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Labeling change: New warning proposed for nonoxynol-9 contraceptive drugs

Spermicide labeling to spell out ineffectiveness against HIV, STDs

Since research appeared in 2000 regarding the ineffectiveness of the spermicide nonoxynol-9 (N-9) against HIV,[1] you have counseled patients not to rely on the spermicide as a means of HIV prevention.

You reinforced that message again in 2002, when further research indicated that N-9 failed to protect against such sexually transmitted diseases (STDs) as urogenital gonorrhea and chlamydia.[2] **(*Contraceptive Technology Update* reported on the data in its October 2000 article, "Nonoxynol-9 fails test as female microbicide," p. 119, and in its June 2002 article, "Nonoxynol-9 not protective against STDs," p. 63.)**

Now the Food and Drug Administration (FDA) is proposing a labeling change for over-the-counter vaginal contraceptives containing N-9. The new labeling, when approved, will help users understand that the use of such products can increase vaginal irritation, which actually may *heighten* the possibility of acquiring the AIDS virus and other STDs from infected partners.

The FDA has published its proposed labeling in the *Federal Register*,[3] and is requesting public comment on the changes. The deadline is April 16 for submitting comments on the proposed labeling statements. **(See**

EXECUTIVE SUMMARY

The Food and Drug Administration has proposed new warning labels for over-the-counter vaginal contraceptive drugs that contain the spermicide nonoxynol 9 (N-9).

- The new label would state that vaginal contraceptives containing N-9 do not protect against infection from HIV or other sexually transmitted diseases (STDs).
- The proposed warnings would say that vaginal contraceptives containing N-9 can increase vaginal irritation, which may heighten the possibility of acquiring the AIDS virus and other STDs.

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the resource box on p. 27 for information on how to submit comments.)

Review label changes

The FDA is proposing to require the following warnings be added to the labeling of all marketed OTC vaginal contraceptives containing N-9:[3]

- "For vaginal use only."
- "Sexually transmitted diseases (STDs) alert: This product does not protect against the AIDS virus (HIV) or other sexually transmitted diseases (STDs)."
- "Ask a doctor before use if you have a new sex partner, multiple sex partners, or unprotected sex. Frequent use (more than once a day) of this product can increase vaginal irritation, which may increase the risk of becoming infected with the AIDS virus (HIV) or other STDs from infected partners. Ask a doctor or other health professional for your best birth control method."
- "Stop use and ask a doctor if you or your partner get burning, itching, a rash, or other irritation of the vagina or penis."

The agency also is proposing the following information, which could be included in the package insert:

- "Studies have raised safety concerns that frequent use (more than once a day) of products containing nonoxynol-9 can increase vaginal irritation, which may increase the risk of getting the AIDS virus (HIV) or other STDs from infected partners. Vaginal irritation may include symptoms such as burning, itching, or a rash, or you may not notice any symptoms at all. If you use these products frequently and/or have a new sex partner, multiple sex partners, or unprotected sex, see a doctor or other health professional for your best birth control and methods to prevent STDs."
- "Correct use of a latex condom with every sexual act will help reduce the risk of getting the AIDS virus (HIV) and other STDs."

Reports spur changes

Reports issued in 2002 by the Atlanta-based Centers for Disease Control and Prevention (CDC) and the Geneva-based World Health Organization (WHO) helped spur the proposed labeling changes. The CDC's May 2002 report recommended that women, particularly those at risk for HIV or STDs, be counseled that N-9 contraceptives do not protect against such infections.[4]

WHO issued revised public health guidelines in

June 2002 on the use of N-9 for HIV and STD prevention, as well as for pregnancy prevention in populations at high risk for HIV.[5] The guidelines stated that "spermicides containing nonoxynol-9 do not protect against HIV infection and may even increase the risk of HIV infection in women using these products frequently.'' The guidelines also advised women at high risk of HIV infection against using N-9 spermicides for contraception. **(*CTU* reported on the WHO report in its article, "Nonoxynol-9 ineffective against HIV infection," September 2002, p. 105.)**

Since the issuance of the two reports, many manufacturers have moved to delete N-9 products from their lines. Such manufacturers include New York City-based Planned Parenthood Federation of America, which has discontinued production of Planned Parenthood condoms lubricated with N-9; New Brunswick, NJ-based Johnson & Johnson, which has ceased production of its KY Plus lubricant with N-9 as well as an N-9 lubricated condom marketed in South America; and Mayer Laboratories of Oakland, CA, which has halted the use of N-9 in its Aqua Lube Plus lubricant, as well as use of the spermicide in any of its condom lubricants.[6]

Rectal use questioned

Impetus to remove N-9 from products has come from a broad-based coalition of more than 85 scientists and health groups that has issued a call to manufacturers to make such a move in light of concerns over use of these products in anal sex. **(See resource box, above right, for contact information to join the call against such products.)** The coalition is not seeking the removal of N-9 contraceptive products designed exclusively for vaginal use because they represent a contraceptive option for women who are at low risk of HIV infection or other STDs.

Use of N-9 condoms and lubricants has been widespread among gay men seeking protection against HIV and other STDs. A 1998 study reported that more than three-fourths of gay men surveyed used lubricants more than 80% of the time; among them, 41% actively sought N-9 products.[7] Despite public health warnings about N-9's inability to prevent such disease transmission, a 2001 survey of gay men in San Francisco indicated many continued to use N-9 products for protection.[8]

"It is of great importance that N-9 should not be used as a lubricant for anal sex, because I believe that the data suggest that the increase in transmission risk is even higher,"[9] states **Allan Rosenfield**, MD, dean of the Mailman School of Public Health at the New York City-based Columbia University.

While the FDA's proposed labeling change is a positive step, further language should be added to strengthen the warning message, says **Lori Heise**, director of the Global Campaign for Microbicides, an international coalition of groups based in the Washington, DC, office of PATH (Program for Appropriate Technology in Health).

"I think there is a missed opportunity in the proposed language to make clear that these products are harmful if used rectally," she says. "And while they do have language in there that says 'for vaginal use only,' I think that is a very weak way to communicate [the warning]."

Another message that must be conveyed is that microbicide options are in the research pipeline and must be pursued, says Heise. The failure of N-9 as a microbicide does not take away from the promise of other potential products, she maintains.

"It is really important, given that the spermicidal products with N-9 do not look to be protective, that we adequately fund and pursue research into microbicides," states Heise.

RESOURCES

- **To submit written comments to the Food and Drug Administration on the proposed labeling changes**, contact: Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville MD 20852. Submit electronic comments to www.fda.gov/dockets/ecomments.Three copies of all written comments are to be submitted; one copy is sufficient for electronic submission. Comments are to be identified with the docket number 80N-0280.
- **To get more information on the "Call to Discontinue Nonoxynol-9 for Rectal Use,"** contact: Global Campaign for Microbicides c/o PATH, 1800 K St. N.W., Suite 800, Washington, DC 20006. Telephone: (202) 822-0033. Fax: (202) 457-1466. E-mail: info@global-campaign.org. Web: www.global-campaign.org; click on "N-9 Call and Resources."

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Stem chlamydia spread in teens with screening

EXECUTIVE SUMMARY

Providers need to step up screening for chlamydia in adolescent females; teen-age girls are about six times more likely than adult women to contract the disease.

- The Centers for Disease Control and Prevention calls for sexually active adolescent women to be screened for chlamydial infection at least annually, even if symptoms are not present.
- The U.S. Preventive Services Task Force calls for clinicians to screen all sexually active women ages 25 and younger, as well as older women at risk, as part of regular health care visits.

What is your practice when it comes to routinely screening teen-age girls for chlamydia? If you aren't performing such testing, you are missing a prime opportunity to reduce the most commonly reported sexually transmitted disease (STD) in the United States.[1]

Routinely screening sexually active teen-age girls during regular provider visits is an effective way to detect chlamydia and help teen-agers avoid infertility due to disease progression, according to a new study of adolescent teens.[2] Providers need to step up such screening; teen-age girls are about six times more likely than adult women to contract the disease, according to the study.

Several important sequelae can result from *C. trachomatis* infection in women; the most serious of these include pelvic inflammatory disease (PID), ectopic pregnancy, and infertility. Some women who have apparently uncomplicated cervical infection already have subclinical upper-reproductive-tract infection. By routinely checking for chlamydia, providers can help prevent these conditions, states **Mary-Ann Shafer**, MD, professor of pediatrics at the University of California, San Francisco, and lead author of the new study.

Shafer and research associates tested the effectiveness of a system-level clinical practice improvement intervention at Kaiser Permanente clinics in northern California designed to boost chlamydia screening among sexually active adolescent girls during routine checkups at pediatric clinics. They found that an average of 5.8% of sexually active girls ages 14-18 tested positive for chlamydia in routine screening — and they were all patients who otherwise would not have been tested.

Waiting for an annual exam to do such screening may not be the best practice in treating adolescent girls, says Shafer.

"Providers need to screen teens whenever they present for any medical care so that an additional visit cost is not incurred," she states.

Has HEDIS helped?

Interest in chlamydia screening has increased since its 2000 inclusion in the HEDIS (Health Plan Employer Data and Information Set) managed care guidelines developed by the Washington, DC-based National Committee for Quality Assurance (NCQA). NCQA is a nationwide organization charged with measuring and reporting on managed care quality. **(*Contraceptive Technology Update* reported on the HEDIS performance measure in its article, "Women's health issues included in managed care report card," February 2000, p. 17.)**

The HEDIS chlamydia-screening measure is designed to assess the percentage of sexually active women ages 15–25 who are screened for chlamydia. What has been the impact on screening since the guideline was implemented? Current figures show that there is room for improvement: in 2000, 27.5% of sexually active women ages 16-20 and 24.2% of sexually active women ages

21-26 in HEDIS-participating managed care plans were screened for chlamydia infection.[3] Only about 180,000 of the more than 650,000 women ages 16-20 who were eligible under the guideline received appropriate screenings in 2000.[3]

When it comes to Medicaid managed care, chlamydia screening recommendations may not be impacting actual clinical practices.[4] A recent study examined the policies and practices of managed care organizations in seven large U.S. cities: Baltimore; Charlotte, NC; Dayton, OH; Louisville, KY; Memphis, TN; Norfolk, VA; and Oklahoma City. All of these are cities with high rates of reported STD cases and large percentages of Medicaid beneficiaries enrolled in managed care. The analysis found that 15% of managed care organizations and 42% of contracted medical groups recommended chlamydia screening for sexually active adolescents, and 55% of primary care providers reported annual screening of sexually active adolescent patients.[4]

Why aren't you testing?

Why aren't providers performing routine chlamydia screenings, particularly in the adolescent population? **Harold Wiesenfeld**, MD, associate professor in the department of obstetrics, gynecology, and reproductive sciences at the University of Pittsburgh School of Medicine offers three possible reasons:

- Adolescents may be fearful of a pelvic examination.
- Because most chlamydia infections in females are asymptomatic, patients may not believe they could be infected.
- Providers either are unaware of the importance of STD screening in adolescents or deny that STDs are common in their patient population. **(See an overview of current public health guidelines on screening, right.)**

Self-testing for chlamydia may be one option in overcoming barriers to testing. Wiesenfeld and other research associates at Magee-Women's Research Institute found undiagnosed sexually transmitted diseases in 18% of teen-age girls who provided vaginal samples they collected themselves during a two-year study.[5] Such a self-testing option was effective in detecting previously undiagnosed STDs in the adolescent population; nearly 13% of the adolescent girls who had never had a gynecological exam tested positive for an STD, and 51% of girls with infections would not have pursued STD testing by traditional gynecological examination.[5]

Self-collection of STD specimens can overcome some of the barriers of STD testing— namely the uncomfortable pelvic exam — and represents less intrusion on an adolescent's privacy, says Wiesenfeld. However, providers must be willing to break past their own barriers to implement screening, he asserts.

"Self-collection will have little impact on this [provider] barrier," states Wiesenfeld. "We need to educate providers on the importance of screening all sexually active adolescents."

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Follow these guidelines for chlamydia screening

What's the current consensus when it comes to chlamydia screening for adolescents? Take a look at national public health guidelines to help direct you in your practice.

The *2002 Guidelines for the Treatment of Sexually Transmitted Diseases*, issued by the Atlanta-based Centers for Disease Control and Prevention (CDC), calls for sexually active adolescent women to be screened for chlamydial infection at least annually, even if symptoms are not present. Annual screening of all sexually active women ages 20-25 years also is recommended, as is screening of older women with risk factors (e.g., those who have a new sex partner and those with multiple sex partners). An appropriate sexual risk assessment always should be conducted and may indicate more frequent screening

for some women, states the CDC.

The third U.S. Preventive Services Task Force issued a 2000 recommendation that primary care clinicians screen all sexually active women ages 25 and younger, as well as older women at risk, as part of regular health care visits. **(Read about the guideline in *Contraceptive Technology Update*'s article, "Task force calls for chlamydia screening," July 2001, p. 81.)**

The Task Force recommendation calls for primary care clinicians to routinely screen all women, whether or not they are pregnant, if they:

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

Despite the recommendations, data indicate that many women are not being screened for the STD. According to a recent physician survey, only 32% said they would screen an asymptomatic sexually active teen-age girl for chlamydia as part of a routine gynecologic examination.[1]

Routine chlamydia screening of sexually active women 15-25 years of age has health and cost benefits, according to research supported by the Agency for Healthcare Research and Quality.[2] The review revealed that screening 100% of sexually active women ages 18-24 would prevent an estimated 140,113 cases of pelvic inflammatory disease each year and result in a savings of $45 for every woman screened.

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Research eyes options in emergency contraception

What if you could simplify your current protocol for emergency contraception (EC)? Results of a recent international multicenter randomized trial indicate that three effective options exist for emergency contraception: two 0.75-mg doses of levonorgestrel 12 hours apart, a single 10-mg dose of mifepristone, or a single 1.5-mg dose of levonorgestrel.[1]

No matter which drug protocol is used, it is important to get emergency contraception into the hands of women who need it. Access can make an impact: a new analysis by the New York City-based Alan Guttmacher Institute estimates that 51,000 abortions were prevented by EC use in 2000, 47,000 more than in 1994, when only 4,000 abortions were averted through EC. Overall, 110,000 fewer abortions occurred in 2000 than in 1994, meaning that increased use of EC may account for up to 43% of the total decline.[2]

"Our research demonstrates that emergency contraception did have an impact on abortions between 1994 and 2000," states **Rachel Jones**, PhD, senior research associate at the institute. "If even more women have knowledge and access to emergency contraception, it is likely that it will have an even greater impact on abortion and specifically will reduce the number of abortions even further."

To compare the different EC regimens, the Geneva-based World Health Organization (WHO), conducted research in 15 family planning clinics in 10 countries. The study included 4,136 healthy women with regular menstrual cycles who requested emergency contraception within five days of unprotected sexual intercourse. Women were randomly assigned to one of three treatment groups: 10-mg single-dose mifepristone; 1.5-mg single-dose levonorgestrel;

EXECUTIVE SUMMARY

Results of a recent international randomized trial indicate that three effective options exist for emergency contraception (EC): two 0.75-mg doses of levonorgestrel 12 hours apart, a single 10-mg dose of mifepristone, or a single 1.5-mg dose of levonorgestrel. U.S. providers choose from two dedicated EC products or administer combined oral contraceptives in the Yuzpe regimen.

- EC works. A new analysis estimates that 51,000 abortions were prevented by EC use in 2000, 47,000 more than in 1994, when only 4,000 abortions were averted through EC.
- Overall, 110,000 fewer abortions occurred in 2000 than in 1994, meaning that increased use of EC may account for up to 43% of the total decline.

or two doses of 0.75-mg levonorgestrel given 12 hours apart.

There were no significant differences in pregnancy rates or side effects between the three groups, with an average pregnancy rate of about 1.6%. Most women menstruated within two days of the expected date, although women given levonorgestrel menstruated earlier than women given mifepristone.

"Low dose mifepristone and levonorgestrel regimens had a similar efficacy in our study," notes **Helena von Hertzen**, MD, medical director of the WHO's Special Programme of Research, Development, and Research Training in Human Reproduction. "Regarding levonorgestrel, the study showed that the dose does not need to be split, and this simplifies its use."

What is your practice?

U.S. providers choose from two dedicated EC products, Plan B (Women's Capital Corp., Washington, DC) and Preven (Gynétics, Belle Mead, NJ), or use the Yuzpe regimen employing combined oral contraceptives. In the 2002 *Contraceptive Technology Update* Contraception Survey, about 66% of providers said they used Plan B, with about 15% prescribing Preven. About 20% said they administered the Yuzpe regimen, using combined oral contraceptives. **(Read more about EC trends in the article, "More providers offer emergency contraception"; November 2002, p. 127.)**

Plan B's current approved dosing regimen is two 0.75-mg tablets of levonorgestrel, with the first pill taken within 72 hours of unprotected sex, followed by the second pill 12 hours later. The Preven regimen is four pills, each containing 0.25-mg levonorgestrel and 0.05-mg ethinyl estradiol; the first dose of two pills is taken within 72 hours of unprotected sex, followed by the second dose of two pills 12 hours later.

Interest is growing in the potential use of mifepristone, marketed in the United States as Mifeprex (Danco Laboratories LLC, New York City) for emergency contraception. In a separate trial conducted in 10 family planning institutes and hospitals in China, women who met recruitment criteria and requested emergency contraception within 120 hours of a single act of unprotected intercourse were randomized to receive 10 mg or 25 mg of mifepristone. Research indicates that the single 10-mg dose of mifepristone is sufficient for emergency contraception.[3]

Mifepristone received approval from the Food and Drug Administration for use in early medical abortion in September 2000, and distribution of the drug began in November 2000. According to new research from the New York City-based Alan Guttmacher Institute, early medical abortion accounted for 37,000 abortions, or 6% of all abortions, in the first half of 2001.[4]

Mifepristone for abortion only

While research has shown that mifepristone is an effective EC option,[5] the drug's only approved indication in the United States is for use in early medical abortions. While mifepristone appears to be safe, highly effective, and acceptable for use in emergency contraception, it may be some time before it is used in this context by American providers. **(Read more about research of mifepristone's EC use in the article, "Mifepristone eyed for emergency contraception," in *Contraceptive Technology Update*, February 2001, p. 18.)**

Even though the study shows that the three various EC methods were effective in preventing pregnancy, they are much less effective than modern methods of contraception for regular use, says von Hertzen.

"This is why emergency contraception should never be the only method of contraception, even for occasional use, as using it repeatedly is like playing some kind of Russian roulette until unwanted pregnancy occurs," she observes. "Emergency contraception will serve us best as a backup; it gives a second chance to avoid pregnancy."

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Contraceptive coverage: Is it headed your way?

How many of your patients have insurance coverage for contraceptives? Get ready to see more of them, as 20 states have passed legislation requiring health plans to pay for contraceptive products.

New York, Arizona, and Massachusetts are the latest states to enact contraceptive coverage laws.[1] Most laws require health insurance policies that cover prescription drugs to pay for contraceptives. Some states, however, include an exemption for employers who object to such coverage for religious reasons. **(See listing, right.)**

States with contraceptive equity bills pending include Alaska, Florida, Illinois, Michigan, Nebraska, New Jersey, Ohio, Oklahoma, Pennsylvania, South Carolina, Tennessee, Utah and Wisconsin, according to www.covermypills.org, the Internet headquarters for the Fair Access to Contraception project. The project, sponsored by the Seattle-based Planned Parenthood of Western Washington and the New York City-based Planned Parenthood Federation of America (PPFA), includes a coalition of supporting organizations committed to contraceptive equity. ***(Contraceptive Technology Update* reported on the coalition in its article, "Ruling opens door for coverage of prescription contraceptives," March 2001, p. 25.)**

Action to spur contraceptive coverage has moved forward not only on the legislative scene, but in the courts as well, according to **Eve Gartner**, senior staff attorney at PPFA. A hearing is scheduled this month to consider a tentative settlement reached in the *Erickson v. Bartell* case, filed in July 2000 in the U.S. District Court of Western Washington.

EXECUTIVE SUMMARY

Contraceptive coverage is on the upswing: New York, Arizona, and Massachusetts are the latest states to enact contraceptive coverage laws. Twenty states have now passed legislation requiring health plans to pay for contraceptive products.

- Action to spur contraceptive coverage has moved forward in the courts as well.
- A tentative settlement has been reached in one case that alleged that it is sex discrimination for an employer to exclude prescription contraception from an employee health plan that covers other prescription drugs.

States that Have Coverage Laws

- Arizona
- California *
- Connecticut *
- Delaware *
- Georgia
- Hawaii *
- Iowa
- Maine *
- Maryland *
- Massachusetts
- Missouri *
- New Hampshire
- New Mexico
- New York *
- Nevada *
- North Carolina *
- Rhode Island
- Texas
- Vermont
- Washington

* State law includes exemption that permits businesses and insurance companies to refuse contraception coverage based on a religious view held by the employer and/or insurance company, though not necessarily by the employees and/or policyholders.

Source: www.covermypills.org.

Suit alleged sex discrimination

The lawsuit, initially filed on behalf of Jennifer Erickson, RPh, a pharmacist employed by the Seattle-based Bartell Drug Co., alleged that it is sex discrimination for an employer to exclude prescription contraception from an employee health plan that covers other prescription drugs. The federal court ruling, issued in June 2001, was the first to follow the landmark 2000 decision by the federal Equal Employment Opportunity Commission (EEOC), which called for companies to provide coverage of prescription contraceptives if their group health plans pay for other prescription medications. ***(CTU* reported on the federal court ruling in its article, "Court ruling advances contraceptive coverage," August 2001, p. 91.)**

Other class-action lawsuits have followed, claiming similar violations under Title VII of the Civil Rights Act. Title VII law prohibits companies with 15 or more employees from making decisions on the basis of gender or pregnancy, or other discriminatory reasons. Since women are the sole users of prescription contraceptives, the lawsuits contend an employer's refusal to cover the methods constitutes sex discrimination.

One of the largest class-action lawsuits includes

one filed against the Wal-Mart retail chain; the Bentonville, AR-based company has 1.4 million employees nationwide, the majority of whom are women.[2] The complaint, which still is pending, was filed on Oct. 16, 2001, in the Northern District of Georgia. It alleges that Wal-Mart's practice of excluding prescription contraceptives while providing coverage for other prescription drugs and devices violates federal law. The lawsuit includes all female employees of Wal-Mart nationwide who are covered, or who have been covered, by the company's health insurance plan at any time after March 8, 2001, and who used prescription contraceptives during the relevant period, says **Jennifer Schirmer**, Esq., of the New York City-based legal firm Milberg Weiss, which is representing the plaintiffs.

Check what's covered

An increasing share of insured workers have coverage for oral contraceptives, according to a national survey of more than 3,200 public and private employers. In 2002, 78% of covered workers received coverage for oral contraceptives, up from 64% of workers in 2001, survey results indicate.[3]

Coverage for the Pill varies between different types of insurance plans, survey findings show. Employees in HMO plans are the most likely to have coverage for oral contraceptives, but many in preferred provider organizations and point-of-service plans also receive assistance with contraceptive costs.

Gartner confirms that employers are voluntarily covering contraception much more than they were five years ago. However, it is important to note exactly what costs are being provided for in employee health plans, she says. While coverage of oral contraceptives is important, other methods should be included as well, she notes.

"What the EEOC required, and what the district court in Seattle required, is that health plans, in being nondiscriminatory, have to cover every method," she states.

References

1. Sidoti L. More states pushing contraceptive coverage. *Boston Globe*, Dec. 21, 2002:A2.

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Costs rise for Title X clinics, but not funds

By **Cynthia Dailard**
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Mounting federal deficits coupled with an administration that favors abstinence promotion over contraception means that funding for the Title X family planning program is likely to remain stagnant in the coming years. President Bush sought no additional funding for the program during his first two years in office, and funding increases during the late 1990s did little more than keep pace with inflation.

During this period, however, the cost of doing business for Title X providers skyrocketed. In 2002, the Alan Guttmacher Institute (AGI) conducted a small scale investigation designed to identify the key factors responsible for these rising costs.[1] The results will help guide future AGI research, and offer providers, advocates, and policy-makers a unique glimpse into some of the major financial pressures weighing on publicly funded family planning clinics.

Family planning providers routinely bemoan the rising cost of contraceptives, and with good reason: For Title X projects participating in AGI's investigation, the per client cost of purchasing contraceptive supplies rose from an average of less than $8 in 1995 to $12.50 in 2001, an increase of 58%.

Increasingly, clients are shifting from oral contraceptives, which clinics can purchase at deep discounts, to newer, longer-lasting methods that are more expensive for clinics to provide. For example, clinics can provide three women with an annual supply of oral contraceptives for less than the cost of providing one woman with Depo-Provera (Pharmacia Corp., Peapack, NJ).[2] Yet between 1995 and 2001, the proportion of contraceptive clients in Title X projects nationwide who used oral contraceptives fell from 62% to 52%, while the proportion of using Depo-Provera rose from 12% to 20%.[3] This trend is only likely to continue now that a

monthly contraceptive injection, a vaginal ring, a new intrauterine device, and a contraceptive transdermal patch have come on the market. ***(Contraceptive Technology Update* reported on this trend in its article, "Will rising prices limit the options for patients at family planning clinics?" August 2002, p. 85.)**

Diagnostic tests increase

Title X clinics are major providers of sexually transmitted disease (STD) tests and Pap smears: In 2001, Title X funded clinics provided 5.1 million STD tests, 600,000 HIV tests and 3 million Pap tests, according to The Alan Guttmacher Institute.

The costs of STD and HIV tests, however, also are rising. The Title X projects providing data to AGI for 1998 and 2001 reported that the average purchase price for STD and HIV tests almost doubled, from $3.50 to almost $7 per test. For chlamydia specifically, the average cost per test rose from slightly more than $4 in 1998 to nearly $6 in 2001. Compounding the situation, the Atlanta-based Centers for Disease Control and Prevention and the U.S. Preventive Services Task Force are calling for even more chlamydia screening among populations of women likely to rely on clinics.

The same is true for Pap test costs: The projects reporting data said that the average purchase price for a Pap test increased from slightly more than $6 in 1998 to about $8 in 2001. These cost increases are likely to continue as clinics move to Thin Prep (Cytyc Corp., Boxborough, MA), which is rapidly becoming the standard of care in American gynecology but can cost family planning providers as much as triple what they pay for conventional tests. **(Read more about cervical cancer screening changes in the article, "Improve cervical cancer screening: Review new technology, guidelines," July 2002, p. 73.)**

Together, the average per client cost to these Title-X-funded projects to purchase contraceptive supplies and STD and Pap tests rose from $18 in 1998 to $21 in 2001, an increase of 19% in a three-year period.

While Medicaid provides up to half of all public dollars used to fund family planning services in this country, Medicaid does not pay the full cost of serving clients in Title X programs. The Title X projects studied indicated that, on average, 28% of their clients are Medicaid recipients. Nonetheless, only 22% of their revenues came from Medicaid reimbursements.

This disparity is even more evident when viewed at the individual client level. It cost the Title X projects studied an average of $118 to provide an initial client visit. These same projects reported, however, that Medicaid reimburses them an average of only $62. Title X funds, according to these clinics, often are used to fill this gap, effectively subsidizing the care of clients enrolled in Medicaid.

Check Medicaid's impact

Title X projects in the AGI investigation also reported two other major sources of financial pressure: the increasing demand for assistance to clients in a multiplicity of languages, and the rising cost of staffing. Additionally, states are going through their worst fiscal crisis since World War II, meaning that state contributions for subsidized family planning services may be slashed. With a major infusion of new cash unlikely at the federal level, Title X projects will be hard-pressed in the coming years to continue to provide the high-quality services that have been the hallmark of the program for more than three decades.

References

1. Gold RB. Nowhere but up: Rising costs for Title X clinics. *Guttmacher Report on Public Policy* 2002; 5:6-9. [AGI's investigation included information from 12 publicly funded family planning agencies that met four key criteria: They had been in existence for at least 10 years; served at least 1,000 contraceptive clients annually; had budget and funding data going back to the mid-1990s; and had at least one contract with a managed care plan (an arrangement that generally involves a high level of sophistication in the agency's data and financial system.)]
2. Dailard C. Title X family planning clinics confront escalating costs, increasing needs. *Guttmacher Report on Public Policy* 1999; 2:1-3.
3. Alan Guttmacher Institute. *Family Planning Annual Report, 2001 Summary*; August 2002. ■

COMING IN FUTURE MONTHS

- Microbicide research: Status report
- Update on contraceptive implants
- Tips on contraceptive counseling for teens
- New oral contraceptives under development
- Get a handle on herpes

Get set for National Women's Health Week

Promote women's health issues during the annual observance of National Women's Health Week, scheduled this year for May 11-17. Use the following web sites as resources:

1. National Women's Health Week. Web: www.4woman.gov/WHW/.

Organizers are planning National Women's Check-Up Day on May 12. Many health providers will offer free preventive health services to women. Sign up your facility's participation at the web site.

2. Centers for Disease Control and Prevention's Office of Women's Health. Web: www.cdc.gov/od/spotlight/nwhw.

Look for tips on women's topics on this web site and read the current issue of its newsletter, *Health Matters for Women*. Test your knowledge of women's health issues and follow links to learn more.

3. Food and Drug Administration's Office of Women's Health. Web: www.fda.gov/womens.

Check out the free English and Spanish material on diabetes on this web site, part of the organization's "Take Time to Care" campaign. The campaign offers a brochure, *Diabetes,* available in portable document format (PDF), as well as recipes and a wallet-sized diabetes alert card.

4. MEDLINE Plus Women's Health. Web: www.nlm.nih.gov/medlineplus/womenshealth.

A service of the U.S. National Library of Medicine and the National Institutes of Health, MEDLINE Plus Women's Health offers an A-to-Z listing of women's topics. Click on each topic, and you will be directed to a page listing general overview articles, prevention/screening, organizations, lists of print publications, and dictionaries. You also can have each topic searched on MEDLINE to draw a list of abstracts on chosen subjects.

5. Department of Health and Human Services' Office on Women's Health National Women's Health Information Center. Web: www.4woman.gov.

This site offers a database on women's health and directs readers to topic areas. Click on "For Health Professionals" to read current information on women's health research, as well as print out patient handouts in PDF format. You also can use the toll-free call center, (800) 994-WOMAN [(800) 994-9662], where English- and Spanish-speaking information and referral specialists will find and order free health information or provide organizational referrals to assist you with any health questions.

6. Healthfinder.gov. Web: www.healthfinder.gov.

This web site was developed by federal agencies as a resource for government and nonprofit health and human services information on the Internet. Type "Women's Health" in the search engine at the opening page, and you will be directed to a listing of more than 200 documents on women's health. A 2003 calendar contains national health observances, conferences, meetings, and events related to medical and health issues that specifically affect women. ■

CE/CME instructions

Physicians and nurses participate in this continuing medical education/continuing education program by reading the articles, using the provided references for further research, and studying the questions at the end of the issue. Participants should select what they believe to be the correct answers and refer to the list of correct answers to test their knowledge. To clarify confusion surrounding any questions answered incorrectly, please consult the source material. After completing this activity with the June issue, you must complete the evaluation form provided in the June issue and return it in the reply envelope provided in that issue to receive a certificate of completion. When your evaluation is received, a certificate will be mailed to you. ■

CE/CME objectives

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

- State why organizations issued reports on nonoxynol-9.
- Identify which sequelae can result from *C. trachomatis* infection in women.
- Name the three regimens of emergency contraception examined in a recent trial conducted by WHO.
- Discuss the landmark 2000 decision by the Equal Employment Opportunity Commission. ■

CE/CME Questions

Effective with this issue, Contraceptive Technology Update *is changing its testing procedure. You no longer will need to return a Scantron answer sheet to earn credit for the activity at the end of the semester. Please review the text, answer the following questions, check your answers against the key below, and then review the materials again regarding any questions answered incorrectly. To receive credit for this activity, you must return the CE/CME evaluation that will be included in the June issue. For further information, refer to the "CE/CME Instructions" on p. 35.*

This testing procedure has proven to be an effective learning tool for adults. If you have any questions about the new testing method, please contact customer service at (800) 688-2421.

9. Why did the CDC and the WHO issue reports in 2002 on nonoxynol-9 (N-9)?

A. Research indicates that spermicides containing N-9 do not protect against HIV infection and may even increase the risk of HIV infection in women using these products frequently.
B. Research indicates that the spermicides are not an effective method of contraception.
C. Research indicates that spermicides with N-9 are teratogenic.
D. Research indicates that spermicides with N-9 are carcinogenic.

10. What sequelae can result from *C. trachomatis* infection in women?

A. Ectopic pregnancy, infertility, and uterine atony
B. Ectopic pregnancy, infertility, and ectoparasitic infection
C. Pelvic inflammatory disease (PID), ectopic pregnancy, and infertility
D. PID, ectopic pregnancy, and pediculosis pubis

11. What were the three regimens of EC examined in the trial conducted by WHO?

A. Two 0.75-mg doses of levonorgestrel 12 hours apart, a single 10-mg dose of mifepristone, and a single 1.5-mg dose of levonorgestrel
B. Two 0.75-mg doses of levonorgestrel 12 hours apart, a single 10-mg dose of misoprostol, and a single 1.5-mg dose of levonorgestrel
C. Two 0.75-mg doses of desogestrel 12 hours apart, a single 10-mg dose of mifepristone, and a single 1.5-mg dose of desogestrel
D. Two 0.75-mg doses of levonorgestrel 12 hours apart, a single 10-mg dose of methotrexate, and a single 1.5-mg dose of levonorgestrel

12. What was the landmark 2000 decision by the Equal Employment Opportunity Commission in regard to contraceptive coverage?

A. It stated that women could pay up to $20 for contraception, with companies picking up the remaining costs.
B. It called for companies to provide coverage of prescription contraceptives if their group health plans pay for other prescription medications.
C. It called for companies to cover the cost of condoms for men, as well as contraceptives for women.
D. It called for companies to deny contraceptive coverage if their religious beliefs were in conflict with such provision.

Answer key: 9. A; 10. C; 11. A; 12. B.

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