AMERICAN HEALTH CONSULTANTS

CONTRACEPTIVE TECHNOLOGY UPDATE®

A Monthly Newsletter for Health Professionals

INSIDE

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NOVEMBER 2001

VOL. 22, NO. 11 (pages 125-136)

Are you concerned about infection, infertility risks with IUD? You can relax

New data underscore safety of intrauterine conception

Your patient says she wants a highly effective, safe, long-term form of birth control. If the ensuing discussion does not include the intrauterine device (IUD), then perhaps it is time to rethink your contraceptive counseling. New research now points to the safety of the IUD and should encourage both providers and patients to take a fresh look at the method.[1]

According to **Philip Darney**, MD, MSc, professor at the University of California at San Francisco, and chief of the department of OB/GYN at San Francisco General Hospital Medical Center, the case control study of 1,895 women helps refute the myths that IUDs cause pelvic infection, increase ectopic pregnancy and infertility, and are inappropriate for young or never-pregnant women. Darney authored an accompanying commentary to the published study.[2]

Concerns regarding pelvic infection and tubal infertility prevent many U.S. clinicians and women from using IUDs, observes **Andrew Kaunitz**, MD, professor and assistant chair in the obstetrics and gynecology department at the University of Florida Health Science Center/Jacksonville. Because of ongoing concerns regarding the safety of IUDs among

EXECUTIVE SUMMARY

Previous studies of intrauterine devices (IUDs), many of which are no longer in use, suggested they might cause tubal infertility.

- In a recently published study that examined the risk of tubal infertility and use of copper IUDs in nulligravid women, tubal infertility was not associated with the duration of use, the reason for the IUD removal, or the presence or absence of gynecologic problems related to its use. The presence of antibodies to chlamydia was associated with infertility.
- While recommendations preclude use of IUDs in HIV-positive women, research suggests they may be safe for women with access to medical services.

clinicians and women, fewer than 1% of U.S. women choose these devices for their birth control method.[3] In contrast, 10%-20% of Northern European women use IUDs, states Kaunitz.[3]

"With the publication of this and other recent reassuring data regarding the safety of IUDs, it is time to re-educate ourselves and our patients regarding this convenient, safe, effective, inexpensive, and underutilized birth control method," says Kaunitz.

Look at the study

Previous IUD studies — many of which examined IUDs no longer in use — suggested that the devices might cause tubal infertility. The recently published case control study, conducted in Mexico where IUDs are widely accepted, assessed prior contraceptive use in women with primary infertility who had undergone hysterosalpingography in 358 cases with documented tubal occlusion and 953 infertile controls who did not have occlusion. In a second analysis, cases were compared with 584 primigravid pregnant controls. Each woman also was tested for antibodies to chlamydia.

Compared with women who had not used hormonal, intrauterine, or barrier contraception, use of a copper IUD was not associated with an increased risk of tubal infertility in the analysis involving infertile controls or primigravid controls, says Kaunitz. Neither duration of IUD use nor the removal of an IUD due to such problems as bleeding or cramping was associated with tubal infertility. The presence of antibodies to chlamydia, however, was associated with infertility, he notes.

The key points from the study are as follows, says lead author **David Hubacher**, PhD, epidemiologist with Research Triangle Park, NC-based Family Health International:

- Copper IUDs are much safer than previously thought.
- Copper IUDs are an appropriate form of birth control for women in mutually monogamous relationships.
- Bacteria, such as those that are sexually transmitted, cause pelvic inflammatory disease (PID) and subsequent infertility; a plastic device with copper on it does not.

Dispel the myths

Myths persist that pelvic and upper genital tract infections are common with intrauterine contraception, according to a recent publication issued by the Washington, DC-based Association of Reproductive Health Professionals.[3] These concerns are based, in part, on observational research that found an increased risk of salpingitis or tubal infertility among IUD users.

A 2000 literature review concluded that many previous studies were unreliable because of inappropriate use of comparison groups (such as women using contraceptives that lower the risk of PID), systematic overdiagnosis of salpingitis among IUD users, and inability to control for confounding factors.[4]

Analysis of data from Geneva-based World Health Organization (WHO) clinical trials indicate that the incidence of PID is very low with appropriate patient selection.[5] A 2001 review concludes that fully symptomatic PID attributable to IUD use is quite uncommon, even with high STD prevalence.[6]

According to *A Pocket Guide to Managing Contraception*, the recommended patient profile for IUD candidacy includes parous women in stable, mutually monogamous relationships (at low risk for sexually transmitted diseases) with no history of PID.[7] However, nulliparous women at low risk for sexually transmitted diseases also might be candidates. Women with a history of PID might be candidates if they are in stable mutually monogamous relationships and have had a pregnancy since the PID episode.[7]

Women with HIV infection face challenges when selecting appropriate birth control options. Both a WHO expert group and the London-based International Planned Parenthood Federation have made general recommendations against use of the IUD by HIV-positive women based on concerns about pelvic infection and female-to-male HIV transmission.[8,9] New research, however, suggests

COMING IN FUTURE MONTHS

- Update on contraceptive coverage
- Increase teen compliance with pills, condoms
- Status report of microbicide research
- Male contraceptive methods on the horizon
- Tips on dealing with difficult patients

that the IUD may be an appropriate contraceptive method for HIV-1-infected women with ongoing access to medical services.[10]

Researchers designed a prospective cohort study, examining 649 women (156 HIV-1-infected, 493 noninfected) in Nairobi, Kenya, who requested an IUD for contraceptive use. Information was gathered on complications related to IUD use; including PID; removals due to infection, pain, or bleeding; expulsions; and pregnancies at one, four, and 24 months after insertion.

Low rates of IUD-related complications were reported over the 24-month period by the HIV-positive women, researchers note. The infected women were not at increased risk of overall or infection-related complications when compared with noninfected women, although there was some evidence that they may have a somewhat increased risk of infection-related complications with IUD use longer than five months.

Cervical infection one month after insertion of an IUD was associated with both overall and infection-related complications after adjusting for HIV-infection status; conversely, HIV status was not associated with either endpoint after adjusting for cervical infection. This finding suggests that clinical focus best may be placed on avoiding IUD insertion in women with cervical infections rather than in women with HIV infection, researchers note.

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Do contraceptives offer protection against PID?

Is the use of popular forms of birth control — including oral contraceptives (OCs) — associated with a protective effect against pelvic inflammatory disease (PID)? Findings from a just-published study indicate that use of OCs, depot medroxyprogesterone acetate (DMPA) injections, and barrier methods, including condoms, do not reduce a woman's risk for the sexually transmitted disease (STD).[1]

The University of Pittsburgh-led study analyzed contraceptive use among 563 women who had signs and symptoms of PID and who were enrolled in the PID Evaluation and Clinical Health (PEACH) Study, a randomized clinical treatment trial. Participants were between ages 14 and 37 and were recruited from emergency departments, clinics, and STD clinics at each of 13 sites. The PEACH study was designed as a randomized clinical trial to evaluate the effectiveness of inpatient vs. outpatient treatment of PID, explains lead author **Roberta Ness**, MD, MPH, associate professor of epidemiology, medicine, and OB/GYN at the University of Pittsburgh. Other findings from the study have been published previously.[2-4]

Each women in the study was interviewed, examined, and received an endometrial biopsy and upper genital tract isolate microbiologic evaluation. Condoms were the most common method of contraception used, followed by OCs, DMPA

EXECUTIVE SUMMARY

Women with pelvic inflammatory disease (PID) have elevated rates of infertility, ectopic pregnancy, and chronic pelvic pain. There has long been speculation on whether oral contraceptives offer some protection against PID.

- In a recent study of women with signs and symptoms of PID, researchers found that neither recent oral contraceptive use nor barrier method use (condoms or other) reduced the risk of upper genital tract disease among women presenting with signs and symptoms consistent with PID.
- Inconsistent condom use elevated the risk of upper genital tract inflammation.

injections, and other barrier methods.

Investigators found that neither recent oral contraceptive use nor barrier method use (condoms or other barrier methods) reduced the risk of upper genital tract disease among women presenting with signs and symptoms consistent with PID. Inconsistent condom use elevated the risk of upper genital tract inflammation.

"In [our] paper, we compared contraceptive methods in those women with endometritis with upper genital tract infection vs. those without either," observes Ness. "We found no contraceptive method to protect against true PID."

Look at OCs and PID

PID is a common condition in which microorganisms spread from the lower genital tract to infect and inflame the upper genital tract, including the endometrium, fallopian tubes, ovaries, and peritoneum. Women with PID have elevated rates of infertility, ectopic pregnancy, and chronic pelvic pain.

For more than a decade, there has been speculation on whether OCs offer some protection against PID caused by the ascent of chlamydial infection from the cervix into the fallopian tubes.[5] OCs have been associated with a decreased risk of symptomatic PID.[6]

What are some possible reasons for this protective effect? According to *Contraceptive Technology*:

• The average amount of menstrual blood a woman loses each month is decreased. Menstrual blood may act as a cultural medium, facilitating PID's development.

• Scanty and thick cervical mucus produced by OC use is difficult to penetrate, thereby discouraging the ascent of sperm into the vagina. Bacteria attached to the surface of sperm gain entry to the upper genital tract through the ascent of sperm.

• The cervical canal is less dilated, principally because the volume of cervical secretions and menstrual blood is diminished.

• Uterine contractions are decreased in strength, thereby decreasing the likelihood of spreading an infection from the uterine cavity into the fallopian tubes.[7]

Although some studies have shown that women are protected from gonorrhea and chlamydia by condoms,[8] in recent prospective cohort studies, inconsistent condom use and even reports of consistent condom use have been less than optimal in preventing the acquisition of gonorrhea, chlamydia, and other bacterial STDs,[9,10] observe Ness and co-authors.

In the current study, inconsistent use of condoms was associated with an increased risk of upper genital tract infection. Specifically, condom use in fewer than 100% of sexual encounters was associated with a more than twofold increase in risk.

However, consistent condom use was more protective than no contraceptive use, and inconsistent condom use increased risk, Ness points out. A major take-home point from the study is for providers to counsel patients not only on condom use, but their consistent and correct use as well, she states.

"Inconsistent [condom] use actually is a sign of increased risk, probably because patients who know that they are at risk feel that they should use condoms, but they don't always use them," agrees **Steven Sondheimer**, MD, professor of obstetrics and gynecology at the University of Pennsylvania Medical Center in Philadelphia and a study co-author. "[Condoms are] protective only if they are used consistently and correctly."

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Is EC available in your local emergency department?

Your office dispenses emergency contraceptive pills (ECPs), your local pharmacies may fill ECP prescriptions, but do you know what your local hospital emergency department's policy is on provision of emergency contraception?

According to a national survey of Catholic-owned hospitals, 82% denied women emergency contraception, even in cases of rape. Only 22% of the emergency departments that did not provide emergency contraception provided a useful referral.[1]

And in Washington state, a state noted for its progressive approach to ECPs, a 2000 survey revealed that out of 88 hospitals surveyed, just 25 supply ECPs, with nine of those hospitals only giving the drug to rape victims.[2]

The Clara Bell Duvall Reproductive Freedom Project at the Philadelphia-based American Civil Liberties Union of Pennsylvania contacted hospital emergency departments throughout the state. Only 28% of the hospitals surveyed routinely offered and provided EC to victims of sexual assault.[3]

"One of the interesting findings was that all of the hospitals provide prophylaxis for sexually transmitted diseases," observes **Carol Petraitis**, director of the Duvall Project. "So the question is: Why aren't they providing prophylaxis for pregnancy?"

EC is standard of care

More than 300,000 women are raped in the United States each year, statistics show.[4] Each year, more than 32,000 women become pregnant as a result of rape; about half of these pregnancies end in abortion.[5]

EXECUTIVE SUMMARY

What is your local hospital's policy on providing emergency contraception (EC), particularly to victims of rape?

- Surveys indicate that many hospitals may not be following guidelines set by the American Medical Association.
- Those guidelines require that rape victims be counseled about their risk of pregnancy and offered EC.

Emergency contraception is the standard of care for treatment of rape victims. Guidelines established by the Chicago-based American Medical Association require that rape victims be counseled about their risk of pregnancy and offered EC.[6]

There is growing concern that rape victims are not provided with EC in many hospital emergency departments, particularly in Catholic hospitals. A survey of 58 large urban hospitals across the nation, including 28 Catholic hospitals, shows that while policies at the 30 non-Catholic hospitals allow discussion of EC, prescription of EC, and hospital pharmacy dispensing of the drug, Catholic hospitals vary in their approach to these issues.[7] Twelve of the Catholic hospitals surveyed said policy prohibits EC discussion, seven prohibit EC prescription, and 17 would not allow hospital pharmacies to dispense EC.

Advocate EC use

The Washington chapter of the National Abortion and Reproductive Rights Action League (NARAL) has launched a campaign to get hospitals in Pierce County and other parts of western Washington to provide the drug in their emergency departments. While Seattle has many 24-hour pharmacies that provide EC, there are few in Tacoma, Everett, and other smaller communities in western Washington. **(Information on Washington's collaborative practice project is reviewed in the August 1999 issue of *Contraceptive Technology Update*, p. 85.)**

Washington NARAL presently is working with five hospitals, reports **Dawn Merydith**, program director. Of the five, three hospitals — Stevens Hospital in Edmonds, Tacoma General in Tacoma, and Providence of Everett in Everett — are "on board," and the other two hospitals are moving in that direction, states Merydith. The organization plans to work with all 88 Washington hospitals so that they will dispense ECPs (specifically Plan B, marketed by Bellevue, WA-based Women's Capital Corp.) to all women, as well as educate hospital staff on EC and the hospital's policy to dispense it. Catholic hospitals will be asked to dispense Plan B to all rape survivors, provide adequate referrals to all other women, and to educate staff on EC and their EC policies, says Merydith.

Washington NARAL is involving the community by asking community members to spread the word about EC and its availability at hospitals,

says Merydith. The organization has developed a press release with the goal to release the information in local papers after the hospital has agreed to provide EC care, she notes.

In the Pennsylvania hospital survey, 51% of the facilities questioned said that information about EC and provision of ECPs is "physician-dependent" — given at the discretion of the emergency department physician on duty. About 70% of Catholic hospitals indicated such a response, compared to 49% of non-Catholic hospitals.

The Duvall Project is working with the Pennsylvania Coalition Against Rape in plotting the progress of EC in hospital use. Results of the survey are posted on the project's web site (www.aclupa.org/duvall/ecinPA.html) and can be viewed by county. Sample letters are available so local hospitals may be contacted in regard to their current care standards. The Duvall Project is contacting emergency department chairpersons to direct their attention to the site and to have them provide updated information so that women have the most current data on local hospital practices.

"I think there is a great amount of room for work with the hospitals," observes Petraitis. "I think there are a certain number that will change their policies or improve their policies, but I also feel like there are quite a number who are not willing to do it."

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Check SCHIP coverage for uninsured teens

Uninsured teens in your care may be eligible for free or low-cost insurance, including coverage for reproductive health services, provided through your state-administered Children's Health Insurance Program (SCHIP). According to a just-published analysis, however, state programs are inconsistent in guaranteeing the kinds of information, confidentiality, and flexibility in choosing providers that teens need to access such care.[1]

Most SCHIP programs are covering a nearly complete range of reproductive health care services and contraceptive drugs and devices, but some key deficiencies exist, points out analysis co-author **Rachel Benson Gold**, assistant director for policy analysis of the Washington, DC, bureau of the Alan Guttmacher Institute (AGI). At the time of the nationwide survey:

- Some programs did not cover emergency contraception.
- Information to adolescents about covered services and accessing reproductive health care was inadequate.
- Many states had not developed specific provisions in their plan to protect teen-agers' confidentiality.
- Too few programs allowed access to out-of-network providers for managed care enrollees.
- Many states failed to creatively reach out to uninsured adolescents for enrollment.

Family planners can serve as advocates by reviewing the design of their state CHIP coverage and identifying the gaps, says **Claire Brindis**, DrPH, professor of pediatrics and

EXECUTIVE SUMMARY

Uninsured teens in your care may be eligible for free or low-cost insurance, including coverage for reproductive health services, provided through your state-administered Children's Health Insurance Program (SCHIP).

- The SCHIP program targets children up to age 19 whose families earn too much to qualify for Medicaid but cannot afford private health insurance.
- According to a just-published analysis, state SCHIP programs are inconsistent in guaranteeing the kinds of information, confidentiality, and flexibility in choosing providers that teens need.

health policy in the Division of Adolescent Medicine and the Institute for Health Policy Studies at the University of California at San Francisco. Brindis co-authored a 1999 report that analyzed strategies tested in 12 states to use the SCHIP program to improve health care.[2]

"SCHIP represents an unprecedented opportunity for states to expand health insurance for children of all ages, but particularly the underserved population of adolescents," Brindis states.

Passed by Congress in 1997, the SCHIP program targets children up to age 19 whose families earn too much to qualify for Medicaid but cannot afford private health insurance. With nearly $40 billion in federal funds available to them over 10 years, the states are charged with establishing SCHIP programs, which may enroll children under age 19 in families with incomes up to 200% of the federal poverty level.[3]

States are allowed to design their SCHIP programs in one of three ways: by expanding Medicaid programs, creating or expanding a state-designed program not based on Medicaid, or using a combination of the two programs.[3]

Get the word out

It takes a teen-oriented message to reach adolescents with information about SCHIP programs, says Brindis. Outreach materials targeted to teens and their parents and use of adolescents to spread the message have been shown to be effective. Simplified application and enrollment procedures also aid in ease of enrollment.

Brindis points to an effort in Escambia County, AL, where a local pediatrician enlisted seven of her adolescent patients for SCHIP outreach efforts targeting teens in their county. The young counselors were trained to help identify other adolescents and their families in need of health insurance. Their efforts were highly effective: In one local hospital, the percentage of children and youth coming in without insurance dropped from 25% to 11%.[2]

Groups such as the Washington, DC-based American College of Obstetricians and Gynecologists (ACOG) and the New York City-based Planned Parenthood Federation of America have asked members to advocate for the extension of adolescent reproductive health coverage in their states and actively participate in outreach efforts to enhance teen access to health care. Since about 41% of SCHIP-eligible children use a doctor's office as their regular source of care, OB/GYN gynecologists are well positioned to assist with SCHIP recruitment efforts, says ACOG.[4]

Check confidentiality

While it is important to enroll qualified teens into SCHIP, equal efforts must be made to educate them on available services, particularly when it comes to reproductive health care, says Brindis. According to the AGI analysis, only about half the programs surveyed provided teens with information, even about whether contraceptive services were covered, and less than half of the programs were clear on coverage and accessing care for the full range of reproductive health services.[1]

Also look at what kind of adaptations have been made to your state's SCHIP program so that those who are enrolled can have access to appropriate care, says Brindis.

"We found no states really planned for identifying adolescent-friendly providers, so that kids could really have a chance to find those providers who would be more teen-friendly," she says.

The AGI analysis also found that many programs provided a limited degree of confidentiality. Many teens may delay or shun reproductive health services if high levels of confidentiality are not maintained.

States should establish procedures to ensure confidentiality for adolescent health care, to work with health plans and providers to increase awareness of each state's confidentiality law, and to educate adolescents about the confidentiality protections available to them, says Brindis. There are concerns that current confidentiality laws will be dismantled, Brindis states. While the laws have not been perfect, they have worked for many adolescents, she notes.

"We need to be thinking about how we can help balance the rights of parents with the rights of teen-agers, [for those] parents who say, 'I want my kid to tell me.' There are many kids who do talk to their parents," says Brindis. "But we need to be really helpful to those kids who don't have that type of relationship."

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Reach Hispanic teens with targeted message

How can your clinic reach Hispanic adolescents with an effective prevention message against sexually transmitted diseases (STDs) and HIV? American Social Health Association (ASHA) in Research Triangle Park, NC, is developing a fresh approach with its new STD prevention program, ¡SALSA! (STDs, Adolescents, and Latinos: Sexual Health Awareness).

Prevention programs for Hispanics, if they are to make a difference, must take into account cultural characteristics, says **Lanya Shapiro**, ¡SALSA! project manager. Programs must attempt to break the silence about sexuality and incorporate specific cultural aspects to reinforce healthy behaviors, she states.

¡SALSA!'s goal is to increase the availability of bilingual, culturally appropriate STD prevention and education resources for Hispanic teens in North Carolina. If ¡SALSA! is successful, ASHA plans to look into the possibility of partnering with national organizations to modify and disseminate the model, says **Tracey Adams**, ASHA's director of community outreach and media relations.

EXECUTIVE SUMMARY

Hispanic youths are disproportionately affected by sexually transmitted diseases (STDs), according to American Social Health Association (ASHA).

- ASHA is piloting an STD prevention program, ¡SALSA! (STDs, Adolescents and Latinos: Sexual Health Awareness) to increase the availability of bilingual, culturally appropriate STD prevention and education resources for Hispanic teens.
- The three-year program includes an educational comic-novela and a peer educator program.

Hispanics constitute a growing segment of the U.S. population, comprising 11.8% of U.S. residents.[1] North Carolina has seen a rise in its Hispanic population; the 2000 U.S. Census listed 379,000 Hispanics, well above the 230,000 figure listed in 1995.

U.S. Hispanics are disproportionately affected by STDs, according to ASHA.[1] Rates of reportable STDs are known to be higher in Hispanics than in non-Hispanic whites, ASHA states, and Hispanics represent 17% of all AIDS cases diagnosed within the United States.[1] **(See chart on p. 133.)**

Hispanic communities are rapidly growing in the United States, and there is a huge, unmet need for improved health messages — including STD and AIDS prevention messages — within those populations, says Adams.

"ASHA is committed to stopping the spread of STDs, and we believe that the most effective way to do this is through education," says Adams. "To be effective, this education has to incorporate health messages that are accurate, reliable, usable, and accessible; they must be culturally appropriate, building on the knowledge and the strengths that exist in every community."

Check 'novela' approach

In Latin America, novelas are a common entertainment medium, typically using photography or drawings to illustrate a story, says Shapiro. More than just an alternative to traditional educational materials, the real-life situations presented in novelas can spark discussions about health issues, model positive health behaviors, and facilitate changing social norms, she notes.

ASHA partnered with El Centro Hispano, a local Latino organization, to create *Calenturas,* an educational comic-novela on STD prevention. ¡SALSA! staff and members of El Centro's youth group, Jóvenes Líderes en Acción (Young Leaders in Action), jointly guided the development of the novela's key themes, story, and artwork. *Calenturas* was focus group-tested with young Hispanics throughout the state, and national Hispanic leaders in sexual health education provided additional input, says Shapiro. **(See resource box for ordering information, p. 133.)**

Written originally in Spanish, *Calenturas* follows Luis and Ana, a young couple who recently have become sexually active. When her period is late, a worried Ana seeks a pregnancy test and is shocked to learn she has chlamydia. Despite tension and

Hispanics and STD Risks

- Hispanics are among those populations at the greatest risk for contracting the hepatitis C virus.
- Hispanic women are seven times more likely to contract AIDS and have higher rates of syphilis compared to non-Hispanic white women.
- Among minorities, Hispanic women report the second highest number of cases of gonorrhea.
- Nearly one in four cases of AIDS reported in children under the age of 13 is among Hispanics.

Source: American Social Health Association, Research Triangle Park, NC.

suspicion of betrayal, the diagnosis creates an opportunity for education, increased communication, and ultimately, a commitment to healthier sexual practices in the future, says Shapiro.

The comic-novela has four main themes:

• STDs are very common, often asymptomatic, and have long-term medical consequences if untreated.

• The only way to know for sure if you have an STD is to get tested.

• If you are sexually active, using latex condoms is the best way to prevent STDs.

• Communicating about sexual health with partners, family, and health care providers is not always easy, but well worth the effort.

In developing the content of the comic-novela, it was a challenge to balance realism with good (role model) behavior, entertainment with education, and cultural specificity with accessibility, says Shapiro. Teaming ASHA's expertise in sexual health with the Hispanic adolescents' expertise in culture- and age-appropriateness was essential, she says. **(See story, right, for a brief overview of cultural values.)**

"Writing the script in Spanish [as opposed to translating from English] was key to making it real and natural to the intended audience," Shapiro says of *Calenturas.* "To underscore the critical health education, an informational page was added, which reiterates the STD facts in an engaging Q&A format and highlights other resources."

¡SALSA!'s next step is to develop and schedule peer education training throughout the state. The program will use Hispanic teens as community education resources. Some 25,000 comic-novelas will be distributed to teens throughout the state through the peer educators' networks, collaborating agencies, local festivals, and other channels, says Shapiro.

Designed as a three-year project, ¡SALSA! has received approximately $250,000 from the Kate B. Reynolds Charitable Trust to develop, implement, and evaluate the comic-novela and the peer educator program, says Shapiro.

RESOURCE

Calenturas is available in bulk free of charge to health care providers, schools, and community-based organizations in North Carolina. Those outside of North Carolina can receive a single free copy. To order, contact:

- **¡SALSA! c/o American Social Health Association**, P.O. Box 13827, Research Triangle Park, NC 27709. Fax: (919) 361-8425. E-mail: salsa@ashastd.org.

Reference

1. American Social Health Association. *Hispanics and Sexually Transmitted Diseases.* Research Triangle Park, NC: American Social Health Association; accessed at www.ashastd.org/news/hisp.html. ■

Cultural values are key to reaching Hispanics

To effectively reach Hispanic youths with sexually transmitted disease (STD) prevention messages, providers must understand that traditional cultural values may make safer sex practices difficult.

Traditional cultural values include:

• **Machismo,** which may dictate that intercourse is a way for males to prove masculinity.

• **Familismo,** which looks to the importance of the family as a social unit and source of support. While it can be a barrier to changing social norms, familismo can be a powerful factor to motivate behavior change.

• **Simpatía** refers to the importance of polite social relations that shun assertiveness, negative responses, and criticism.

• **Personalismo** refers to the preference for

relationships that reflect familiarity and warmth. Health information and service delivery is most effective when workers establish warm relationships and ask questions about family and shared experiences.

Source: Center for AIDS Prevention Studies, University of California, San Francisco. *What Are Latinos' HIV Prevention Needs?* San Francisco: Center for AIDS Prevention Studies; 1996. Accessed at: www.caps.ucsf.edu/latinotext.html. ■

Follow global health with these web sites

To gain a perspective on emerging contraceptive technology research, family planners may benefit from an international perspective on reproductive health care. Get a global overview with the following web sites:

1. World Health Organization, "Reproductive Health." Web: www.who.int/reproductive-health/.

The Geneva-based World Health Organization offers this introductory web page to access information on international reproductive health issues, including family planning, sexual and reproductive rights, and adolescent sexual health. Click on the "What's New" link to read articles from the current issue of the quarterly newsletter, Progress in Reproductive Health Research, published by the UNDP/UNFPA/WHO/World Bank Special Programme of Research, Development, and Research Training in Human Reproduction, Department of Reproductive Health and Research at the World Health Organization.

2. International Planned Parenthood Federation Medical Bulletin. Web: www.ippf.org.

The London-based International Planned Parenthood Federation (IPPF) links national autonomous family planning associations in more than 180 countries. Its IPPF Medical Bulletin provides up-to-date and unbiased information on clinical, service delivery, and managerial aspects in family planning and sexual and reproductive health. For example, the August 2001 issue offers information on transdermal contraception, barrier methods of contraception, and sexually transmitted infections. The site carries issues in English, French, and Spanish versions dating back to 1998. All issues are available in Adobe Acrobat (PDF) format. Click on "Medical" under the "Resources" box on the home page, then click on "IPPF Medical Bulletin" to access the publication.

3. Alan Guttmacher Institute's International Family Planning Perspectives. Web: www.agi-usa.org.

The New York City-based Alan Guttmacher Institute is a nonprofit organization focused on sexual and reproductive health research, policy analysis, and public education. Its *International Family Planning Perspectives* provides the latest peer-reviewed research on sexual and reproductive health and rights in Africa, Latin America, the Caribbean, and Asia. The quarterly publication emphasizes contraception; fertility; adolescent pregnancy; abortion; family planning policies and programs; sexually transmitted diseases, including HIV/AIDS; and reproductive, maternal, and child health. Articles from the current issue are provided in HTML (can be read from your Internet browser program) and Adobe Acrobat (PDF) format. Click on *"International Family Planning Perspectives"* under "Periodicals" on the home page to access the publication.

4. Program for Applied Technology (PATH) *Outlook*. Web: www.path.org.

Program for Applied Technology (PATH) is a Seattle-based nonprofit international organization that focuses special attention on improving the quality of reproductive health services and preventing and reducing the impact of widespread communicable diseases. Its publication, *Outlook,* features news on reproductive health products and drug regulatory decisions of interest to developing country readers. Readers can download issues dating from 1995 in Adobe Acrobat (PDF) format. Click on "Publications" under "Resources Online" on the home page, then click on *"Outlook"* to access the publication.

5. *British Medical Journal*. Web: www.bmj.com.

The London-based *British Medical Journal (BMJ)* "publishes rigorous, accessible information that will help doctors improve their practice and influence the international debate on health." The Internet *BMJ* contains a portion of the material published in the weekly *BMJ;* nonsubscribers can view the current contents pages, structured abstracts, editor's choice, and "This weekin *BMJ,*" as well as search the archives.

6. *The Lancet*. Web: www.thelancet.com.

The Lancet is an on-line version of the London-based *The Lancet* medical journal. Nonsubscribers to the printed journal can register free of charge with the web site to access selected articles. ■

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Editorial Questions

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

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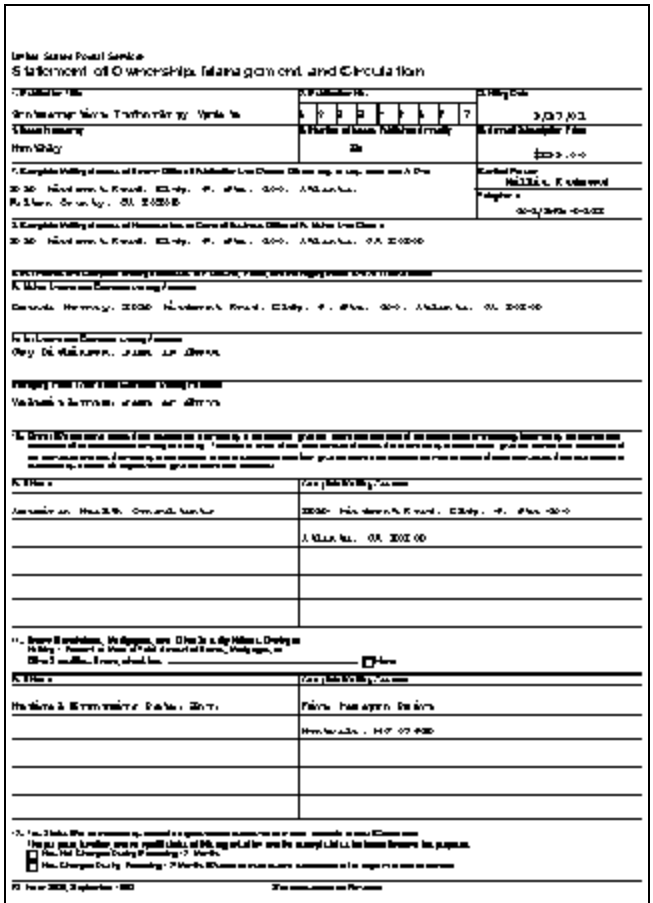

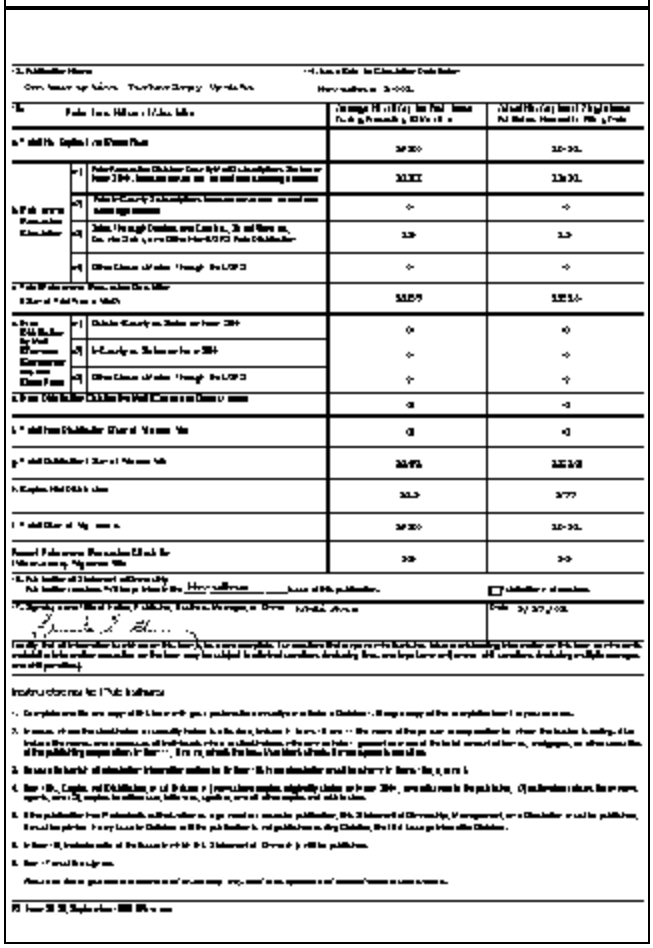

CE/CME Questions

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

- State an important outcome of a 2001 study (Hubacher D, et al., *N Engl J Med)* of copper T380A intrauterine device (IUD) users.
- Identify an important finding from a 2001 study (Ness RB, et al., *Am J Obstet Gynecol),* which examined pelvic inflammatory disease (PID) risks in women using contraception.
- Name the standards for care for rape victims as established by the American Medical Association.
- Define the State Children's Health Insurance Program (SCHIP).

17. What was an important outcome of a 2001 study (Hubacher D, et al., *N Engl J Med)* of copper T380A IUD users?
    A. Compared with women who had not used hormonal, intrauterine, or barrier contraception, use of a copper IUD was greatly associated with an increased risk of tubal infertility.
    B. Compared with women who had not used hormonal, intrauterine, or barrier contraception, use of a copper IUD was not associated with an increased risk of tubal infertility.
    C. Women who used the copper IUD had more incidents of chlamydia infection.
    D. Women who used the copper IUD had fewer incidents of bacterial vaginosis infection.
18. State an important finding from a 2001 study (Ness RB, et al., *Am J Obstet Gynecol),* which examined PID risks in women using contraception.
    A. Neither recent oral contraceptive use nor barrier method use (condoms or other barrier methods) reduced the risk of upper genital tract disease among women presenting with signs and symptoms consistent with PID.
    B. Oral contraceptive use was associated with a lower risk for PID.
    C. Use of depot medroxyprogesterone acetate was associated with a higher risk for PID.
    D. Use of a diaphragm was associated with a lower risk for PID.
19. What are the standards for care for rape victims as established by the American Medical Association?
    A. Rape victims should receive a pregnancy test at the time of the initial emergency department visit.
    B. Rape victims should not receive emergency contraception at the time of the initial emergency department visit.
    C. Rape victims should receive a Pap smear at the time of the initial emergency department visit.
    D. Rape victims should be counseled about their risk of pregnancy and offered emergency contraception.
20. What is the State Children's Health Insurance Program (SCHIP)?
    A. The SCHIP program targets children up to age 13 whose families earn too much to qualify for Medicaid but who cannot afford private health insurance.
    B. The SCHIP program offers general health care, but excludes reproductive health services, for children up to age 19 whose families earn too much to qualify for Medicaid but who cannot afford private health services.
    C. The SCHIP program targets children up to age 15 whose families earn too much to qualify for Medicaid but who cannot afford private health insurance.
    D. The SCHIP program targets children up to age 19 whose families earn too much to qualify for Medicaid but who cannot afford private health insurance.

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AMERICAN HEALTH CONSULTANTS

2001 SALARY SURVEY RESULTS

CONTRACEPTIVE TECHNOLOGY UPDATE®

A Monthly Newsletter for Health Professionals

Family planners continue salary course, hold steady on staffing

Advanced practice providers look to boost visibility

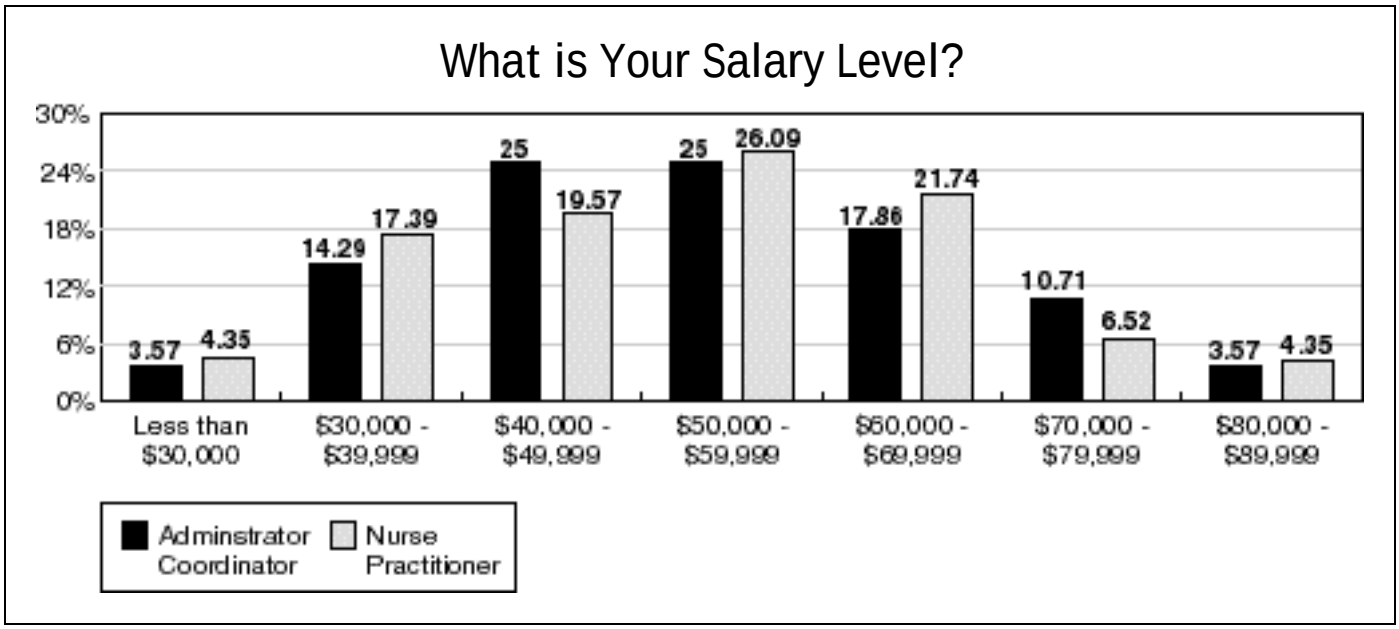
How did your paycheck fare in 2001? For family planners who participated in the 2001 *Contraceptive Technology Update* Salary Survey, most reported slight salary gains and no decreased hiring trends at their respective facilities.

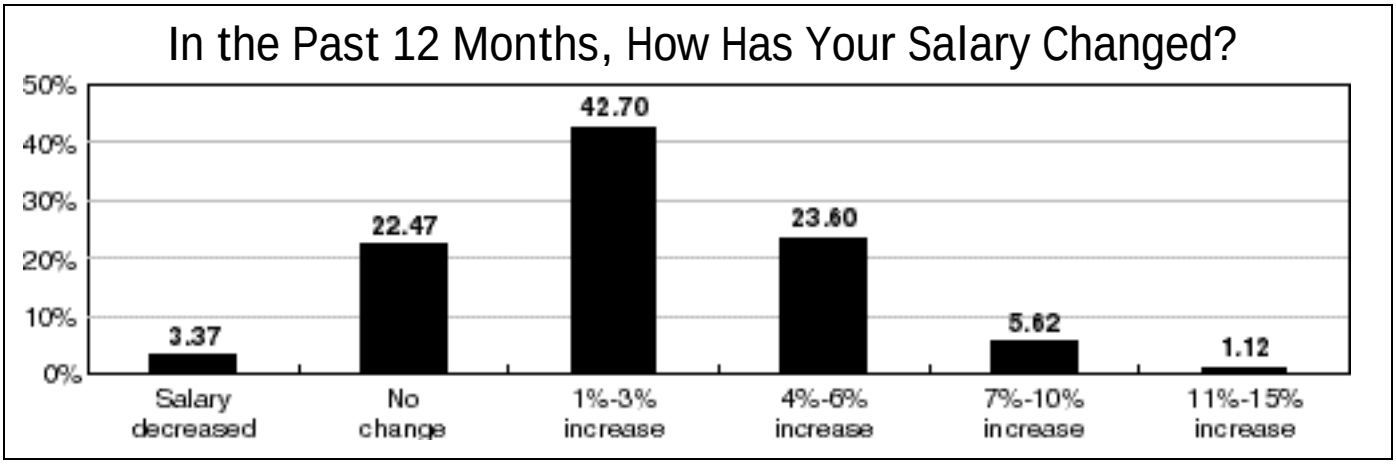
The results reflect a continued trend of modest increases and steady staffing, particularly for administrators / coordinators and nurse practitioners. The two groups comprised the majority of respondents to the survey, which was mailed in July 2001 to 1,436 readers and had a response of 89, for a response rate of 6%.

Nurse practitioners (NPs) saw a continuance of a three-year climb in annual salary figures, according to the *CTU* survey. **(See "What is Your Salary Level?" below.)** Average salary for NPs was $53,043, up from $50,003 in 2000. Median salary also increased; $48,333 in 2001, compared to $47,857 in 2000. More than half of the responses (52%) came from nurse practitioners.

Average salary for administrators / coordinators rose slightly, from 2000's $53,538 to $53,571 in 2001; however, median salary dipped from $48,000 to $47,857. The group represented 31% of 2001's total responses.

Overall, 43% of survey respondents reported increases of 1%-3% in the past year, with 24% receiving a 4%-6% bump in pay. **(See "In the**





Past 12 Months, How Has Your Salary Changed?"above.) Six percent of those surveyed said they received a 7%-10% increase.

Employment figures at family planning facilities remain steady, survey respondents report. More than half (54%) say no changes have taken place, while 28% say employee numbers have increased. Less than one-fifth (18%) of those surveyed said staffing levels had declined. About half (44%) of responses came from those employed by state / city / county government, with 34% from nonprofit agencies and 14% from college or university settings.

Check national figures

The 2001 Physician Compensation Report, compiled by *Modern Healthcare* magazine, looks at 10 national data tracking sources to gain insight on physician's financial health.[1] According to the report, compensation for OB / GYNs ranged from $138,000 to $250,000, with four sources showing pay increases, three groups reporting decreases, and three with figures not available.

While median gross income in 2000 climbed 19% for OB / GYNs, their net income rose only by 1%, according to *Medical Economics* magazine's Continuing Survey, which samples providers in office-based private practice.[2] These physicians make almost 7% percent less than they did in 1996, according to the report.[2]

Physicians' assistants (PAs) are reporting slight increases, as noted by the American Academy of Physician Assistants (AAPA) in Alexandria, VA. Results of its *2000 AAPA Physician Assistant Census Survey* show the median income for clinically practicing PAs working full time is $65,177, up from $64,780 in 1999.

Certified nurse-midwives (CNMs) are making strides in salary gains. According to an analysis of the Washington, DC-based American College of Nurse-Midwives' membership survey, the 1999 salary for CNMs with full-time employment fell into the $60,000-$69,000 range, up from 1995 levels.[3]

Registered nurses also are recording slight pay increases. According to the most current federal Bureau of Labor Statistics, the median annual salary for registered nurses was $40,690 in 1998.[4] The middle 50% earned between $34,430 and $49,070 a year, the lowest 10% earned less than $29,480, and the highest 10% earned more than $69,300 a year. Allied Consulting, an Irving, TX-based professional search firm, reports that the average salary for its RN candidates was $43,000 in 2000, up from $41,300 in 1999.

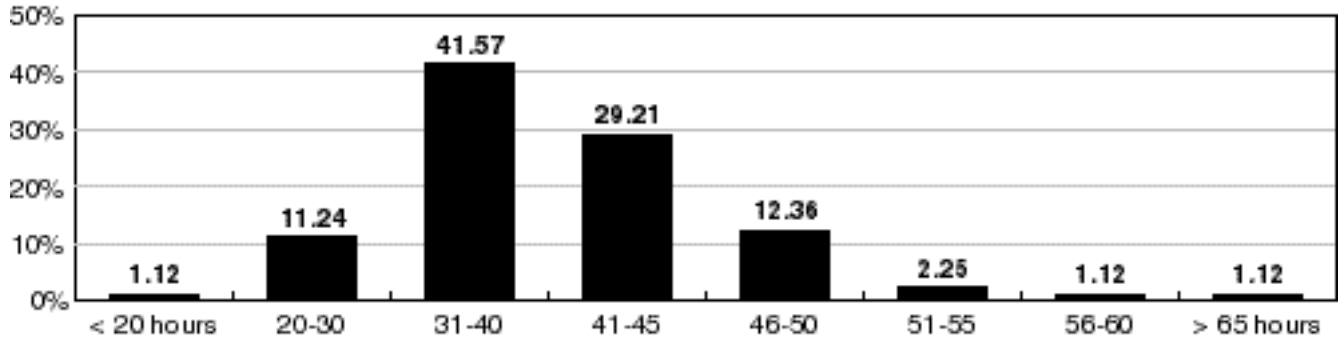
One way to enhance the value of any profession is to raise awareness of its role in the marketplace. The newly formed Nurse Practitioner National Marketing Campaign is seeking to raise visibility and representation of nurse practitioners among major employers, legislators, regulators, and health maintenance organizations / health insurance industry executives.

The campaign is the outgrowth of a privately sponsored professional "think tank" held in March 2000 in Annapolis, MD. Nationally-recognized NP leaders from clinical practice, education, research, administration, and health policy looked at the challenges facing nurse practitioners, including such issues as lack of reimbursement for clinical services and barriers to designation as primary care providers. Groups participating in the campaign include the American College of Nurse Practitioners, the National Organization of Nurse Practitioner Faculties, the National Association of Nurse Practitioners in Women's Health (NPWH), and the National Conference of Gerontological Nurse Practitioners, all based in Washington, DC;

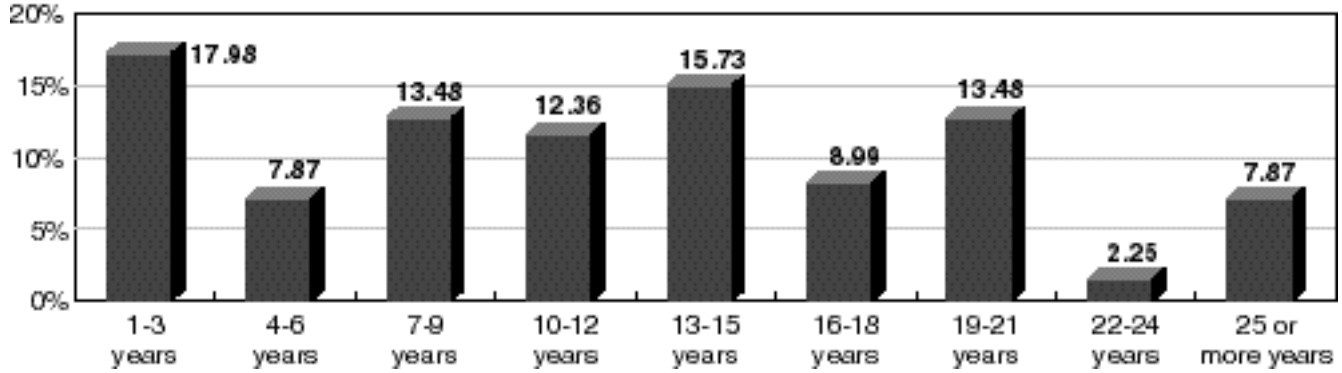
(Continued on page 4)

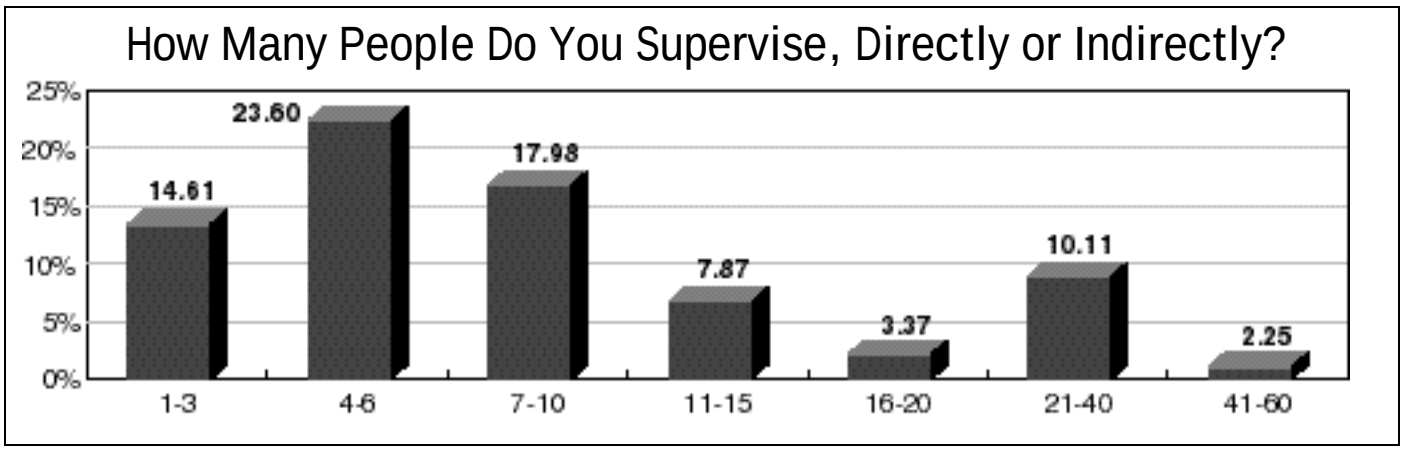
What is Your Highest Academic Degree?

How Many Hours a Week Do You Work?



How Long Have You Worked in Positions with the Same or Similar Responsibilities as Your Current Position?





and the National Association of Pediatric Nurse Associates and Practitioners in Cherry Hill, NJ.

The campaign's agenda is to disseminate information about the positive role that NPs play in the provision of comprehensive health care services, including improved patient access, satisfaction, and outcomes, via advertisements in critical media markets across the country. A national NP speakers bureau database also has been established so that media may access NP spokespersons at the local, state, regional, and national level.

NPs are being asked to support the awareness program through financial donations, says **Susan Wysocki**, RNC, NP, NPWH president and CEO.

"If every nurse practitioner in the country gave $20, we would have it beat, but unfortunately, not everyone contributes," Wysocki observes. "The board of directors of NPWH each individually gave $50 or more; we would love others to match that amount and take up the NPWH challenge."

RESOURCES

For donations to the Nurse Practitioner National Marketing Campaign, checks should be made payable to NP-PR Campaign, contact:

- **NP National Marketing Campaign**, P.O. Box 337, Water Mill, NY 11976.

To become a local spokesperson for the Nurse Practitioner National Marketing Campaign, contact:

- **Susan Wysocki**, RNC, NP, National Association of Nurse Practitioners in Women's Health. Telephone: (202) 543-9693. E-mail: NPWHDC@aol.com.

For more information on MidwifeJobs.com, contact:

- **Jonathan Sakai**, On-line Services Manager, American College of Nurse-Midwives, 818 Connecticut Ave. N.W., Suite 900, Washington, DC 20006. Telephone: (202) 728-9714. E-mail: jsakai@acnm.org. Web: www.midwife.org.

(See resource box, below left, for contact information on contributions and participation in the speakers' bureau.)

Nurse midwives are raising visibility of their profession through the launch of MidwifeJobs.com, sponsored by the American College of Nurse-Midwives (ACNM). The web site, designed to connect midwives, hospitals, birth centers, physicians, and any health care organization seeking midwives to expand their services, was unveiled during the organization's 2001 annual meeting and exhibit.

It is free for job seekers to search the listings, and the cost to advertise on MidwifeJobs.com is $250 for a four-week job posting, says **Eric Dyson**, ACNM communications manager. The organization has helped numerous midwives find new placements, he states.

"Statistics show that the demand for midwife care has increased steadily every year since 1972, and with more public awareness of midwifery care, the numbers are sure to continually rise," said ACNM executive director **Deanne Williams**, CNM, MS, FACNM. "By providing a comprehensive career web site, we not only help midwives find positions, but bring about awareness of the growth of one of the most rewarding careers anyone could choose."

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1. Romano M. 2001 physician compensation report. Unequal opportunities. Anesthesiologists, radiologists lead the pay parade, while generalists lag behind. *Mod Healthc* 2001; 31:30-34.

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AMERICAN HEALTH CONSULTANTS

Contraceptive Technology Reports

A supplement to *Contraceptive Technology Update* **November 2001, BB #503A**

An examination of Cyclessa — Efficacy, cycle control, and side effects

Author: **Lynn Borgatta, MD, MPH,** Associate Professor, Obstetrics and Gynecology, Boston University School of Medicine, Boston.
Peer Reviewer: **Steven J. Sondheimer, MD,** Professor of Obstetrics and Gynecology, University of Pennsylvania Medical Center, Philadelphia.

Introduction

Cyclessa (Organon, West Orange, NJ) is a new triphasic oral contraceptive containing ethinyl estradiol (EE) and desogestrel. The dosing and schedule of both components are new to the United States. The dose of EE is 25 mcg for 21 days; other pills on the market have doses of 35, 30, or 20 mcg EE, and some phasic pills have 40 mcg during part of the cycle. All but one of the phasic pills previously available have mean EE doses of at least 30 mcg throughout the active cycle.

Cyclessa is the first phasic oral contraceptive containing desogestrel in the United States. The other phasic pills, which are all triphasic schedules, are listed in a table enclosed in this issue. Desogestrel is used in several monophasic pills with 20 mcg EE (Mircette) or 30 mcg EE (Ortho-cept/Desogen and others), but the dose of desogestrel is 150 mcg for all. The desogestrel dose in Cyclessa increases from 50 mcg in the first week, to 100 mcg, to 150 mcg in the final week of active pills.

As both the estrogen dose and the progestin dose have been decreased simultaneously, there may be some concern about efficacy as well as anticipation about beneficial effects on cycle control and the incidence of side effects. There are only a few papers published about tricyclic desogestrel-containing pills, so direct comparisons are limited, but evaluations of similar combinations is helpful.

Efficacy

Kaunitz compared Cyclessa to Ortho-Novum 7/7/7 (EE 30 mcg/phasic norethindrone) using a randomized, open-label design.[1] This multicenter trial enrolled 5,654 women for a six-month period. There were 12 pregnancies among Cyclessa users and nine among Ortho-Novum users; the estimated pregnancy rate over six months was 0.5% for Cyclessa and 0.4% for Ortho-Novum, which is not a significant difference.

Another phasic desogestrel-containing formulation, not available in the United States, contains the same amount and pattern of desogestrel as does Cyclessa. The EE dose, however, is higher: 35 mcg the first week and 30 mcg for the second two weeks. In a single-agent series of 2,070 women and 10,408 treatment cycles, there were only two pregnancies, a Pearl index (pregnancies per hundred woman-years) of 0.25.[2]

Other trials have evaluated pregnancy rates among other contraceptives using less than 30 mcg EE. These contraceptives are listed in a table enclosed in this issue. Two monophasic combinations using 150 mcg of desogestrel are widely used; Mircette is available in the United States and is unique among existing oral contraceptives in having EE 10 mcg during days 23-28. In a randomized, open-label trial of Mircette, Ortho-Novum TriCyclen (35 mcg EE and phasic norgestimate), and Alesse (20 mcg EE and levonorgestrel 100 mcg), 463 women were enrolled.[3] Although the Pearl indices were 0, 4.4, and 1.5 respectively for Mircette, Alesse, and Ortho-Novum, these pregnancy rates do not significantly differ among the groups; there were only four pregnancies in the entire cohort. Mercilon (20 mcg EE and 150 mcg of desogestrel for 21 days) is used widely outside of the United States. Compared to Meliane, a 20 mcg EE monophasic pill containing gestodene (a progestin not available in the United States) in a randomized trial, the one-year Pearl index was 1.06 (per hundred woman-years) for gestodene and 0.53 for desogestrel.[4] Finally, the relationship of different EE doses (20 and 30 mcg EE) with 150 mcg desogestrel and contraceptive failure was evaluated in another large European study. There was no significant difference in rates, and there were only two pregnancies in

4,543 cycles, consistent with a Pearl rate of about 0.5.[5]

In each study, the efficacy for all studied pills is similar. However, the rates of pregnancy differ from study to study. An extraordinarily low Pearl index reported by Ferguson[6] in a large series, 0.25, is half that (0.53) of another study,[4] for example. The rates in the Kaunitz study probably would be consistent with a Pearl index around 1. Since the Kaunitz and Ferguson studies were conducted with different designs, different preparations, and different populations, their pregnancy rates cannot be compared directly. A large (1,143) series of women using Mircette showed a Pearl index of 1,[7] in contrast to the observed rate of zero for Mircette in a much smaller study.[3] Pearl indices and life table estimates of contraceptive failure represent a "best guess" and are not accompanied by confidence intervals. With the range of comparisons for oral contraceptives containing between 20 and 35 mcg, there is no consistent evidence to show superior efficacy of one pill over another.

The evaluation of efficacy according to progestational agent and dose is more complex because of the number of different progestins and the number of phasic preparations, but the conclusions are similar: There is no consistent evidence to show superiority of one progestin agent over another, or of one dosing schedule another. The phasic dosing of desogestrel (50, 100, and 150 mcg), which reduces the total dose of desogestrel, has not been compared directly to the existing oral contraceptives containing monophasic desogestrel at 150 mcg for 21 days.

Indirect support for the equivalent efficacy of oral contraceptives in the interval of 20-35 mcg is provided by a European oral contraceptive with a decrease in both the EE dose and progestin dose compared to other marketed oral contraceptives. The combination of 15 mcg of EE and 60 mcg of gestodene represents a 25% and 20% decrease, respectively, for each component. It was formulated with either a 21- or 24-day active cycle, and the 24-day packet has been marketed as Minesse.[8] A small trial of 58 women showed that with either schedule, ovulation was suppressed;[9] only one ovulatory cycle occurred by ultrasound criteria, and that was accompanied by a progesterone level that was too low to be likely to support pregnancy. Apparently this combination with 15 mcg of EE is enough to prevent ovulation, which implies that 20 or 25 mcg is likely to be enough, even with a different progestin.

Cycle Control

Cycle control is extremely important to women using oral contraceptives. Deviations from perfect cycle control, including amenorrhea and midcycle bleeding or spotting, generally are unrelated to contraceptive efficacy bur are reasons for dissatisfaction and discontinuation.

In the Kaunitz study of Cyclessa and Ortho-Novum, 18.4% of women in each group discontinued their oral contraceptive before the six-month mark.[1] In that study, 4.4% of Cyclessa users and 3.9% of Ortho-Novum users discontinued because of side effects, and the proportion of women discontinuing because of bleeding was the same in each group: 0.8%. Despite the low rate of discontinuation for bleeding, there were some differences between Cyclessa and Ortho-Novum in bleeding patterns. Lack of withdrawal bleeding in a cycle was more common for Ortho-Novum than Cyclessa (5.1% vs. 2.9%, $p = 0.001$). Breakthough bleeding or spotting or both occurred in more cycles with Ortho-Novum than Cyclessa (15.5% vs. 11.0%, $p = 0.001$); however, the mean number of total bleeding or spotting days during the six-month period was similar: 17% vs. 17.8%. As expected, the incidence of bleeding and spotting decreased from the first cycle to the sixth. For Cylessa users, the rate for bleeding went from 4% to 3.5%, and the rate for spotting went from 10% to 8%. Rates of bleeding by month were higher initially for Ortho-Novum, but decreased more during the study period.

For desogestrel and gestodene pills containing 20 mcg EE, recorded bleeding rates are higher than in the Kaunitz study, although they are similar for desogestrel (150 mcg for 21 days) and gestodene.[10] This study showed bleeding or spotting in the desogestrel cohort occurred in 24.6% initially, decreasing to 9.4% by six months, and the rates for gestodene were 19.7% and 8.6%. Rates of amenorrhea ranged from 1% to 2.8% throughout the study, and the mean rate for both agents was 2% per cycle. Comparing the same formulations over a 12-month period, one study[4] found a similar pattern: The desogestrel combination has slightly more bleeding initially, whether measured by total spotting or bleeding days. The difference between the agents decreased with continued use.

When 20 mcg EE and either levonorgestrel (Alesse) or desogestrel (Mircette) combinations are compared, bleeding rates are similar during the first half of the cycle, but Alesse had more bleeding in the second half of the cycle (Day 12 and beyond).[3] Mircette has 10 mcg EE on days 23-28, and the additional estrogen might make a difference in bleeding pattern. In the same study, Ortho-Novum TriCyclen has bleeding patterns that are similar to Mircette. While EE dose has a relationship to cycle control when identical progestins are used, this study and others show that the dose of EE is not the sole determinant of cycle control. While 150 mcg desogestrel in combination with 20 mcg had significantly more bleeding or spotting days than desogestrel /30 mcg EE, (24%

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

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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.

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Statement of Financial Disclosure

To reveal any potential bias in this publication, we disclose the following: Lynn Borgatta, MD, (author) discloses that she is on the speaker's bureau for Berlex Laboratories and Organon and performs research for Berlex. Steven Sondheimer, MD, (peer reviewer) discloses that he is a consultant, on the speaker's bureau, and performs research for Berlex Laboratories, Pfizer, and Pharmacia.

more during the first cycle and 38% during the sixth cycle),[5] Gestodene with the same dose of EE had better cycle control than either desogestrel combination.[5,11]

Finally, another study by Rosenberg confirms the adverse effect of smoking on cycle control; the effect of smoking was larger than the effect of different progestins.[12]

Weight Gain

Weight gain is feared by many women and is cited as a reason for discontinuing oral contraceptives. In the Cyclessa study[1] the baseline mean body weight was similar for both Cyclessa and Ortho-Novum groups, and women over 130% of ideal body weight were excluded from enrollment. The mean weight change for Cyclessa users was a loss of 0.2 kg, and the mean weight change for Ortho-Novum users was a gain of 0.1 kg. This is numerically significant ($p = 0.0002$), but may not be clinically noticeable.

Drospirenone, a new contraceptive progestin with structural similarities to desogestrel, has anti-mineralocorticoid properties that might result in weight loss. It is marketed with 30 mcg EE as Yasmin. Froidart, comparing 30 mcg EE with either 3 mg drospirenone or 150 mcg desogestrel, found a slight weight loss for drospirenone users compared to a slight weight gain for desogestrel users, over the course of a year.[13] However, a study of Yasmin users alone showed a weight loss of 0.5 kg at six months and a net gain of 0.5 at 12 months.[14] Both gestodene 75 mcg EE and desogestrel 150 mcg EE in combination with 20 mcg EE had a mean weight change of zero after one year.[10] One study found that users of desogestrel with 30 mcg EE had a slight weight gain over a year, while desogestrel with 20 mcg EE resulted in a slight weight loss.[5] When 30-40 mcg EE were used, phasic desogestrel and levonorgestrel users had a statistically significant increase in body mass index (2% and 4%).[15] It's questionable whether any of the oral contraceptives currently on the market have a large effect on body weight, but users of 20 mcg EE preparations appear to have slightly less weight gain. Desogestrel appears to be the equivalent or better than other progestins in this respect.

Other Side Effects

Other side effects, probably related to estrogen, also can be distressing and lead to discontinuation. Comparing Ortho-Novum 7/7/7 to both 20 mcg EE pills, Rosenberg found common symptoms of bloating (30%-80%), nausea (5%-40%), and breast tenderness (20%-60%) were more common with 35 mcg EE than with 20 mcg EE (RR about 1.5 for each symptom, $p < .005$ for each symptom).[3] Other investigators have found lower baseline rates: Ferguson found the baseline rate for breast tenderness, 5%, fell to 1.6% after continuous use of phasic desogestrel with 30-35 mcg EE; nausea also fell, from 2.1% to 0.9%.[2] In contrast, with equivalent desogestrel doses, women using 20 mcg EE had more side effects than the 30 mcg EE users although the incidence was low overall. Users of 20 mcg EE were more likely to discontinue pills.[5] One study found that women using 20 mcg EE had the same incidence and pattern of side effects whether they used gestodene or desogestrel.[4] The side effect rates for both groups, before and after treatment, were higher than those of Ferguson, but much lower than those of Rosenberg.[3,11] This limits ability to compare studies, as it appears that the population and research techniques have a large effect on reported rates, while the difference between formulations is generally modest.

One study found that dysmenorrhea resolved for 53% and 70% of women using desogestrel or gestodene with 20 mcg EE.[10] The incidence of premenstrual syndrome (defined as water retention, mood changes, and breast pain) decreased from 20%-26% at baseline to 12% in both groups.

Oral contraceptives can be used to treat acne, and new-onset acne may be an unwanted side effect. Ortho-Tricyclen (phasic norgestimate with 35 mcg EE) was effective in treating mild and moderate acne; this study used a placebo control group.[16] Gestodene and desogestrel with 30 mcg EE had equivalent beneficial effects on pre-existing acne.[17] It's possible that any EE-containing oral contraceptive might have comparable effectiveness in treating acne. There was no difference in the occurrence of acne in 20 mcg compared to 35 mcg EE.[3]

Effects on bone density are a long-term concern, and as the dosage of EE decreases, the protective effect on bone density might decrease. A literature review[18] concluded that there was good evidence for a protective effect even with very low EE preparations, and a subsequent study[19] showed that bone density increased in perimenopausal women taking 20 mcg EE and 150 mcg desogestrel. Cyclessa and all other current oral contraceptives can be expected to maintain or increase bone density.

Cardiovascular Risks

Oral contraceptives have complex effects on serum markers associated with cardiovascular disease. In 1995, several European papers, including Jick,[20] reported an association between progestin compound and the occurrence of venous thromboembolic disease, with "third-generation" progestins such as gestodene and desogestrel having the highest rates. Furthermore, it appeared as if lower doses of EE (20 mcg as opposed to higher doses) also were associated with increased rates of thromboembolism. Subsequent re-analysis indicated that the EE dose probably was unrelated to rates; prescribing bias occurred as practitioners used the lowest does of EE for women at higher risk for thromboembolism.[21] One study[22] concluded that an association Sof progestin type and thromboembolism could not be supported. The earlier reports could have been a result of prescribing bias, healthy user effect, and confounding variables.

Hemostatic parameters probably are related to risk of venous thromboembolism. One study[15] compared phasic desogestrel in doses identical to Cyclessa, but with 30-35 mcg EE, was to phasic levonorgestrel with 30-40 mcg EE (Triphasil) over a six-month period. Measures of multiple compounds such as antithrombin III and Protein C were similar, while Factor V and free Protein S decreased with desogestrel and increased slightly with levonorgestrel. As the factors have opposite effects on the clotting cascade, the clinical effect is probably small or nonexistent. A meta-analysis[23] concluded that levonorgestrel, gestodene, and desogestrel showed no differences in serum risk factors for

thromboembolism. Clotting parameter data for Cyclessa's formulation was not studied, but it doesn't appear as if the patterns would be different.

Clinical Considerations

Contraceptive failure rates are very low for all oral contraceptives, and therefore the choice of oral contraceptive does not need to be made on the basis of efficacy. Although gestodene appears to have a slight advantage over desogestrel in terms of cycle control, the differences are small. Phasic and monophasic desogestrel have similar or better cycle control compared to each other. Therefore, Cyclessa can be expected to have cycle control similar to, or better than, other oral contraceptives available in the United States. "Nuisance" side effects such as bloating/water retention, breast tenderness, and premenstrual symptoms have the same, or lower, incidence.

As Cyclessa lowers the total hormone dose without detriment to efficacy, and with similar or better side effect profiles, it is suited for new starts and may be useful for women who have had problems with cycle control on another oral contraceptive.

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CME Objectives/Questions

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

• After reading this issue, the CME participant will be able to identify a characteristic that makes Cyclessa unique, identify when weight gain is most likely to occur during oral contraceptive use, and identify when pregnancy is most likely to occur.

1. Cyclessa is a newly marketed oral contraceptive that has:
   A. a phasic estrogen component.
   B. less estrogen in total than other contraceptive pills.
   C. less desogestrel in total than other contraceptive pills.
   D. a shorter pill-free interval (more than 21 active pills).

2. Weight gain during oral contraceptive use appears more likely to occur with:
   A. desogestrel.
   B. drospirenone.
   C. gestodene.
   D. phasic progestin.
   E. ethinyl estradiol doses of 30 mcg or above.

3. Pregnancy (contraceptive failure) is more like to occur with:
   A. ethinyl estradiol doses of 20 mcg compared to 30 mcg.
   B. desogestrel compared to levonorgestrel.
   C. desogestrel compared to norethindrone.
   D. desogestrel compared to gestodene.
   E. none of the above.

Oral Contraceptives Containing Less than 30 mcg Ethinyl Estradiol Per Day

	Ethinyl Estradiol Dose	Progestin
Available in the United States		
Cyclessa	25 mg	Desogestrel 50 mcg Day 1-7 100 mcg Day 8-14 150 mcg Day 15-21
Alesse	20 mcg	Levonorgestrel 150 mcg
Mircette	20 mcg (Contains 10 mcg Day 23-28)	Desogestrel 150 mcg
Loestrin 1/20 and others	20 mcg	Norethisterone 1,000 mcg
Not Available in the United States		
Mercilon and others	20 mcg	Desogestrel 150 mcg
Meliane and others	20 mcg	Gestodene 75 mcg
Minesse	15 mcg for 24 days	Gestodene 60 mcg for 24 days

Source: Adapted from Hatcher RA, Trussell J, Stewart F, et al. *Contraceptive Technology.* 17th ed. New York City: Ardent Media; 1998, and Using oral contraceptives. *Population Reports* 2000; 28:1-7. Cyclessa information is from Kaunitz AM. Efficacy, cycle control, and safety of two triphasic oral contraceptives: Cyclessa (desogestrel/ethinyl estradiol) to Ortho-Novum 7/7/7 (norethindrone/ ethinyl estradiol): A randomized clinical trial. *Contraception* 2000; 61:295-302.

Phasic Oral Contraceptives Available in the United States

	Estrogen	Estrogen Dose(s)	Progestin	Progestin Doses
Cyclessa	Ethinyl estradiol	25 mg	Desogestrel	50 mcg Day 1-7 100 mcg Day 8-14 150 mcg Day 15-21
Ortho Tri-Cyclen		35 mcg	Norgestimate	180 mcg Day 1-7 215 mcg Day 8-14 250 mcg Day 15-21
Ortho Novum 7/7/7		35 mcg	Norethindrone	500 mcg Day 1-7 750 mcg Day 8-14 1,000 mcg Day 15-21
Triphasil, TriLevlen, Trivora, and others		35 mcg Day 1-6 40 mcg Day 7-11 35 mcg Day 12-21	Levonorgestrel	50 mcg Day 1-6 75 mcg Day 7-11 125 mcg Day 12-21
Estrostep		20 mcg Day 1-5 30 mcg Day 6-12 35 mcg Day 13-21	Norethindrone acetate	1,000 mcg

Source: Adapted from Hatcher RA, Trussell J, Stewart F, et al. *Contraceptive Technology.* 17th ed. New York City: Ardent Media; 1998. Cyclessa information is from Kaunitz AM. Efficacy, cycle control, and safety of two triphasic oral contraceptives: Cyclessa (desogestrel/ethinyl estradiol) to Ortho-Novum 7/7/7 (norethindrone/ ethinyl estradiol): A randomized clinical trial. *Contraception* 2000; 61:295-302.