AMERICAN HEALTH CONSULTANTS

CONTRACEPTIVE TECHNOLOGY UPDATE®

A Monthly Newsletter for Health Professionals

INSIDE

AUGUST 2002

VOL. 23, NO. 8 (pages 85-96)

Will rising prices limit the options for patients at family planning clinics?

Providers may need to make hard choices to add new methods to list

Your fellow clinicians are buzzing about the new methods of contraception that have emerged this summer, and patients are talking about stories in the popular press touting the contraceptive patch and the vaginal ring. But when it comes to stocking your clinic's pharmacy shelves with these new options, will your facility's budget be able to cover these choices?

According to **Joan Malin**, president and chief executive officer of Planned Parenthood of New York City (PPNYC), the biggest challenge her organization faces is providing new options to clients who come in under the agency's sliding-fee scale. Since the public dollars that fund the sliding-scale program have been curtailed for so long, the agency has had to absorb some amount of the costs to purchase and provide new technologies for low-income and uninsured women, she explains.

Through private funds and general funds received by the agency, PPNYC plans to subsidize the extra costs to add the Evra contraceptive patch (Ortho-McNeil Pharmaceutical, Raritan, NJ) and the NuvaRing (Organon, West Orange, NJ) because it believes availability of such options for all women is crucial, says Malin.

Malin is preparing cost figures to present to state and regional funding agencies to request their help in meeting the funding shortage.

EXECUTIVE SUMMARY

With the advent of two new forms of birth control, the contraceptive transdermal patch and the contraceptive vaginal ring, family planning clinics are looking at balancing the cost of supplying such methods against limited budgets.

- While pharmaceutical companies are making concessions to keep public pricing low, costs for the new methods are more than the prices federally funded clinics pay for oral contraceptives.
- Some clinics are joining in group-purchasing cooperative networks to realize cost savings on a wide range of goods and services.

"We are really at loggerheads on how to do this, because we want to make the new options available," she notes. "Women should be able to make the best decision for themselves, as opposed to what it costs."

It's all about money

While Ortho-McNeil Pharmaceuticals has made significant concessions in negotiating a Title X price of $9.90 for each box of Evra patches, agencies still must look at their finite dollars and balance their budgets based on the projected numbers of clients served, observes **Judith DeSarno**, chief executive officer of the Washington, DC-based National Family Planning and Reproductive Health Association (NFPRHA). And when administrators look at the numbers, $9.90 remains seven times higher than the $1.25 public sector price for a monthly supply of oral contraceptives, she concludes.

DeSarno praises Ortho-McNeil for working with family planning advocates in reaching the Title X price, which is lower than the estimated $40 retail cost. Discussions have just begun with Organon on public pricing for the NuvaRing, which is scheduled to hit retail pharmacy shelves later this summer.

The contraceptive patch and the vaginal ring represent important new birth control options for women, since they do not rely on daily pill-taking for their efficacy, says DeSarno. However, the higher costs of the drugs will lead clinics to offer limited availability to them, she predicts. **(Get in-depth coverage of both options in the *Contraceptive Technology Reports* supplements inserted in *Contraceptive Technology Update*. Check the May 2002 issue for "A Transdermal Delivery System Examined: Ethinyl Estradiol and Norelgestromin for Contraception" and the February 2002 issue for "The Vaginal Contraceptive Ring—Efficacy, Caution, and Instructions.")**

NFPRHA has launched a public campaign in the wake of its recent annual meeting to seek increased funding for the Title X program, the only federal program that provides categorical funding for family planning. Annual Title X appropriations have been flat or declining since 1982.[1] Medicaid has replaced Title X as the largest source of agency funding.[2]

While some clinics are able to raise dollars through private funding, those who are able to do so already have tapped into available funds, says DeSarno. With the advent of the two new contraceptive methods, there are no new sources of private monies to augment agencies' public dollars, she notes.

Don't expect increased state funding for family planning, DeSarno says. States that can run budget deficits already are in the red, and those states required by law to run balanced budgets have had to make major funding cuts, she states.

"I find it very unlikely that we are going to see big increases in the states that have family planning budgets," observes DeSarno. "What we have been seeing is the opposite: We have been seeing cuts."

In the United States, nearly 25% of women who obtain contraceptive services from a medical provider receive their care from clinics run by publicly funded agencies.[3] It is estimated that publicly funded family planning clinics serve more than 7 million contraceptive clients per year.[3] To ensure that all women have access to the full range of reproductive health care, more federal dollars must be mandated for family planning, DeSarno urges.

"We have got to get this funding level [for Title X] to at least $325 million, or frankly, we have to serve far less women so that we do not have two standards of care," she says.

Add education costs

Adding any new contraceptive method represents additional costs in staff training and patient education, says **Margie Fites Seigle**, chief executive officer of the California Family Health Council in Los Angeles.

The council has just developed informed consent forms and informational materials in 13 written languages, with three of those language options also presented in audio tapes for those who cannot

COMING IN FUTURE MONTHS

- Male contraceptive injectable: Is it on the horizon?
- Test for STDs from single ThinPrep sample
- Clear confusion about human papillomavirus
- Abortion training on increase in medical schools
- Low literary skills: How to combat the challenge

RESOURCES

For more information on the Family Planning Cooperative Purchasing Program and the Cooperative Purchasing Network, contact:

- **Sue Speth**, 3600 Wilshire Blvd., Suite 600, Los Angeles, CA 90010-2648. Telephone: (213) 386-5614. Fax: (213) 368-4410. E-mail: speths@cfhc.org. Web: www.fpcpp.org.

For more information on family planning funding issues, contact:

- **National Family Planning and Reproductive Health Association**, 1627 K St., N.W., 12th Floor, Washington, DC 20006. Telephone: (202) 293-3114. E-mail: info@nfprha.org. Web: www.nfprha.org.

comprehend their written language, she notes.

"So in fact, we have about 15 core languages now that we work with in California," says Seigle. "It becomes an incredible challenge."

Staff training and client education for any method of birth control should be tailored so that the most appropriate method is chosen for the patient, she says. Proper patient education improves success with complicated regimens and explains anticipated or possible side effects, which can help decrease anxiety and increase success with the method.

Check group purchasing

Look to the power of group purchasing as one option to stretching clinic dollars, says Seigle. She and Sue Speth, director of the council's cooperative programs, presented tips on how to manage the rising costs of contraceptives at the recent NFPRHA conference.

The council administers two programs, the Family Planning Cooperative Purchasing Program and the Cooperative Purchasing Network. The programs are funded by a Title X federal family planning grant. They assist agencies in managing their higher-cost/usage products and services, and they have approximately 600 agencies with 2,000 clinic sites across the country. The agencies include state, county, multisite, and single-site nonprofit facilities. The Family Planning Cooperative-Purchasing Program has existed for more than 10 years and supports locations that receive Title X funding. The Cooperative Purchasing Network spread nationwide in 2002 and is available to all nonprofit, licensed locations that don't receive Title X federal funding.

Membership in the Family Planning Cooperative Purchasing Program and the Cooperative Purchasing Network is entirely voluntary. Participation in the Family Planning Cooperative Purchasing Program is free; an annual membership fee of $199 is required for the Cooperative Purchasing Network. **(See resource box, left, for more information on these two organizations.)**

Administrators also may want to look at more than just method costs when examining funding options, says Seigle. Facilities should check their cost of disposables; a cost savings in this area may allow a clinic to add more dollars for contraceptive supplies, she suggests.

DeSarno says NFPRHA has met with its members, which include Planned Parenthood affiliates, state health departments, and family planning councils, to examine how agencies are going to meet the reproductive health needs of uninsured patients while spending more money on screening and treatment with limited federal assistance. Clinics funded with public dollars face a significant challenge, she asserts.

"Are there other places we could make some changes to get more money available for clinical services? And the fact of the matter is that this program is so severely underfunded, that we can't," comments DeSarno.

References

1. Alan Guttmacher Institute. *Fulfilling the Promise: Public Policy and U.S. Family Planning Clinics.* New York City; 2000.
2. Finer LB, Darroch JE, Frost JJ. U.S. agencies providing publicly funded contraceptive services in 1999. *Fam Plann Perspect* 2002; 34(1):15-24.
3. Frost JJ. Public or private providers? U.S. women's use of reproductive health services. *Fam Plann Perspect* 2001; 33(1):4-12. ■

4-periods-per-year OC: Comparable to pill

Initial research presented at the recent national meeting of the Washington, DC-based American College of Obstetricians and Gynecologists (ACOG) indicates that a four-periods-per-year pill appears to prevent pregnancy and has a comparable safety profile to more traditional

EXECUTIVE SUMMARY

A four-periods-per-year pill may prevent pregnancy and offer a comparable safety profile to traditional oral contraceptives, initial research findings indicate.

- The pill, Seasonale, is being developed by Pomona, NY-based pharmaceutical manufacturer Barr Laboratories in agreement with the Medical College of Hampton Roads, Eastern Virginia Medical School in Norfolk. The company seeks Food and Drug Administration approval for the drug.
- Breakthrough bleeding and spotting were the most common side effects of the Seasonale regimen noted during the clinical investigation; however, the bleeding and spotting were reported to decrease over time.

oral contraceptives (OCs.)[1,2]

The pill, Seasonale, is being developed by Pomona, NY-based pharmaceutical manufacturer Barr Laboratories in agreement with the Medical College of Hampton Roads, Eastern Virginia Medical School in Norfolk. **(*Contraceptive Technology Update* reported on Seasonale in the May 1999 article, "4-periods-per-year pill eyed for use in U.S. market," p. 51.)**

At press time, Barr Laboratories said it expects to file a New Drug Application for the drug with the Food and Drug Administration in mid-2002, based upon its preliminary review of the results of the trial. The company is continuing to examine the drug's performance in an ongoing extension study, with 300 patients enrolled in the investigation.

Look at the results

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

Seasonale's Phase III clinical program was designed to investigate the efficacy and safety of the drug's extended OC therapy used for one year in women seeking pregnancy prevention. About 1,400 women at 47 sites in the United States participated in the randomized four-arm, open-label, multicenter trial. Women received one of the following OC therapies:

- Seasonale (continuous 84/7 0.15 mg of levonorgestrel/0.03 mg of ethinyl estradiol);
- Seasonale (continuous 84/7 0.100 mg of levonorgestrel/0.020 mg of ethinyl estradiol);
- Nordette 28-day tablets (King Pharmaceuticals, Bristol, TN), (0.15 mg of levonorgestrel/0.03 mg of ethinyl estradiol);
- Levlite 28-day tablets (Berlex Laboratories, Montville, NJ), (0.100 mg of levonorgestrel/0.020 mg of ethinyl estradiol).

Among treated patients, both levels of Seasonale extended OC therapy prevented pregnancy comparable to Nordette and Levlite (based on the Pearl index) in women between the ages of 18 and 35. The adverse profile of the Seasonale drug was similar to that of other OCs, study findings suggest.

Breakthrough bleeding and spotting were the most common side effects of the Seasonale regimen; however, the bleeding and spotting decreased over time, says **Freedolph Anderson**, MD, an OB/GYN at Eastern Virginia Medical School and author of the poster presentation at the ACOG meeting. About 7% of women using the Seasonale regimen discontinued it because of breakthrough bleeding and spotting.

Fate of fewer periods?

Women's attitudes regarding menstruation are changing, observes **Andrew Kaunitz**, MD, professor and assistant chair in the obstetrics and gynecology department at the University of Florida Health Science Center/Jacksonville. When Kaunitz brings up the potential benefits of hormonal therapy to decrease menstruation with his patients, he says they seem more familiar with and receptive to this approach than before; nonetheless, many women still ask, "Isn't that unnatural?" Educating women about their reproductive anatomy and physiology will represent a key part of encouraging greater use of "Seasonale-type" extended cycle OC use, as well as use of other hormonal contraceptives to reduce menses, he notes. **(As more women examine foregoing their period, scientists look to new methods; see the *CTU* January 2002 article, "Research eyes extending the menstrual cycle," p. 3.)**

In addition to extended cycle OC use, Kaunitz says he uses Depo-Provera (depot medroxyprogesterone acetate injection, Pharmacia Corp., Peapack, NJ) and Mirena (levonorgestrel intrauterine system, Berlex Laboratories) in his practice for the purpose of reducing menstrual flow, including use in

women with menorrhagia associated with fibroids.

He looks to results of clinical trials of extended use of the contraceptive patch (Evra, Ortho McNeil Pharmaceuticals, Raritan, NJ) and vaginal ring (NuvaRing, Organon, West Orange, NJ) to see if these new contraceptives can be used to safely and effectively reduce menstruation.

Most women "loved" the Seasonale regimen, comments Anderson. Even many of those who had difficulty with bleeding and spotting wanted to continue, or wanted to stop the regimen and try again, even though the protocol would not allow such practice, said Anderson.

If the product does reach the marketplace, clinicians will need to offer careful counseling to prepare women to expect some breakthrough bleeding and spotting with postponement of menses, he notes.

References

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

2. Anderson FD. The safety and efficacy of Seasonale, a novel 91-day extended oral contraceptive regimen. *Obstet Gynecol* 2002; 99(suppl):26S. ■

OTC access sought for emergency contraception

EXECUTIVE SUMMARY

U.S. advocates continue the press for over-the-counter (OTC) status of emergency contraception (EC), with the Women's Capital Corp. requesting OTC approval of its levonorgestrel-only drug, Plan B.

- New Zealand is the latest country to increase EC access. Women there can buy EC without prescription from local pharmacists who have undergone special training in providing the drug.
- To demonstrate that Plan B can be used safely and effectively without a physician's supervision, Women's Capital Corp. is analyzing the drug's use. Two investigations have been completed: a label comprehension study and an actual-use study.

Could the United States see over-the-counter (OTC) status for emergency contraception (EC)? Washington, DC-based Women's Capital Corp. says it plans to submit an OTC application for its levonorgestrel-only drug, Plan B, to the Food and Drug Administration (FDA) in late summer 2002.

According to the company, the studies required to support the application are completed, and final data analysis is under way. Women's Capital Corp. will ask the FDA for priority review of six months or less; if the agency moves forward on the request, a decision could be reached in early 2003.

While the company moves forward toward the OTC request, it is broadening its access through the retail drug distribution network, says **Sharon Camp**, PhD, company president and chief executive officer. All wholesale drug companies, including regional wholesalers, are stocking Plan B.

"While there are still gaps in coverage, clinicians should have less trouble finding a community pharmacy that regularly stocks Plan B and less trouble getting it stocked when needed," says Camp.

New Zealand goes OTC

Other countries have made the move to remove EC products from prescription-only status. In Scandinavian countries, levonorgestrel-only ECs share drugstore shelf space with other OTC drugs. In France, Great Britain, and a growing number of other European countries, EC is available "behind the counter" from a pharmacist without a prescription; in France, school nurses also can give out the drug.

As of *Contraceptive Technology Update* press time, women in New Zealand were scheduled to be able to buy EC without prescription from local pharmacists who have undergone special training in providing the drug.[1] About 700 pharmacists have undergone training, with plans under way for a second session, says **Helen Roberts**, MD, a clinical spokeswoman for the Family Planning Association based in Wellington. There are 3,000 pharmacists in New Zealand, and the majority will want to complete the three-hour education program, she predicts.

The training involves a one-hour didactic session looking at EC safety and explanations of how the drug works and how to take it, including the pharmacy guidelines set out by the New Zealand Pharmacy College, says Roberts. Participants then are assigned to small groups to work through

various pharmacy scenarios, followed by a final closing session.

EC will continue to be available on prescription in New Zealand from family planning doctors, and women can access the subsidized drug, she adds Roberts. About $30 or $40 will be charged for the drug and a 10-minute consultation by the pharmacist through the pharmacy program.[1]

Look to study results

To demonstrate that Plan B can be used safely and effectively without a physician's supervision, Women's Capital Corp. is analyzing the drug's use through a variety of investigations. Two that will be reviewed by the FDA in the initial quest for OTC status include a label comprehension study and an actual use study, both conducted by Family Health International of Research Triangle Park, NC. Look soon for publication of the label comprehension study, with results indicating that women regardless of age, ethnicity, or medical literacy readily understand proposed labeling for the product. The actual-use study will be published at a later date, say company officials. **(Look to future issues of *Contraceptive Technology Update* for coverage of study results.)**

The label study included responses from 663 women in eight U.S. cities. The actual-use study was conducted at five Planned Parenthood clinics and five pharmacies in the Seattle area that are part of the Washington State pharmacy access program. ***(CTU* has reported on the Washington program; see the article "Pharmacists, providers linking to provide emergency contraception" in the August 1999 issue, p. 85.)**

In addition to these two studies, Women's Capital Corp. also is examining adolescent use of Plan B through two investigations. A large-scale behavioral study also is under way.

According to Women's Capital Corp. officials, the following three points should demonstrate Plan B's ability to meet the FDA's criteria for an OTC product:

- Since unprotected sex is a self-diagnosable condition, a clinician is not necessary to diagnose the need for EC.
- Plan B should be safe for self-medication since no exams or tests are needed prior to administration, its regimen is appropriate for almost all women, and its side effects, if any, are mild and short term.
- Plan B should be effective when self-administered. All patients take the same dose, the regimen is simple to follow, and labeling already is tailored to self-administration.

Reference

1. Gregory A. Morning-after pill soon selling over the counter nationwide. *New Zealand Herald*, May 23, 2002. Accessed at www.nzherald.co.nz/storydisplay.cfm?thesection=news&thesubsection=&storyID=2042675&reportID=16. ■

Mammography screening backed by task force

Women age 40 and older should have a mammogram every one to two years, with or without clinical breast examination, to screen for breast cancer, according to new guidance from the U.S. Preventive Services Task Force.

The task force, which systematically reviews the evidence of effectiveness of a wide range of clinical preventive services, published two earlier breast cancer-screening recommendations that endorsed mammography for women older than age 50. The panel now is extending that recommendation to all women older than age 40, but found that the strongest evidence of benefit and reduced mortality from breast cancer is among women ages 50-69.[1]

The recommendation acknowledges that there are some risks associated with mammography, such as false-positive results that lead to unnecessary biopsies or surgery, but that these risks lessen

EXECUTIVE SUMMARY

Women age 40 and older should have a mammogram every one to two years, with or without clinical breast examination, to screen for breast cancer, according to new guidance from the U.S. Preventive Services Task Force.

- Screening for breast cancer, the most common form of cancer in women in the United States, poses potential benefits and harms.
- While mammography studies have limitations, there is fair evidence that mammography screening every one to two years could reduce breast cancer mortality by about 20%-25% over 10 years.
- While the evidence was strongest for women ages 50-69, benefits were likely to extend to women ages 40-49.

as women get older. Women should discuss their personal preferences with their clinicians to determine when they should have their first mammogram and how often to have the screening procedure, says **Janet Allan**, PhD, RN, professor and dean at the University of Texas Health Science Center at San Antonio School of Nursing and vice chair of the task force.

"I think the task force's position is that we want women to be as informed as possible when making choices about this," she says. "And we do think that women have choices here."

Balance risks, benefits

Screening for breast cancer, the most common form of cancer in women in the United States, poses potential benefits and harms. While studies of mammography have limitations, the task force concluded there was fair evidence that mammography screening every one to two years could reduce breast cancer mortality by approximately 20%-25% over 10 years. While the evidence was strongest for women ages 50-69, the panel concluded benefits were likely to extend to women ages 40-49. (The task force's breast cancer screening recommendation and materials for clinicians and patients are available on the web at www.ahrq.gov/clinic/3rduspstf/breastcancer/.)

The Bethesda, MD-based National Cancer Institute also has reaffirmed its support of mammography screening. It continues to recommend that women in their 40s should be screened every one to two years with mammography, as should women age 50 and older. Women who are at higher-than-average risk of breast cancer should seek expert medical advice about whether they should begin screening before age 40 and how frequently to be screened.

In addition to age, other factors may increase a woman's risk of breast cancer. The strongest risk factors are a family history of breast cancer in a mother or sister, having already been diagnosed with breast cancer, or having had a previous breast biopsy showing atypical hyperplasia, an irregular pattern of cell growth.[2]

Review spurs debate

An October 2001 critique of seven clinical trials of mammography done in the 1960s through the 1980s questioned the benefit of the procedure and fueled an ongoing scientific debate on the subject.[3] The ensuing coverage in the popular press about the ongoing scientific dialogue generated news stories that may have been misunderstood or provoked anxiety among patients, says **Carolyn Runowicz**, MD, vice chairwoman of the department of obstetrics and gynecology at St. Luke's-Roosevelt Hospital Center in New York City.

It is important that clinicians make it clear that the recent "media hype" was not about new data, stresses Runowicz. The members of the review group decide to re-review the clinical trials on mammography; based on their selected criteria, all but two of the trials were included, she adds.

"Based on a review of this very selected data, they concluded that mammography may not save as many lives as we have believed," states Runowicz. "However, this was a selective review and not new data."

Screening saves lives

Based on early detection and improved therapies, scientists are seeing a decline in mortality attributable to breast cancer, says Runowicz. Research is indicating that the earlier cancer is detected, the more likely it is to be in an early stage, which is associated with an improved survival rate, she notes.

The National Cancer Institute continues to address the uncertainties surrounding screening mammograms by monitoring and evaluating new data. Until better screening tools are developed, mammograms are an important part of the fight to save women's lives through early detection, stresses Allan.

"Mammography as a tool is pretty flawed, [but] it is the best we've got right now," Allan observes. "I think in 10 years, with research and looking at new technologies, we will have better ways of doing screening, which I think will hopefully reduce the amount of false-positives."

References

1. National Cancer Institute. *NCI Statement on Mammography Screening.* Jan. 31, 2002. Accessed at http://newscenter.cancer.gov/pressreleases/mammstatement31jan02.html.

2. Agency for Healthcare Research and Quality. *Press Conference Transcript: Task Force Recommendation on Breast Cancer Screening.* February 2002. Accessed at www.ahrq.gov/clinic/3rduspstf/breastcancer/transcripta.htm.

3. Olsen O, Gotzsche PC. Cochrane review on screening for breast cancer with mammography. *Lancet* 2001; 358: 1,340-1,342. ■

Address health needs of lesbians, bisexual women

As a clinician, you may be comfortable with providing care to lesbians and bisexual women. But does your office environment and the forms used in your practice reflect your open approach?

Take a moment to look at your front waiting room. If there's no printed statement that your office appreciates the diversity of women and does not discriminate on the basis of race, age, religion, ability, marital status, or sexual orientation, and your intake forms offer no listing for "domestic partner" or "significant other," then those female patients who have sex with women may not get the message that they are welcome in your care.

Displaying such a sign and using forms that recognize domestic partnerships or significant others give an important message to patients, says **Katherine O'Hanlan**, MD, attending gynecologic oncologist at Stanford Medical Center and partner in Gynecologic Oncology Associates of Portola Valley, CA. O'Hanlan led a clinical seminar on lesbian health at the May 2002 annual meeting of the Washington, DC-based American College of Obstetricians and Gynecologists.

"No. 1, it tells the 97% of women that your office would respect and has a place for the lesbian and bisexual and transgender patient, but no. 2, it tells that 3% of women who are lesbian, bisexual, or transgender that you welcome them," she says.

About 75% of doctors polled in a 2001 national survey say they would be very comfortable treating an openly gay or lesbian patient, and 19% say they would be somewhat comfortable.[1] One in 20 physicians (5%) say they would be somewhat uncomfortable treating an openly gay or lesbian patient, and 1% say they would be very uncomfortable.

If clinicians are comfortable with providing care to lesbian, bisexual, and transgender patients, they need to do a little extra to reverse the negative and false messages that their patients get from society so that the patients will feel comfortable in the office, says O'Hanlan.

"When the patient feels comfortable, you're going to get a better history, you're going to have a better clinician / patient relationship, and you're going to have more successful outcomes in your medical and surgical care, because you'll have a higher quality of relationship with your patient," she states. **(See tips on how to provide optimal care on p. 93.)**

Some shun care

Many lesbians delay seeking health care because they feel alienated by providers, says **Ellen Kahn**, director of the lesbian services program at the Whitman-Walker Clinic in Washington, DC. A needs assessment survey conducted by the program found that even though 87% of survey respondents had health insurance, many delayed seeking health care for reasons that included "homophobia, whether real or perceived, on the part of the health care providers."[2]

This avoidance of health care may have important medical implications, since an analysis of data from several lesbian health surveys shows that lesbians and bisexual women in the United States have above-average prevalence rates of several risk factors for breast and gynecologic cancers.[3] In comparison with adjusted estimates for U.S. women, lesbians / bisexual women exhibited greater prevalence rates of obesity, alcohol use, and tobacco use and lower rates of parity and birth control pill use, the findings indicate. These women also were less likely to have health insurance coverage or to have had a recent pelvic examination or mammogram.

Some programs, such as the Whitman-Walker Clinic, are reaching out to the community with targeted information on special areas of care, such as breast health. The Washington clinic's Breast Health Initiative provides breast examinations, mammograms, and information on breast cancer to lesbians and bisexual women throughout the Washington, DC, metropolitan area, and sponsors "Breast Health Days" when women can receive clinical breast exams and mammograms

EXECUTIVE SUMMARY

Improving provider awareness and sensitivity can help increase utilization of health care services by women who have sex with women, say health care advocates.

- Many lesbians delay seeking health care because they feel alienated by providers. Clinicians should check their office environment and printed patient material to see that it is inclusive of all women.
- Dispel the misconception that lesbians and bisexual women have little or no risk for sexually transmitted diseases (STDs). This myth is fueled by the lack of reliable studies of STD transmission in these communities, say researchers.

RESOURCE

October 2001 issue of *Health & Sexuality*, the quarterly magazine for clinicians published by Washington, DC-based Association of Reproductive Health Professionals. The special issue was developed in collaboration with the Mautner Project for Lesbians with Cancer. Read the entire issue on-line free of charge at www.arhp.org/lesbianhealth/.

regardless of their ability to pay.

Be sure to dispel the misconception that lesbians and bisexual women have little or no risk for sexually transmitted diseases (STDs). This myth is fueled by the lack of reliable studies of STD transmission in these communities, according to information provided at www.lesbianstd.com, an informational web site maintained by **Jeanne Marrazzo**, MD, MPH, an assistant professor of medicine, and other researchers at the University of Washington in Seattle.

Human papillomavirus can be sexually transmitted between women.[4] The prevalence of bacterial vaginosis among lesbians has been reported to be 18%-36%.[5] Several studies indicate that HIV-related risk behavior is not uncommon among some lesbians, particularly those seen at STD clinics and who report concurrent sex with men.[4]

Clinicians should assume that lesbians and bisexual women have the same risks for STDs as do heterosexual women, says O'Hanlan. Many lesbians and bisexual women have had intercourse with a male partner[5]; clinicians should approach screening for each woman on an individual basis without any assumptions, she notes.

References

1. Kaiser Family Foundation. *National Survey of Physicians. Part I: Doctors on Disparities in Medical Care*. March 2002. Accessed at: www.kff.org/content/2002/20020321a/Physician_SurveyPartI_disparities.pdf.

2. Lesbians, bisexual women have special OB/GYN needs. *ACOG Today* 2002, 4:11.

3. Cochran SD, Mays VM, Bowen D, et al. Cancer-related risk indicators and preventive screening behaviors among lesbians and bisexual women. *Am J Public Health* 2001; 91:591-597.

4. Marrazzo JM. Sexually transmitted infections and gynecologic health in lesbians: Research update. Presented at the 2002 National STD Prevention Conference. San Diego; March 2002.

5. Institute of Medicine. Solarz AL, ed. *Lesbian Health: Current Assessment and Directions for the Future*. Washington, DC: National Academy Press; 1999. ■

Check your care of lesbians/bisexual women

How do you enter a dialogue with a new female patient about sexual health? Take a tip from **Katherine O'Hanlan**, MD, attending gynecologic oncologist at Stanford Medical Center and partner in Gynecologic Oncology Associates of Portola Valley, CA.

O'Hanlan says simply ask the neutral question, "Are you currently being sexual? If so, with whom? Men, women, or both?"

She suggests that once the question has been asked, move on to "Do you need advice about safer sex?" This approach allows patients to maintain their privacy if they are not ready to enter a full-blown discussion about their sexuality, says O'Hanlan.

Since lesbian, bisexual, and transgender women are such a small minority of the population and have been exposed to negative societal messages, clinicians should go the extra mile to make their office environment a comforting space for these patients, advocates O'Hanlan. Patients who feel safe and cared for will return for standard routine screening, she notes.

Talk with patients in a warm and familiar way, offers O'Hanlan. Get the patient talking and let her know that you're comfortable discussing her personal life, she says. ■

SCHIP expansion entangled in politics

By **Rachel Benson Gold** and **Heather Boonstra**
Public Policy Division
The Alan Guttmacher Institute
Washington, DC

Over the course of the last year, attempts to expand the State Children's Health Insurance Program (SCHIP) to include coverage of pregnant women have become entangled in the murky

politics of the abortion issue, a development that could sidetrack an important policy initiative and leave large numbers of low-income pregnant women without insurance at a critical time.

Enacted in 1997, SCHIP covers low-income, uninsured individuals through age 18. By 2001, 4.6 million children were enrolled, which makes the program a critical source of care for low-income families.

Because SCHIP was enacted following the demise of broad-based health care reform in the 1990s, its supporters have always seen the program as a first step in a broader strategy to reduce disparities in health insurance coverage. Proponents viewed covering low-income children, an issue with obvious political appeal, as a first — but by no means final — step in that direction. Armed with the knowledge that 38.7 million Americans remain uninsured, advocates and policy-makers have offered a variety of proposals to expand SCHIP.

One group high on just about everyone's list to bring into SCHIP is pregnant women, based in no small measure on data showing that more than 400,000 pregnant women reported having no health insurance coverage in 1999. This initiative would build directly on the Medicaid expansions of the 1980s to cover pregnant women with incomes well above the traditional state-determined income ceilings.

Under Medicaid, pregnant women are covered throughout pregnancy — with important health benefits for both women and their newborns — and through 60 days postpartum, including coverage for family planning services and supplies. Over the last few years, a handful of states received federal approval to experiment with expanding their SCHIP efforts to pregnant women not eligible for Medicaid, and several proposals to expand the program along these lines are pending in Congress.

Enter abortion politics

As enthusiasm for an SCHIP expansion mounted, the Bush administration threw a wrench into the works in the summer of 2001 by announcing that it intended to take a controversial approach using the regulatory, rather than legislative, process. This, argued the administration, would be a more expeditious route than the often-tortuous process of enacting legislation. With the underlying SCHIP statute clearly limited to "children," the administration announced that it would propose defining "child" to include "children from conception to birth through age 19" for purposes of the program. This move would have the effect of considering fetuses, rather than pregnant women, to be beneficiaries. Regulations along these lines were formally proposed in March 2002.

Supporters of reproductive health and rights reacted quickly. While agreeing that expanding access to prenatal care is of paramount importance, many expressed grave concerns about unnecessarily involving abortion politics by appearing to establish a precedent for granting legal personhood to fetuses.

Grave consequences to occur?

Reproductive health advocates also fear the route chosen by the administration could have serious consequences for the health and well-being of pregnant women. Since the proposed rule would confer eligibility only upon the fetus, and not directly upon the pregnant woman, the rule would not ensure that pregnant women would be entitled to the full range of medical care needed by woman during pregnancy. In addition, supporters of reproductive health are concerned that while the proposed rule would guarantee the newborn access to necessary health care, it would not provide any coverage of postpartum care for women, an integral component of perinatal care, according to the Washington, DC-based American College of Obstetricians and Gynecologists.

As a result, many supporters of reproductive health care argue that any expansion for pregnant women should draw on the longstanding tradition of other federal programs. They argue that it should include the comprehensive package of pregnancy-related services needed by women during and immediately after pregnancy, including family planning services and supplies, covered under the Medicaid program.

The Centers for Medicare & Medicaid Services accepted public comments on the proposed rule through early May and, at press time, is developing a final regulation. In the meantime, several members of Congress are seeking to move legislation forward that not only would avoid the entanglement of abortion politics, but also provide the full package of benefits needed by pregnant and postpartum women. The extent to which achieving this widespread goal is possible in the current political and economic climate remains to be seen. ■

New ARHP brochure highlights bone health

Help women learn about the lifelong importance of diet, exercise, and healthy habits to build and maintain strong bones in a new patient education brochure, *Building Strong Bones: It Takes a Lifetime*, from the Washington, DC-based Association of Reproductive Health Professionals (ARHP).

Building Strong Bones emphasizes strategies for optimum care at every age. The value of calcium supplementation, as well as information on who should take it and how much they should take, also is discussed. The 10-panel brochure is designed to fit into a standard-letter envelope or display rack in a clinical setting. Its contents also may be found on the organization's web site at www.arhp.org/bone health, where it complements ARHP's on-line interactive quiz, *Test Your Calcium IQ* (www.arhp.org/calcium/).

To order a free copy of the brochure, call (202) 466-3825 or e-mail arhp@arhp.org. Providers may order up to 25 brochures free of charge; 25 or more copies are 10 cents each for ARHP members, 15 cents for nonmembers, plus shipping charges of $3 for 25, up to a maximum of $10. ■

New methods included in interactive program

Women can get an on-line idea of what contraception options might best fit their lifestyle and health profile by using an updated interactive program found at the Washington, DC-based Association of Reproductive Health Professionals' (ARHP) web site, www.arhp.org.

The program, *Choosing a Birth Control Method*, provides information about all Food and Drug Administration-approved contraceptive options and gives users recommendations on which methods may be best suited for them. Click on the program title to activate the program.

The updated program includes information on both the Evra contraceptive patch (Ortho McNeil Pharmaceutical, Raritan, NJ) and the NuvaRing contraceptive vaginal ring (Organon, West Orange, NJ). *Choosing a Birth Control Method* replaces ARHP's previous interactive program, *Successful Contraception*. The tool is composed of 20 questions regarding lifestyle choices and medical history, and is designed to be completed in about five minutes. Once the questions are anonymously submitted, the user receives a list of possible contraceptive options. The tool also provides a general description, effectiveness rates, side effects, and the approximate cost for each method. ■

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

Subscriber Information

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

Subscription rates: U.S.A., one year (12 issues), $429. Approximately 18 nursing contact hours or Category 1 CME credits, $479; Outside U.S., add $30 per year, total prepaid in U.S. funds. Two to nine additional copies, $343 per year; 10 to 20 additional copies, $257 per year; for more than 20, call (800) 688-2421. **Back issues**, when available, are $67 each.(GST registration number R128870672.)

Editor: **Rebecca Bowers**.
Vice President/Group Publisher: **Brenda Mooney**, (404) 262-5403, (brenda.mooney@ahcpub.com).
Editorial Group Head: **Valerie Loner**, (404) 262-5475, (valerie.loner@ahcpub.com).
Senior Managing Editor: **Joy Daughtery Dickinson**, (229) 377-8044, (joy.dickinson@ahcpub.com).
Production Editor: **Nancy McCreary**.

Editorial Questions

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

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

THOMSON
AMERICAN HEALTH CONSULTANTS

CE/CME Questions

Correction: In last month's issue, the CE/CME questions were numbered incorrectly. Those questions should have been numbered 1-4.

After reading *CTU,* the participant will be able to:

- Name the active hormones in the Seasonale oral contraceptive.
- Cite the mammography-screening interval recommended by the U.S. Preventive Services Task Force.
- Name the STD among lesbians that is reported to have a prevalence rate of 18%-36%.
- State the CDC's recommended schedule for rescreening for chlamydia in female patients.

5. What are the active hormones in the Seasonale oral contraceptive?

A. ethinyl estradiol and levonorgestrel
B. ethinyl estradiol and norgestimate
C. ethinyl estradiol and gestodene
D. ethinyl estradiol and desogestrel

6. What is the mammography-screening interval recommended by the U.S. Preventive Services Task Force?

A. Women age 40 and older must have a mammogram every year, with or without clinical breast examination, to screen for breast cancer.
B. Women age 60 and older should have a mammogram every one to two years, with or without clinical breast examination, to screen for breast cancer.
C. Women age 40 and older should have a mammogram every one to two years, with or without clinical breast examination, to screen for breast cancer.
D. Women age 40 and older should have a mammogram every three years, with or without clinical breast examination, to screen for breast cancer.

7. The prevalence of which STD infection among lesbians has been reported to be 18%-36%?

A. HIV
B. gonorrhea
C. syphilis
D. bacterial vaginosis

8. What is the CDC's 2002 recommendation regarding chlamydia rescreening for women?

A. All women with chlamydial infections should be rescreened 2-3 months after treatment is completed.
B. All women with chlamydial infections should be rescreened 3-4 months after treatment is completed.
C. All women with chlamydial infections should be rescreened six months after treatment is completed.
D. Women who have been treated for chlamydia require no rescreening.

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.*

NPWH
National Association of Nurse Practitioners in Women's Health

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

S·T·D QUARTERLY™

Take your STD skills to the next level with new guidelines

Check new CDC recommendations on chlamydia rescreening, herpes tests

Break the chain of sexually transmitted disease (STD) transmission by detecting and treating infection using the latest recommendations from the just-released *2002 Guidelines for the Treatment of Sexually Transmitted Diseases*, issued by the Atlanta-based Centers for Disease Control and Prevention (CDC).

The publication, the fifth edition of the guidelines, are designed to advise health care providers on the most effective STD treatment regimens, screening procedures, and prevention strategies, says **Stuart Berman**, MD, chief of the epidemiology and surveillance branch in CDC's Division of STD Prevention.

What are some of the most important changes in recommendations that clinicians will need to integrate in their practices? Berman and other CDC officials reviewed the revisions during a recent press briefing held at the May 2002 release date of the publication. **(Get ordering information for the guidelines from the resource box on p. 2.)**

EXECUTIVE SUMMARY

The Centers for Disease Control and Prevention (CDC) has just released the *2002 Guidelines for the Treatment of Sexually Transmitted Diseases* (STDs).

- The CDC now recommends that all women with chlamydial infections be rescreened three to four months after treatment is completed, which marks the first time the agency has recommended such rescreening in the management of the STD.
- The guidelines also address other STD issues, such as the use of new testing options for herpes, antibiotic treatment options for gonorrhea, and revised screening recommendations for men who have sex with men.

Rescreen for chlamydia

The CDC now recommends that all women with chlamydial infections be rescreened three to four months after treatment is completed. This is the first time CDC has recommended such rescreening in the management of chlamydia. Why did the agency move in this direction?

Most post-treatment chlamydial infections result from reinfection, often occurring because a patient's sex partners were not treated or because the patient resumed sex among a network of persons with a high prevalence of infection, states **Kimberly Workowski**, MD, lead author of the new guidelines.

"Repeat infection also confers an elevated risk of PID [pelvic inflammatory disease] and other complications when compared with initial infection," she states. "Therefore, women with chlamydial infection should be rescreened three to four months after treatment." ***(Contraceptive Technology Update* reported on the research behind the move to rescreen for this STD; see "Rescreening can stem repeat chlamydia" in the October 2001 issue, p. 118.)**

According to the CDC, chlamydia is the most commonly reported infectious disease in the

United States, with 702,093 cases reported in 2000; the infection is asymptomatic in the majority of cases. Health care providers are now advised to annually screen sexually active adolescent women ages 19 and younger and young adult women, ages 20-24, even if symptoms are not present. Older women with risk factors for chlamydia, such as new partners or multiple sexual partners, also should be screened.

Use new herpes tests

The new CDC guidelines outline new testing procedures that may help providers with diagnosing and managing genital herpes type 1 (HSV-1) or type 2 (HSV-2). Since antiviral therapy may benefit individuals with herpes symptoms, providers who are aware of their patient's viral serotype can tailor counseling and treatment plans to best fit their needs, says the CDC. **(Check out information on new diagnostic methods in "Get a handle on herpes with these new tests," published in the *STD Quarterly* inserted in the August 2000 issue.)**

Most patients with recurring genital outbreaks are infected with HSV-2, which is almost always spread during sexual contact with a partner who has a genital HSV-2 infection. Patients infected with HSV-2 can choose from suppressive or episodic antiviral treatments that can prevent or shorten the duration of outbreaks. **(Read about herpes treatment in "Missed opportunities: Family planners receive call to action for herpes screening," published in *the STD Quarterly* inserted in the February 2002 issue.)**

Genital HSV-1, which is often caused by oral-genital sexual contact with a person with an oral HSV-1 infection (fever blister), is much less likely to recur, and treatment may be needed only in patients with initial symptoms, states the CDC.

It is important to counsel symptomatic patients, regardless if they have HSV-1 or HSV-2, about herpes, its initial and recurring manifestations, and how to avoid transmission of the virus to sexual partners and newborns, the new guidelines state.

Check gonorrhea info

The *2002 STD Treatment Guidelines* now warns providers that ciprofloxacin-resistant strains have become so common on the West Coast that the use of fluoroquinolone antibiotics to treat gonorrhea is inadvisable in California. These guidelines signal the first time the CDC has issued this guidance in the continental United States.

The federal agency had previously recommended that fluoroquinolones, which include ciprofloxacin, ofloxacin, and levofloxacin, not be prescribed for treating gonorrhea in Hawaii and in those patients who visited the island state, other Pacific Islands, or Asia, because many of the gonorrhea cases in those areas are resistant to ciprofloxacin. The CDC now advises the use of the antibiotics cefixime and ceftriaxone as first-line drugs to treat gonorrhea in Hawaii and California. ***(CTU* reported on the rise of resistant**

RESOURCES

Providers have several options for checking out the *Sexually Transmitted Diseases Treatment Guidelines 2002* published by the Atlanta-based Centers for Disease Control and Prevention (CDC). The guidelines can be viewed and printed online in Adobe Acrobat PDF format from the CDC web site, www.cdc.gov/std. Click on "Sexually Transmitted Diseases Treatment Guidelines 2002," and follow instructions on how to view or print the files. To submit an e-mail order for printed copies of the guidelines, e-mail stdguidelines@cdc.gov. Please include your shipping address in the e-mail. To request more than five copies of the guidelines, include a justification for your request and telephone contact information. Larger requests without accompanying justification will receive five copies.

To submit a telephone request (single copies only): call the CDC Information System at (888) 232-3228. Press the numbers 2, 5, 1, 1 when the system answers, wait for the next announcement, press 1 and follow directions. To submit orders over the Internet, visit the CDC web site, www.cdc.gov/std. Click on "Sexually Transmitted Diseases Treatment Guidelines 2002," and follow instructions on how to order on-line. To request more than five copies of the guidelines, include a justification for your request and telephone contact information. Larger requests without accompanying justification will receive five copies. Web visitors can opt to print out the order form and fax it to the Office of Communications at (404) 639-8910, or mail it to STD Treatment Guidelines, Office of Communications, NCHSTP, CDC, 1600 Clifton Road, N.E., Mailstop E-07, Atlanta, GA 30333.

strains in "Ciprofloxacin-resistant gonorrhea on the rise," in the June 2002 issue, p. 64.) If clinicians in other states have any concerns that a patient may have ciprofloxacin-resistant gonorrhea, they should use cefixime or ceftriaxone.

Gonorrhea is the second most common infectious disease reported to CDC, with nearly 360,000 cases in 2000. Since drug-resistant strains are becoming increasingly common in the United States, the agency moved to issue the warning.

Fluoroquinolone antibiotics have been recommended by the CDC for the treatment of gonorrhea since 1993. Penicillin and tetracycline once were recommended for the treatment of the STD, but widespread resistance rendered them ineffective. Treatment with tetracycline was halted in 1985, while penicillin was abandoned in 1987.

N-9: No STD prevention

Advise patients that spermicides, especially those that contain nonoxynol-9 (N-9), should not be used for STD protection, state the new guidelines. Lubricants containing N-9 should not be used during anal intercourse, the guidelines note.

Recent research indicates that the spermicide agent falls short in prevention of transmission of chlamydia and gonorrhea.[1] ***(CTU* reported on the research in "Nonoxynol-9 not protective against STDs," in the June 2002 issue, p. 63.)** Frequent use of the spermicide can cause genital lesions (in the vagina) and, therefore, may increase the risk of HIV transmission. It also has been found to cause damage to the lining of the rectum, which provides an entry point for HIV and other STDs.

"While the level of N-9 used as a lubricant in condoms is much lower than the level found to be harmful, condoms lubricated with N-9 spermicide also are not recommended because they have a shorter shelf life, cost more, and have been associated with urinary tract infections in women," states the CDC.[2] "However, previously purchased condoms with N-9 can be used, provided they have not passed their expiration date, since the protection provided by the condom against HIV outweighs the potential risk of N-9."

Recent increases in the rates of syphilis, gonorrhea, and chlamydia have been reported in many U.S. cities, largely among men who have sex with men (MSM) who are HIV-infected, states Workowski. Other MSMs are at high risk for STDs due to the frequency of unsafe sexual practices, she notes. To reduce the likelihood of acquisition or transmission of HIV and other STDs, providers should assess sexual risk of all male patients through nonjudgmental STD / HIV risk assessment and client-centered prevention counseling, says Workowski.

The new guidelines recommend that for those MSM patients who are sexually active, annual screening should be performed for HIV, chlamydia (anal and urethral), syphilis, and gonorrhea (anal, pharyngeal, urethral), as well as vaccination against hepatitis A and B. More frequent STD screenings may be indicated for those patients who indicate multiple anonymous partners or who have sex in conjunction with illicit drug use.

References

1. Roddy RE, Zekeng L, Ryan KA, et al. Effect of nonoxynol-9 gel on urogenital gonorrhea and chlamydial infection. *JAMA* 2002; 287:1,117-1,122.

2. Centers for Disease Control and Prevention. *New CDC Treatment Guidelines Critical to Preventing Health Consequences of Sexually Transmitted Diseases.* May 9, 2002. ■

Company to resume shipping HIV test kits

The company that manufactures one of the two HIV-1 Western blot (WB) kits licensed by the Food and Drug Administration (FDA) for supplemental testing of serum, plasma, and dried whole-blood spot specimens obtained for medical diagnosis or blood and plasma donor screening has announced that it has resumed production, thus averting a shortfall of the kits.

Calypte Biomedical Corp. of Alameda, CA, issued news it was winding down operations in April 2002. The Atlanta-based Centers for Disease Control and Prevention (CDC) alerted health care providers of a possible shortage of Calypte Biomedical's Cambridge Biotech HIV-1 Western blot kit.[1] Since that time, the company has received new funding and is resuming production, confirms **Joe Bunning**, company spokesman.

With just two FDA-approved kits for confirmatory HIV testing, public health officials have

EXECUTIVE SUMMARY

Calypte Biomedical Corp. has announced that it has resumed production of its Cambridge Biotech HIV-1 Western blot kit.

- The kit is one of two HIV-1 Western blot kits licensed by the Food and Drug Administration for supplemental testing of serum, plasma, and dried whole-blood spot specimens obtained for medical diagnosis or blood and plasma donor screening.
- The company announced an intention to wind down operations early in 2002; however, it has received new funding and is resuming production. The Centers for Disease Control and Prevention issued options for confirmatory testing in light of the potential shortage of kits.

moved quickly to make sure testing options remain available. According to **Thomas Hearn**, deputy director of the CDC's Public Health Practice Program Office's Division of Laboratory Systems, the agency has remained in close communication with the FDA, the Association of Public Health Laboratories, and other private and public partners to monitor problems with test kit production, check access to test kits, monitor delays in obtaining test results, and examine data that may have had a bearing on alternative confirmatory testing strategies.

Other test targets oral fluid samples

The other Western blot test used for confirmatory purposes is the Genetic Systems Western blot kit, manufactured by BioRad Laboratories of Hercules, CA. While the OraSure HIV-1 Western blot kit made by OraSure Technologies of Bethlehem, PA, is approved for supplemental testing of oral fluid samples found reactive for antibodies to HIV-1 in screening tests performed on oral fluids, use of oral-fluid specimens is not approved for screening and supplemental testing of blood and plasma donors, according to the CDC.

The algorithm for HIV testing in the United States begins with an initial screening enzyme immunoassay (EIA). If reactive, the EIA is repeated in duplicate on the same specimen. If repeatedly reactive, the specimen is tested with a more specific supplemental test to validate the true-positive EIA results and to prevent notification based on false-positive results that might occur during the screening tests. Supplemental tests include the WB test or the indirect immunofluorescence assay (IFA). This algorithm is used with serum, plasma, dried whole-blood spots, and oral fluid specimens.

Check test options

If laboratories are unable to obtain the Cambridge Biotech HIV-1 Western blot kit, the CDC outlines three options[1]:

• Supplemental testing can be performed on serum, plasma, and dried whole-blood spots using the Genetic Systems Western blot kit. Information about the availability of the test kit is available by calling the company at (800) 224-6723, or checking its web site, www.biorad.com.

• Supplemental testing can be performed on serum, plasma, and dried whole-blood spots using the Fluorognost HIV-1 IFA kit made by Sanochemia of Vienna, Austria, and distributed by Home Access Health of Hoffman Estates, IL. To check availability of this product, call (203) 227-6880, or visit the web site www.fluorognost.com. Sanochemia provides a self-taught course on performing the HIV-1 IFA and a proficiency panel free of charge, according to the CDC.

• Patient (but not blood or plasma donor) screening for antibodies to HIV can be performed on an oral fluid specimen collected with the OraSure HIV-1 oral fluid collection device made by OraSure Technologies using an approved EIA test kit (Oral Fluid Vironostika HIV-1 MicroElisa) manufactured by bioMérieux of Durham, NC. Repeatedly EIA reactive oral fluid samples can be tested further with the supplemental OraSure HIV-1 Western blot kit.

For more information on the availability of the OraSure HIV-1 collection device, call (800) 869-3538, or visit the company's web site, www.orasure.com. Information about the availability of the oral fluid EIA and WB kits can be obtained from bioMérieux, telephone (800)682-2666.

Reference

1. Notice to readers: Potential shortage of supplemental test kits for detecting HIV-1 antibodies. *MMWR* 2002; 51:395-396. ■