AMERICAN HEALTH CONSULTANTS®

CONTRACEPTIVE TECHNOLOGY UPDATE®

A Monthly Newsletter for Health Professionals

INSIDE

MAY 2001

VOL. 22, NO. 5 (pages 49-60)

What to expect in the next five years? Innovative contraceptive delivery

Patches, rings, implants, and gels are in research

What can American women expect to see as new contraceptive options in the next five years? While novel forms of hormonal delivery might not yet be approved, family planning experts say there will be new forms of birth control available for use in the form of contraceptive patches and rings.

Several strides already have been made this year with the U.S. introduction of the monthly contraceptive injectable Lunelle, marketed by Pharmacia Corp. of Peapack, NJ, and the Mirena levonorgestrel-releasing intrauterine system (IUS), marketed by Berlex Laboratories of Montville, NJ, says **Daniel Mishell Jr.**, MD, professor in the department of obstetrics and gynecology at the University of Southern California School of Medicine in Los Angeles. **(More information on Lunelle is contained in a special news bulletin inserted in *Contraceptive Technology Update,* November 2000. The U.S. introduction of the Mirena is the focus of an**

CTU launches web site!

As a free service to subscribers of *Contraceptive Technology Update*, we are offering a new web site that offers free access to *Contemporary OB/GYN, OB/GYN Alert,* and *Physicians' Desk Reference*, among other features. The address is www.contraceptiveupdate.com.

You can read stories from the current issue of *CTU*, plus get free access to previous issues of the newsletter and selected publications published by American Health Consultants. The web site includes women's health articles from peer-reviewed journals and patient handouts. Participate in our poll, respond to readers' questions and comments, or post some of your own. There are also links to several valuable web sites and a bookstore.

To access the site, you will need your subscriber number, which is printed above your name on your *CTU* mailing label. If you need help identifying your subscriber number, please contact customer service at (800) 688-2421 or customerservice@ahcpub.com. ■

EXECUTIVE SUMMARY

New forms of hormonal delivery will highlight contraceptive advances in the next five years.

- The Evra contraceptive patch, developed by the R.W. Johnson Pharmaceutical Research Institute, is under review by the Food and Drug Administration. A patch, which carries the progestin/estrogen combination of norelgestromin and ethinyl estradiol, is worn three weeks with a patch-free fourth week. The Population Council is developing another patch with a different progestin.
- The Nuvaring contraceptive vaginal ring from Organon USA is nearing the end of clinical development. It combines the progestin etonogestrel and the estrogen ethinyl estradiol.

article in the February 2001 issue, p. 13.)

The Evra contraceptive patch, developed by the R.W. Johnson Pharmaceutical Research Institute in Raritan, NJ, is under review by the Food and Drug Administration (FDA). The transdermal patch serves as a carrier for the progestin / estrogen combination of norelgestromin and ethinyl estradiol. It is worn for one week at a time and is changed on the same day of the week three times a month, with the fourth week patch-free. **(See *CTU,* March 2001, p. 29, for further information on Evra.)**

Mishell also points to the U.S. introduction of the Nuvaring contraceptive vaginal ring from Organon USA of West Orange, NJ. The ring, which carries a combination of the progestin etonogestrel and ethinyl estradiol, is nearing the end of clinical development. **(Learn more about ring delivery systems in *CTU,* May 1998, p. 57.)** A just-published study shows that the ring — worn three weeks, then removed for one week — offered good cycle control with favorable patient compliance.[1]

The New York City-based Center for Biomedical Research, the research arm of the Population Council, also is investigating contraceptive patch and ring delivery systems, reports **Regine Sitruk-Ware**, MD, the council's executive director of contraceptive development. By the end of 2001, Phase III testing is scheduled to begin on a vaginal ring containing two hormones: Nestorone, a progestin developed by the council, and the synthetic estrogen ethinyl estradiol. The ring is inserted for three weeks, removed for one week to allow menstruation, then returned, for a total of 13 consecutive cycles.

Nestorone is ideally suited for transdermal drug delivery systems since it is readily absorbed through the skin into the bloodstream, and its high efficacy can be maintained at low, stable daily doses, according to the Population Council. Its use also is being evaluated in patch form, as well as in gel form, says Sitruk-Ware. **(Information on Nestorone is included in *CTU,* October 1997, p. 121, and the May 1998 issue, p. 57.)**

Implants offer options

Several European markets have seen the introduction of the single-rod contraceptive implant Implanon, marketed by Organon USA's parent company, NV Organon, in Oss, the Netherlands. Intended for three years of use, the progestin-only implant offers an excellent contraceptive action and an acceptable safety profile, according to research.[2] In a comparison study that evaluated the contraceptive efficacy, tolerability, and bleeding patterns of Implanon vs. the six-rod Norplant implant (marketed in the United States by Wyeth-Ayerst Pharmaceuticals of Philadelphia), researchers found less frequent bleeding, a higher incidence of infrequent bleeding, and amenorrhea in the single-rod system.[3]

The Population Council's two-rod levonorgestrel implant, marketed internationally as Jadelle, offers a similar side effect profile and contraceptive efficacy as its sister six-rod implant, Norplant.[4] Jadelle has been found to be equally as effective and acceptable as Norplant and provides safe, highly-effective reversible contraception, according to research. Because it consists of only two rods, insertion and removal of Jadelle is easier and takes less time than that of Norplant, studies show.[4]

Family planners may recognize Jadelle as Norplant II, which was approved by the FDA in

COMING IN FUTURE MONTHS

- Evaluate risks, benefits of estrogen therapy
- Supporting vasectomy: One program's story
- Reaching teens with an STD prevention message
- Emergency contraception: Now on the Web
- Check out new condoms on the market

1996. Wyeth-Ayerst Pharmaceuticals, which holds the U.S. marketing rights to the device, has not introduced it for sale and has chosen to further research the two-rod implant.

New OCs under review

New oral contraceptives (OCs) are now in the research pipeline, says Mishell. One candidate includes a four periods-per-year pill called Seasonale. Manufacturer Barr Laboratories of Pomona, NY, has signed an exclusive rights agreement with Eastern Virginia Medical School of Norfolk, the original developers of the product, to bring the OC to market. Clinical trials are now under way. If successful — and the FDA approves — Seasonale could reach the shelves of U.S. pharmacies by 2003. **(See *CTU*, May 1999, p. 51, for more information on Seasonale.)**

> "The promise offered by these new methods will not be met unless U.S. insurance plans begin to more routinely cover contraception."

Wyeth-Ayerst is investigating a new oral contraceptive using the novel progestin trimegestone with the established estrogen ethinyl estradiol. The formulation is in Phase II studies in the research pipeline.

The next five years will bring to American women more new choices in contraception than the previous 30 years combined, predicts **Philip Darney**, MD, MSc, professor at the University of California, San Francisco, and chief of the department of OB/GYN at San Francisco General Hospital Medical Center.

"Providers will have increased responsibility to help their patients understand the positive and negative aspects of these new methods," observes Darney. "The big question is whether new methods will mean greater individual and collective success in avoiding unintended pregnancy."

More choices may not mean increased access, says **Andrew Kaunitz**, MD, professor and assistant chair in the obstetrics and gynecology department at the University of Florida Health Science Center/Jacksonville. Even with the debut of the Lunelle injectable and the Mirena IUS, many women may not be able afford such methods because their insurance policies do not offer contraceptive coverage.

"The promise offered by these new methods will not be met unless U.S. insurance plans begin to more routinely cover contraception," states Kaunitz. "That many plans continue not to cover reversible control remains a national disgrace."

RESOURCES

- **Philip Darney**, MD, MSc, San Francisco General Hospital,1001 Potrero Ave., Ward 6D, San Francisco, CA 94110. Telephone: (415) 206-8358. Fax: (415) 206-3112. E-mail: Darney@ob.ucsf.edu.
- **Daniel Mishell Jr.,** MD, Women's and Children's Hospital, 1240 N. Mission Road, Room L1009, Los Angeles, CA 90033.
- **Regine Sitruk-Ware**, MD, The Population Council, One Dag Hammarskjold Plaza, New York, NY 10017.

References

1. Roumen FJ, Apter D, Mulders TM, et al. Efficacy, tolerability, and acceptability of a novel contraceptive vaginal ring releasing etonogestrel and ethinyl oestradiol. *Hum Reprod* 2001; 16:469-475.
2. Croxatto HB, Urbancsek J, Massai R, et al. A multicentre efficacy and safety study of the single contraceptive implant Implanon. Implanon Study Group. *Hum Reprod* 1999; 14:976-981.
3. Zheng SR, Zheng HM, Qian SZ, et al. A randomized multicenter study comparing the efficacy and bleeding pattern of a single-rod (Implanon) and a six-capsule (Norplant) hormonal contraceptive implant. *Contraception* 1999; 60:1-8.
4. Sivin I, Campodonico I, Kiriwat O, et al. The performance of levonorgestrel rod and Norplant contraceptive implants: a five-year randomized study. *Hum Reprod* 1998; 13:3,371-3,378. ■

ECPs over the counter? Studies to determine use

The wheels are in motion for moving emergency contraceptive pills (ECPs) to over-the-counter status, as study protocols are being designed to evaluate the use of the drug without a prescription.

The Bellevue, WA-based Women's Capital Corp.,

EXECUTIVE SUMMARY

Proponents of moving emergency contraceptive pills (ECPs) to over-the-counter (OTC) status have surged forward on two fronts.

- The Women's Capital Corp., marketer of the levonorgestrel-only ECP Plan B, has met with the Food and Drug Administration (FDA) to review study protocols the company will undertake to support the switch from prescription to OTC. Results of the company's actual use study will be available in early 2002.
- A petition has been filed with the FDA by the Center for Reproductive Law and Policy on behalf of more than 60 medical groups to change the status of ECPs to OTC.

marketer of the levonorgestrel-only ECP Plan B, has met with Food and Drug Administration (FDA) officials to review study protocols the company will undertake to support the switch from prescription to over-the-counter (OTC) status for Plan B, confirms **Sharon Camp**, PhD, Women's Capital Corp. president.

The studies include the two normally required for an OTC switch: a label comprehension study and an actual use study, which mimics OTC use, Camp explains.

"The actual use study will be done in Washington State pharmacies now dispensing Plan B without a prescription — a sort of living laboratory," says Camp. "The company also is doing some additional studies addressed to the broader behavioral questions about which the FDA and others have expressed concern, namely the likelihood of repeated use, special problems related to use by young teens, the impact on use of regular contraception, and specifically the possibility of increased HIV / sexually transmitted diseases risk if couples use condoms less consistently."

Data key for decision

The FDA's decision will be based in large part on the actual use study that will take place in Washington State pharmacies, says Camp.

"For study subjects, we will take the pharmacist out of the loop," she explains. "Women will be consented for the study, then given the prototype OTC product, which will look very much like Plan B does now."

There will be no screening or counseling involved with the drug's distribution, says Camp. Participants will undergo follow-up at various intervals to assess such issues as contraindicated and incorrect use, she states.

"Given FDA's suggested revisions to both study protocols, we have been delayed by a couple of months and will probably not be able to submit the study results until early next year," Camp reports. "We expect to ask for priority review status and would hope for approval sometime in 2002."

A petition has been filed on behalf of more than 60 medical groups to change the status of emergency contraceptive pills from prescription to OTC. The legal document has been filed with the FDA by the New York City-based Center for Reproductive Law and Policy.

"Because emergency contraception poses no known health risks, has minor side effects, and can be taken in two simple, identical doses without medical supervision, it meets all the criteria necessary for over-the-counter status," states **Bonnie Scott Jones**, staff attorney with the Center. "Most importantly, easy access to emergency contraception would, in fact, protect public health by eliminating millions of unwanted pregnancies and abortions."

The FDA has 180 days to respond to the petition, which was filed on Feb. 14, says **Linda Robayo**, a spokeswoman for the center. The agency does not have to issue a decision in this time period; it can acknowledge its receipt and delay its decision for as long as it wishes, Robayo explains.

How can proponents of emergency contraception(EC) show their support for the petition?

"If they are a medical or health public group, they should contact us about signing on as petitioners," says Scott Jones. "If not, they should try and do press [stories] on the issue or local lobbying." **(See the resource box on p. 53 for contact information.)**

The Washington, DC-based American College of Obstetricians and Gynecologists (ACOG) has issued new and revised documents on the safety and availability of EC.

The group supports making EC available to women OTC in a designated (prepackaged) product and has issued a formal statement on the subject.[1] It also has issued a revised practice bulletin, which updates its recommendations to physicians regarding the safety and efficacy of prescription EC.[2]

The revised bulletin includes charts on how to combine common prescription oral contraceptives in dosages that provide EC and has added

RESOURCE AND SOURCES

Medical groups who wish to join the petition to move emergency contraceptive pills to OTC status should contact:

- **Center for Reproductive Law and Policy**, 120 Wall St., New York, NY 10005. Telephone: (917) 637-3600. Fax: (917) 637-3666. Web: www.crlp.org.

For more information on emergency contraceptive pills and OTC status, contact:

- **Sharon Camp**, PhD, Women's Capital Corp., 1990 M St. N.W., Suite 250, Washington, DC 20036. Telephone: (800) 330-1271. E-mail: scamp@go2planb.com.
- **Linda Robayo**, Center for Reproductive Law and Policy, 120 Wall St., New York, NY 10005. Telephone: (917) 637-3605. Bonnie Scott Jones may be contacted via Robayo.
- **James Trussell**, PhD, Office of Population Research, Wallace Hall, Princeton University, Princeton NJ 08544. Telephone: (609) 258-4810. Fax: (609) 258-1418. E-mail: trussell@princeton.edu.

information on two EC designated products: Preven (from Gynétics of Belle Mead, NJ) and Plan B. To increase access, ACOG suggests physicians may wish to offer patients an advance prescription for EC during routine gynecologic visits.

Get the word out

It will be important for EC proponents to address the public concerns about OTC availability, says Camp.

"Research to date suggests that public opposition to the switch could be significant without more educational efforts," Camp notes. "If public opposition is effectively mobilized by the religious right over issues such as access by minors, the application might be denied or held up indefinitely."

Increased education is going to have to go hand in hand with moving EC to the forefront in terms of public awareness, says **James Trussell**, PhD, professor of economics and public affairs, faculty associate of the Office of Population Research, and associate dean of the Woodrow Wilson School of Public and Interna-tional Affairs at Princeton (NJ) University. The Office of Population Research and the Washington, DC-based Reproductive Health Technologies Project operate the Emergency Contraception Hotline [(888) NOT-2-LATE], a national toll-free, automated, confidential hotline available 24 hours a day in English, Spanish, and French, as well as an affiliated web site (not-2-late.com).

"The clinical bottleneck in the United States is that currently clinicians think EC is safe and effective and are waiting for women to come and ask for it, while women don't know to come and ask for it," says Trussell. "We're not going to get anywhere much toward solving that problem just by making it available over the counter."

References

1. American College of Obstetricians and Gynecologists. *Statement Supporting the Availability of Over-the-Counter Emergency Contraception.* Washington, DC; 2001.
2. American College of Obstetricians and Gynecologists. *Emergency Oral Contraception.* Washington, DC; 2001. ■

Women and weight gain: OCs are not the culprit

Four out of 10 women in a just-released survey say weight gain is a reason to stop taking or avoid the Pill, and increased weight is the primary concern voiced by patients when inquiring about the Pill's side effects.[1]

The survey, conducted on behalf of the Washington, DC-based National Association of Nurse Practitioners in Women's Health (NPWH), found that women seeking to avoid weight gain may choose a less-effective method of birth control than

EXECUTIVE SUMMARY

Many women avoid the Pill due to misconceptions about oral contraceptives' (OC) impact on weight. Four out of 10 women in a just-released survey say weight gain is a reason to stop taking or avoid the Pill, and increased weight is the primary concern voiced by patients when inquiring about the side effects.

- Although weight gain is often cited as a reason to stop or never use OCs, studies fail to associate use of low-dose pills with significant weight gain.
- According to current overall weight changes among Americans, more than half of women over age 20 are classified as overweight or obese. Counsel women on healthy eating habits and exercise to address weight concerns.

oral contraceptives (OCs) or no method, which may result in unintended pregnancies. **(Review highlights of the report at the organization's web site: www.npwh.org.)**

"There's a paradox, because oral contraceptives are one of the best, most effective methods that we have, and in fact women aren't using it because they think they are going to gain weight," says **Susan Wysocki**, RNC, NP, NPWH president and CEO.

NPWH is encouraging providers to do a better job of educating women about oral contraceptives. With studies showing that today's low-dose pills do not cause weight gain, clinicians need to provide adequate information to women who are seeking to preserve healthy weight, self-image, and reproductive wellness.

The myths persist

Why do the myths persists when it comes to it OCs and weight gain? **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-based private research firm specializing in reproductive health, offers the following observations:

• OCs are an easy target. "With other things going on, they are the first thing many women think of," comments Rosenberg.

• The largest group of OC users tends to be young women, a common age for weight gain.

• Although some women lose weight while using OCs, providers do not hear complaints to that effect. The absence of such reports creates the impression that weight gain, but not loss, is associated with OC use, explains Rosenberg.

Rosenberg explored the weight/OC issue in a study analyzing the daily weights of 128 women during four cycles of triphasic OC use.[2] The mean weight at the end of the fourth cycle of use was the same as baseline weight. The largest proportion of women, 52%, remained within two pounds (0.9 kg) of their starting weight, and 72% of women had either no weight change or a loss. Over each menstrual cycle, regular but minor weight shifts were observed, with the mean weight rising by one-half pound (0.2 kg) during the first weeks of each cycle and falling by the same amount during the last few days. These results emphasize the lack of association of OC use with weight gain, but OC may be blamed at least in part, based on cyclic fluctuations, he concludes.

Although weight gain is often named as the reason for nonuse or discontinued use of OCs, studies fail to associate use of low-dose OCs with significant weight gain.[3,4]

Studies that have examined the Pill against placebo for use in other indications outside of contraception also show no association with increased weight. One such study, conducted for use of Ortho Tri-Cyclen (marketed by Ortho-McNeil Pharmaceuticals of Raritan, NJ) for treatment of acne, showed no difference in weight gain vs. placebo; in fact, more women taking placebo discontinued prematurely due to weight gain.[5]

Discuss ways to manage weight goals

Women who avoid OCs and other hormonal contraception due to their fear of gaining weight should be brought up to date on the current status of weight changes in the U.S. population.[6] More than half of women over age 20 are overweight (defined as a body mass index: kg/m^2 of 25.0 to 29.9) or obese (defined as a body mass index:kg/m^2 of 30 or more.)[6]

Talk with patients about their weight concerns, and identify steps for managing weight goals.

Prospective information and reassurance about weight issues are important, especially when it comes to keeping up physical activities, notes Rosenberg. Over two-thirds of women do not participate in regular and sustained physical activity, and almost one-third are physically inactive.[6] Counsel women on healthy eating habits and exercise to address weight concerns.

"I do think that with the literature pretty consistently and clearly indicating a lack of problem associated with OCs, we're back to efforts to educate," Rosenberg observes. "Weight gain is a powerful issue."

SOURCES

For more information on weight gain and oral contraceptives, contact:

- **Susan Wysocki**, RNC, NP, National Association of Nurse Practitioners in Women's Health, 503 Capitol Court N.E., Suite 300, Washington, DC 20002.
- **Michael Rosenberg**, MD, MPH, Health Decisions, 1512 E. Franklin St., Suite 200, Chapel Hill, NC 27514.

References

1. National Association of Nurse Practitioners in Women's Health. *Weight, Sexuality, and Women's Birth Control Decisions.* Washington, DC; January 2001. Web: www.npwh.org.
2. Rosenberg M. Weight change with oral contraceptive use and during the menstrual cycle: Results of daily measurements. *Contraception* 1998; 58:345-349.
3. Reubinoff BE, Grubstein A, Meirow D, et al. Effects of low-dose estrogen oral contraceptives on weight, body composition, and fat distribution in young women. *Fertil Steril* 1995; 63:516-521.
4. Endrikat J, Müller U, Düsterberg B. A 12-month comparative clinical investigation of two low-dose oral contraceptives containing 20 mg ethinylestradiol / 75 mg gestodene and 30 mg ethinylestradiol / 75 mg gestodene, with respect to efficacy, cycle control, and tolerance. *Contraception* 1997; 55:131-137.
5. Redmond G, Godwin AJ, Olson W, et al. Use of placebo controls in an oral contraceptive trial: Methodological issues and adverse event incidence. *Contraception* 1999; 60:81-85.
6. Kushner R, Westhoff CL. Hormonal contraception and weight issues. *Dialogues in Contraception* 2000; 6:5-6. ■

Oral sex: Tell teens it's not without risk

Teens may be saying they aren't having sex. But does their definition of "sex" include noncoital behavior, such as oral sex? Such a distinction is important, as oral sex can be a risk factor for HIV and other sexually transmitted diseases (STDs).

Adolescents are a high-risk group for STDs; about one-quarter of the estimated 15 million new cases of STD each year occur to 15- to 19-year-olds.[1] Despite the risks, however, a national survey of U.S. adolescents now shows that one in five teens considers oral sex as "safe sex."[2]

EXECUTIVE SUMMARY

Adolescents are a high-risk group for sexually transmitted diseases (STDs); about one-quarter of the estimated 15 million new cases of STDs each year occur to 15- to 19-year-olds. Despite the risks, however, a national survey of U.S. adolescents now shows that one in five teens considers oral sex as "safe sex."

- Measuring the number of teens who are participating in such risky behavior is difficult, given a lack of solid national data.
- Numerous studies have demonstrated that oral sex can result in the transmission of HIV and other STDs. Teens need to understand the risks involved with this form of noncoital sex.

"Teens are using oral sex as 'safe sex,' and it isn't," says **Willa Brown**, MD, director of personal health services in the Howard County Health Department in Columbia, MD. "We see teens who have acquired STD infections though oral sex."

Measuring the number of teens who are participating in such risky behavior is difficult, given a lack of solid national data. A new report from the New York City-based Alan Guttmacher Institute takes an in-depth look at the subject and concludes that the lack of information leaves parents, educators, health professionals, and policy-makers at a disadvantage for addressing the issue.[3]

What are teens doing?

Given the apparent levels of sexual risk taking occurring among teen-agers, there is a need for better data about how frequently teens are engaging in a broad range of sexual behaviors, not just vaginal intercourse, says **Freya Sonenstein**, PhD, director of the Population Sciences Center at the Washington, DC-based Urban Institute.

"We also need to know whether they understand the risks they are taking and what they are doing to protect themselves," observes Sonenstein. "Collecting these data, in both qualitative and quantitative studies, will be a challenge."

More representative information on the range of sexual behaviors in which adolescents are engaging is essential, states **Lawrence Finer**, PhD, assistant director of research at the Alan Guttmacher Institute in New York City.

"So far, nationally representative data are available only on heterosexual penile-vaginal intercourse," Finer comments. "On any behaviors other than this, what we have are small-scale and anecdotal studies."

A study that does look at a range of heterosexual activity is an analysis of teen-age boys aged 15-19 who were interviewed in 1988 and 1995 as part of the National Survey of Adolescent Males.[4] In 1995, 49% said they had ever received oral sex, and 39% reported they had ever given oral sex. More than three-quarters of males who had had vaginal intercourse noted experience with masturbation or oral sex by a female.

Magazines published for teens offer another insight into adolescent behavior. According to a survey of teens ages 15-19, 49% consider oral sex "not as big a deal as intercourse," and 40% did not consider it as "sex."[5] A summer 2000 Internet survey conducted by *Twist* magazine revealed

SOURCES

For more information on the risks of oral sex, contact:

- **Lawrence Finer**, PhD, The Alan Guttmacher Institute, 120 Wall St., New York, NY 10005. E-mail: info@agi-usa.org.
- **Linda Dominguez**, RN-C, NP, Planned Parenthood of New Mexico, 719 San Mateo N.E., Albuquerque, NM 87108. Telephone: (505) 265-5976.

that 18% of girls ages 13-19 believe that oral sex is a safe substitute for intercourse.[6]

Noncoital sexual behavior also is often a precursor to intercourse and can therefore shed light on patterns of sexual progression, notes Finer. In addition, research indicates that precocious sexual behavior is often linked to risk behaviors such as drug use and delinquency,[7] he adds.

"If, for example, noncoital sexual behavior generally leads to intercourse, then individuals who begin noncoital behaviors at early ages could be considered at risk for these other kinds of risk behavior," states Finer. "But without data on the range of sexual behavior, there is no way to know either the relationship between noncoital and coital behavior or the groups or individuals at greatest risk."

Defining what 'it' is

Adults are behind the curve on when it comes to assessing the level of oral sex in the adolescent population, says **Linda Dominguez**, RN-C, NP, assistant medical director of the Albuquerque-based Planned Parenthood of New Mexico. Teens are doing 'it'; it's just a new 'it' for adults to consider, she contends.

"Today's parents grew up in an era when oral sex was considered beyond getting a 'home run,' where oral sex was perceived to be reserved for a long-term, safe, and trusting relationship," explains Dominguez. "For kids today, it is part of the game, the warm up, the supposedly safe practice swings."

The time to start talking to adolescents about the full range of risk behaviors is now, states Dominguez. Numerous studies has demonstrated that oral sex can result in the transmission of HIV and other STDs.[8]

"The health of our kids and our nation is at risk until here in the United States we adopt an approach that recognizes that sexual health is part of overall health and should be treated in the same manner, with information, education, and prevention," she asserts. **(Obtain tips on how to talk with teens in the story below.)**

References

1. Kaiser Family Foundation and American Social Health Association. *STDs in America: How Many Cases And At What Cost?* Menlo Park, CA; December 1998.
2. Kaiser Family Foundation and *Seventeen* magazine. *National Survey of Teens: Safer Sex, Condoms, and the Pill*. Menlo Park, CA; November 2000.
3. Remez L. Oral sex among adolescents: Is it sex or is it abstinence? *Fam Plann Perspect* 2000; 32:298-304.
4. Gates GJ, Sonenstein FL. Heterosexual genital sexual activity among adolescent males: 1988 and 1995. *Fam Plann Perspect* 2000; 32:295-297, 304.
5. News release. *Seventeen* news. National survey conducted by *Seventeen* finds that more than half of teens ages 15-19 have engaged in oral sex. Feb. 28, 2000.
6. Birnbaum C. The love and sex survey 2000. *Twist* Oct. / Nov. 2000; 54-56.
7. Jessor R, ed. *New perspectives on adolescent risk behavior*. New York: Cambridge University Press; 1998.
8. Centers for Disease Control and Prevention. *Preventing the Sexual Transmission of HIV, the Virus that Causes AIDS. What You Should Know About Oral Sex*. Atlanta; December 2000. ■

How to talk with teens about oral sex

Have you taken a look at how you address the subject of noncoital sexual behavior — specifically oral sex — with your patients, particularly adolescents? While adding more questions to your written and oral histories might add time to patient exams, such effort is necessary, says **Linda Dominguez**, RNC, NP, assistant medical director of the Albuquerque-based Planned Parenthood of New Mexico.

"The pressures of time that dictate the clinician's day compound the reasons the topic of oral sex may not be broached," observes Dominguez. "But would we short-shrift our patients by only listening to only one lung or examining only one breast, or in this case, ask only for part of the history?"

Include questions regarding sexual preference and sexual activity in the self-taken history to initiate the conversation with patients about oral sex, suggests Dominguez. The self-taken history then sets the stage for one-to-one conversation and clinical assessment regarding such risks.

Since the advent of HIV, an increasing number

of clinicians, even those not in reproductive health, see the necessity and value in prompting discussion regarding the risks of sexually transmitted diseases (STDs), says Dominguez. However, the written interrogatories are not sufficient.

"The clinician must be willing to risk some discomfort by asking more specific questions regarding sexual activity," she states. "Admittedly, this is difficult, especially when the teen is accompanied by a parent, or the teen states she is virginal or abstinent."

Talk about it

Screening for oral sex risks includes a written and verbal assessment of sexual history and practices. The physical examination should include assessment of the oral and pharyngeal surfaces, and swab testing as needed by clinical finding or as indicated by history.

Engaging a patient in a verbal assessment is difficult, Dominguez admits. This is an area where "the art of healing meets the science," she notes.

• **Use oblique statements.**

Use statements such as: "Some of my teen patients have told me that they worry about infections and germs they might have caught from heavy petting or oral sex. Have you been worried or have questions or ever heard about problems about things like that?"

• **Time your questions as you perform the physical exam.**

Try using the following approach: "I am now going to look in your mouth for any sores or problems. Have you noticed anything unusual or have concerns regarding your mouth and throat that you want me to check out?"

Many teens (and adults) believe that if they or their partners have had a negative HIV test, then they are free of infection risk of any type, says Dominguez. Help patients to understand that the HIV test only gives information about one type of infection and risk.

"Patients will say to me, 'I feel safe with him because he had a negative test,'" Dominguez observes. "They are not considering the other entities in the alphabet soup of risk such as HSV, HPV, GC, or CT [genital herpes, human papillomavirus, gonorrhea, or chlamydia]."

According to information from the Atlanta-based Centers for Disease Control, the risk for HIV and other STDs from oral sex can be lowered by using latex condoms each time. For cunnilingus (oral/vaginal sex) or anilingus (oral/anal contact), plastic food wrap, a condom cut open, or a dental dam can serve as a physical barrier to prevent transmission of HIV and STDs.[1]

Reference

1. Centers for Disease Control and Prevention. *Preventing the Sexual Transmission of HIV, the Virus that Causes AIDS. What You Should Know About Oral Sex.* Atlanta; December 2000. ■

Get web information on vasectomy services

About 500,000 men in the United States each year choose vasectomy as a permanent form of birth control. Chosen by men who have completed their families or by men who want no children, men elect to undergo vasectomy because most reversible methods are less reliable, sometimes inconvenient, and might have unpleasant side effects for the women in their lives. All vasectomies should be considered permanent; reversal operations are expensive and not always successful, according to EngenderHealth.

Following are web sites with good information on vasectomy options:

1. EngenderHealth (formerly AVSC International). Web: www.engenderhealth.org.

In March 2001, the New York City-based AVSC International formally changed its name to EngenderHealth. The organization made the move to better reflect its continuing mission of working "worldwide to improve the lives of individuals by making reproductive health services safe, available, and sustainable."

EngenderHealth has a strong commitment to no-scalpel vasectomy (NSV). It pioneered the introduction of NSV in the United States in 1988 following its 1985 visit to China to learn the vasectomy technique developed by Chinese surgeon Li Shunqiang.

The NSV technique is less invasive, less painful, heals more quickly, and has fewer complications than the traditional vasectomy procedure. **(To learn more about NSV, check out *Contraceptive***

***Technology Update*, May 2000, p. 56.)**

Click on the "Family Planning" link under "Women's Health" on the opening page of the EngenderHealth web site, then scroll down to see the available information under the "Vasectomy" heading.

Information on the web site addresses common questions about vasectomy such as:

- Does vasectomy cause any medical problems?
- Will it affect me emotionally?
- Will it affect my masculinity?
- How will it affect me sexually?
- Will it protect me from sexually transmitted infections, like AIDS?
- Can the operation be reversed?
- Can I store semen in a sperm bank in case I change my mind?

An especially helpful section, titled "Is vasectomy right for me?" guides the reader through a series of questions to help determine if the contraceptive method is the proper route.

Information also is available on the Vasectomy Information Line [(888) VASEC-4-U], a toll-free, 24-hour confidential service. Callers hear prerecorded information about vasectomy, and if desired, have the option to be connected with a vasectomy provider at a local public health facility. The telephone service is available in English and Spanish.

The web site also carries a listing by state and province of physicians in the United States and Canada who have reportedly received training in no-scalpel vasectomy, either by attending a training seminar / workshop or by receiving hands-on training in the technique. Providers who have received such training and wish to be listed on the site should send an e-mail to the following address: nsvdoctors@engenderhealth.org.

2. National Institute of Child Health and Human Development. Web: www.nichd.nih.gov.

Click on "Publications" under "Health Information and Media" to find the on-line version of *Facts About Vasectomy Safety*, published by the Bethesda-based National Institute of Child Health and Human Development. The brochure covers vasectomy techniques and advantages and disadvantages of vasectomy. The publication also addresses vasectomy's impact on masculinity and sexuality, immune reactions to sperm, and what to expect post-vasectomy.

3. Planned Parenthood Federation of America. Web: www.plannedparenthood.org.

Click on "Birth Control" under "Sexual Health" to read the on-line version of *All About Vasectomy*, published by Planned Parenthood Federation of America. The publication covers facts on how vasectomy works; reasons to consider the method, as well as reasons to choose another option; and information on other issues, such as cancer risks.

4. Vasectomy.com. Web: www.vasectomy.com.

This commercial web site carries general information on vasectomy and vasectomy reversals. It offers information on anatomy, risks and complications, what to expect, alternatives, no-scalpel vasectomy, and vasectomy reversals. The information is prepared by Theodore Benderev, MD, an associate clinical professor of surgery / urology at the University of California at Irvine, who performs vasectomies and vasectomy reversals in his Mission Viejo private practice. ■

Return of the global gag rule

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

On his first day in office, President George W. Bush issued an executive memorandum that reimposed the international family planning gag rule. The policy prohibits the transfer of U.S. family planning aid to overseas health care organizations that use their *own, non-U.S. funds* to provide legal abortion services, provide counseling to pregnant women that includes information about legal abortion, or conduct a "public information campaign about" legal abortion. The president's restrictions also bar recipients of family planning funds from engaging in political speech designed to legalize abortion in their own country or to support an existing law legalizing abortion.

The Bush policy went into effect Feb.15, the date that $425 million in fiscal year 2001 international family funds became available.

As a result, any organization that applies for U.S. family planning assistance or seeks to renew its grant must sign an agreement with the

Washington, DC-based United States Agency for International Development promising to comply with the new Bush policy.

Originally known as the "Mexico City Policy," the global gag rule was first announced by the Reagan administration at the 1984 United Nations International Conference in Mexico City and remained in place until President Clinton took office. President Bush justified the reimposition of the gag rule based on his "conviction that taxpayer funds should not be used to pay for abortions or advocate or actively promote abortion, either here or abroad" and on his desire to make abortion more rare.

Family planning supporters, however, were quick to point out that no U.S. funds are spent to perform or promote abortions overseas. In fact, a provision authored by Sen. Jesse Helms (R-NC) in 1973 and renewed on an annual basis as part of the foreign aid funding bill forbids any U.S. dollars from being used for this purpose.

Proponents speak out

Family planning advocates on Capitol Hill and elsewhere contend that rather than making abortion more rare, the gag rule will lead to more abortions by undermining the delivery of high-quality family planning services.

Sen. Olympia Snowe (R-ME) says, "Too often, women in developing nations do not have access to the contraceptive or family planning services they need because contraceptives are expensive, supplies are erratic, services are difficult to impossible to obtain, or the quality of care is poor. Yet it is now the policy of the United States not to support these organizations — a policy that is confounding to me, because these very organizations *reduce the number of abortions through their services.*"

Along these lines, family planning proponents note that when the restrictions were in place between 1984 and 1992, many of the most effective and experienced family planning providers in developing countries chose to forgo U.S. population aid, rather than comply with restrictions that forced them to abandon their legal rights under the laws of their country and to abandon their ethical responsibilities to their patients.

Family planning advocates also point out that, historically, the global gag rule made abortion less safe instead of more rare. Fear of losing desperately needed family planning funds, they say, led some health care providers to refuse to treat women with severe complications or infection resulting from unsafe abortions. This, in turn, meant that medical personnel were not trained to deal with the consequences of unsafe abortions. Finally, family planning advocates contend that the HIV / AIDS epidemic, and the role that family planning programs play in providing condoms and information that curtails the spread of HIV, makes the imposition of a gag rule more dangerous than ever before.

In response to the president's action, supporters

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

Subscriber Information

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

Subscription rates: U.S.A., one year (12 issues), $377. Approximately 18 nursing contact hours or Category 1 CME credits, $427; Outside U.S., add $30 per year, total prepaid in U.S. funds. Two to nine additional copies, $302 per year; 10 to 20 additional copies, $226 per year; for more than 20, call (800) 688-2421. **Back issues**, when available, are $63 each.(GST registration number R128870672.) **Photocopying:** No part of this newsletter may be reproduced in any form or incorporated into any information retrieval system without the written permission of the copyright owner. For reprint permission, please contact American Health Consultants®. Address: P.O. Box 740056, Atlanta, GA 30374. Telephone: (800) 688-2421. World Wide Web: http://www.ahcpub.com.

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

Statement of financial disclosure: To reveal any potential bias in this publication, and in accordance with the Accreditation Council for Continuing Medical Education guidelines, we disclose the following: Dr. Hatcher (chairman of the editorial advisory board and peer reviewer) reports being on the speaker's bureau for Organon, Wyeth-Ayerst Laboratories, Ortho-McNeil Pharmaceuticals, and Parke-Davis. Dr. Nelson (board member) serves on the speaker's bureau for Berlex Laboratories, Gynetics, Eli Lilly and Co., 3M Pharmaceuticals, Ortho-McNeill, Organon, Parke-Davis, Pfizer, Pharmacia & Upjohn Co., and Wyeth Ayerst; she conducts research for Ortho-McNeil and Pharmacia & Upjohn. Dr. Rosenfield (board member) is a stockholder and board member of Biotechnology General Corp. Dr. Rosenberg (board member) is a consultant for Organon; serves on the speaker's bureau for Organon, Wyeth-Ayerst, and Parke-Davis; and conducts research for Organon, Wyeth-Ayerst, Ortho-McNeil, and Parke-Davis. Dr. Kaunitz (board member) conducts research for Merck, Pfizer, Pharmacia & Upjohn, RW Johnson Pharmaceutical Research Institute, and Solvay; he is a consultant for Ortho-McNeil, Parke-Davis, and Pharmacia & Upjohn; he is a stockholder in Johnson & Johnson; and he does CME presentations and publications for Merck, Organon, Pharmacia & Upjohn, and Wyeth-Ayerst.

AMERICAN HEALTH CONSULTANTS™
THOMSON HEALTHCARE

of family planning introduced "The Global Democracy Promotion Act." The legislation, introduced on a bipartisan basis by Barbara Boxer (D-CA) and Olympia Snowe in the Senate and Nita Lowey (D-NY) and Jim Greenwood (R-PA) in the House, would negate the Bush policy and ensure that U.S. foreign policy is consistent with American principles of medical ethics and free speech.

The legislation specifies that overseas health care organizations cannot be denied funding based on the medical services they provide, including counseling and referral services. It also says that foreign nongovernmental organizations, as a condition of eligibility for U.S. development assistance, cannot be forced to sacrifice their right to use their own funds to engage in free speech any more than U.S.-based groups are asked to do.

Bill sponsor Nita Lowey explains, "[Our legislation] says that it is wrong to withhold medical information from women in developing countries that women in the United States can access every day. It says it is wrong to force groups to stop talking to their elected officials about reproductive rights. And it says it is wrong to deny women in other countries access to legal abortions."

The sponsors, who were joined by 18 Senate and 79 House co-sponsors, hope to offer the legislation as an amendment to the annual foreign assistance funding bill with the goal of overturning the Bush policy. ■

CE objectives

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

• Identify clinical, legal, or scientific issues related to development and provisions of contraceptive technology or other reproductive services. **(See "What to expect in the next five years? Innovative contraceptive delivery" and "Emerging technologies for detection and treatment of STDs hold promise" in this issue.)**

• Describe how those issues affect service delivery and note the benefits or problems created in patient care in the participant's practice area.

• Cite practical solutions to problems and integrate information into daily practices, according to advice from nationally recognized family planning experts. **(See "How to talk with teens about oral sex.")** ■

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

American Health Consultants® designates this continuing medical education activity for approximately 18 credit hours in Category 1 of the Physicians' Recognition Award of the American Medical Association. Each physician should claim only those hours of credit that he/she actually spent in the educational activity.

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

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

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

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

S·T·D QUARTERLY™

Emerging technologies for detection and treatment of STDs hold promise

Research is ongoing for microbicide candidates and vaccines

What will be the status of detection and treatment of sexually transmitted diseases (STDs) in the next five years? While that timeline may be too close in for the market debut of an effective microbicide for HIV or a vaccine for genital herpes, experts point to promising research on several fronts in the field of reproductive health.

"With new emerging technologies in diagnostic and treatment options for people with sexually transmitted diseases, health care providers will have better resources to manage infections," predicts **Linda Alexander**, PhD, FAAN, president of the American Social Health Association in Research Triangle Park, NC. "New diagnostic options will provide more sensitive and specific tools to detect multiple STDs and new treatment options will afford better management of viral infections."

This year will bring new prevention and treatment guidelines from the Atlanta-based Centers for Disease Control and Prevention (CDC). The agency's *STD Treatment Guidelines* are being revised following a comprehensive evaluation performed in September 2000.

The new guidelines will recommend that sexually active adolescent women be screened for chlamydial infection at least annually, even if symptoms are not present, states **Judith Wasserheit**, MD, MPH, director of the division of STD prevention in CDC's National Center for HIV, STD, and TB Prevention. Annual screening of all sexually active women ages 20-25 also will be recommended, as will screening of older women with risk factors such as new sexual partners or multiple sexual partners, she states.

EXECUTIVE SUMMARY

Promising research aimed at the detection and treatment of sexually transmitted diseases (STDs) will yield better resources for identifying and managing infections.

- 2001 will yield new STD prevention and treatment guidelines from the Centers for Disease Control and Prevention (CDC).
- Fall 2001 is the projected start for a Phase III efficacy trial of two microbicide candidates in the search for female-controlled prevention methods against HIV.
- Initial reports from two large clinical trials indicate that a herpes simplex virus 2 vaccine developed by Smith Kline Beecham Biologicals proves highly effective compared with a placebo, but is effective only in women who have not been previously infected with herpes simplex virus 1, the strain responsible for most cases of oral herpes.

Focus on microbicides

Fall 2001 is the projected start for a Phase III efficacy trial of two microbicide candidates in the search for a female-controlled prevention method against HIV. The trial is sponsored by the HIV Prevention Trials Network (HPTN), a program established by the Bethesda, MD-based National

Institutes of Health (NIH) to develop and test nonvaccine strategies to prevent the spread of HIV infection and AIDS. The two products to be evaluated are BufferGel from ReProtect LLC of Baltimore and PRO 2000 from Interneuron Pharmaceuticals Inc. of Lexington, MA.

BufferGel is a nonirritating lubricant made of a carbopol gel, which is a high-molecular weight, cross-linked, polyacrylic acid. Pro 2000 is a naphthalene sulphonate derivative in a gel formulation. **(See *Contraceptive Technology Update,* April 1999, p. 37, for more information on these two novel microbicides.)** The international study protocol is in development, reports **Roberta Black**, PhD, a microbiologist in the division of AIDS at the Bethesda, MD-based National Institute of Allergy and Infectious Diseases (NIAID).

There are many promising microbicide products now in the research pipeline, with several having completed Phase I or II testing, observes **Willard Cates Jr.,** MD, MPH, president of Family Health International (FHI). FHI is a Research Triangle Park, NC-based research organization that has been designated by the NIH to coordinate the HPTN effort.

"A big push is needed during the next several years to support global phase III microbicide research infrastructures capable of assessing the effectiveness of these new products," states Cates.

Added emphasis to the search for effective microbicides comes with the July 2000 release of preliminary results from a large international study of a microbicide gel containing the spermicide nonoxynol-9 (N-9).[1] Results indicate that among the study population of female sex workers, those using a gel containing N-9 had a higher risk of acquiring HIV than those using the placebo vaginal moisturizer. **(See *CTU,* October 2000, for the CDC's recommendations concerning use of N-9 in STD prevention, as well as a companion story on the use of the spermicide in pregnancy prevention.)**

While the results of the study indicated that N-9 is not effective in preventing HIV, further research is needed to study its impact in more typical N-9 users, says Cates. Until there are more data on the risks of the spermicide in typical settings, women who use N-9 for contraception should continue in their current practice, he says.

The search for an effective vaccine against herpes simplex virus 2 (HSV-2), the strain responsible for most cases of genital herpes, continues following initial reports from two large clinical trials.[2] Preliminary research indicates that the vaccine proves highly effective compared with a placebo, but is effective only in women, not men, and only in women who have not been previously infected with herpes simplex virus 1 (HSV-1), the strain responsible for most cases of oral herpes.[3] The trial data are under review by Smith-Kline Beecham Biologicals in Belgium, the vaccine manufacturer, and the Food and Drug Administration.

On one hand, the findings suggest the vaccine may be helpful for a relatively small portion of the population, but on the other hand, it is proof that scientists can develop a vaccine that can make a difference, comments **Edward Hook III**, MD, professor of medicine at the University of Alabama at Birmingham and medical director of the Jefferson County STD Control Program.

"Even if you can only protect a portion of the women, that's a whole lot better than anything you could do before," states Hook. "Further evaluation of those tests and further tests of even better vaccines are on the horizon and are very important areas."

Hook points to the increased use of type-specific serologic tests as an important step in the fight against HSV-2. Testing options for herpes simplex virus (HSV) have expanded in the United States, with three companies offering new diagnostic methods. **(See the *STD Quarterly* inserted in the August 2000 issue of *CTU*, p. 3, for a review of the current tests.)**

While it is a treatable infection, there is no cure at present for HSV-2. The debate over increasing the knowledge of one's HSV-2 status in light of no known cure will be an important one in the coming years, Hook predicts.

Rapid testing moves up

The recent availability of inexpensive, noninvasive tests and single-dose therapy will make it easier to identify and treat women infected with chlamydia, states Wasserheit. **(See the *STD Quarterly* inserted in the February 2001 issue of *CTU,* p. 1, for more information on nucleic acid amplification tests.)**

Point-of-care rapid diagnostics will have patient and public health impact in the coming years, predicts **Holli Hamilton**, MPH, branch chief for the Office of Clinical Research Affairs in the division of microbiology and infectious diseases at NIAID.

New tests are being developed that might provide better ways to diagnose syphilis and define the stage of infection, she notes.

Research is under way to evaluate the use of azithromycin as a suitable one-dose treatment for syphilis, Hamilton reports.[4] If the drug indeed proves efficacious, then the ramifications are great for having one drug for use against the major bacterial STDs, she states.

Look to use of vaginal swabs as an acceptable specimen for certain STDs in the next five years, says Hamilton. For screening purposes, such a collection method would prove "vastly simpler" than a pelvic exam, she states.

"We can expect to see more research into options that enable women to self-sample for STDs," agrees Alexander. "Home testing for STDs is clearly a possibility."

References

1. Van Damme L, Masse B, Laga M, et al. Vaginal microbicides, an update. XIII World Conference on HIV / AIDS. Durban, South Africa, July 12, 2000.

2. Stephenson J. Genital herpes vaccine shows limited promise. *JAMA* 2000; 284:1,913-1,914.

3. Spruance S. Gender-specific efficacy of a prophylactic SBAS4-adjuvanted gD2 subunit vaccine against genital herpes disease: Results of two clinical efficacy trials. Presented at the 40th Interscience Conference on Antimicrobial Agents and Chemotherapy. Toronto; Sept. 17, 2000. Abstract L-6.

4. Hook EW, Stephens J, Ennis DM. Azithromycin compared with penicillin G benzathine for treatment of incubating syphilis. *Ann Intern Med* 1999; 131:434-437. ■

Cure STD misconceptions with proper counseling

Your next patient has an abnormal vaginal discharge. Upon further inspection, a positive finding for gonorrhea is made. When you share this news with her, she says, "I can't have a sexually transmitted disease; I'm on the Pill." Sound familiar?

Many patients may have misguided notions about prevention of sexually transmitted diseases (STDs), but counseling might help, according to the results of a study of some 3,500 STD clinic visitors.[1]

EXECUTIVE SUMMARY

Many patients may have misguided notions about sexually transmitted disease (STD) prevention, but counseling may help, according to the results of a study of some 3,500 STD clinic visitors.

- Washing the genitals after sex, urinating after sex, douching, and use of oral contraceptives are some common STD prevention misconceptions.
- The didactic approach to counseling used in several STD clinics might need to be replaced with a client-centered, interactive approach. Clinicians can take cues from Project RESPECT, a program developed by the Centers for Disease Control. An analysis shows that using such a counseling approach results in an overall reduction in STD incidence.

The study's findings come from a secondary analysis of a large-scale randomized controlled trial for Project RESPECT, sponsored by the Atlanta-based Centers for Disease Control and Prevention (CDC). Project RESPECT demonstrated that interactive, client-centered HIV / STD counseling resulted in an overall reduction in STD incidence of about 30% after six months and 20% after 12 months of follow-up.[2]

"Misconceptions about STD-protective behaviors are common, and the event of an STD or STD counseling or both generally reduces these misconceptions," state the scientists involved in the Project RESPECT analysis group. "Although these misconceptions may not directly translate into risky behavior, they may preclude movement toward safer sex."

Patients enrolled in the Project RESPECT study completed an interview upon study enrollment and every three months following enrollment for a one-year period. A portion of the routine interview assessed participants' misconceptions about STD-protective behaviors.

At baseline, about 16% believed that washing the genitals after sex protected from STDs. Other common inaccurate STD prevention beliefs included urinating after sex (38.7%), douching (45.7%), and use of oral contraceptives (19.9%). Prevalence of misconceptions was significantly diminished at a three-month follow-up.

Of those study participants who still held misconceptions even after their clinic visit, several demographic characteristics emerged. For

example, those age 24 and older with less than a high school education were especially likely to continue to believe that douching prevents STDs.

Routine douching for hygienic purposes has been associated with an increased risk for pelvic inflammatory disease (PID), states **Mary Kamb**, MD, MPH, a medical epidemiologist at CDC and co-author of the original and secondary Project RESPECT analyses.

"[Douching] is associated with PID, but everyone's mother tells them to do it," says Kamb. "That [misconception] would be a good one to clarify for young women."

Although barriers to effective patient education do exist, clinics can take steps to keep messages prevention-focused.

The didactic approach to counseling used in several STD clinics may need to be replaced with the client-centered, interactive approach demonstrated in the Project RESPECT model, suggests Kamb. **(Clinic managers and counselors can get counseling protocols, quality assurance protocols, and further information about Project RESPECT at the following CDC web page: www.cdc.gov/hiv/projects/respect/default.htm.)**

"This large randomized controlled trial evaluating interactive risk reduction counseling among STD clinic patients is the first to report that counseling leads to reduction in sexually transmitted infections," note the scientists participating in the original analysis. "In addition to concerns about efficacy, concerns that interactive counseling is not feasible for busy, publicly funded clinics, or cannot be conducted by the personnel currently employed by health departments, should now be put to rest."

Although long recommended and supported by counselors, client-centered HIV prevention counseling is seldom done in STD clinics, perhaps because program managers might not believe that a two-session intervention can work, state the scientists. However, the brief counseling model was designed for implementation, at low cost and with existing personnel, in the context of routine health care services.

"The intervention adherence we found suggests that two-session counseling would have at least the same retention as the didactic approach that is currently used and would have greater retention than longer therapies," state the scientists.

Although barriers to effective patient education do exist, clinics can take steps to keep messages prevention-focused, says **William DeJong**, PhD, professor at the Department of Social and Behavioral Sciences at Boston University's School of Public Health. Clinics should review quality assurance procedures and guidelines to see that they pose no obstacles to educational innovation. Examine guidelines to encourage experimentation with such strategies as group counseling and see that staff members receive training in prevention-focused communication.[3]

DeJong is developing an interactive patient education video with Boston City Hospital and the Boston University School of Public Health for use in inner-city STD clinics. While the study to evaluate it is still under way, DeJong says it will examine how to motivate people with STDs to practice safer sex to avoid reinfection.

"The computer-assisted video allows STD patients to select from a series of dramatic vignettes about various prevention-related topics, especially condom use," he explains. "Our expectation is that making their choices will help patients be more engaged with the materials, which should enhance their power to motivate behavior change."

It is crucial for health care providers to concentrate their counseling efforts on people at risk for repeat infections, DeJong observes.

"Beyond that, we need to find ways to engage people in thinking about how to protect their reproductive health," he notes. "This requires time, money, and imagination, but I think the investment is worth it."

References

1. Crosby RA, Newman D, Kamb ML, et al. Misconceptions about STD-protective behavior. *Am J Prev Med* 2000; 19:167-173.

2. Kamb ML, Fishbein M, Douglas JM, et al. Efficacy of risk-reduction counseling to prevent human immunodeficiency virus and sexually transmitted diseases: A randomized controlled trial. Project RESPECT Study Group. *JAMA* 1998; 280:1,161-1,167.

3. DeJong W, O'Donnell L, San Doval AD, et al. The status of clinic-based STD patient education: The need for a commitment to innovation in health communication. *J Health Commun* 1996; 1:51-63. ■

AMERICAN HEALTH CONSULTANTS®

Contraceptive Technology Reports

A supplement to *Contraceptive Technology Update* **May 2001, BB #458**

The Levonorgestrel Intrauterine System: An Effective New Contraceptive Option

Author: **Andrew M. Kaunitz**, **MD**, Professor and Assistant Chair, Department of Obstetrics and Gynecology, University of Florida Health Science Center/Jacksonville.

Peer Reviewer: **Amy Pollack**, **MD**, **MPH**, President, EngenderHealth, New York City.

Introduction

Despite data showing that intrauterine devices (IUDs) are safe, convenient, and highly effective for appropriately selected candidates, these devices remain an underutilized contraceptive option in the United States. Indeed, many women will choose sterilization rather than IUDs because of concerns about the method's mechanism of action, as well as their safety and comfort.

The newest type of IUD is an intrauterine hormonal contraceptive system called the levonorgestrel intrauterine system (LNG IUS), also known as Mirena, from Berlex Laboratories of Montville, NJ. It was approved by the Food and Drug Administration in December 2000, and might help to change the perception of IUDs in the United States thanks to its high efficacy rate, lack of serious side effects, and important therapeutic benefits. The unit cost is approximately $355.

Structure and History

The LNG IUS is comprised of a small T-shaped frame that holds a cylinder containing levonorgestrel, the same potent progestin found in many combination oral contraceptives (OCs), progestin-only "mini-pills," and the contraceptive implant, Norplant. The system is 32 mm in length and, when placed in the uterus, releases levonorgestrel into the uterine cavity at a rate of 20 mcg a day. It is approved for five years of use and its effectiveness has been demonstrated for seven years.

LNG IUS has been available for use in Europe for more than a decade and has been used by more than 2 million women worldwide.

Mechanism of Action

The LNG IUS prevents pregnancy in much the same way that levonorgestrel-containing implants and mini-pills do: The progestin thickens cervical mucus, which inhibits sperm motility and function.[1-3] Typically, use of the LNG IUS does not suppress ovulation; indeed, 85% of menstrual cycles are ovulatory, and background serum estrogen levels among users are comparable to those of ovulatory women not using hormonal contraception.[4]

The levonorgestrel in the LNG IUS also prevents endometrial proliferation — endometrial suppression takes full effect three months after insertion of the system — leading to a substantial reduction in menstrual flow and, often, amenorrhea.[5,6] A weak foreign-body (sterile inflammatory) effect also has been noted, but is less pronounced than with copper-releasing IUDs.[5] The system is not an abortifacient and does not appear to have a role as an emergency contraceptive.[3]

Pharmacokinetics

After insertion of the LNG IUS, levonorgestrel is released into the uterine cavity. It is then rapidly absorbed from the basal layer of the endometrium into the systemic circulation. Within 15 minutes after insertion, levonorgestrel can be detected in the serum.[7] Maximum plasma levels occur within a few hours of insertion, and hormone levels reach steady-state (around 150 pg/mL to 200 pg/mL) within several weeks.[8] Levonorgestrel plasma levels are lower than those observed in women using Norplant, mini-pills, and combination OCs, and without the peaks and valleys common to the latter methods.[9-12] Plasma levels of levonorgestrel decline over five years' time from a high of approximately 250 pg/mL just

after insertion to a low of 100 pg/mL.[13-14]

The release of levonorgestrel into the uterine cavity results in high concentrations of progestin in the endometrium ranging from 470 ng/g to 1,500 ng/g tissue wet weight. This occurs within weeks of insertion of the system. Tissue concentrations subsequently fall over time.[11]

Efficacy

The overall failure rate during use of the LNG IUS is 0.14 per 100 woman-years, based on more than 12,000 woman-years of use.[15]

This rate is comparable to annual failure rates for female sterilization.[16] Over five years, the cumulative pregnancy rate is 0.71.[15]

Safety and Side Effects

For several months after insertion, LNG IUS users may experience edema, headache, breast tenderness, acne, lower abdominal or back pain, vaginal discharge, or nausea.[16,17] These side effects tend to abate with time. Spotting may occur during the initial use (e.g., the first six months), and absence of bleeding (amenorrhea) has been observed in 20% of users at one year.[17,18] The development of functional ovarian cysts also has been observed, as occurs with other progestin-only contraceptive pills and implants, but such cysts rarely require treatment or necessitate removal of the intrauterine system. Typically, they resolve on their own.[19] Clinical trials have not suggested that the LNG IUS causes weight gain.

Serious side effects, as with other intrauterine contraceptives, occur rarely with LNG IUS and include:

• **Pelvic Inflammatory Disease (PID).** The rate of PID associated with LNG IUS use is less than one per 100 woman-years at five years.[20] It has been postulated that the levonorgestrel in LNG IUS might have a protective effect on the cervical mucus, making the ascent of pathogens to the upper genital tract less likely to occur. This protection also might be a result of endometrial suppression or reduced bleeding associated with LNG IUS use.[21]

For all intrauterine contraceptive devices, the risk of PID diminishes substantially with time and is greatest at insertion.[22] Only one woman in 1,000 will develop PID in the first three months of using an IUD, and a recent meta-analysis showed that there is no overall benefit to administering prophylactic antibiotics.[23,24]

• **Sepsis.** Four cases of Group A streptoccocal sepsis have been reported among 1.3 million estimated users of the LNG IUS since 1989. In all cases, the patients experienced severe pain within hours of insertion of the system and developed sepsis within days. All were treated successfully.[25]

• **Perforation.** The risk of uterine perforation with the LNG IUS is very low: less than one per 1,000 insertions.[25]

• **Expulsion.** The five-year cumulative expulsion rate for the LNG IUS is 4.9 per 100 woman-years. Expulsion is most likely to occur during the first six months after insertion.[16]

Return to Fertility

After removal of the LNG IUS, fertility quickly returns to baseline.[26-29] At 12 months after removal, the cumulative conception rate ranges between 79% and 96%.[27,28] In addition, no abnormalities have been detected or reported among children born of women who have used the LNG IUS for contraception.[17]

Comparison to Other IUDs

In contrast with copper-releasing IUDs, which increase menstrual blood loss, use of the LNG IUS reduces blood loss. In contrast with the Progesterone T, the LNG IUS lowers the risk of ectopic pregnancy. The annual failure rate for the LNG IUS is comparable to that for the Copper T 380A and lower than that of the progesterone T. The LNG IUS is approved for five years of use, compared with the Copper T IUD, which is approved for 10 years, and the progesterone IUD, which is approved for one year of use. The latter device releases 66 mcg of progesterone into the uterine cavity each day, whereas LNG IUS releases 20 mcg of levonorgestrel a day.

Pregnancy rates. The system is extremely efficacious. The cumulative five-year failure rates have ranged from 0.5% to 1.1%, in comparison to the Copper T 380A IUD, which has a 1.4% five-year cumulative failure rate, and sterilization, which overall has an 1.3% five-year failure rate.[15,16]

PID. Two randomized trials compared the LNG IUS to copper IUDs. In one multicenter, prospective, randomized trial of the LNG IUS vs. a copper IUD, the cumulative removal rate at 36 months for PID was 0.5 per 100 women for LNG IUS and two per 100 women for the copper IUD. At 60 months, these rates

Contraceptive Technology Reports, is published by American Health Consultants, 3525 Piedmont Rd., NE, Bldg. 6, Suite 400, Atlanta, GA 30305.

VICE PRESIDENT/GROUP PUBLISHER: Brenda Mooney.
EDITORIAL GROUP HEAD: Valerie Loner.
MANAGING EDITOR: Joy Daugherty Dickinson.
PRODUCTION EDITOR: Nancy McCreary.

***Contraceptive Technology Reports*™** continuing education materials are sponsored and supervised by American Health Consultants. American Health Consultants designates this continuing education activity as meeting the criteria for 1 credit hour in Category 1 for Education Materials for the Physician's Recognition Award of the American Medical Association, provided it has been completed according to instructions.

This CME activity was planned and produced in accordance with the ACCME Essentials.

American Health Consultants is accredited by the Accreditation Council for Continuing Medical Education to sponsor continuing medical education for physicians.

Subscriber Information

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

Questions and Comments

For editorial questions and comments, please contact **Joy Daughtery Dickinson** at (229) 377-8044 or joy.dickinson@ahcpub.com.

AMERICAN HEALTH CONSULTANTS™
THOMSON HEALTHCARE

Statement of Financial Disclosure

To reveal any potential bias in this publication, we disclose the following: Dr. Kaunitz (author) participated in the clinical trials of the LNG IUS for Berlex Laboratories (funding to the University of Florida Research Foundation). He is a consultant for the American College of Obstetricians and Gynecologists, Association of Professors of Obstetrics and Gynecology, Association of Reproductive Health Professionals (ARHP), Barr Laboratories, Organon, Ortho-McNeil, Parke Davis, Pharmacia-Upjohn, Procter and Gamble, and Rhone-Poulenc Rorer. He is a stockholder in Johnson and Johnson and Ostex International. Dr. Kaunitz also has participated in clinical trials for Galen, Lilly, National Institutes of Health, Parke Davis, Pfizer, Pharmacia-Upjohn, R.W. Johnson Pharmaceutical Research Institute, and Solvay. He has participated in clinical trials and done CME presentations and publications for Merck and Organon. He had done CME presentations and publications for Ortho-McNeil, Pharmacia-Upjohn, and Wyeth-Ayerst. He is on the speaker's bureau for ARHP. Dr. Pollack (peer reviewer) has no affiliations with companies related to this field of study.

The Mirena LNG IUS

Source: Berlex Laboratories, Montville, NJ.

climbed to 0.8 for the LNG IUS and 2.2 per 100 for the study Copper T IUD.[15] A second prospective trial found LNG IUS had a comparable removal rate for PID (approximately four per 100 women) at seven years to the Copper T 380A IUD.[30]

Ectopic Pregnancy. Use of the LNG IUS confers less risk of ectopic pregnancy than other IUDs or use of no contraceptive method at all. Women using LNG IUS have a 0.20 incidence of ectopic pregnancy per 1,000 woman-years of use vs. 0.34 for the copper IUD, 3.60 for the progesterone IUD, and 1.20-1.60 for no method.[31]

Menstrual Patterns. Use of the LNG IUS decreases blood loss and duration of blood loss.[32] In comparison to users of the Copper T380A IUD, who experience four to five days of withdrawal bleeding during the first two years of use, use of the LNG IUS is associated with one day of bleeding from eight months of use on.[32,33] After 12 months of use, 20% of women of those using the LNG IUS are amenorrheic.[18]

Use of the LNG IUS also often results in a substantial decrease in dysmenorrhea: For instance, Nilsson et al. reported that 35% of LNG IUS users experienced improvements in dysmenorrhea compared with 9% of copper IUD users.[33]

Therapeutic Benefits

The LNG IUS also differs from the other two IUDs available in the United States in that its use appears to confer several important noncontraceptive therapeutic benefits.

Menorrhagia. Studies suggest that the LNG IUS effectively treats menorrhagia. In one trial of 25 women with menorrhagia and adenomyosis, insertion of LNG IUS reduced menstrual blood loss over 12 months by 90% to 97% compared with pre-treatment levels. These changes were accompanied by a significant increase in hemoglobin levels and a decrease in uterine volume.[34]

In an open, randomized Finnish trial of 56 women aged 33-49 years conducted to assess whether the levonorgestrel intrauterine system could provide an alternative to hysterectomy for excessive uterine bleeding, it was found that at six months, 64% of women in the LNG IUS group had canceled their surgery for hysterectomy compared with 14.3% of women who continued with standard medical therapy. At an average follow-up of three years, half of the women were still using the LNG IUS, which suggests the system may offer a long-term conservative alternative to hysterectomy for women suffering from menorhagia.[35]

Another study found that the mean reduction in blood loss with the LNG IUS (90%) was greater than that reported for nonsteroidal anti-inflammatory drugs (NSAIDs) (25% to 35%), danazol (60%), tranexamic acid (50%), oral progestogens (12%), and oral contraceptives (50%).[36]

Prevention of endometrial hyperplasia during estrogen replacement therapy (ERT). Withdrawal bleeding is the most common reason that women discontinue hormone replacement therapy. The levonorgestrel intrauterine system suppresses the endometrium to such an extent that 83% to 88% of users cease to have withdrawal bleeding at 12 months, leading to an 82% continuation rate at three years.[34,37,38] The LNG IUS also might be an appropriate choice for noncontraceptive use in perimenopausal women who are experiencing endometrial proliferation and uterine bleeding as a consequence of oral or transdermal estradiol use.[27,39,40]

Suitable Candidates

The LNG IUS represents an appropriate contraceptive option for women in mutually monogamous sexual relationships who have had at least one child. Insertion should be performed within seven days of the onset of a normal menstrual period, first-trimester abortion, or six weeks after delivery.[25]

Contraindications

Women who should not use LNG IUS include those:

- with known or suspected pregnancy;
- genital infection;
- confirmed or suspected uterine or cervical malignancy;
- undiagnosed abnormal uterine bleeding;
- congenital or acquired uterine anomalies that might interfere with proper insertion of the system, including fibroids if they distort the uterine cavity;
- acute liver disease or liver tumor;
- active thrombophlebitis or thromboembolic disorders.[25]

Insertion Technique

The insertion technique for the LNG IUS is distinct from techniques used for other IUDs. Insertion is performed with a one-hand technique rather than two hands. The system is opened inside the endometrial cavity but before reaching the fundus, and the system's strings are longer than those of the Copper T IUD.

Table 1. Insertion Technique

- Use aseptic technique during insertion.
- Cleanse the cervix and vagina with antiseptic solution.
- With a tenaculum, grasp the upper lip of the cervix. Apply light traction to align the cervical canal with the uterine cavity.
- Sound the uterus with a calibrated plastic (e.g. endometrial biopsy device) or metal sound. Depths fewer than 6 cm or more than 9 cm contraindicate insertion of the LNG IUS. Occasionally, use of cervical dilators might be necessary prior to LNG IUS insertion. Some clinicians premedicate patients with nonsteroidal anti-inflammatory agents.
- Open the sterile package containing the intrauterine system.
- Release the threads of the system so they hang freely, and make sure the slider is in the furthest position away from you (closest to the patient).
- Check to make sure the arms of the system are horizontal. If they aren't, align them on a flat, sterile surface while maintaining moderate pressure.
- Pull on both threads to draw the system into the insertion tube. The knobs at the ends of the arms now will close the open end of the inserter. Fix the threads tightly in the cleft at the near end of the handle.
- Set the flange to the depth measured during sounding. The system's package provides a convenient surface with a groove to facilitate flange adjustment.
- Insert the LNG IUS while maintaining firm pressure on the slider with your forefinger or thumb, ensuring that the slider remains in position (furthest from you/closest to the patient).
- Move the inserter through the cervical canal into the uterus until the flange is 1.5- 2 cm from the cervix. Do not force the inserter.
- Hold the inserter steady and release the arms by pulling the slider back until it reaches the raised horizontal mark on the handle.
- Hold the slider in position, and gently push the inserter inward until the flange touches the cervix. The system should be in the fundal position. (You can tell this has occurred when you meet resistance while pushing the insertion tube against the fundus.) Don't be concerned if the flange is pushed a short distance along the tube by the cervix; because the arms of the system are unfolded and you're not exerting excess force, this should not result in perforation.
- While maintaining the inserter steady in position against the top of the uterine fundus, release the intrauterine system by pulling the slider all the way back (toward you/away from the patient). The threads automatically will release from the cleft.
- After ensuring that the threads are not tangled, remove the inserter from the uterus. Make sure the threads run freely through the tube, and don't pull the system away from its fundal position.
- Cut the threads to leave approximately 2 cm of thread visible outside the cervix.

Source: Mirena labeling. On file: Berlex Laboratories, Montville, NJ. 2000.

As with all IUDs, the skill of the provider in inserting the system can impact expulsion and complication rates. With all IUDs, close attention to sterile technique is important when inserting the LNG IUS. The packaging for the LNG IUS, which allows no-touch calibration of the flange and loading of the device into the insertion tube, facilitates strict asepsis. Hence, supervised training in the insertion technique for the LNG IUS is essential.

Prior to inserting the device, the clinician should:

• review the method with the patient and obtain written consent;

• examine the patient to exclude the presence of vaginitis/cervicitis and establish the size and position of her uterus. If the clinician deems this appropriate, testing for chlamydial and gonococcal infection should be performed. **(For information on the insertion technique, see table, at left.)**

If You Question Proper Insertion

If there is concern that LNG IUS is not properly positioned in the uterus, check the placement with vaginal ultrasound. Remove the LNG IUS if it is not fundally positioned. Do not reinsert a used system.

Potential Insertion Problems

Difficulty might be experienced when attempting to enter the uterine cavity with the LNG IUS. This situation often may be overcome by opening the speculum further and placing more traction on the tenaculum, straightening the cervix, and bringing it closer to you. Be sure to recheck the direction of the endometrial cavity with uterine sounding after these maneuvers, and, if appropriate, use local anesthesia and cervical dilators.

The system also might get stuck within the plunger. This indicates that the LNG IUS was loaded in the wrong horizontal position and/or that too much pressure was used to pull the threads. In this scenario, discard the system and start over with a new system.

To ensure success with insertion:

• Maintain firm contact with the slider during the entire insertion process.

• Envision the space needed for the system's arms to swing open inside the uterus.

• Clinicians wanting to insert this IUS are being encouraged to attend one of the 200 training programs being held throughout the country. For more information on training sessions in your community, or to request one, call toll-free (866) LNG-IUS1.

Patient Counseling Following Insertion

After insertion, schedule patients for a follow-up appointment within three months to check for partial or complete expulsion of the system. Caution them that the intrauterine system does not protect against sexually transmitted diseases (STDs). Instruct women who develop STD risk factors during use of the LNG IUS, as with any IUD, to use condoms in addition to the IUS. After the initial follow-up visit, patients should return for routine well-woman care as would be appropriate for women not using IUDs.

All patients should be educated:

• to expect irregular periods for three to six months after

insertion. Most women will experience spotting or light bleeding, but a few may have heavier-than-normal bleeding. These menstrual irregularities typically abate within a few months of insertion;

• not to be alarmed if they develop amenorrhea. An absence of bleeding occurs in 1/5 of women who use the LNG IUS for a year or longer. Typically, amenorrhea is not a sign of pregnancy, ovarian or pituitary dysfunction, or the onset of menopause. What's more, menstruation will return after removal of the system. Performance of urine pregnancy tests at home or at the office might provide reassurance to LNG IUS users concerned about the possibility of pregnancy;

• to check for the LGN IUS' threads at the top of the vagina after each menstrual period, or monthly. Patients should be told NOT to pull on the threads. Their partners should be instructed likewise.

Patients should be counseled to contact their health care provider under the following circumstances:

• if they can't feel the threads or they feel more of the system than just the threads. This may indicate the system is not in the proper position;

• if they believe, because of a missed menstrual period or for any reason, they may be pregnant (note: even if clinicians are not concerned regarding the possibility of pregnancy, users may find negative urine pregnancy tests to be highly reassuring);

• if they experience pelvic pain or pain during intercourse (which suggests perforation or infection);

• if they develop unusual vaginal discharge;

• if they have unexplained fever (which suggests infection);

• if they develop very severe or migraine headaches;

• if they develop jaundice;

• if they experience severe or prolonged vaginal bleeding (which suggests dislocation or perforation);

Removal

To remove the LNG IUS, use forceps to apply gentle traction on the threads. This will cause the arms of the system to fold upward as the IUS is withdrawn from the uterus. A new LNG IUS or other IUD may be inserted immediately after removal of a used system. If a patient with regular cycles wants to use a different method of contraception after removal of the LNG IUS, remove the system during the first seven days of the menstrual cycle and instruct her to start the new method immediately. If the system is removed after the seventh day of the menstrual cycle, or the patient has irregular cycles or amenorrhea and wants to switch to a different method, her new contraceptive should be initiated at least seven days prior to removal of the system.[25]

Summary

Because the LNG IUS provides safe, highly effective, convenient, and reversible contraception, its availability in the United States should increase the number of women using modern effective birth control. Candid counseling of LNG IUS candidates regarding contraceptive selection and close attention to insertion technique, as described in this review, should enhance users' success with this new method. The noncontraceptive benefits provided by the LNG IUS should further expand the number of U.S. women who will benefit from this innovative system.

References

1. Jonsson G, Landgren B-M, Eneroth P. Effects of various IUDs on the composition of cervical mucus. *Contraception* 1991; 43:447-458.
2. Barbosa I, Bakos O, Olsson SE, et al. Ovarian function during use of a levonorgestrel-releasing IUD. *Contraception* 1990; 42:51-66.
3. Videla-Rivero L, Etchepareborda J, Kesseru E. Early chorionic activity in women bearing inert IUD, copper IUD, and levonorgestrel-releasing IUD. *Contraception* 1987; 36:217-226.
4. Nilsson CG, Lahteenmaki PLA, Luukkainen T, et al. Ovarian function in amenorrheic and menstruating users of a levonorgestrel-releasing intrauterine device. *Fertil Steril* 1984; 41:52-55.
5. Silverberg SG, Haukkamaa M, Arko H, et al. Endometrial morphology during long-term use of levonorgestrel-releasing intrauterine devices. *Int J Gynecol Pathol* 1986; 5:235-241.
6. Zhu P, Hongzhi L, Ruhua X, et al. The effect of intrauterine devices, the stainless steel ring, the Copper T 220, and releasing levonorgestrel, on the bleeding profile and the morphological structure of the human endometrium — a comparative study of three IUDs. *Contraception* 1989; 40:425-438.
7. Luukkainen T. Levonorgestrel-releasing intrauterine device. *Ann NY Acad Sci* 1991; 626:43-49.
8. Haukkamaa M, Stranden P, Jousimies-Somer H, et al. Bacterial flora of the cervix in women using different methods of contraception. *Am J Obstet Gynecol* 1986; 154:520-524.
9. Diaz S, Pavez M, Miranda P, et al. Long-term follow-up of women treated with Norplant implants. *Contraception* 1987; 35:551-567.
10. Kuhnz W, Al-Yacoub G, Fuhrmeister A. Pharmacokinetics of levonorgestrel and ethinylestradiol in nine women who received a low-dose oral contraceptive over a treatment period of three months and, and after a washout phase, a single oral administration of the same contraceptive formulation. *Contraception* 1992; 46:455-469.
11. Nilsson CG, Lahteenmaki PLA, Luukkainen T, et al. Sustained intrauterine release of levonorgestrel over five years. *Fertil Steril* 1986; 45:805-807.
12. Weiner E, Victor A, Johansson EDB. Plasma levels of d-norgestrel after oral administration. *Contraception* 1976; 14:563-570.
13. Haukkamaa M, Holma P. Five-year clinical performance of the new formulation of the levonorgestrel intrauterine system and serum levonorgestrel concentration with the new formulation compared to that with the original one. *Leiras Clinical Study Report* 1996; 1 No. 02-89532-07.
14. Lahteenmaki P. Serum levonorgestrel concentration during 78-month use of LNG IUD. *Leiras Clinical Study Report* 1991; No. 1,207.

15. Andersson K, Odlind V, Rybo G. Levonorgestrel-releasing and copper-releasing (Nova T) IUDs during five years of use: A randomized comparative trial. *Contraception* 1994; 49:56-72.
16. Peterson HB, Xia Z, Hughes JM, et al. The risk of pregnancy after tubal sterilization: Findings from the U.S. collaborative review of sterilization. *Am J Obstet Gynecol* 1996; 174:1,161-1,168.
17. Luukkainen T, Lahteenmaki P, Toivonen J. Levonorgestrel-releasing intrauterine device. *Ann Med* 1990; 22:85-90.
18. Pekonen F, Nyman T, Lahteenmaki P, et al. Intrauterine progestin induces continuous insulin-like growth factor-binding protein-1 production in the human endometrium. *J Clin Endocrinol Metab* 1992; 75:660-664.
19. Robinson GE, Bounds W, Kubba AA, et al. Functional ovarian cysts associated with the levonorgestrel-releasing intrauterine device. *Br J Fam Plann* 1989; 14:131-132.
20. Anonymous editorial. Does infection occur with modern intrauterine devices? *Lancet* 1992; 339:783-784.
21. Toivonen J, Luukkainen T, Allonen H. Protective effect of intrauterine release of levonorgestrel on pelvic infection: Three years' comparative experience of levonorgestrel- and copper-releasing intrauterine devices. *Obstet Gynecol* 1991; 77:261-264.
22. Farley TMM, Rosenberg MG, Rowe P, et al. Intrauterine devices and pelvic inflammatory disease: An international perspective. *Lancet* 1992; 339:785-788.
23. Grimes DA, Schultz KF. Prophylactic antibiotics for intrauterine device insertion: A meta-analysis of the randomized controlled trials. *Contraception* 1999; 60:57-63.
24. Walsh T, Grimes D, Frezieres R, et al. Randomised controlled trial of prophylactic antibiotics before insertion of intrauterine devices. IUD Study Group. *Lancet* 1998; 351:1,005-1,008.
25. Mirena labeling. On file: Berlex Laboratories, Montville, NJ, 2000.
26. Nilsson CG, Lahteenmaki P. Recovery of ovarian function after the use of a d-norgestrel-releasing IUD. *Contraception* 1977; 15:389-400.
27. Andersson K, Mattsson L-A, Rybo G, et al. Intrauterine release of levonorgestrel — a new way of adding progestogen in hormone replacement therapy. *Obstet Gynecol* 1992; 72:963-967.
28. Belhadj H, Sivin I, Diaz S, et al. Recovery of fertility after use of a levonorgestrel-20 mcg/d or Copper T 380Ag intrauterine device. *Contraception* 1986; 34:261-267.
29. Sivin I, Stern J, Diaz S, et al. Rates and outcomes of planned pregnancy after use of Norplant capsules, Norplant II rods, or levonorgestrel-releasing or Copper TCu 380 Ag intrauterine contraceptive devices. *Am J Obstet Gynecol* 1992; 166:1,208-1,213.
30. Sivin I, Stern J, Coutinho E, et al. Prolonged intrauterine contraception: A seven-year randomized study of the levonorgestrel 20 mcg/day (LNg20) and the Copper T380A IUDs. *Contraception* 1991; 44:473-480.
31. Sivin I. IUDs and ectopic pregnancy. *Stud Fam*

Plann 1983; 14:57-63.
32. Luukkainen T, Lahteenmaki P. Treatment of menorrhagia by levonorgestrel-releasing intrauterine device. *Immunology* 1992; 36:261-267.
33. Nilsson CG. Fertility after discontinuation of levonorgestrel-releasing intrauterine devices. *Contraception* 1982; 25:273-278.
34. Andersson JK, Rybo G. Levonorgestrel-releasing intrauterine device in the treatment of menorrhagia. *Br J Obstet Gynaecol* 1990; 97:690-694.
35. Lahteenmaki P, Haukkamaa M, Puolakka J, et al. Open randomised study of use of levonorgestrel releasing intrauterine system as alternative to hysterectomy. *Br Med J* 1998; 316:1,122-1,126.
36. Farquhar CM. Management of dysfunctional uterine bleeding. *Drugs* 1992; 44:578-584.
37. Ettinger B. Personal perspective on low-dosage estrogen therapy for postmenopausal women. *Menopause* 1999; 6:273-276.
38. Suhonen S, Holmstrom T, Lahteenmaki P. Three-year follow-up of the use of a levonorgestrel releasing intrauterine system in hormone replacement therapy. *Acta Obstet Gynecol Scand* 1997; 76:145-150.
39. Raudaskoski TH, Lahti EI, Kauppila AJ, et al. Transdermal estrogen with a levonorgestrel-releasing intrauterine device for climacteric complaints: Clinical and endometrial responses. *Am J Obstet Gynecol* 1995; 172:114-119.
40. Suhonen SP, Holmstrom T, Allonen HO. Intrauterine and subdermal progestin administration in postmenopausal hormone replacement therapy. *Fert Steril* 1995; 63:336-342.

CME Question

To earn CME credit for this issue of Contraceptive Technology Reports, *please refer to the enclosed Scantron form for directions on taking the test and submitting your answer.*

1. For how many years of contraceptive use is the LNG IUS is approved?
   A. three years
   B. five years
   C. seven years
   D. 10 years

June 8 is deadline for conference abstracts

Abstract submissions for the Washington-DC based Association of Reproductive Health Professionals (ARHP) 38th annual CME conference, "Reproductive Health 2001" must be received by June 8. The conference will be held Sept. 12-15 at the Capitol Hilton in Washington, DC.

Authors who submit abstracts are eligible for various levels of conference participation including presentations of their clinical research papers at the conference. The author(s) of the best physician/clinician abstract will receive a $1,000 award, provided by Ortho Pharmaceutical Corp. in Raritan, NJ. The author(s) of the best student abstract will receive a $500 award, provided by ARHP's Fund for the Future of Reproductive Health.

Abstract submission forms may be downloaded from the ARHP web site at www.arhp.org or requested by calling toll-free (877) 444-ARHP, sending a fax to (202) 466-3826, or sending an e-mail to conferences@arhp.org.

The ARHP conference general educational sessions will feature didactic lectures, followed by question-and-answer sessions. Lecture topics will include information on sexually transmitted infections, abortion, contraception, and social issues.