AMERICAN HEALTH CONSULTANTS®

20th Anniversary

CONTRACEPTIVE TECHNOLOGY UPDATE®

A Monthly Newsletter for Health Professionals

INSIDE

Also inserted in this issue:
Sample EC telephone screening protocol

AUGUST 2000

VOL. 21, NO. 8 (pages 89-100)

NOW AVAILABLE ON-LINE!
www.ahcpub.com/online.html
Call (800) 688-2421 for details.

Suggested FDA restrictions might curtail access to mifepristone

Discussions continue with federal agency toward drug approval

The long road to availability of mifepristone for American women has taken a sharp detour as the Food and Drug Administration considers new restrictions that could hamper access to the medical abortion method when it receives final FDA approval.

"The FDA's initial approach is more restrictive than we had envisioned for a drug that has been used safely by so many women around the world," says **Heather O'Neill**, spokeswoman for the New York City-based Danco Group. Danco is the company charged with manufacturing and distributing mifepristone by the owner of the drug's U.S. license, the New York City-based Population Council.

While those involved in the negotiations declined to give specific details of the proposed restrictions, proponents of abortion access fear that any restrictions will limit access to the drug should it receive FDA marketing clearance. The agency has issued two "approvable" letters — one in March 1996 and the second in February 2000 — declaring the drug's safety and efficacy.

Vicki Saporta, executive director of the National Abortion Federation

EXECUTIVE SUMMARY

The Food and Drug Administration has indicated it might place restrictions on how the abortion drug mifepristone is distributed and who can prescribe it. While no final decisions have been reached, advocates fear such restrictions would hamper access to the method.

- The FDA will not maintain a national registry of providers, as reported in the popular press. Discussions are centering on such possible restrictions as limiting prescribing privileges to doctors who perform surgical abortions and requiring certification in mifepristone's use.
- The federal agency has three avenues of action prior to its Sept. 30 action date. It can approve mifepristone for U.S. marketing and distribution, disapprove it for such use, or issue an "approvable" letter, which affirms the drug's safety and efficacy.

(NAF) in Washington, DC, says, "What the FDA is now proposing in terms of restrictions are even more strict than the restrictions that were in place during their own clinical trial. That is fairly unprecedented, since they have already ruled that this drug is safe and effective for use in terminating pregnancy."

The FDA declined to comment on the restrictions. According to FDA spokeswoman **Susan Cruzan**, the agency is not in a position to comment on a product application. "For any new product, FDA's job is to examine not only whether that product is safe but also whether it can be used safely," she states.

No registry planned

Initial reports of the suggested restrictions stated that the FDA would maintain a national registry of mifepristone providers, a move immediately questioned by abortion access advocates. Requiring a listing of physicians and patients would be an invasion of privacy, says **Mitchell Creinin**, MD, director of family planning and family planning research and associate professor in the department of obstetrics, gynecology, and reproductive sciences in the University of Pittsburgh School of Medicine. Such an invasion would deter the drug's use, which is the opposite of the FDA's mission, he maintains.

The FDA has not proposed a registry, says **Sandra Arnold**, vice president for corporate affairs at the Population Council. News of such a registry is a "mischaracterization," she said during a recent Emerging Issues in Reproductive Health media conference on medical abortion, part of an ongoing series for journalists organized by the Kaiser Family Foundation of Menlo Park, CA.

One restriction now in discussion centers on certification of mifepristone providers. If the restriction addresses training, then NAF's current educational efforts should provide ample coverage without a specific mandate from the FDA. NAF developed a wide variety of educational and training programs to coincide with the launch of mifepristone in the United States, says Saporta. **(For an overview, see *Contraceptive Technology Update*, May 2000, p. 53.)**

"We don't believe that the training should be government-mandated," she explains. "It wasn't even in [the FDA's] own clinical trial."

NAF has a journal supplement on mifepristone that will be printed this month in the *American Journal of Obstetrics & Gynecology*. Its training slides, interactive CD-ROM, and self-study guide will be available pending FDA approval to allow the final labeling to be incorporated in the educational material.

A NAF-sponsored Web site, www.earlyoptions.org, offers detailed information on mifepristone, including its history worldwide, experience with the drug, regimens, side effects, and the availability of mifepristone in the United States, says Saporta. It also includes information about NAF's "early options" educational materials, with ordering information to be added upon marketing approval. **(See resource box, p. 91, for NAF contact information.)**

A soon-to-be added section will instruct women on how to access information and materials, as well as direct them to NAF's telephone hotline, (800) 772-9100. When the drug is available, hotline operators will be able to refer women to qualified providers in their area, notes Saporta.

Restrictions questioned

Another proposed constraint would call for mifepristone providers to be certified in surgical abortion. Advocates do not believe such a limitation should be established. Just 2% of women who had a mifepristone abortion 49 days following their last menstrual period in clinical trials required hospitalization, surgical intervention, and/or intravenous fluid administration.[1]

"We don't think that it should be limited to those who can provide surgical abortions because physicians who would like to add it to their practices can always work out an arrangement with a surgical provider to arrange the backup that is necessary," Saporta states.

There is no certification process in existence

COMING IN FUTURE MONTHS

- OCs over the counter: Will FDA approve?
- Hospital mergers impact reproductive services
- Consider contracting with private insurers
- The contraceptive patch: Will women want it?
- Nonoxynol-9 in gel form not effective in microbicide trial

now for surgical providers of abortion, nor does there need to be any state certification of abortion providers, she adds. Legal induced abortion is the most frequently performed and one of the safest surgical procedures in the country.[2] Adding additional legislation would only hinder access for women, she notes.

"We would like to see mifepristone achieve its promise of expanding accessibility to women," she says. "The current restrictions that are being proposed by the FDA would disqualify / qualify physicians and would even disqualify some current providers of surgical services from offering this service to women, thereby denying access to hundreds of thousands of women."

One in three gynecologists who have never performed a surgical abortion or haven't done so in the past five years say they would use mifepristone for medical abortions, according to a just-released survey from the Kaiser Family Foundation of Menlo Park, CA.[3] Slightly more than 30% of family practice physicians, most of whom do not provide abortions, say they, too, would offer the drug. In this survey, 26% of all gynecologists said they routinely or currently perform abortions, while only 5% of family practice physicians said they provide such services.

However, some providers would have second thoughts about providing mifepristone if they were required to undergo a certified training program or were mandated to strictly adhere to product labeling, the survey results reveal. Almost half of gynecologists who said they were likely to offer the drug would be less likely to do so under those conditions, as would 40% of family practitioners.

If mifepristone provision required additional malpractice insurance, many providers would be less likely to offer the drug. Survey results showed that 54% of gynecologists and 60% of family practice physicians who expressed interest in providing the drug would be disinclined to do so if extra insurance were required.

The FDA has three options before Sept. 30: It can give its approval to the U.S. manufacture and marketing of mifepristone, decline such approval, or issue another "approvable" letter, says O'Neill. "The issues they have raised will require additional responses from us," she notes. "We'll just keep discussing [those issues] with them until we reach agreement."

Saporta calls for closure on the issue. "The FDA really needs to approve this drug on Sept. 30, and they need to approve it without politically motivated restrictions that aren't medically necessary," she says. "While we need to make sure that physicians are educated in this method, and we are prepared to do that, it is important that as many women as possible who want access to the medication are able to have it."

RESOURCE

- **National Abortion Federation**, 1755 Massachusetts Ave. N.W., Suite 600, Washington, DC 20036. Telephone: (202) 667-5881. Fax: (202) 667-5890. Web: www.prochoice.org.

References

1. Spitz IM, Bardin CW, Benton L, et al. Early pregnancy termination with mifepristone and misoprostol in the United States. *N Engl J Med* 1998; 338:1,241-1,247.
2. Henry J. Kaiser Family Foundation. *Abortion Fact Sheet*. Menlo Park, CA; May 1999.
3. Henry J. Kaiser Family Foundation. *National Survey of Women's Health Care Providers on Abortion*. Menlo Park, CA; June 2000. ■

New data show Norplant effective for 7 years

Just-published research indicates that the current model of Norplant levonorgestrel contraceptive implant offers up to seven years of effective use, two years beyond the current labeling approved by the Food and Drug Administration.[1]

The studies submitted for the FDA's 1990 approval included data on currently manufactured "soft-tubing" implants and "hard-tubing" implants, which are no longer manufactured,

EXECUTIVE SUMMARY

Research in seven countries shows the Norplant contraceptive implant is safe and highly effective for seven years, two years longer than approved by the Food and Drug Administration.

- The research includes data on women with "soft-tubing" implants. The majority of the data in the current labeling was based on earlier "hard-tubing" implants.
- The new data show the cumulative seven-year pregnancy rates among Norplant users are comparable to rates among women who have been surgically sterilized.

says **Irving Sivin**, a researcher in the New York City-based Population Council's Center for Biomedical Research. The hard-tubing implants were used early in the introduction of the method and were later replaced by the soft-tubing implants, which are less dense and release hormone at a higher rate.[2]

Three-quarters of the subjects included in the data analysis on which the current U.S. product labeling is based used "hard-tubing" capsules. As a result, the pregnancy rates in the labeling are substantially greater than data reflecting "soft-tubing" implants alone, Sivin states.

The Population Council is compiling the information needed for updating the product labeling for submission to the U.S. manufacturer, Wyeth-Ayerst Laboratories in Philadelphia. The company subsequently will decide whether to seek revised labeling for the drug.

Look at the data

The research involves two independent studies of 1,210 women ages 18 to 40 in Chile, the Dominican Republic, Egypt, Finland, Singapore, Thailand, and the United States. All the women were using soft-tubing Norplant implants. Of the enrollees, 42% were U.S. residents. One-sixth of the women weighed 70 kg (154 lbs) or more at the time of implant placement.

No pregnancies occurred during the study in the 400 women who were both 30 years old or older and who weighed less than 100 kg (220 lbs) at the time Norplant was inserted. None of the women weighing less than 50 kg (110 lbs) when they entered the study became pregnant.

Women who weighed less than 70 kg when they entered the study had a pregnancy rate of less than one per 100 throughout the seven years. Women who weighed 80 kg (176 lbs) or more when they entered the study, however, experienced higher pregnancy rates at the five-year point and beyond.

"It seems to me that for the great majority of women, there is just no question that it is a seven-year method," Sivin observes. "However, for women who weigh 80 kg, we saw that the pregnancy rate over the seven years was above 10 per 100, so I think one simply has to advise these women what are the rates so they may make their own decision."

Among women ages 18 to 33, the seven-year Norplant pregnancy rates are comparable to the median pregnancy rates of tubal sterilization methods for women of the same age and duration of use. For women ages 34 and older, without regard to weight at admission, the seven-year effectiveness of soft-tubing Norplant equals or surpasses that of tubal sterilization, researchers found.

The news of Norplant's extended effectiveness will be an even stronger motivation for women who are looking for safe, long-term, reversible contraception, predicts **Haleh Sangi-Haghpeykar**, PhD, assistant professor in the department of OB/GYN's division of contraceptive research and development at Baylor College of Medicine in Houston. Sangi-Haghpeykar has conducted research of long-term Norplant users and says the majority of women she has interviewed would reuse the method at the current five-year reinsertion date.[3]

"If they think they can use it for seven years, I think it will be even a stronger motivation for them to keep it," she says.

Many of the women who were included in Sangi-Haghpeykar's research had experienced side effects with Norplant, particularly during the first year. However, they chose to continue its use due to their strong desire for a long-term, effective, convenient contraceptive, coupled with their ability to control the method with no need of cooperation from their partners. Thorough counseling prior to implant insertion also prepared women for reduction of side effects following the first year or two of use.

Many of the women had negative experiences with other contraceptives, or other methods simply didn't work for them, Sangi-Haghpeykar notes. All of the users had tried most other methods and were dissatisfied with the results.

"The study indicates that women do need long-term methods; there is really nothing else out there besides sterilization," she says. "Women need something, and they are willing to put up with side effects if they think it is going to work for a long period of time."

References

1. Sivin I, Mishell DR, Diaz S, et al. Prolonged effectiveness of Norplant capsule implants: A 7-year study. *Contraception* 2000; 61:187-194.

2. Anonymous. Norplant found highly effective up to seven years. *Population Briefs* 2000; 6:3.

3. Sangi-Haghpeykar H, Frank M, Leonard L, et al. A qualitative study of perceptions, attitudes, and experiences of long-term levonorgestrel implant users. *Women and Health* 2000; 30:91. ■

Improving access to emergency contraception

Is emergency contraception readily available at your facility? If it is, are you taking the next step by providing emergency contraceptive pill (ECP) prescriptions or pills in advance so women have a backup in case their birth control method fails or they have unprotected sex?

If ECP provision isn't on your service menu, you may want to consider adding it. A new reference, *A Clinician's Guide to Providing Emergency Contraceptive Pills,* offers tips on policies, organizational and management issues, staff training, and billing and insurance procedures. It is published by the Pacific Institute for Women's Health in Los Angeles, the Family Planning Council of Southeastern Pennsylvania in Philadelphia, and the California Family Health Council in Los Angeles. **(See resource box, p. 94.)**

The reference guide grew out of research by the institute in partnership with the Family Planning Council at eight family planning clinics in and around Philadelphia, says **Rochelle Fabb**, the institute's director of communications. The study examined the responses of directors, staff, and clinicians to the council's policy to distribute ECPs prophylactically to all family planning patients and responses to its attendant ECP media campaign.[1]

Research findings pointed to a specific need for a clear, concise "how-to" manual aimed at family planning clinicians that would promote awareness of the method and ease the introduction of ECPs into clinical practice, says Fabb. "It is our hope that this guide [which includes a sample telephone screening protocol and instructions for use] will help many more clinicians to implement a quick response system so that they and their staff can provide ECPs when women need it." **(See screening protocol, inserted in this issue.)**

To reach that goal, the guide is being widely disseminated to physicians, nurse practitioners, family planning clinics, and state-funded family planning providers, thanks to the efforts of many organizations, including AVSC International in New York City; Medical Students for Choice in Berkeley, CA; the National Family Planning and Reproductive Health Association and the Reproductive Health Technologies Project, both in Washington, DC; the American Medical Women's Association in Alexandria, VA; and the Program for Appropriate Technology in Health in Seattle.

If your facility is providing ECPs, how can you boost awareness of the method? Take a tip from Planned Parenthood of Los Angeles, which has

EXECUTIVE SUMMARY

Reproductive health centers are finding successful ways to improve access to emergency contraceptive pills (ECPs) in an effort to reduce the nation's high rate of unplanned pregnancies.

- The Pacific Institute for Women's Health, in partnership with the Family Planning Council of Southeastern Pennsylvania and the California Family Health Council, has published a clinicians' reference guide on ECPs; it is being distributed to a wide national audience.
- Clinics affiliated with the Planned Parenthood of Los Angeles offer most patients ECPs to take home with them "just in case." In the first month of operation, the number of patients who took home ECPs doubled, report clinic officials.

Before You Start Providing ECPs

Questions to consider	Yes	No
Will you refer clients requesting emergency contraceptive pills (ECPs) after hours?	❑	❑
Can you schedule "emergency" clients within the 72-hour time limit for effectiveness?	❑	❑
Do you have sufficient staff to provide counseling, education, and follow-up for clients?	❑	❑
Can your practice serve more clients? Will providing ECPs expand your practice?	❑	❑
Are there other health services that would refer ECP clients to your practice?	❑	❑
Do you share a practice or office space with clinicians who are opposed to offering contraceptive services or who are opposed to emergency contraception? Does your staff share these opinions?	❑	❑
Are the ECPs you are prescribing available in the local pharmacies?	❑	❑

Source: Reprinted with permission from Pacific Institute for Women's Health (Web: www.piwh.org) from *A Clinician's Guide to Providing Emergency Contraceptive Pills* by Mary Ann Castle, PhD, and Francine Coeytaux, MPH.

Thinking about ECP Policies

Thinking about policies	Yes	No
Will you offer emergency contraceptive pills (ECPs):		
• To women of all ages, including adolescents?	❑	❑
• As part of your patients' general reproductive health care education?	❑	❑
• To women who are not your regular patients?	❑	❑
• To men?		
Will you provide ECPs:		
• By dispensing prescriptions?	❑	❑
• By dispensing pills?	❑	❑
• By prescription over the phone?	❑	❑
• In advance, "just in case"?	❑	❑
To rule out pregnancy, will you:		
• Be satisfied with a brief, self-administered medical history, as opposed to a physical exam and/or pregnancy test? (Note: These procedures are not recommended.)	❑	❑
• Require that a medical history form be reviewed by a nurse practitioner or clinician before ECPs are provided?	❑	❑

Source: Reprinted with permission from Pacific Institute for Women's Health (Web: www.piwh.org) from *A Clinician's Guide to Providing Emergency Contraceptive Pills* by Mary Ann Castle, PhD, and Francine Coeytaux, MPH.

seen its numbers rise since instituting a campaign this spring. In the first month of operation, the number of patients who took home ECPs, including those who came to the affiliate clinics specifically because they had unprotected sex, jumped from 448 to 976.

The Los Angeles affiliate began looking at ways to promote awareness and access to EC following the Food and Drug Administration's 1997 declaration of ECPs' safety and effectiveness. However, 1999 market research showed that EC awareness was still low, with the method used by only a small percentage of patients, says **Nancy Sasaki**, president and chief executive officer of Planned Parenthood Los Angeles.

The affiliate decided the best way to market EC was through its clinics to existing patients. The campaign's goals? The first was to promote the use of EC for women whose regular birth control method failed. The second goal was to increase awareness by educating women who already are inclined to get birth control information from Planned Parenthood, who then would spread the information by word of mouth.

These audiences were chosen to receive emergency contraception to take home at the time of their clinic visit: women with negative pregnancy tests who decline a regular method of birth control, women who use condoms as their only method of birth control, women who use the Pill as their main method of birth control (because many women abandon use of the Pill when not in a relationship), and women who test positive for a sexually transmitted infection (because women who have had sex without a condom might also be at risk for an unplanned pregnancy).

The campaign was designed by the affiliate's marketing department with input from the clinical services administration staff, clinicians, and clinic staff. It centered on posters reading, "If you have unprotected sex, you have 72 hours to prevent unintended pregnancy" and buttons with "EC — Ask me." Cost of the materials was less than $250, says Sasaki. Easy access to EC is important, she stresses. "Studies[2-3] into the use of EC indicate that women are much more likely to use emergency contraception when they need it if they already have it at home."

References

1. Castle MA, Friedlander E, Bird ST, et al. Introducing Emergency Contraceptive Pill Services at Family Planning Clinics in Philadelphia: The Organizational and Social Context. Los Angeles; Pacific Institute for Women's Health; 1999.
2. Glasier A, Baird D. The effects of self-administering emergency contraception. *N Engl J Med* 1998; 339:1-4.
3. Raine T, Harper C, Leon K, et al. Emergency contraception: Advance provision in a young, high-risk clinic population. *Obstet Gynecol* 2000; 96:1-7. ■

RESOURCE

For a copy of *A Clinician's Guide to Providing Emergency Contraceptive Pills*, contact:

- **Melody Sokolow**, Pacific Institute for Women's Health, 2999 Overland Ave., Suite 111, Los Angeles, CA 90064. Telephone: (310) 842-6828. Fax: (310) 280-0600. Printed copies are $6 (including shipping and handling); the guide also may be downloaded as an Adobe Acrobat PDF format file from the Web: www.piwh.org/publications.html.

Does the Pill affect bone mineral density?

When you name the noncontraceptive benefits offered by today's low-dose oral contraceptives (OCs), you can list protective effects against endometrial cancer, ovarian cancer, benign breast disease, ovarian cysts, ectopic pregnancy, pelvic inflammatory disease, and anemia. What if a definitive study could show that use of pills is associated with favorable effects on bone mineral density (BMD)?

Osteoporosis is a major public health threat for 28 million Americans, 80% of whom are women, according to the National Institutes of Health's Osteoporosis and Related Bone Diseases National Resource Center in Washington, DC.[1] One of every two women over 50 will have an osteoporosis-related fracture in her lifetime. **(For more on osteoporosis, see *Contraceptive Technology Update,* June 2000, p. 71.)**

Researchers at the Boston University School of Medicine have performed a retrospective review of the literature to determine the association of OC use and BMD.[2] Their conclusion? Based on the review of 13 studies, fair evidence supports the hypothesis that the use of low-dose OCs is associated with favorable effects on BMD.

"The review was motivated by curiosity, since low-dose OCs have not been considered separately. Perhaps they should be," says **Lynn Borgatta**, MD, clinical associate professor in the obstetrics/gynecology department in Boston University's medical school and a review co-author.

The just-published review was limited to studies of women using low-dose OCs with BMD measurement analyzed by bone densitometry. A total of 13 studies met the inclusion criteria. Nine of the studies showed a positive effect of OC use on BMD,[3-11] and four did not show an association.[12-15] However, none of the studies showed a decrease in BMD with OC use. The researchers classified the level of evidence from each study according to the guidelines of the U.S. Preventive Services Task Force.[16]

The researchers offer suggestions for a randomized, controlled study design to yield more definitive results.

EXECUTIVE SUMMARY

A review of medical literature examined oral contraceptive (OC) use and bone mineral density (BMD). It concluded that fair evidence supports the hypothesis that low-dose OCs are associated with favorable effects on BMD. A randomized controlled trial is needed to gain definitive information.

- Osteoporosis is a major public health threat for 28 million Americans, 80% of whom are women. One of every two women over 50 will have an osteoporosis-related fracture in her lifetime.
- OC impact on BMD may best be demonstrated in hypoestrogenic women, including those with eating disorders (anorexia), hypothalamic amenorrhea, and perimenopausal women.

Can OCs make an impact?

Will a randomized, controlled study be able to show that OC use does have a major impact on the BMD of healthy, ovulatory women? **Andrew Kaunitz**, MD, says he is skeptical. Kaunitz is professor and assistant chair in the obstetrics and gynecology department at the University of Florida Health Science Center/Jacksonville and director of menopause and gynecology services at the Medicus Women's Diagnostic Center in Jacksonville. Based on the existing literature, he does not see OC use having a major positive effect on the BMD of healthy, ovulatory women. That should not be surprising, because such women are already estrogen replete, he notes.

"In contrast, combination OCs have consistently been found to positively impact BMD in hypoestrogenic women, including those with eating disorders [anorexia], hypothalamic amenorrhea, and perimenopausal women," Kaunitz says. "It is in these latter high-risk women where use of OCs can make an important positive impact."

A recently published study that measured BMD in long-term OC users and compared it to levels in menstruating women who had never used pills found no differences in bone density.[17] This finding should not be a surprising one, says **John Guillebaud**, MA, FRCS(Ed), FRCOG, MFFP, professor of family planning and reproductive health at University College and medical director of the Margaret Pyke Family Planning Centre, both in London.

"You cannot expect the OC estrogen to provide an additional advantage in comparison with women with normal ovarian function, only in a population which includes a good proportion who have diminished ovarian function," he explains. "That is why the positive studies tend to be in the

older age groups when the comparison population has an increasing proportion of women with hypoestrogen levels, due to the beginnings of ovarian failure prior to their menopause."

According to Guillebaud, in studies of younger women, only about 2% to 5% would be expected to be short of estrogen. Although those women certainly would benefit from the Pill, there would be too few of them in the average study to show a population difference, he concludes.

"There is no particular need for a definitive study; in my view, our study shows the Pill is as good as a woman's own ovaries, and the positive studies show it is better than a woman's defective ovaries," he says. "To confirm the latter, one could randomly allocate underweight athletes with oligomenorrhea to the combined OC or to nonhormonal contraception, or target older women above age 45 [who are without contraindications] for a similar randomized controlled trial."

Guillebaud says the results of such a study would show that the estrogen of the OC works just as well as ERT and neither better nor worse than a woman's own ovarian estrogen with respect to bone health. "What is often overlooked is that estrogen is estrogen wherever it comes from."

References

1. National Institutes of Health. "Osteoporosis and Related Bone Diseases National Resource Center." *Osteoporosis Overview*. Washington, DC. Web: www.osteo.org/osteo.html.

2. Kuohung W, Borgatta L, Stubblefield P. Low-dose oral contraceptives and bone mineral density: An evidence-based analysis. *Contraception* 2000; 61:77-82.

3. Kanders B, Lindsay R, Dempster D, et al. Determinants of bone mass in healthy young women. *Proceedings of the Copenhagen International Symposium of Osteoporosis.* Copenhagen: 1984, pp. 337-339.

4. Shargil AA. Hormone replacement therapy in perimenopausal women with a triphasic contraceptive compound: A three-year prospective study. *Int J Fertil* 1985; 30:15, 18-28.

5. Recker RR, Davies KM, Hinders SM, et al. Bone gain in young adult women. *JAMA* 1992; 268:2,403-2,408.

6. Mais V, Fruzzetti F, Ajossa S, et al. Bone metabolism in young women taking a monophasic pill containing 20 mcg ethinyl estradiol: A prospective study. *Contraception* 1993; 48:445-452.

7. Volpe A, Silferi M, Genazzani AD, et al. Contraception in older woman. *Contraception* 1993; 47:229-239.

8. Gambacciani M, Spinetti A, Cappagli B, et al. Hormone replacement therapy in perimenopausal women with a low dose oral contraceptive preparation: Effects on bone mineral density and metabolism. *Maturitas* 1994; 19:125-131.

9. Gambacciani M, Spinetti A, Taponeco F, et al. Longitudinal evaluation of perimenopausal vertebral bone loss: Effects of a low-dose oral contraceptive preparation on bone mineral density and metabolism. *Obstet Gynecol* 1994; 83:392-396.

10. Volpe A, Amram A, Cagnacci A, et al. Biochemical aspects of hormonal contraception: Effects on bone metabolism. *Eur J Contraception Repro Health Care* 1997; 2:123-126.

11. Masaryk P, Lunt M, Benevolenskaya L, et al. Effects of menstrual history and use of medications on bone mineral density: The EVOS Study. *Calcif Tissue Int* 1998; 63:271-276.

12. Sowers M, Wallace RB, Lemke JH. Correlates of forearm bone mass among women during maximal bone mineralization. *Prev Med* 1985; 14:585-596.

13. Mazess RB, Barden HS. Bone density in premenopausal women: Effects of age, dietary intake, physical activity, smoking, and birth-control pills. *Am J Clin Nutr* 1991; 53:132-142.

14. Rodin A, Chapman M, Fogelman I. Bone density in users of combined oral contraception. *Br J Fam Plann* 1991; 16:125.

15. Murphy S, Khaw KT, Compston JE. Lack of relationship between hip and spine bone mineral density and oral contraceptive use. *Eur J Clin Invest* 1993; 23:108-111.

16. U.S. Preventive Services Task Force. *Guide to Clinical Preventive Services.* 2nd ed. Washington, DC: U.S. Department of Health and Human Services; 1996.

17. MacDougall J, Davies MC, Overton CE, et al. Bone density in a population of long term oral contraceptive pill users does not differ from that in menstruating women. *Br J Fam Plann* 1999; 25:96-100. ■

Universal HIV tests eyed for prenatal care

Which women should undergo prenatal HIV testing? All of them, according to a new education campaign launched by the Washington, DC-based American College of Obstetricians and Gynecologists (ACOG). Every pregnant woman, regardless of her apparent risk for HIV, should be tested for evidence of the infection, along with being informed that the test will be run, according to ACOG. While the test is not mandatory — women can refuse it — the organization hopes the campaign will make HIV testing an ordinary part of the prenatal screening process.

The new standard of "universal, routine testing with patient notification" has been adopted by ACOG and the Elk Grove Village, IL-based American Academy of Pediatrics following the 1998 recommendation of such practice by the Institute of Medicine (IOM) in Bethesda, MD.[1]

A grant from the Centers for Disease Control

EXECUTIVE SUMMARY

All pregnant women in the United States, regardless of apparent risk, should be tested for HIV as a routine part of prenatal care, says a new campaign launched by the American College of Obstetricians and Gynecologists (ACOG). Such testing would not be mandatory; women could refuse the test.

- The new standard of "universal, routine testing with patient notification" has been adopted by ACOG and the American Academy of Pediatrics following the 1998 recommendation of such practice by the Institute of Medicine.
- Research shows that use of zidovudine during pregnancy and the neonatal period reduces the rate of mother-to-child HIV transmission by about two-thirds. By identifying HIV infection early, more mothers-to-be can get treatment that may protect their babies from infection.

and Prevention (CDC) in Atlanta has enabled ACOG to produce and distribute packets of provider and patient information to all its members, according to **Stanley Zinberg**, MD, vice president of ACOG's practice activities division. While the funds don't cover distribution to other groups, ACOG plans to share the educational material with other professional organizations in hopes it can be replicated for other providers, says Zinberg.

Why should HIV testing become a routine part of pregnant women's prenatal care? Patients may ask this question, particularly if they are in a stable, monogamous relationship. ACOG sums up the reason in its patient information materials:[2] "You can have HIV for years and not know it or feel sick. To get early help for yourself, you need to know for sure." Without treatment, one in four babies born to women infected with HIV will become infected, notes ACOG. However, taking special medication for HIV during pregnancy can greatly reduce the risk of an infant getting HIV.

Indeed, there has been much progress since 1994 in prevention of transmission of HIV from mothers to babies in the United States, notes **Mary Glenn Fowler**, MD, chief of the maternal-child transmission section of the epidemiology branch of the CDC's Division of HIV / AIDS Prevention. The current strategy is to eliminate as many cases as possible of perinatal HIV transmission, she says.

According to research data, use of the drug zidovudine during pregnancy and the neonatal period reduces the rate of mother-to-child HIV transmission by about two-thirds.[3,4] New cases of AIDS in newborns declined 67% between 1992 and 1997, due in large part to increased treatment with zidovudine.[5]

"Given all the new, effective interventions for preventing mother-to-child transmission and also for HIV-infected women's health care, we thought it was very important that every woman be offered [testing]," says Fowler. "She then can make her decision whether she accepts testing or not."

To reach those women who had not been covered under existing perinatal prevention programs, the CDC determined that obstetricians should be included in the effort, explains Fowler. ACOG, which estimates that its members perform about 85% of the nation's 3.9 million deliveries each year, was tapped for the CDC partnership.

In further efforts to reduce the rate of perinatal HIV transmission, ACOG has released a new committee opinion that recommends HIV-positive pregnant women with high viral loads be counseled by providers about both the benefits and risks of elective cesarean delivery.[6]

For women being treated with zidovudine, a cesarean delivery before the onset of labor and rupture of membranes reduces the likelihood of HIV transmission to the newborn to about 2%; however, cesarean delivery is associated with higher maternal complications. Patients will need to be counseled on the risks and benefits associated with the procedure and make their own decision about delivery.

Check state laws

While ACOG recommends that its members adopt the new testing standard, it also recognizes that laws or policies in many states require counseling and informed consent for HIV testing, says Zinberg. ACOG encourages members to include counseling as a routine part of care but not as a prerequisite to prenatal HIV testing, unless it is required by state law. Check with your state department of health to determine whether it is a requirement.

"We still feel pretty strongly that counseling is an important component, and we said this in our joint statement with the pediatricians, even though we are accepting the IOM's recommendation," Zinberg notes.

The education packets include tear pads of information, written in English and Spanish, to inform patients about perinatal HIV testing and treatments, as well as patient pamphlets and

posters to emphasize the importance of testing for all women. The tear pad is very informative, Zinberg observes. It addresses the general prenatal tests performed near or at the first provider visit and concentrates on the HIV test. A laminated card with HIV facts for the provider is included for use in discussing the HIV test.

Counseling requirements indeed may vary from state to state, notes Fowler; however, many state laws have language with "strong urging" for obstetricians and other health care providers to offer testing. "Some states are a little bit stronger on how it's worded," she says. "I think the thrust of the states has been very much in line in making it much more available to all pregnant women."

References

1. Stoto MA, Almario DA, McCormick MC, eds. *Reducing the Odds. Preventing Perinatal Transmission of HIV in the United States*. Bethesda: Institute of Medicine; 1998.
2. American College of Obstetricians and Gynecologists. *Important News for Pregnant Women*. Washington, DC; 2000.
3. Connor EM, Sperling RS, Gelber R, et al. Reduction of maternal-infant transmission of human immunodeficiency virus type 1 with zidovudine treatment. *N Engl J Med* 1994; 331:1,173-1,180.
4. Sperling RS, Shapiro DE, Coombs RW, et al. Maternal viral load, zidovudine treatment and the risk of transmission of human immunodeficiency virus type 1 from mother to infant. *N Engl J Med* 1996; 335:1,621-1,629.
5. Lindegren ML, Byers RH, Thomas P, et al. Trends in perinatal transmission of HIV / AIDS in the United States. *JAMA* 1999; 282:531-538.
6. American College of Obstetricians and Gynecologists. *Scheduled Cesarean Delivery and the Prevention of Vertical Transmission of HIV Infection*. ACOG Committee Opinion 219: Washington, DC; 1999. ■

Debate over adoption 'promotion' in clinics

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

In May, the House of Representatives overwhelmingly passed an omnibus children's health bill (H.R. 4365) that contains the "Infant Adoption Awareness Act," a provision largely directed at pregnancy-options counselors in Title X family planning clinics. The provision, included in the children's health bill at the insistence of House Commerce Committee chairman Tom Bliley (R-VA), represents a hard-fought compromise between family planning advocates and antiabortion legislators seeking to "promote" adoption in family planning clinics.

Bliley first signaled his intent to place the issue on the Congressional agenda last year when he and Rep. Jim DeMint (R-SC) introduced "The Adoption Awareness Act" (S.2511), a bill purporting to correct what the sponsors perceive to be an "anti-adoption bias" among federally funded pregnancy counselors. The legislation would have required Title X and other federally funded health care providers to undergo mandatory training — or risk losing federal funds — in "adoption counseling" and "promoting" adoption.

Family planning advocates strongly opposed the DeMint/Bliley bill. First, they argued, the Title X program already requires family planning providers to provide basic information to pregnant women interested in learning more about adoption, along with a referral to a licensed adoption agency. Requiring family planning clinics to provide the much more specialized service of adoption counseling and to assume functions historically performed by adoption agencies necessarily would have diverted resources away from the provision of family planning services to low-income clients. Second, they contended, the goal of promoting adoption stands in sharp contrast to existing Title X guidelines that require family planning providers to offer "nondirective" counseling about *all* of the options available to women facing a crisis pregnancy in a manner that is free from bias or judgment. Third, the bill redefined "nondirective counseling" to exclude abortion, thus imposing a gag on Title X providers.

Review the history

Such efforts to promote adoption in family planning clinics to the exclusion of any information about abortion are not new. They hearken back to the 1988 "gag rule" regulation promulgated by the Reagan administration, which barred counselors in Title X clinics from discussing abortion as one of the alternatives available to women facing an unplanned pregnancy and from referring women to a provider of abortion services — even when a woman specifically requested such information. At the same time, counselors were required to give all patients referrals for prenatal care and delivery services.

The gag rule was opposed by 78 national organizations, including the American Medical Association in Chicago and the American College of Obstetricians and Gynecologists in Washington, DC, as well as 36 state health departments, on the basis that it violated Title X providers' First Amendment right to free speech and the doctor-patient relationship. The U.S. Supreme Court, however, rejected those arguments in 1991, when it voted 5-4 in *Rust v. Sullivan* to uphold the regulations as a permissible exercise of executive power.

The next year, Congress moved to repeal the regulations, but fell 10 votes short of the two-thirds necessary to override President Bush's veto. Challenged again on procedural grounds, the gag rule ultimately was in effect for only one month. As one of his first acts in office, President Clinton suspended the regulations in January 1993.

When Bliley announced his intention to include S.2511 in the omnibus children's health bill pending before the House of Representatives, family planning advocates entered into behind-the-scenes negotiations to remove its most onerous provisions. Those negotiations were successful.

The language that was ultimately included in the children's health bill and passed by the House

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

Subscriber Information

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

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

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

Editor: **Rebecca Bowers**.
Vice President/Group Publisher: **Brenda Mooney**, (404) 262-5403, (brenda.mooney@ahcpub.com).
Editorial Group Head: **Valerie Loner**, (404) 262-5475, (valerie.loner@ahcpub.com).
Managing Editor: **Joy Daughtery Dickinson**, (912) 377-8044, (joy.dickinson@ahcpub.com).
Senior Production Editor: **Terri McIntosh**.

Editorial Questions

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

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.

does not mention adoption counseling and does not contain a gag. Instead, it would fund adoption organizations to train counselors in Title X clinics and community health centers "in providing adoption *information and referrals* to pregnant women on an equal basis with all other courses of action included in nondirective counseling" (emphasis added). Participation in the training would be voluntary, and clinics that don't participate could not lose their federal funds. Adoption organizations and family planning providers would collaborate to develop best-practice guidelines on the provision of adoption information and referrals to pregnant women. Within one year following enactment, the Secretary of the Department of Health and Human Services would be required to submit a report to Congress evaluating the extent to which adoption information and referral upon request are provided by family planning clinics "in order to determine the effectiveness of the training."

The Senate is likely to consider its own version of the children's health bill in the coming months. It is not yet clear whether it will include an adoption provision. ■

CE objectives

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

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

• Identify clinical, legal, or scientific issues related to development and provisions of contraceptive technology or other reproductive services. **(See "Suggested FDA restrictions may curtail access to mifepristone," p. 89, and "New data show Norplant effective for 7 years," p. 91.)**

• 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 "Universal HIV tests eyed for prenatal care," p. 96, and "Get a handle on herpes with these new tests," *STD Quarterly,* p. 3.)** ■

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™

You can help bridge the herpes 'disconnect'

Those most at risk underestimate their chances of getting the disease

As you discuss your patient's sexual history, she tells you that she has had five partners in the last seven months. When you ask her about herpes, she says she has not been at risk, since no partner had any signs of the disease.

Welcome to the "herpes disconnect," a term coined by health professionals who are all too familiar with the fact that while most Americans may have some knowledge of herpes, they underestimate their risk for contracting the disease.

"Three out of four people will tell you the ways that genital herpes is transmitted and will tell you that having multiple partners is a risk factor," says **Linda Alexander**, PhD, FAAN, president of the American Social Health Association (ASHA) in Research Triangle Park, NC. "But when you ask them about their own risk, all too many throw out the facts and minimize the risks."

80% to 90% don't recognize disease

According to ASHA, genital herpes is one of the most widespread sexually transmitted diseases in the United States, and it is estimated to infect 50 million Americans, with 1 million new infections each year. As many as 80% to 90% of those infected fail to recognize herpes or have no symptoms at all. **(For an overview of the U.S. prevalence of the disease, see *Contraceptive Technology Update, STD Quarterly* supplement, January 1998.)**

Why is it important that providers help bridge the herpes knowledge gap? A recently published study reveals that people who appear asymptomatic and who likely don't know they have the disease are just as likely to be infectious as people who know their diagnosis.[1]

"We still have work to do in educating the public," says **Hilary Baldwin**, MD, vice chair and associate professor of clinical dermatology at the State University of New York Health Science Center at Brooklyn. "We also need health professionals to do a better job identifying genital herpes in their patients, as too many patients go undiagnosed and untreated."

ASHA just conducted a national Web-based survey of 1,414 men and women, with more than half the respondents between ages 18 and 39.

EXECUTIVE SUMMARY

While many Americans may have some knowledge of genital herpes, one of the most widespread sexually transmitted diseases in the United States, those at the most risk underestimate their chances of contracting the disease. A national survey shows that among respondents not previously diagnosed with genital herpes, only 27% of men and 23% of women believe they are at risk.

- Providers need to step up their discussions of herpes: Only 9% of men and 14% of women not diagnosed with the STD reported their health care provider initiated discussions on herpes.
- A number of resources, both in print and on the Internet, are available to raise awareness of the disease.

Try these educational tools

The American Social Health Association (ASHA) booklet, ***Understanding Herpes***, is designed primarily for the newly diagnosed patient. The 16-page overview explains how herpes is transmitted, the symptoms, treatment issues, and how to deal with the social and psychological pressures. The cost is $6, which includes shipping/handling.

Also, ASHA's quarterly publication, ***the helper***, provides information on herpes research, suppression therapies, new treatment, and diagnosis options. Subscription costs (including shipping/handling) are one year, $25; two years, $45; and three years, $60. Discounts are available for large orders; please call to discuss. Phone orders may be made to the customer service department from 8:30 a.m. to 4:30 p.m. ET, Monday-Friday (24-hour voice mail), (800) 783-9877.

The Updated Herpes Handbook, written by Terri Warren, RN, MS, and Rick Warren, PhD, and published by The Portland (OR) Press, is available as text and as a PDF file on the Westover Heights Clinic's World Wide Web site, www.westoverheights.com. It offers a concise and easy-to-read reference on the subject. Copies also are available for purchase for $3; please write the clinic at 2330 N.W. Flanders, Suite 207, Portland, OR 97210. Phone: (503) 226-6678. E-mail: handbook@westoverheights.com. ■

Findings show that more than 70% of those polled correctly identified the major ways in which herpes is spread, including oral sex and unprotected intercourse. Among respondents not previously diagnosed with genital herpes, only 27% of men and 23% of women believe they are at risk of contracting the disease. About half of respondents were unaware that condoms provide incomplete protection against genital herpes, and 41% did not know that herpes can be spread from mother to baby.

"While a majority of respondents feel comfortable discussing herpes with health care providers, we'd like to see more of these discussions take place in a preventative context," Alexander says. "In this survey, among the nondiagnosed, only 9% of men and 14% of women reported that their health care provider initiated discussions on herpes."

The ASHA survey also reveals that people are unlikely to talk about herpes with family members or friends, Alexander reports. Just 6% of respondents feel comfortable talking about herpes with a family member, and only 13% indicate being comfortable discussing it with friends. "The major challenge with herpes is getting people to talk about it and feeling responsible for protecting themselves," asserts Alexander.

In other key findings from the study, acceptance of personal risk was highest in the youngest age sets. Some 44% of those between ages 18 and 29 scored themselves at risk, compared with 35% of those between ages 30 and 49.

One in four survey respondents (26%) had been diagnosed with herpes; about half reported taking medication to treat it, the study results reveal. An estimated 25% of U.S. adults have genital herpes, according to ASHA.

Clear up misconceptions

What are the most common misconceptions about herpes? **Terri Warren**, RN, MS, owner of Westover Heights Clinic in Portland, OR, and medical director of ASHA's Portland herpes support group, offers her top five list:

- If you have herpes, you will know it.
- Everyone who has herpes has symptoms.
- Herpes symptoms are dramatic.
- You can only spread herpes when you have sores.
- Herpes is a rare disease.

The ASHA survey shows that among those polled who are undiagnosed with the disease, 17% of men and 22% of women report having been tested for herpes. However, it is a common misconception that herpes testing is part of routine physical exams, says Alexander.

"Women think that when they have an annual gynecological exam, it includes testing for STDs, and when people have a battery of laboratory tests, they assume they are being tested for STDs," says Alexander. "Helping people understand that testing for STDs and specifically for herpes is not a routine matter is something we have to work on."

Most patients at Westover Heights Clinic say they have been tested for herpes during their last annual exam, but more than 90% of the time, they have not, says Warren.

"We offer herpes serologic blood testing for

everyone, and if they decline, we make a note that they declined," she states. "I think that if providers are not offering serologic testing in this day and age, which they should be, then they need to make a note in the chart that they did not offer this test." **(See article on new tests for herpes simplex, at right.)**

Once a diagnosis of herpes has been made, what can you do to help your patient?

ASHA serves as a good resource for information, with telephone and Internet support for those living with herpes, says Alexander. It coordinates more than 80 local support groups, called HELP Groups, in the United States, Canada, and Australia, which help people gain understanding of the disease. For those in rural areas, the Internet provides interaction through on-line chat groups at America Online and WebMD, says Warren.

The ASHA HELP Groups offer a safe, confidential place where people can get accurate information and share experiences with others who have the infection. According to ASHA, people with herpes often feel that they must "go it alone." The groups allow an open forum for people to discuss feelings of crisis and isolation, denial and depression; thoughts of anger and resentment toward the person who infected them; perceptions of loss, real or imagined, of future romance or sexual freedom; awareness issues about lifestyle and relationships; perspectives on living with herpes; and information on medications and therapies.

The most important thing providers can do is provide information to help patients change their perceptions about herpes, Warren says.

"I think that if people think about herpes as a disaster, they will feel like their life is ruined," she notes. "But if they learn to think about it as a manageable, common, nondangerous disease, then they won't feel as panicky and distressed."

RESOURCES

- **American Social Health Association**, P.O. Box 13827, Research Triangle Park, NC 27709. Phone: (919) 361-8400. Fax: (919) 361-8425. Web: www.ashastd.org. ASHA offers free herpes counseling through the National Herpes Hotline, (919) 361-8488, from 9 a.m. to 7 p.m., ET, Monday through Friday.

Reference

1. Wald A, Zeh J, Selke S, et al. Reactivation of genital herpes simplex virus type 2 infection in asymptomatic seropositive persons. *N Engl J Med* 2000; 342:844-850. ■

Get a handle on herpes with these new tests

Testing options for herpes simplex virus (HSV) have expanded in the United States, with three companies now offering new diagnostic methods.

The American Social Health Association (ASHA) in Research Triangle Park, NC, reports an estimated 25% of U.S. adults have genital herpes. The most serious risk is the transmission of virus from infected mother to infant during birth, resulting in death or permanent impairment.

Given the increasing prevalence of infection and the increased availability of testing, there is no excuse for not offering serologic testing, says **Terri Warren**, RN, MS, owner of Westover Heights Clinic in Portland, OR, and medical director of ASHA's Portland herpes support group.

"We can do syphilis tests all day long and never come up with a positive; we haven't had a positive [here] in six years now," Warren says. "One in four people is positive for herpes, so it seems like if we're not taking advantage of the new serologic testing that is available that is type-specific, then we are really missing the boat."

Serologic tests defined

Providers often use serologic tests when patients are at risk for the disease but don't have visible symptoms. In the past, type-specific blood tests were not always accurate because they confused other herpes virus antibodies such as varicella zoster (chicken pox) and Epstein Barr (mononucleosis) for herpes simplex (types 1 and 2) antibodies. The new tests offer improved sensitivity and specificity. The Western blot, developed by researchers at the University of Washington in Seattle, continues as the current gold standard for the diagnosis of herpes antibodies. While it is commercially available from several sites, its cost ($80 to $100) has limited its use.

The POCkit HSV-2 Rapid Test, the first point-of-care test for the specific detection of antibodies to the HSV-2 virus, received Food and Drug Administration approval in August 1999. Now available on the U.S. market, it is manufactured by Diagnology in Research Triangle Park, NC.

A patient with genital symptoms such as lesions, rashes, or other irritation or with a high-risk sexual history can be tested rapidly and accurately for HSV-2 infection with the POCkit test, says **Tom Zietlow**, director of technical affairs at Diagnology. The test can be performed in the office from a simple fingerstick, with 10-minute results allowing the clinician to begin herpes management immediately, regardless of the symptoms. Response from patients has been "overwhelmingly positive," says Zietlow. "The accuracy [of the test] and being able to get results immediately have greatly benefited many people," he notes. "We receive many calls daily from patients wanting the test and asking for local clinics or physicians whom they can contact."

The list price of the POCkit HSV-2 Rapid Test is $290 per tower of five kits for a per-kit cost of $58, Zietlow says. Discounts are available for publicly funded clinics and other facilities that likely would use a high volume of tests; such companies are encouraged to contact the company for a formal quote.

Check Meridian's tests

Meridian Diagnostics of Cincinnati offers two diagnostic tests for the herpes simplex virus. The company received FDA clearance in July 1999 for its Premier Type-Specific HSV-1 IgG ELISA Test and Premier Type-Specific HSV-2 IgG ELISA Test, which distinguish HSV-1 and HSV-2 infections via serological blood test methods. Both are developed for use in the clinical laboratory setting.

"There still is a segment of the medical community who may be in the learning process," says **Marlene Jinks**, company spokeswoman. "There is still some educational work that has to be done as to why it is necessary to do type-specific testing." Presentations continue at several professional association meetings, including the recent Clinical Virology Symposium sponsored by the Pan American Society for Clinical Virology in Clearwater, FL.

Providers may be familiar with the tests as those developed by Gull Laboratories in Salt Lake City; Meridian acquired the company and launched the products, says Jinks. The list price is $320 for 96 tests, she says. Costs to providers will depend on processing fees added by the laboratories performing the tests, she notes.

The latest FDA approvals for HSV testing come for products developed by MRL Diagnostics of Cypress, CA. The company has received clearance to market its type-specific HSV ELISA kits for HSV-1 and HSV-2 IgG antibodies in human serum, as well as its HSV-1 and HSV-2 Differentiation Immunoblot IgG Kit, which is designed for use as a reflex test for patient's serum previously determined to have antibodies to HSV-1 and/or HSV-2. The Immunoblot kit can differentiate HSV-1 and HSV-2 from the same specimen and is the only test of its kind on the market, says company spokeswoman **Mary Beth Carpenter**.

Pricing will vary depending on test volume; however, list price for a single patient result, including controls for laboratories performing 20 to 80 samples per kit, are $3.75 to $15 per test for the HSV-1 ELISA, $4.50 to $18 per test for the HSV-2 ELISA, and $17 per sample for the HSV-1/HSV-2 Immunoblot. Discount prices can be obtained by contacting the sales department. ■

RESOURCES

- **Tom Zietlow**, Technical Affairs Department, Diagnology, P.O. Box 14643, Research Triangle Park, NC 27709-4643. Phone: (877) 776-2548. Fax: (919) 460-0459. E-mail: info@diagnology.com. Web: www.diagnology.com.
- **Marlene Jinks**, Marketing Department, Meridian Diagnostics, 3471 River Hills Drive, Cincinnati, OH 45244. Phone: (513) 271-3700, ext. 336. Fax: (513) 272-5432. Web: www.meridiandiagnostics.com.
- **Mary Beth Carpenter**, Marketing Communications Department, MRL Diagnostics, 10703 Progress Way, Cypress, CA 90630. Phone: (800) 445-0185 or (714) 220-1900. Fax: (714) 220-1683. E-mail: jvargas@mrlinfo.com. Web: www.mrlinfo.com.
- **Community Services**, Department of Laboratory Medicine, University of Washington, P.O. Box 15246, Seattle, WA 98115. Phone: (800) 713-5198 or (206) 598-6066. Fax: (206) 598-6189. Web: www.depts.washington.edu/labweb/Division/Commserv.