceutical Co., Raritan, NJ).[13]

The advantage in the delivery of the transdermal hormone is the relatively stable serum blood levels that are obtained for ethinyl estradiol and norelgestromin.[14-16] This is different than the rise and fall that is seen with the use of an oral preparation.[13]

The current dose of the transdermal EE/NEGL delivers 20 mcg per day of ethinyl estradiol and 150 mcg per day of norelgestromin, which is a concentration well within the established reference

range for both hormones used as contraception.[13]

Application of the contraceptive transdermal system (TDS) to the arms, lower abdomen, lower back, or thighs shows slight variability in the overall pharmacokinetic profile. However, the variability is not sufficiently different to be outside of the contraceptively efficacious range.[13]

The use of the transdermal approach for the delivery of contraceptive steroids is unique and avoids the gastrointestinal absorption and first pass effect of the liver. There has been concern over the interaction between oral antibiotics and oral contraceptive steroids, which implies a gastrointestinal alteration in metabolism and a hepatic induction of enzymes.[17] No change in the pharmacokinetic profile of either ethinyl estradiol or norelgestromin delivered transdermally was found with the concomitant use of oral tetracycline.[13]

Contraceptive Efficacy

There have been three clinical trials that have evaluated the contraceptive efficacy of the TDS containing EE/NEGL for contraception.[18-20]

These studies have been combined into one analysis recently reported in *Fertility and Sterility,* which demonstrates a perfect-use failure rate through 13 cycles of 0.8% (95% confidence interval, 0.3-1.3%).[21] The corresponding Pearl index from these three studies was 0.88 (95% confidence interval, 0.44-1.33), which is comparable to that of oral contraceptives in the U.S. marketplace.[21]

There was a small subgroup of women whose body weight was greater than 198 pounds who appear to have an increased risk of pregnancy while using the TDS for contraception.[21] This subgroup was apparent in only one of the three clinical trials.[21] Counseling and clinical judgment should be involved in the decision as to whether to use the transdermal contraceptive for an individual weighing more than 200 pounds (> 90 kg).

The occurrence of breakthrough bleeding was reduced with time for women using an oral contraceptive or the TDS contraceptive.[21] It should be noted, that at all time intervals, there was less incidence of breakthrough bleeding or breakthrough bleeding and spotting with the TDS contraception as compared to the oral contraceptive.[21] This may indeed reflect the consistency of the administration of the hormone by the transdermal route without the fluctuations that are seen with oral administration as evidenced in the pharmacokinetic profile.[13]

Contraceptive efficacy is associated with consumer compliance. There was a trend, although not statistically significant, for the pregnancies to occur in the younger women where the compliance was not as consistent as with older women.[1] Certainly, there is always the potential of a method failure, but many of the pregnancies that do occur in clinical trials appear to be participant failure rather than the method itself.

Side Effects

During this study, 74% of the participants completed all 13 cycles of treatment in all three studies.[21] Common side effects were those associated with standard oral contraceptives. The major reasons for discontinuation of the TDS were adverse events in 12% of the participants, the individual's choice or personal reasons in 7%, and lost to follow-up in 4% of the women.[21]

One of the issues of efficacy in terms of a contraceptive TDS would be the ability of the system to consistently adhere to the skin. Disruption of the interface between the transdermal system and the skin results in a lower flux of the hormone across the skin. Skin adherence was studied in women using the transdermal system in warm humid climates and undergoing a variety of physical activities.[22] In these studies, the individuals were asked to use a sauna, use a whirlpool, exercise, or immerse in cool water for 15-20 minutes to document the adhesive profile of the contraceptive TDS.[22] It was found that only 1.8% of the patches required replacement because of complete detachment. Further, only 2.9% of the patches had to be replaced because of partial detachment, and it appeared that the adhesive properties of the patch improved with time or reapplication.[22]

The contraceptive TDS (Evra/Ortho Evra) comes in one size: a 20-cm square patch. Although lower patch sizes have been shown to have dose proportionality with the delivery of the hormones, the most contraceptively efficacious system is with this larger size that, generally speaking, is applied to the lower abdomen or the buttocks.[13] It has been shown that the buttocks was the sight of application for consumers in more than 50% of the applications. However, the arms, legs, and other parts of the torso, excluding the breast, have been used

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EDITORIAL GROUP HEAD: Valerie Loner.
SENIOR MANAGING EDITOR: Joy Daugherty Dickinson.
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For editorial questions and comments, please contact **Joy Daughtery Dickinson** at (229) 377-8044 or joy.dickinson@ahcpub.com.

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Table 1

Transdermal Contraceptive System Overview

This system uses a 28-day (four-week) cycle. A new patch is applied each week for three weeks (21 total days). Week Four is patch-free. Withdrawal bleeding is expected during this time.

Every new patch should be applied on the same day of the week. This day is known as the "Patch Change Day." For example, if the first patch is applied on a Monday, all subsequent patches should be applied on a Monday. Only one patch should be worn at a time.

On the day after Week Four ends, a new four-week cycle is started by applying a new patch. Under no circumstances should there be more than a seven-day patch-free interval between dosing cycles.

If the woman is starting Ortho Evra for the first time, she should wait until the day she begins her menstrual period. Either a First Day start or Sunday start may be chosen. **(See below.)** The day she applies her first patch will be Day 1. Her "Patch Change Day" will be on this day every week.

- **For First Day Start:** The patient should apply her first patch during the first 24 hours of her menstrual period.

If therapy starts after Day 1 of the menstrual cycle, a nonhormonal backup contraceptive (such as condoms, spermicide, or diaphragm) should be used concurrently for the first seven consecutive days of the first treatment cycle.

OR

- For Sunday start: the woman should apply her first patch on the first Sunday after her menstrual period starts. She must use backup contraception for the first week of her first cycle.

If the menstrual period begins on a Sunday, the first patch should be applied on that day, and no backup contraception is needed.

Where to apply the patch. The patch should be applied to clean, dry, intact healthy skin on the buttock, abdomen, upper outer arm, or upper torso, in a place where it won't be rubbed by tight clothing. Ortho Evra should not be placed on skin that is red, irritated, or cut, nor should it be placed on the breasts.

To prevent interference with the adhesive properties of Ortho Evra, no makeup, creams, lotions, powders, or other topical products should be applied to the skin area where Ortho Evra patch is or will be placed.

Application of the Ortho Evra Patch

The foil pouch is opened by tearing it along the edge using the fingers. The foil pouch should be peeled part and open flat. A corner of the patch is grasped firmly, and it is gently removed from the foil pouch.

The woman should be instructed to use her fingernail to lift one corner of the patch and peel the patch and the plastic liner off the foil liner. Sometimes patches can stick to the inside of the pouch — the woman should be careful not to accidentally remove the clear liner as she removes the patch. Half of the clear protective liner is to be peeled away. (The woman should avoid touching the sticky surface of the patch.) The sticky surface of the patch is applied to the skin, and the other half of the liner is removed. The woman should press down firmly on the patch with the palm of her hand for 10 seconds, making sure that the edges stick well. She should check her patch every day to make sure it is sticking.

The patch is worn for seven days (one week). On the "Patch Change Day," Day 8, the used patch is removed and a new one is applied immediately. The used patch still contains some active hormones — it should be carefully folded in half so that it sticks to itself before throwing it away.

A new patch is applied for Week Two (Day 8) and again for Week Three (on Day 15), on the usual "Patch Change Day." Patch changes may occur at any time on the Change Day. Each new Ortho Evra patch should be applied to a new spot on the skin to help avoid irritation, although they may be kept within the same anatomic area.

Week Four is patch-free (Day 22 through Day 28), thus completing the four-week contraceptive cycle. Bleeding is expected to begin during this time.

The next four-week cycle is started by applying a new patch on the usual "Patch Change Day," the week after Day 28, no matter when the menstrual period begins or ends.

Under no circumstances should there be more than a seven-day patch-free interval between patch cycles.

Source: Johnson & Johnson Pharmaceutical Research and Development, Raritan, NJ. Web: www.ortho-mcneil.com/products/pi/pdfs/orthoevra.pdf.

for application of the transdermal contraceptive.[13] **(See Table 1, "Transdermal Contraceptive System Overview," above.)**

Summary

In summary, the new contraceptive delivery system involving the transdermal delivery of ethinyl estradiol and the progestin norelgestromin (Ortho Evra) is now commercially available on the U.S. marketplace. This contraceptive TDS is highly effective, with a Pearl index and an overall pregnancy rate that is comparable to that found with oral contraceptives. The compliance with the method was high in contrast to oral contraceptive users, which should improve the overall contraceptive efficacy. Loss of adhesive through exercise or immersion in water was minimal and should not detract from the use of this method in the future.

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CME Objectives/Questions

To earn CME credit for this issue, please refer to the enclosed Scantron for directions on taking the test and submitting your answers.

After reading this issue, the CME participant will be able to:

- identify perfect use of the transdermal contraceptive delivery system (patch) in clinical trials;
- compare compliance for the patch and oral contraceptives (OCs) for women ages 18-28;
- contrast the area under the curve for ethinyl estradiol and norelgestromin with the patch and a comparable OC;
- identify whether serum concentrations of ethinyl estradiol and norelgestromin with the patch were found to change or be unmeasurable during one week of extreme temperature, humidity, and exertion; and
- compare the method failure of the patch with OCs.

1. Compliance or perfect use of the patch in clinical trials is reported to be:
   A. 48%-51%.
   B. 68%-71%.
   C. 88%-91%
   D. none of the above

2. Compliance, measured by perfect use, is better for the patch compared to OCs in women ages 18-28.
   A. True
   B. False

3. The area under the curve of the serum concentrations for ethinyl estradiol and norelgestromin following use of the patch compared to a comparable OC is:
   A. lower.
   B. higher.
   C. similar.
   D. not evaluated.

4. Serum concentrations of ethinyl estradiol and norelgestromin with the transdermal system, during one week of extreme temperature, humidity, and exertion, were found to be:
   A. unchanged.
   B. increased.
   C. decreased.
   D. unmeasureable.

5. The perfect-use failure rate of 0.8% with the transdermal contraceptive patch, when compared to OCs, is:
   A. better.
   B. worse.
   C. similar.

S·T·D QUARTERLY™

Research underscores need for increased STD screening

Testing only symptomatic patients may miss undetected infection

What is your facility's policy on testing for sexually transmitted diseases (STDs)? If it is limited to symptomatic patients, significant amounts of undetected infection may be passing under your radar.

Just-published research conducted in Baltimore shows that between 1997 and 1998, undiagnosed gonorrhea and chlamydia infections occurred in a combined one in 12 (7.9%) of young adults ages 18-35 in the city.[1] The number of undetected gonorrhea and chlamydia infections in the city may be as high as the number of cases that are diagnosed and treated, say researchers.

In response to the findings, the Baltimore City Health Department has mailed letters to more than 1,000 doctors and clinics urging them to screen all sexually active patients younger than 30 for gonorrhea and chlamydia, regardless of whether the patients report or exhibit any symptoms of infection.

"Clearly, as the most recent article in the *Journal of the American Medical Association [JAMA]* that actually used Baltimore as a site showed, there is a very significant amount of disease burden of asymptomatic chlamydia and gonorrhea in the community," says **Peter Beilenson**, MD, Baltimore City health commissioner. "The best way to pick that up is urine screening, and that's why we are doing it."

EXECUTIVE SUMMARY

Sexually transmitted diseases may be significantly more prevalent than previously believed, at least in some U.S. areas and populations, according to recent research.

- An investigation conducted in Baltimore shows that between 1997 and 1998, undiagnosed gonorrhea and chlamydia infections occurred in a combined one in 12 (7.9%) of young adults ages 18-35 in the city.
- Urine-based screening represents an effective form of testing for gonorrhea and chlamydia; however, its cost can prove challenging to clinic budgets.

Taking aim at STDs

The new research underscores what public health officials say is the "hidden epidemic" of STD infection in the United States.[2]

Look at the latest statistics presented at the March 2002 National STD Prevention Conference in San Diego. While the overall national gonorrhea rate remained stable, 13 of 20 cities with the highest rates in 1999 had even higher rates in 2000, according to the Centers for Disease Control and Prevention (CDC).[3] In five of the top 20 1999 cities — Kansas City, MO; Buffalo, NY; Jacksonville, FL; Detroit; and Birmingham, AL — the gonorrhea rate rose by more than 20% in 2000. **(See chart on p. 2.)**

On a national level, the overall rate of gonorrhea appears to have stabilized, following a 9% increase between 1997 and 1999. In 2000, the rate of gonorrhea was 131.6 cases per 100,000 people, compared to 132 cases per 100,000 people in 1999. Prior to that upturn, national gonorrhea rates had declined each year since 1975.

Gonorrhea Rates by City, 2000 vs. 1999

No.	City	Cases, 2000	Rate per 100,000 Population, 2000	Rate per 100,000 Population, 1999	Percent chang
1.	Richmond, Va.	1,752	923.6	963.1	-4.1%
2.	Rochester, N.Y.	2,142	894.8	851.0	5.2%
3.	Baltimore, Md.	5,603	885.6	967.9	-8.5%
4.	St. Louis, Mo.	2,879	862.1	861.2	0.1%
5.	Detroit, Mich.	9,610	766.7	630.3	21.6%
6.	Norfolk, Va.	1,490	659.7	571.6	15.4%
7.	New Orleans, La.	3,015	654.1	583.0	12.2%
8.	Kansas City, Mo.	2,688	595.2	433.1	37.4%
9.	Philadelphia, Penn.	8,198	578.3	548.5	5.4%
10.	Milwaukee, Wis.	5,146	567.8	538.9	5.4%
11.	Memphis, Tenn.	4,941	566.0	577.1	-1.9%
12.	Newark, N.J.	1,558	550.0	614.7	-10.5%
13.	Washington, D.C.	2,706	521.4	681.3	-23.5%
14.	Buffalo, N.Y.	1,572	500.8	392.8	27.5%
15.	Jacksonville, Fla.	3,640	492.9	402.4	22.5%
16.	Atlanta, Ga.	3,456	464.0	756.0	-38.6%
17.	Birmingham, Ala.	3,018	459.1	379.1	21.1%
18.	*Nashville, Tenn.	2,404	453.5	336.8	34.6%

Source: Center for Disease Control and Prevention, National Center for HIV, STD, and TB Prevention, Division of Sexually Transmitted Diseases, Atlanta.

In 2000, 702,093 chlamydial infections were reported to CDC. However, the CDC estimates that 3 million new cases of this largely asymptomatic infection occur in the United States each year.

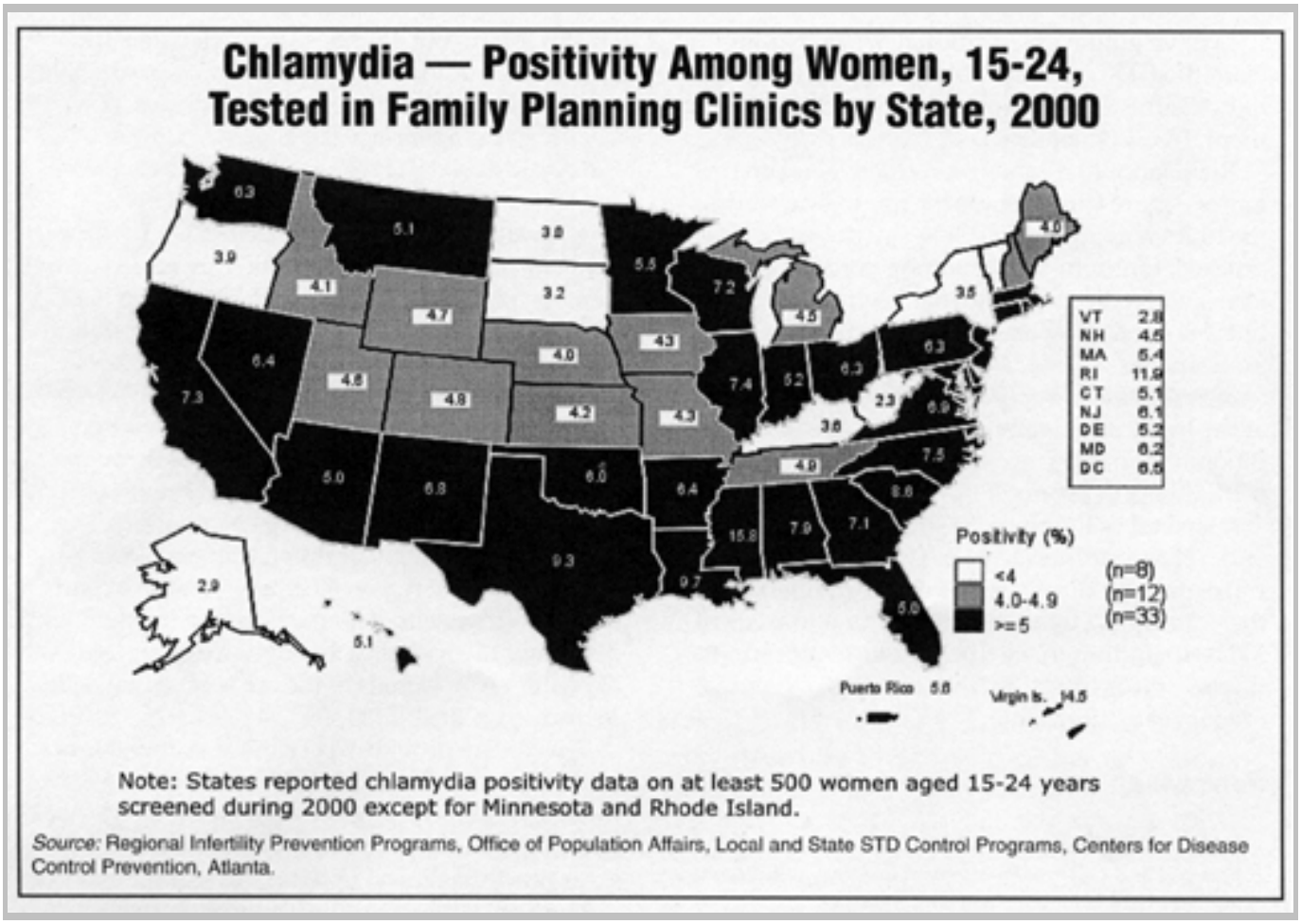
New CDC figures show that chlamydia positivity among young women is lowest in areas with longstanding screening and treatment programs, but remains high in areas where programs are not as widely available. Since case reports do not provide a complete picture of the burden of disease, researchers look to studies of chlamydia prevalence in various groups, such as the percentage of women testing positive for chlamydia in family planning clinics.

In 2000, the 10 states with the highest level of chlamydia positivity among 15- to 24-year-old women in family planning clinics included Mississippi (15.8%), Rhode Island (11.9%), Louisiana (9.7%), Texas (9.3%), South Carolina (8.6%), Alabama (7.9%), North Carolina (7.5%), California (7.3%), Illinois (7.4%), and Wisconsin (7.2%). **(See map on p. 3.)**

Chlamydia, caused by the bacterium *Chlamydia trachomatis,* is known as a "silent" disease because three-quarters of infected women and half of infected men have no symptoms. The infection is frequently not diagnosed or treated until complications develop. For women, the consequences are chilling: genital chlamydial infection is the leading cause of preventable infertility and ectopic pregnancy.[4]

Gonorrhea is caused by *Neisseria gonorrhoeae*, a bacterium that can grow and multiply easily in mucous membranes of the body. When initially infected, the majority of men have some signs or symptoms, such as a burning sensation when urinating and a yellowish-white discharge from the penis. However, the early symptoms of gonorrhea in women are often mild, and many who are infected have no symptoms of infection. When symptoms are present, they may include a painful or burning sensation when urinating and a vaginal discharge that is yellow or occasionally bloody.

Gonorrhea and chlamydia, when left untreated, cause pelvic inflammatory disease and have been linked to increased transmission of HIV, says



Jonathan Zenilman, MD, associate professor of the infectious diseases division at the Baltimore-based Johns Hopkins University School of Medicine. Zenilman served as a co-author of the *JAMA* paper.

Why is it so important to screen for gonorrhea and chlamydia, regardless of whether the patients report or exhibit any symptoms of infection? Studies of asymptomatic STDs in a variety of settings have found that risk factor analysis is a poor tool in identifying a large proportion of gonorrhea and chlamydial infections, states Zenilman.

What prompted the *JAMA* research? STD surveillance traditionally has been based on cases reported to health departments, says Zenilman. Previous reports demonstrated that these estimates are biased toward ascertaining symptomatic cases presenting to public clinics, he states. No population-based estimates have been previously performed on a citywide scale, so the study provided researchers the opportunity to perform such an assessment and to estimate the number of cases of undiagnosed asymptomatic infection in the population.

The rise of new noninvasive nucleic acid amplification tests for gonorrhea and chlamydia made the study possible, he observes. The tests are noninvasive and can be performed on urine.

Researchers interviewed 728 young adults from a randomly selected cross section of Baltimore households and tested urine specimens from 579 participants. Analysis of results from urine specimens subjected to the nucleic acid amplification tests and comparisons with clinically diagnosed cases of gonorrhea and chlamydia showed the high percentages of hidden cases.

The high prevalence rate in the general public and the lack of symptoms suggests that screening programs and extending access to care are critical for reducing the prevalence of these infections, say researchers.

Urine-based screens are being done on a regular basis in most of the family planning and STD programs run by the city of Baltimore, Beilenson reports. However, due to the increased cost represented by the new tests, such screens have not yet been implemented across the board, he notes. The urine-based tests run about $15, as compared to about $3 for traditional tests.[5]

"We've gotten an additional $75,000 grant from the CDC, and we've rebudgeted some of our existing STD money from the federal government," says Beilenson.

Reluctance to discuss reproductive health matters is a more troublesome barrier to uncovering the hidden epidemic of STDs, say public health officials. Embarrassment among patients and clinicians when discussing sexual health is common, but it is not a good reason for avoiding health risk assessments, states **J. Dennis Fortenberry**, MD, associate professor of pediatrics and medicine at the Indiana University School of Medicine in Bloomington, in an accompanying editorial to the Baltimore research.[6]

"Societal willingness to stigmatize sexuality and STDs continues to hide issues that are central aspects of our lives," states Fortenberry in the editorial. "Given the morbidity and costs of STDs, including those due to human immunodeficiency virus infection, these are veils that no longer seem affordable."

References

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3. Centers for Disease Control and Prevention. CDC: Gonorrhea Rates Increased in Two-Thirds of Hardest-Hit U.S. Cities. San Diego; March 5, 2002.

4. Kaiser Family Foundation. Questions & Answers. The Tip of the Iceberg: How Big is the STD Epidemic in the United States? Menlo Park, CA; December 1998.

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6. Fortenberry JD. Unveiling the hidden epidemic of sexually transmitted diseases. *JAMA* 2002; 287:768-769. ■

How do you get your STD skills up to speed?

What are some tips to get your clinical skills up to speed on the state-of-the-art treatment and protocols in diagnosing and treating sexually transmitted diseases (STDs)?

Look at the following ideas suggested by **Ward Cates**, MD, MPH, president of Family Health International in Research Triangle Park, NC, and is author of the chapters on reproductive health infections and vaginal spermicides in *Contraceptive Technology* (1998, Ardent Press). Cates addressed STD topics at the 2002 *Contraceptive Technology* conferences.

• **Await publication of the *2002 STD Treatment Guidelines*.** The guidelines, which are issued by the Centers for Disease Control and Prevention (CDC), should be published this spring in CDC's publication, *Morbidity and Mortality Weekly Report,* says Cates. It then will be available on the CDC's web site, www.cdc.gov, for access and downloading.

• **Check out training opportunities through the National Network of STD/HIV Prevention Training Centers.** The National Network of STD/HIV Prevention Training Centers is a CDC-funded group of regional centers, created in partnership with health departments and universities, dedicated to increasing the knowledge and skills of health professionals in the areas of sexual and reproductive health.

Ten centers provide STD clinical training, four centers provide behavioral and social interventions training, and four centers provide partner services and program support training. The courses offer great practical clinical updates, says Cates.

The STD clinical training courses provide up-to-date information to public and private clinicians who diagnose, treat, and manage patients with STDs. Most courses devote 50% of class time to clinical and laboratory experience under the guidance of a qualified preceptor. Standard clinical training courses are three to five days in length, but centers also offer clinical training courses in the following formats: one- to two-hour "grand rounds," teleconferencing, home study, on-site courses (upon request), and web-based courses. Exact course offerings vary by location, so contact the center serving your geographic area for additional information and a schedule of courses.

Visit the network's web page at http://depts.washington.edu/nnptc/, or contact the individual centers at the following telephone numbers: Seattle (206) 685-9850; Berkeley, CA (510) 883-6600; Denver (303) 436-7226; St. Louis (314) 747-0294; Cincinnati (513) 357-7308; Dallas (214) 819-1947; Austin, TX (512) 490-2535; Tampa, FL (813) 307-8000, ext. 4599; Baltimore (410) 396-4448; New York City (212) 788-4419; Albany, NY (518) 474-1692; and Jamaica Plain, MA (617) 983-6945. ■